WHO Prequalification of In Vitro Diagnostics
PUBLIC ASSESSMENT REPORT

Product: Alinity m HR HPV
WHO reference number: PQDx 09308-027-00

Alinity m HR HPV with product codes 09N15-090, 09N15-080, and 09N15-092, manufactured by Abbott Molecular Inc., CE-marked regulatory version, was accepted for the WHO list of prequalified in vitro diagnostics and was listed on 27 March 2025.

Summary of WHO's Prequalification Assessment for the Alinity m HR HPV

	Date	Outcome
Prequalification listing	27 March 2025	listed
Abridged Dossier assessment	26 March 2025	MR
Product performance evaluation	06 December 2024	MR

MR: Meets Requirements

Report amendments and product changes

This public report has since been amended. Amendments may have arisen because of changes to the prequalified product, for which the WHO has been notified and has undertaken a review. The amendments to the report are summarized in the following table, and details of each amendment are provided below.

Version	Summary of amendment and change request reference, where applicable.	Date of report amendment
2.0	Incorporate self-collected vaginal specimens to the Alinity m HR HPV assay. The following changes are necessary to implement the specimen type of self-collected vaginal samples: Creation of a new list number (09N15-092) for the Alinity m HR HPV AMP Kit containing the additional self-collected vaginal sample claim in the Instructions for Use. Creation of an application specification file (ASF) for self-collected vaginal sample specimens (List No. 09N15-07A). Creation of a simpli-COLLECT™ HPV Collection Kit (List No.09R03-030) and Instructions for Use for both laboratory professionals and patients. Creation of additional reagent kits for pre-analytical processing of self-collected vaginal samples; Alinity m Specimen Buffer (List No. 09R03-050 and 09-30-060). The proposed change does not impact the function, usability, or safety of the Alinity m HR-HPV assay. The change does not include any changes to formulations or	30 January 2026

	specifications of the current assay reagents used or changes to the final release testing of the product. The changes do not affect the manufacturing facility location, principles of operation, or device design. The change is not the result of an adverse event for the Alinity m HR HPV assay. Hardware changes are not required to implement the proposed change (PQC-IVD-2025-0047).	

Intended use

For product list (product codes 09N15-090, 09N15-080)

"The Alinity m High Risk
(HR) HPV assay is a qualitative in vitro test for use with the automated Alinity m System for the detection of DNA from 14 high-risk human papillomavirus (HPV) genotypes 16, 18, 31, 33, 35, 39, 45, 51, 52, 56, 58, 59, 66, and 68 in clinical specimens. The assay specifically identifies HPV genotypes 16, 18, and 45 while reporting the concurrent detection of the other high-risk genotypes (31/ 33/ 52/ 58) and (35/ 39/ 51/ 56/ 59/ 66/ 68) at clinically relevant infection levels.
The Alinity m HR HPV assay is intended for the following uses:

- *To screen patients with ASC-US (atypical squamous cells of undetermined significance) cervical cytology test results to determine the need for referral to colposcopy. The results of this test are not intended to prevent women from proceeding to colposcopy.*
- *To be used with cervical cytology to adjunctively screen to assess the presence or absence of high-risk HPV genotype.*
- *To be used as a first-line primary screening test to identify women at increased risk for the development of cervical cancer or the presence of high-grade disease.*
- *To assess the presence or absence of HPV genotypes 16 and 18 to identify women at increased risk for the development of cervical cancer or the presence of high-grade disease with or without cervical cytology.*

The results from the Alinity m HR HPV, together with the physician's assessment of cytology, history, other risk factors, and professional guidelines, may be used to guide patient management.

INTENDED USER
The intended users for Alinity m HR HPV AMP Kit are laboratory professionals."

For product list (product code 09N15-092)

According to the intended use claim from Abbott Molecular Inc., "*The Alinity m High Risk (HR) HPV assay is a qualitative in vitro test for use with the automated Alinity m System for the detection of DNA from 14 high-risk human papillomavirus (HPV) genotypes 16, 18, 31, 33, 35, 39, 45, 51, 52, 56, 58, 59, 66, and 68 in cervical specimens and self-collected vaginal specimens. The assay specifically identifies HPV genotypes 16, 18, and 45 while reporting the*

concurrent detection of the other high-risk genotypes (31/ 33/ 52/ 58) and (35/ 39/ 51/ 56/ 59/ 66/68) at clinically relevant infection levels.

The Alinity m HR HPV assay is intended for the following uses:

- *To screen patients with ASC-US (atypical squamous cells of undetermined significance) cervical cytology test results to determine the need for referral to colposcopy. The results of this test are not intended to prevent women from proceeding to colposcopy.*
- *To be used with cervical cytology to adjunctively screen to assess the presence or absence of high-risk HPV genotype.*
- *To be used as a first-line primary screening test to identify women at increased risk for the development of cervical cancer or the presence of high-grade disease.*
- *To assess the presence or absence of HPV genotypes 16 and 18 to identify women at increased risk for the development of cervical cancer or the presence of high-grade disease with or without cervical cytology.*

The results from the Alinity m HR HPV, together with the physician's assessment of cytology, history, other risk factors, and professional guidelines, may be used to guide patient management.

INTENDED USER

The intended users for Alinity m HR HPV AMP Kit are laboratory professionals."

Test kit contents:

Component	Number of tests and product codes
Alinity m HR HPV AMP Kit • Alinity m HR HPV AMP TRAY 1 • Alinity m HR HPV ACT TRAY 2	384 tests, product code 09N15-090. 4 trays / 96 tests each 4 trays / 96 tests each
Alinity m HR HPV CTRL Kit • Alinity m HR HPV Negative CTRL • Alinity m HR HPV Positive CTRL	Product code 09N15-080 12 tubes x 0.6 mL 12 tubes x 0.6 mL
Alinity m HR HPV AMP Kit • Alinity m HR HPV AMP TRAY 1 • Alinity m HR HPV ACT TRAY 2	384 tests, product code 09N15-092 4 trays / 96 tests each 4 trays / 96 tests each

Items required but not provided:

- 09N18-001 Alinity m Sample Prep Kit 1
- 09N20-001 Alinity m Lysis Solution

- 09N20-002 Alinity m Ethanol Solution or 09N20-012 Alinity m Bottle for Ethanol Use (filled with customer supplied 190 Proof Ethanol, ACS, Denaturant free)
- 09N20-003 Alinity m Diluent Solution
- 09N20-004 Alinity m Vapor Barrier Solution
- 09N49-010 Alinity m Transport Tube Pierceable Capped
- 09N49-011 Alinity m Transport Tubes
- 09N49-012 Alinity m Pierceable Caps
- 09N65-050 Alinity m Labeled Tube with Pierceable Cap
- Alinity m HR HPV Application Specification File
- Vortex mixer
- Calibrated pipettes capable of delivering 100 to 1000 µL
- Aerosol barrier pipette tips for 100 to 1000 µL pipettes
- Plate adapter for 384 well plates (such as Eppendorf Catalog No. 022638955)
- Centrifuge with swing plate rotor capable of accommodating the plate adapter and capable of ≥ 100 g,

Storage:
The Alinity m HR HPV AMP Kit (both list numbers 09N15-090 and 09N15-092) must be stored between 2 °C and 8 °C.
The Alinity m HR HPV CTRL Kit must be stored between -25 and -15 °C.

Shelf-life upon manufacture[1]:
24 months.

Product dossier assessment

Abbott Molecular Inc. submitted an abridged product dossier for the Alinity m HR HPV as per the "Instructions for compilation of a product dossier" (PQDx_018). The information (data and documentation) submitted in the product dossier was reviewed by WHO staff and external technical experts (assessors) appointed by WHO. The manufacturer's responses to the nonconformities found during dossier screening and assessment findings were accepted on 26 March 2025.

Based on the product dossier screening and assessment findings, the abridged product dossier for Alinity m HR HPV meets WHO prequalification requirements.

[1] The assigned device shelf-life is based on stability data generated from the date of manufacture. The finished goods shelf-life, calculated from the date of packaging completion, may be shorter depending on the time elapsed between manufacture and final packaging of the device.

Manufacturing site inspection

The inspection of the manufacturing site(s) was conducted to assess whether the manufacturer's quality management system (QMS) and manufacturing practices are in alignment with:
(i) applicable international standards, such as ISO 13485 (Medical devices – Quality management systems – Requirements for regulatory purposes);
(ii) the manufacturer's own documented procedures and quality requirements; and
(iii) other relevant international standards and guidelines applicable to in vitro diagnostic (IVD) medical devices. The WHO's Public Inspection Reports are accessible at:

https://extranet.who.int/pqweb/vitro-diagnostics/who-public-inspection-reports

Based on the site inspection and corrective action plan review, the quality management system for the Alinity m HR HPV meets WHO prequalification requirements.

Product performance evaluation

The Alinity m HR HPV assay was evaluated by the Scottish HPV Reference Laboratory, United Kingdom on behalf of WHO in the 3rd quarter of 2024 according to protocol PQDx_255, version 2.0.

Alinity m HR HPV is considered as one of the possible comparator assays for the virologic evaluation of HPV test for prequalification (per protocol PQDx_255, v2.0). As a result, Alinity m HR HPV was waived from virologic evaluation, and the evaluation was limited to the analytical performance evaluation and operational characteristics.

Analytical performance evaluation

Analytical performance characteristics	
Limit of detection (LoD)	The LoD was estimated at 305.2 IU/mL (95% CI: 215.7-431.8) for HPV Type 16; 287.4 IU/mL (95% CI: 180.4-458.0) for HPV Type 18; and 3537 IU/mL (95% CI: 10^{-5} to 10^{12}) for HPV Type 31.
Reproducibility	The hit rates for detection of HPV 16, HPV 18 and HPV 31 at approx. 10^4 IU/mL were 100%, 100%, and 100%, respectively.
Genotype detection	The following genotypes from the genotype detection panel were detected: HPV16, HPV18, HPV31, HPV33, HPV45, HPV52, HPV58, in agreement with the manufacturer's claim. HPV6 and HPV11 were

	not detected, in agreement with manufacturer's claim.
Cross-contamination / carry-over	No cross-contamination was observed when high positive and negative specimens were tested alternatively.

Operational characteristics and ease of use

This assay requires laboratory equipment and cannot be performed in laboratories with limited facilities or in non-laboratory settings. The instrument requires a stable source of electricity and significant physical space. Furthermore, training and implementation of good laboratory practice is essential to obtaining accurate results. Adequate technical support from manufacturer or representative is critical.

The assay was found easy to use by the operators performing the evaluation. It should be noted that the operators were skilled and experienced in molecular laboratory testing, including on the specific platform under evaluation.

Key operational characteristics	
Specimen type(s) and volume	Cervical specimens collected in Alinity m Cervi-Collect Specimen Collection Kit, ThinPrep PreservCyt Solution, or SurePath Preservative Fluid. The minimal volume required in the tube is 0.55 mL.
Time to result for one test	<120 minutes from test initiation to completion
Operator hands-on time for one test/run	Variable as random-access machine and depending on number of specimens tested in a run. For a full rack of specimens (n = 12), hands-on time is approximately 10 minutes to account for vortexing, scanning and addition of assay orders, and loading of specimens.
Level of automation	Fully automated. Once specimens have been loaded, the Alinity m System performs extraction and amplification of nucleic acid, then displays results when complete.
Quality controls	QCs are provided by the manufacturer but should be purchased separately:

	Alinity m HR HPV CTRL Kit contains 12 HPV negative vials and 12 HPV positive vials which should be run at a minimum frequency of every 48 hours.
Operating temperature	15°C - 28°C
Result display and connectivity	Results are displayed on the instrument and can be interfaced. The results can be exported to the laboratory information system and other health information systems, in addition to CSV Excel exports or single result reports.
Power sources	Main power. The use of a UPS is recommended, as stable electricity is required.
Biosafety *(outside of infectious specimen handling)*	Operators reported biosafety considerations. Some reagents contain hazardous components, including guanidine hydrochloride and guanidine thiocyanate, that may cause skin or eye irritation, are harmful if swallowed, cause skin burns and eye damage, and are harmful to aquatic life. Furthermore, reagents and waste containing, or contaminated with, guanidine hydrochloride and/or guanidine thiocyanate pose an environmental hazard as the reagents react with sodium hypochlorite and can produce toxic fumes.
Waste	The volume of waste generated by the Alinity m is difficult to quantify as the machine is random-access and was shared between different departments at the time of evaluation. Both solid and liquid waste was generated. Waste disposal requires specific measures in addition to usual laboratory biohazard waste disposal procedures. Waste containing, or contaminated with, guanidine hydrochloride and/or guanidine thiocyanate require specialist chemical uplift and should not be discarded down sinks. This this poses an environmental hazard as the reagents react with sodium hypochlorite and can produce toxic fumes.

Calibration	Calibration of the Alinity m System is performed as part of annual preventative maintenance by an Abbott Molecular Inc. engineer.
Maintenance	Weekly and monthly maintenance are required as a minimum and enforced by the Alinity m System. In addition, yearly preventative maintenance is performed by an Abbott Molecular Inc. engineer.
Other specific requirements	The Alinity m System has a considerable footprint (approximately 248 cm (length) x 102 cm (width) x 188 cm (height)) and requires consistent maintenance and service by Abbott-authorized engineers/service providers.

Based on these results, the performance evaluation for Alinity m HR HPV meets the WHO prequalification requirements.

Labelling review

The labelling submitted for the Alinity m HR HPV was reviewed by WHO staff and external technical experts appointed by WHO. The review evaluated the labelling for clarity and consistency with the information submitted in the product dossier, alignment with international guidance and standards, and suitability for the intended users and settings in WHO Member States, including low- and middle-income countries.

The table below provides traceability of the labelling documents reviewed during the assessment, including document titles, version numbers, approval dates, and control identifiers.

Controlled Labelling References

Document Type	Document Title	Version / Revision	Date Approved	Controlled Document No.
Outer box artwork	Alinity m HR HPV AMP Kit (09N15-092	R1	Jan 2024	53-602370
Outer box artwork	simpli-COLLECT HPV Collection Kit, Case Label	R1	Oct 2024	AL1218.1
Outer box artwork	simpli-COLLECT HPV Collection Kit, Box Label	R1	Oct 2024	AL1217.1
Outer box artwork	Alinity m Specimen Buffer Kit II (09R03-050)	R2	Sep 2024	53-602969
Outer box artwork	Alinity m Specimen Buffer Kit III (09R03-060)	R1	Dec 2023	AL1196.1
Pouch / Device label	Alinity m HR HPV AMP Pouch	R1	June 2024	53-602094
Pouch / Device label	Alinity m HR HPV ACT Pouch	R1	Mar 2018	53-602093
Pouch / Device label	simpli-COLLECT HPV Collection Kit, Outer Pouch (Blister Pack)	R1	Oct 2024	AL1216.1
Reagent bottle labels	Alinity m Specimen Buffer Kit II (09R03-050), Bottle Label	R2	Sep 2024	53-602970
Accessory labeling (e.g., pipettes, buffer caps)	Alinity m Sample Tube for Dry Swab	R1	Nov 2023	AL1202.1
Accessory labeling (e.g., pipettes, buffer caps)	Alinity m Specimen Buffer Kit III, Tube Label	R1	Dec 2023	AL1195.1

Instructions for Use (IFU)	Alinity m HR HPV AMP Kit (09N15-092	R1	April 2024	53-608488
Instructions for Use (IFU)	simpli-COLLECT HPV Collection Kit, Laboratory Personnel (09R03-030)	R1	November 2024	53-608547
Instructions for Use (IFU)	simpli-COLLECT HPV Collection Kit, Patient (09R03-030)	R2	February 2025	53-608546
Instructions for Use (IFU)	Alinity m Specimen Buffer Kit II (09R03-050)	R2	August 2024	53-608399
Instructions for Use (IFU)	Alinity m Specimen Buffer Kit III (09R03-060)	R1	April 2024	53-608469

1. Labels

Alinity m

Abbott

UNIT 1

IVD

HR HPV 2

8°C
2°C

ACT TRAY

Σ 96

REF 9N15M

53-602093/R1

Abbott Molecular Inc.
1300 East Touhy Avenue
Des Plaines, IL 60018 USA

LOT

Colors:
- Pantone 376 C
- Pantone 185 C
- Black

Labeling: Renee

Alinity m

Abbott

UNIT 1

IVD

HR HPV 1

8°C
2°C

AMP TRAY

Σ 96

REF 9N15P

53-602094/R1

LOT

Abbott Molecular Inc.
1300 East Touhy Avenue
Des Plaines, IL 60018 USA

Colors:
- Pantone Reflex Blue C
- Pantone 185 C
- Black

Labeling: Renee

Alinity m

HR HPV AMP Kit

Abbott

HR HPV AMP Kit

REF 09N15-092

AMP TRAY 4 x Σ 96

ACT TRAY 4 x Σ 96

H302, H316, H317, H370, H412, P260, P264, P272, P273, P280, P301+P312, P302+P352, P308+P311, P333+P313, P362+P364, P501

IVD

In Vitro Test

www.molecular.abbott/portal

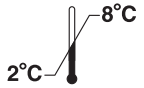
Abbott Molecular Inc.
1300 East Touhy Avenue
Des Plaines, IL 60018 USA

CE 2797

EC REP Abbott GmbH
Max-Planck-Ring 2
65205 Wiesbaden, Germany

Abbott

REF 09N15-092



53-602370/R1

LOT

Alinity m

Abbott

Specimen Buffer Kit II

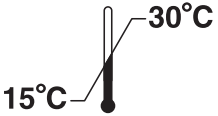
SPECIMEN BUFFER II **4 x 237 mL**

IVD

In Vitro Test

For In Vitro Diagnostic Use

EUH032, P501



53-602969/R2

PN 73012

CE

R2

www.molecular.abbott

REF 09R03-050

EC REP Abbott GmbH
Max-Planck-Ring 2
65205 Wiesbaden, Germany

LOT

Abbott Molecular Inc.
1300 East Touhy Avenue
Des Plaines, IL 60018 USA

Alinity m

Specimen Buffer Kit III

Abbott

Specimen Buffer Kit III

REF 09R03-060

SPECIMEN BUFFER III 36 x 2.95 mL

EUH032
P501

Abbott Molecular Inc.
1300 East Touhy Avenue
Des Plaines, IL 60018 USA

EC REP Abbott GmbH
Max-Planck-Ring 2
65205 Wiesbaden, Germany

PRODUCED BY MML Diagnostics Packaging Troutdale, OR 97060 USA

Abbott

IVD

In Vitro Test

For In Vitro Diagnostic Use

R1

www.molecular.abbott/portal

REF 09R03-060

AL1196.1

LOT

simpli-COLLECT™ HPV Collection Kit

SAMPLE TUBE 1

SWAB 1

REF 09R03-030

IVD

In Vitro Test

STORE AT

30°C
86°F
15°C
59°F

R1

AL1216.1

Abbott Molecular Inc.
1300 East Touhy Avenue
Des Plaines, IL 60018 USA

CE

EC REP Abbott GmbH
Max-Planck-Ring 2
65205 Wiesbaden, Germany

PRODUCED BY MML Diagnostics Packaging, Inc., Troutdale, OR 97060 USA

7 OTHER

22 PAP

Abbott

Abbott

simpli-COLLECT™

HPV Collection Kit

UNIT 40

SAMPLE TUBE 1

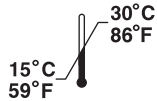
SWAB 1

REF 09R03-030

IVD

In Vitro Test

STORE AT



R1

www.molecular.abbott AL1217.1

LOT

Abbott Molecular Inc.
1300 East Touhy Avenue
Des Plaines, IL 60018 USA

CE **EC REP** Abbott GmbH
Max-Planck-Ring 2
65205 Wiesbaden, Germany

PRODUCED BY MML Diagnostics Packaging, Inc., Troutdale, OR 97060 USA

2. Instructions for use[2]

[2] WHO assessed the English versions of the IFU. The manufacturer is responsible for ensuring the correct translation into other languages.

HR HPV AMP Kit

Created April 2024

REF 09N15-092
53-608488/R1

CUSTOMER SERVICE: 1-800-553-7042
CUSTOMER SERVICE INTERNATIONAL: CALL YOUR ABBOTT REPRESENTATIVE

Instructions must be carefully followed. Reliability of assay results cannot be guaranteed if there are any deviations from these instructions.

NOTICE TO USER

If a serious incident occurs in relation to this device, the incident should be reported to the manufacturer and to the appropriate competent authority of the member state in which the user and/or the patient is established. To report to the manufacturer, see the contact information provided in the customer service or technical assistance section of these instructions.

NAME

Alinity m HR HPV AMP Kit

INTENDED USE

The Alinity m High Risk (HR) HPV assay is a qualitative in vitro test for use with the automated Alinity m System for the detection of DNA from 14 high-risk human papillomavirus (HPV) genotypes 16, 18, 31, 33, 35, 39, 45, 51, 52, 56, 58, 59, 66, and 68 in cervical specimens and self-collected vaginal specimens. The assay specifically identifies HPV genotypes 16, 18, and 45 while reporting the concurrent detection of the other high-risk genotypes (31/ 33/ 52/ 58) and (35/ 39/ 51/ 56/ 59/ 66/ 68) at clinically relevant infection levels.

The Alinity m HR HPV assay is intended for the following uses:

- To screen patients with ASC-US (atypical squamous cells of undetermined significance) cervical cytology test results to determine the need for referral to colposcopy. The results of this test are not intended to prevent women from proceeding to colposcopy.
- To be used with cervical cytology to adjunctively screen to assess the presence or absence of high-risk HPV genotype.
- To be used as a first-line primary screening test to identify women at increased risk for the development of cervical cancer or the presence of high-grade disease.
- To assess the presence or absence of HPV genotypes 16 and 18 to identify women at increased risk for the development of cervical cancer or the presence of high-grade disease with or without cervical cytology.

The results from the Alinity m HR HPV, together with the physician's assessment of cytology, history, other risk factors, and professional guidelines, may be used to guide patient management.

INTENDED USER

The intended users for Alinity m HR HPV AMP Kit are laboratory professionals.

SUMMARY AND EXPLANATION OF THE TEST

HPV is a small, non-enveloped, double-stranded DNA virus (approximately 8,000 base pairs) that replicates in the nucleus of squamous epithelial cells and induces hyperproliferative lesions.[1] HPV infections are among the most common sexually transmitted infections.[2] Most HPV infections have a benign clinical consequence and are cleared spontaneously.[3] However, persistent HPV infection may result in progression to cervical cancer.[4-7] More than two hundred different HPV genotypes have been identified,[8] among which over forty infect mucosal and genital epithelia.[9] Genital HPV genotypes are generally classified into high risk (HR) and low risk (LR) groups based on their carcinogenic potential. HR HPV genotypes (16, 18, 31, 33, 35, 39, 45, 51, 52, 56, 58, 59, 66 and 68) are associated with invasive cervical cancer (squamous cell carcinoma or adenocarcinoma) or its immediate precursor (high-grade squamous intraepithelial lesion, cervical intraepithelial neoplasia, carcinoma in situ, or adenocarcinoma in situ), whereas LR HPV genotypes induce benign lesions and are not associated with cervical cancer.[10-13] Three of the 14 HR HPV genotypes, 16, 18 and 45, are associated with approximately 70-80% of invasive cervical cancer cases worldwide.[14-16] For adenocarcinoma, which is more difficult to detect, HPV 16, 18, and 45 have been observed in 78-94% of cases.[14,15,17] Infection by HPV 16 or HPV 18 is associated with higher risk of disease progression compared to other HR HPV genotypes.[18]

Compared with cervical screening methods identifying cytological abnormalities, molecular tests that specifically detect the presence of HR HPV DNA can potentially increase sensitivity and cost-effectiveness of cervical cancer screening programs.[19-25] Furthermore, HPV DNA tests can be effectively used in triaging patients with equivocal cytology, in post therapeutic follow-up and in monitoring vaccine efficacy.[26-28]

The Alinity m HR HPV assay is a qualitative in vitro test for use with the automated Alinity m System for the detection of DNA from 14 high risk human papillomavirus (HPV) genotypes 16, 18, 31, 33, 35, 39, 45, 51, 52, 56, 58, 59, 66, and 68 in cervical specimens and self-collected vaginal specimens. The assay specifically identifies HPV genotypes 16, 18, and 45 while reporting the concurrent detection of the other high risk genotypes (31/ 33/ 52/ 58 and 35/ 39/ 51/ 56/ 59/ 66/ 68) at clinically relevant infection levels.

BIOLOGICAL PRINCIPLES OF THE PROCEDURE

The Alinity m HR HPV assay requires 2 separate assay specific kits:

- Alinity m HR HPV AMP Kit (09N15-092) consisting of 2 types of multi-well assay trays. The amplification trays (AMP Trays) contain lyophilized, unit-dose PCR amplification/detection reagents. The activation trays (ACT Trays) contain liquid unit-dose activation reagent. The intended storage condition for the Alinity m HR HPV AMP Kit is 2°C to 8°C.
- Alinity m HR HPV CTRL Kit (09N15-080) consisting of negative controls and positive controls, each supplied as liquid in single-use tubes. The intended storage condition for the Alinity m HR HPV CTRL Kit is −25°C to −15°C.

The Alinity m HR HPV assay utilizes real-time polymerase chain reaction (PCR) to amplify and detect DNA sequences from 14 HR HPV genotypes (16, 18, 31, 33, 35, 39, 45, 51, 52, 56, 58, 59, 66, and 68) and human genomic DNA sequences that have been extracted from cervical and self-collected vaginal specimens.

Cervical specimens collected with the Alinity m Cervi-Collect Specimen Collection Kit or specimens collected in ThinPrep PreservCyt Solution or SurePath Preservative Fluid can be used with the Alinity m HR HPV assay. Cervical specimens collected in ThinPrep PreservCyt Solution or SurePath Preservative Fluid are transferred to an Alinity m Transport Tube for processing on the Alinity m System.

Self-collected vaginal specimens collected in a clinical or non-clinical setting using the simpli-COLLECT™ HPV Collection Kit or the Evalyn® Brush (Rovers Medical Devices) device can be used with the Alinity m HR HPV assay.

Self-collected vaginal specimens collected in a clinical or non-clinical setting using the simpli-COLLECT HPV Collection Kit are prepared using the Alinity m Specimen Buffer Kit II for processing on the Alinity m System. Self-collected vaginal specimens collected in a clinical or non-clinical setting using the Evalyn Brush are transferred to an Alinity m Specimen Buffer III tube from the Alinity m Specimen Buffer Kit III for processing on the Alinity m System.

The steps of the Alinity m HR HPV assay consist of sample preparation, PCR assembly, amplification/detection, and result calculation and reporting. All steps of the Alinity m HR HPV assay procedure are executed automatically by the Alinity m System.

The Alinity m System is designed to be a random access analyzer that can perform the Alinity m HR HPV assay in parallel with other Alinity m assays on the same instrument.

Nucleic acids from specimens are extracted using the Alinity m Sample Prep Kit 1, Alinity m Lysis Solution, Alinity m Ethanol Solution or Alinity m Bottle for Ethanol Use (filled with customer supplied 190 Proof Ethanol, ACS, Denaturant free) and Alinity m Diluent Solution. The Alinity m System employs magnetic microparticle technology to facilitate nucleic acid capture, wash and elution.

The resulting purified nucleic acids are then combined with liquid unit-dose Alinity m HR HPV activation reagent and lyophilized unit-dose Alinity m HR HPV amplification/detection reagents and transferred into a reaction vessel. Alinity m Vapor Barrier Solution is then added to the reaction vessel which is then transferred to an amplification/detection unit for PCR amplification, and real-time fluorescence detection of HR HPV.

The Alinity m HR HPV amplification/detection reagents include primers and probes that amplify and detect an endogenous human beta globin (BG) sequence as sample validity control for cell adequacy, sample extraction and amplification efficiency. The Alinity m HR HPV amplification/detection reagent also contains Uracil-DNA Glycosylase (UDG) as a contamination control for amplicons containing uracil, which may be present in molecular laboratories.

Assay controls are tested at or above an established minimum frequency to help ensure that instrument and reagent performance remains satisfactory. During each control event, a negative control and a positive control are processed through sample preparation and PCR procedures that are identical to those used for specimens.

The possibility of nucleic acid contamination on the Alinity m System is minimized because:

- Aerosol barrier pipette tips are used for all pipetting. The pipette tips are discarded after use.
- PCR amplification and detection is carried out automatically in a sealed reaction vessel.
- Disposal of the reaction vessel is performed automatically by the Alinity m System.

For additional information on system and assay technology, refer to the Alinity m System Operations Manual, Section 3.

REAGENTS

Kit Contents

Alinity m HR HPV AMP Kit List No. 09N15-092

The Alinity m HR HPV AMP Kit is comprised of 2 types of multi-well trays: Alinity m HR HPV AMP TRAY 1 and Alinity m HR HPV ACT TRAY 2.

Each Alinity m HR HPV AMP TRAY 1 (individually packed in a foil pouch with a desiccant bag) contains 96 unit-dose lyophilized amplification reagent wells. One reagent well is used per test.

- Amplification reagent wells consist of synthetic oligonucleotides, DNA Polymerase, excipient, dNTPs, Uracil-DNA Glycosylase in a buffered solution.

Each Alinity m HR HPV ACT TRAY 2 (individually packed in a foil pouch without a desiccant bag) contains 96 unit-dose liquid activation reagent wells. One reagent well is used per test.

- Activation reagent wells consist of magnesium chloride, potassium chloride, and tetramethyl ammonium chloride. Preservative: 0.15% ProClin® 950.

	Quantity
Σ	384 tests
Alinity m HR HPV AMP TRAY 1	4 trays / 96 tests each
Alinity m HR HPV ACT TRAY 2	4 trays / 96 tests each

WARNINGS AND PRECAUTIONS

IVD

- **For In Vitro Diagnostic Use**

Safety Precautions

Human specimens should be handled as if infectious using safe laboratory procedures, such as those outlined in Biosafety in Microbiological and Biomedical Laboratories,[29] OSHA Standard on Bloodborne Pathogens,[30] CLSI Document M29-A4,[31] and other appropriate biosafety practices.[32] Therefore all human sourced materials should be considered infectious.

These precautions include, but are not limited to, the following:

- Wear gloves when handling specimens or reagents.
- Do not pipette by mouth.
- Do not eat, drink, smoke, apply cosmetics, or handle contact lenses in areas where these materials are handled.
- Clean and disinfect spills of specimens by including the use of a tuberculocidal disinfectant such as 1.0% sodium hypochlorite or other suitable disinfectant.[29]

Decontaminate and dispose of all potentially infectious materials in accordance with local, state and federal regulations.[32]

The following warnings and precautions apply to:
Alinity m HR HPV ACT Tray 2.

DANGER	Contains Tetramethylammonium chloride, and methylisothiazolone
H302	Harmful if swallowed.
H316	Causes mild skin irritation.[a]
H317	May cause an allergic skin reaction.
H370	Causes damage to organs.
H412	Harmful to aquatic life with long lasting effects.
Prevention	
P260	Do not breathe mist / vapours / spray.
P264	Wash hands thoroughly after handling.
P272	Contaminated work clothing should not be allowed out of the workplace.
P273	Avoid release to the environment.
P280	Wear protective gloves / protective clothing / eye protection.
Response	
P301+P312	IF SWALLOWED: Call a POISON CENTER/doctor if you feel unwell.
P302+P352	IF ON SKIN: Wash with plenty of water.
P308+P311	IF exposed or concerned: Call a POISON CENTER/doctor.
P333+P313	If skin irritation or rash occurs: Get medical advice / attention.
P362+P364	Take off contaminated clothing and wash it before reuse.
Disposal	
P501	Dispose of contents / container in accordance with local regulations.

[a] Not applicable where regulation EC 1272/2008 (CLP) or OSHA Hazard Communication 29CFR1910.1200 (HCS) 2012 have been implemented.

Important information regarding the safe handling, transport and disposal of this product is contained in the Safety Data Sheet.

Safety Data Sheets are available from your Abbott Representative.

For a detailed discussion of safety precautions during system operation, refer to the Alinity m System Operations Manual, Section 7 and Section 8.

Reagent Shipment

	Shipment Condition
Alinity m HR HPV AMP Kit	On dry ice

Reagent Storage

In order to minimize damage to foil pouches, it is recommended that the Alinity m HR HPV AMP TRAY 1 (AMP TRAY 1) and Alinity m HR HPV ACT TRAY 2 (ACT TRAY 2) are stored in the original kit packaging. Open the foil pouch for the reagent trays just prior to loading onto the instrument. Onboard storage time begins when reagents are loaded on the Alinity m System.

	Storage Temperature	Maximum Storage Time
Unopened	2°C to 8°C	Until expiration date
Onboard	System Temperature	30 days (not to exceed expiration date)

Reagent Handling

- Do not use reagents that have been damaged.
- Minimize contact with the surface of reagent trays during handling.
- Only load AMP TRAY 1 and ACT TRAY 2 from the same AMP Kit lot on the same Alinity m Assay Tray Carrier. Do not load AMP TRAY 1 and ACT TRAY 2 from different AMP Kit lots on the same Alinity m Assay Tray Carrier.
- The Alinity m System will track the onboard storage time of AMP TRAY 1 and ACT TRAY 2 while on the instrument. The Alinity m System will not allow the use of AMP TRAY 1 and ACT TRAY 2 if the maximum onboard storage time has been exceeded.
- For a detailed discussion of reagent handling precautions during system operation, refer to the Alinity m System Operations Manual, Section 8.

Indications of Reagent Deterioration

- Deterioration of the reagents may be indicated when a control error occurs or control values are repeatedly out of the specified ranges.
- Reagents are shipped on dry ice and are stored at 2°C to 8°C upon arrival. If reagents arrive in a condition contrary to this recommendation or are damaged, immediately contact your Abbott Representative.
- For troubleshooting information, refer to the Alinity m System Operations Manual, Section 10.

INSTRUMENT PROCEDURE

The Alinity m HR HPV assay application specification file must be installed on the Alinity m System prior to performing the assay.

For detailed information on viewing and editing the customizable assay parameters, refer to the Alinity m System Operations Manual, Section 2.

For information on printing assay parameters, refer to the Alinity m System Operations Manual, Section 5.

For a detailed description of system operating instructions, refer to the Alinity m System Operations Manual, Section 5.

SPECIMEN COLLECTION AND PREPARATION FOR ANALYSIS

Specimen Collection

Users must follow the instructions in the Alinity m Cervi-Collect Specimen Collection Kit (List No. 09N29-001) for collecting cervical specimens with the Alinity m Cervi-Collect Specimen Collection Kit.

Users must follow the respective manufacturer's instructions for collecting cervical specimens in ThinPrep PreservCyt Solution (Hologic Inc.) or SurePath Preservative Fluid (BD).

Patients must follow the instructions in the simpli-COLLECT HPV Collection Kit (List No. 09R03) or Evalyn Brush for self-collecting vaginal specimens in a clinical or non-clinical setting.

For simpli-COLLECT HPV specimens, only the orange-shaft swab provided in the kit should be used. An Alinity m Sample Tube from the simpli-COLLECT HPV Collection Kit containing no swab, a different type of swab, multiple swabs, or other foreign material cannot be used with the Alinity m HR HPV assay, and a new specimen should be collected.

Specimen Types

Specimens collected in ThinPrep PreservCyt Solution, SurePath Preservative Fluid, or using Alinity m Cervi-Collect Specimen Collection Kit (List No. 09N29-001), simpli-COLLECT HPV Collection Kit (List No. 09R03), or Evalyn Brush can be tested with the Alinity m HR HPV assay. For ThinPrep PreservCyt and SurePath specimens, the aliquot that is removed either prior to or after cytological processing from the collection vial can be used.

Collection Device	Specimen Type[a]
Alinity m Cervi-Collect Specimen Collection Kit	Cervical Specimens
ThinPrep PreservCyt Solution	Cervical Specimens
SurePath Preservative Fluid	Cervical Specimens
simpli-COLLECT HPV Collection Kit	Vaginal Specimens
Evalyn Brush	Vaginal Specimens

[a] The instrument does not provide the capability to verify specimen types. It is the responsibility of the operator to use the correct specimen types in the assay.

Specimen Storage

Collection Device	Temperature	Maximum Storage Time from Date of Collection
Alinity m Cervi-Collect Specimen Collection Kit	2°C to 30°C	6 months
	–25°C to –15°C	6 months [a]
ThinPrep PreservCyt Solution	2°C to 30°C	6 months
	–25°C to –15°C	6 months
SurePath Preservative Fluid	15°C to 30°C	2 weeks
	2°C to 8°C	6 months
	–25°C to –15°C	6 months
simpli-COLLECT HPV Collection Kit	2°C to 30°C	30 days (dry) [b]
	2°C to 30°C	30 days (resuspended) [b,c]
	–25°C to –15°C	6 months (resuspended) [a,c]
Evalyn Brush	2°C to 30°C	30 days (dry) [b]
	2°C to 30°C	30 days (resuspended) [b,d]
	–25°C to –15°C	6 months (resuspended) [a,d]

[a] Avoid more than 4 freeze-thaw cycles.

[b] Total storage time for dry and resuspended specimens at 2°C to 30°C must not exceed a combined total of 30 days from date of collection.

[c] Resuspend the specimen in Alinity m Specimen Buffer II.

[d] Resuspend the specimen in an Alinity m Specimen Buffer III tube pre-filled with buffer.

Specimen Shipping

Ship cervical specimens according to the recommended storage temperature listed in the **Specimen Storage** section. Ship simpli-COLLECT HPV specimens and Evalyn Brush specimens at ambient temperature. Package and label specimens in compliance with applicable state, federal, and international regulations covering the transport of clinical, diagnostic, or biological specimens.

Preparation for Analysis

Cervical Specimens

Alinity m Cervi-Collect Specimen Collection Kit specimens arriving in the laboratory containing a cervical brush cannot be tested with the Alinity m HR HPV assay. The collection of a new specimen is required.
For ThinPrep PreservCyt specimens, vortex each specimen for 15 to 20 seconds and immediately transfer a volume between 0.55 mL and 2.00 mL to an Alinity m Transport Tube (List No. 09N49-010 or 09N49-011) or Alinity m Labeled Tube with Pierceable Cap (List No. 09N65-050) prior to loading on the Alinity m System.
The Alinity m Transport Tube may be capped with an Alinity m Pierceable Cap (List No. 09N49-012).

For SurePath specimens from the original SurePath vial, vortex each specimen for 15 to 20 seconds and immediately transfer 0.5 mL of each specimen to an Alinity m Transport Tube (List No. 09N49-010 or 09N49-011) or Alinity m Labeled Tube with Pierceable Cap (List No. 09N65-050) prior to loading on the Alinity m System.
The Alinity m Transport Tube may be capped with an Alinity m Pierceable Cap (List No. 09N49-012).

NOTE: Do not use specimens which appear bloody or have a dark brown color.

NOTE: Do not use Alinity m Aliquot Tube (List No. 09N49-013).

Self-collected Vaginal Specimens

Self-collected vaginal specimens using the simpli-COLLECT HPV Collection Kit:

1. Uncap the Alinity m Sample Tube for Dry Swab and place in a sample rack or a tube holder.
2. Transfer 2.5 mL of Alinity m Specimen Buffer II from the Alinity m Specimen Buffer Kit II (List No. 09R03-050) into the Alinity m Sample Tube for Dry Swab.
3. Replace the pierceable cap on the tube.
   NOTE: The swab should remain in the tube while being processed on the Alinity m System.

Self-collected vaginal specimens using the Evalyn Brush:

1. Uncap an Alinity m Specimen Buffer Kit III tube. Place uncapped tube in a sample rack or a tube holder to avoid spilling buffer out of the tube; place the pierceable cap on a clean table liner to avoid contamination.
2. Hold the Evalyn Brush device and remove the pink cap by squeezing the cap sides.
3. Push the pink plunger to expose the brush head and the base of the brush head. Do not touch the Evalyn Brush white bristles.
4. If using Evalyn Tweezers to detach the brush head, position the tweezers around the base of the brush head. If using a ReMover to transfer the brush head, guide the Evalyn Brush into the ReMover until the casing hits the ReMover.
   NOTE: A new pair of Evalyn Tweezers or a new ReMover must be used for each brush.
5. Squeeze the Evalyn Tweezers or the ReMover firmly together and pull the brush head off. Keep the Evalyn Tweezers or ReMover compressed.
6. Hold the Evalyn Tweezers or ReMover over the opening of the Alinity m Specimen Buffer Kit III tube and release the brush head into the tube with the bristles oriented up.
7. Replace the pierceable cap on the tube.

PROCEDURE

Materials Provided

09N15-092 Alinity m HR HPV AMP Kit

Materials Required but not Provided

- 09N15-080 Alinity m HR HPV CTRL Kit
- 09N18-001 Alinity m Sample Prep Kit 1
- 09N20-001 Alinity m Lysis Solution
- 09N20-002 Alinity m Ethanol Solution or 09N20-012 Alinity m Bottle for Ethanol Use (filled with customer supplied 190 Proof Ethanol, ACS, Denaturant free)
- 09N20-003 Alinity m Diluent Solution
- 09N20-004 Alinity m Vapor Barrier Solution
- 09N49-010 Alinity m Transport Tube Pierceable Capped
- 09N49-011 Alinity m Transport Tubes
- 09N49-012 Alinity m Pierceable Caps
- 09N65-050 Alinity m Labeled Tube with Pierceable Cap
- 09R03-050 Alinity m Specimen Buffer Kit II
- 09R03-060 Alinity m Specimen Buffer Kit III
- Alinity m HR HPV Application Specification File
- Vortex mixer
- Calibrated pipettes capable of delivering 100 to 1000 µL
- Aerosol barrier pipette tips for 100 to 1000 µL pipettes
- Plate adapter for 384 well plates (such as Eppendorf Catalog No. 022638955)
- Centrifuge with swing plate rotor capable of accommodating the plate adapter and capable of ≥ 100 *g*

For information on materials required for operation of the instrument, refer to the Alinity m System Operations Manual, Section 1.

For general operating procedures, refer to the Alinity m System Operations Manual, Section 5.

For optimal performance, it is important to perform routine maintenance as described in the Alinity m System Operations Manual, Section 9.

Procedural Precautions

- Read the instructions in this package insert carefully before processing samples.
- Use aerosol barrier pipette tips or disposable pipettes only one time when pipetting specimens. To prevent contamination to the pipette barrel while pipetting, care should be taken to avoid touching the pipette barrel to the inside of the sample tube or container. The use of extended aerosol barrier pipette tips is recommended.
- Do not use specimens if the specimen tube is damaged or if buffer has leaked from the specimen tube. Discard unused, damaged or leaking specimen tubes in accordance with local, state, and federal regulations.
- Work area and instrument platforms must be considered potential sources of contamination.
- Ensure the Alinity m HR HPV AMP TRAY 1 is tapped prior to loading on the Alinity m System per instructions in the **Assay Procedure** section.
- Ensure the Alinity m HR HPV ACT TRAY 2 is centrifuged prior to loading on the Alinity m System per instructions in the **Assay Procedure** section.
- Monitoring procedures for the presence of amplification product can be found in the Alinity m System Operations Manual, Section 9.
- To reduce the risk of nucleic acid contamination, clean and disinfect spills of specimens by including the use of a tuberculocidal disinfectant such as 1.0% (v/v) sodium hypochlorite or other suitable disinfectant.
- To prevent contamination, change to new gloves before handling the Alinity m Sample Prep Kit 1, assay trays, system solutions, Integrated Reaction Unit (IRU) sleeves, and pipette tips. Also change to new gloves whenever they are contaminated by a specimen, a control, or a reagent. Always use powder-free gloves.
- The use of the Alinity m HR HPV CTRL Kit is integral to the performance of the Alinity m HR HPV assay. Refer to the **QUALITY CONTROL PROCEDURES** section of this package insert for details. Refer to the Alinity m HR HPV CTRL Kit package insert for preparation and usage.
- The Alinity m HR HPV control reagents are contained in single-use tubes with pierceable caps. Avoid contamination or damage to the caps after removal from their original packaging. Discard tubes after use.

Assay Procedure

Prior to loading on the Alinity m System, hold the AMP TRAY 1 by the edges with the label facing up and tap three times on the bench.

Prior to loading on the Alinity m System, ACT TRAY 2 must be centrifuged as follows:

1. Load ACT TRAY 2 onto the plate adapter (Eppendorf Catalog No. 022638955).
2. Load the plate adapter (with ACT TRAY 2) on a swing plate centrifuge capable of accommodating the plate adapter. Spin at 100 to 800 *g* for 1 to 5 minutes to remove potential bubbles.
3. Immediately following centrifugation, carefully transfer the ACT TRAY 2 to the Alinity m Assay Tray Carriers. Take care to minimize disturbance to the ACT TRAY 2. Load the tray carriers per the Alinity m System Operations Manual, Section 5.
4. If disturbance occurs during transfer that could potentially introduce bubbles (eg, dropping, bumping, inversion of the ACT TRAY 2), re-centrifuge the ACT TRAY 2.
5. Proceed with the **Reagent and sample inventory management** procedure per the Alinity m System Operations Manual, Section 5.

For a detailed description of how to run an assay, refer to the Alinity m System Operations Manual, Section 5.

Prior to testing specimens, check control status. If control testing is required, refer to **QUALITY CONTROL PROCEDURES** section. Controls may be tested separately or with specimens.

For preparation of samples, refer to the instructions under **SPECIMEN COLLECTION AND PREPARATION FOR ANALYSIS**: **Preparation for Analysis** section. Vortex specimens for 15 to 20 seconds prior to loading on the Alinity m System. If the specimen is stored frozen, it must be completely thawed prior to sample preparation.

From the Create Order screen, select the assay (HR HPV 07A) being tested.

The Alinity m System will track the onboard storage time of amplification reagents, controls, and specimens while on the instrument. The Alinity m System will not allow the use of amplification reagents, controls, or process specimens that have exceeded the allowable onboard storage time. Specimen tubes need to meet the requirements for minimum sample volume and use of caps when loaded on the Alinity m System.

Specimen tubes may be placed on the Alinity m Universal Sample Rack (sample rack) onboard the system for up to 4 hours prior to processing. Specimens collected with the simpli-COLLECT HPV Collection Kit and Evalyn Brush must be loaded onto the sample rack capped and with the retention bar on. Clean the retention bar after each use.

Tube Type [a]	List No.	Minimum Specimen Volume	Cap Requirement on Instrument
Alinity m Cervi-Collect Specimen Collection Transport Tube	09N29-001	0.55 mL	Capped or Uncapped
Alinity m Transport Tube Pierceable Capped	09N49-010	ThinPrep: 0.55 mL SurePath: 0.50 mL	Capped or Uncapped
Alinity m Transport Tube Alinity m Pierceable Cap	09N49-011 09N49-012	ThinPrep: 0.55 mL SurePath: 0.50 mL	Capped or Uncapped
Alinity m Labeled Tube with Pierceable Cap	09N65-050	ThinPrep: 0.55 mL SurePath: 0.50 mL	Capped or Uncapped
Alinity m Sample Tube for Dry Swab (for simpli-COLLECT HPV Collection Kit)	AB887	Fill volume allows initial test and one retest	Capped
Alinity m Specimen Buffer III (for Evalyn Brush)	09R03-060	Fill volume allows initial test and one retest	Capped

[a] Do not use Alinity m Aliquot Tube (List No. 09N49-013)

Post Processing Procedure

Upon completion of sample processing, specimens collected with the Alinity m Cervi-Collect Specimen Collection Kit and ThinPrep PreservCyt and SurePath specimens that have been transferred in Alinity m Transport Tubes can be recapped using new, unused Alinity m Pierceable Caps (List No. 09N49-012). Store specimens according to the **Specimen Storage** section.

Upon completion of sample processing, specimens collected with the simpli-COLLECT HPV Collection Kit and Evalyn Brush can be recapped using new, unused Alinity m Pierceable Caps (List No. 09N49-012). Store specimens according to the **Specimen Storage** section.

QUALITY CONTROL PROCEDURES

Negative and Positive Controls

One Alinity m HR HPV Negative CTRL and one Alinity m HR HPV Positive CTRL are recommended to be tested, at or above the minimum frequency of once every 48 hours, to monitor the performance of the assay and Alinity m System. Valid results for all control levels must be obtained before specimen results are reported. Additional controls may be tested in accordance with local, state, and/or federal regulations or accreditation requirements and your laboratory's quality control policy.

If quality control results do not meet the acceptance criteria, refer to the Alinity m System Operations Manual, Section 10, for troubleshooting information. A flag is displayed for specimens when a control result is invalid. All of the specimens processed following an invalid assay control must be retested.

If control results are invalid, refer to the Alinity m System Operations Manual, Section 5 for a description of quality control flags, and Section 10 for troubleshooting information.

The presence of HPV must not be detected in the negative control. HPV detected in the negative control is indicative of contamination by other samples or by amplified product. To avoid contamination, clean the Alinity m System and repeat sample processing for controls and specimens following the Procedural Precautions in this package insert. Monitoring procedures for the presence of amplification product can be found in the Alinity m System Operations Manual, Section 9.

If negative controls are persistently reactive, contact your Abbott Representative.

Detection of Inhibition and/or Cell Inadequacy

The Alinity m HR HPV assay detects the endogenous human beta globin (BG) sequence as Cellular Control (CC) signal to evaluate cell adequacy, sample extraction and amplification efficiency. The CC cycle number (CN) is assessed against a defined range to determine specimen validity.

A Flag or Message Code is displayed when CC CN value of a specimen is out of the established range.

- If the HPV signal(s) in a specimen is detected and CC CN is out of range, the specimen will yield an HR HPV Detected interpretation. A Flag will be displayed.
- If the HPV signal(s) in a specimen is not detected and CC CN is out of range, no HPV result will be reported and a Message Code will be displayed.

Refer to the Alinity m System Operations Manual, Section 5 for an explanation of the corrective actions for Flags.

Refer to the Alinity m System Operations Manual, Section 10 for an explanation of the corrective actions for Message Codes.

RESULTS

Results and interpretations for the Alinity m HR HPV assay are determined based on the comparison of specimen's cycle number (CN) values in each HPV signal against signal-specific, established cutoff values. Five HPV signals measured in separate fluorescence channels corresponding to HPV 16, HPV 18, HPV 45, HPV 31/33/52/58 (pooled signal: a single signal corresponding to any individual genotype or combination of genotypes within the group) and HPV 35/39/51/56/59/66/68 (pooled signal) are evaluated for each sample. Each signal is either determined as "Detected" if the CN is less than or equal to a fixed assay cutoff cycle for that signal or is determined as "Not Detected" if either the CN is not generated or the CN is greater than the assay cutoff cycle. All the detected signals (HPV 16, HPV 18, HPV 45, Other HR HPV A or Other HR HPV B) are reported in the sample result. The detection of Other HR HPV A is reported when HPV 31/33/52/58 signal is detected. The detection of Other HR HPV B is reported when HPV 35/39/51/56/59/66/68 signal is detected. Samples with any of the HR HPV signals detected have an interpretation of "HR HPV Detected." Samples with all HR HPV signals not detected will have an interpretation of "Not Detected."

Interpretation of Results

Results	Interpretation	Flags
Not Detected	Not Detected	
HPV 16	HR HPV Detected	
HPV 18	HR HPV Detected	
HPV 45	HR HPV Detected	
Other HR HPV A	HR HPV Detected	
Other HR HPV B	HR HPV Detected	
HPV16; HPV18	HR HPV Detected	
HPV16; HPV45	HR HPV Detected	
HPV16; Other HR HPV A	HR HPV Detected	
HPV16; Other HR HPV B	HR HPV Detected	
HPV18; HPV 45	HR HPV Detected	
HPV18; Other HR HPV A	HR HPV Detected	
HPV18; Other HR HPV B	HR HPV Detected	
HPV45; Other HR HPV A	HR HPV Detected	
HPV45; Other HR HPV B	HR HPV Detected	
Other HR HPV A; Other HR HPV B	HR HPV Detected	
HPV16; HPV18; HPV45	HR HPV Detected	
HPV16; HPV18; Other HR HPV A	HR HPV Detected	
HPV16; HPV18; Other HR HPV B	HR HPV Detected	
HPV16; HPV45; Other HR HPV A	HR HPV Detected	
HPV16; HPV45; Other HR HPV B	HR HPV Detected	
HPV16; Other HR HPV A; Other HR HPV B	HR HPV Detected	
HPV18; HPV45; Other HR HPV A	HR HPV Detected	
HPV18; HPV45; Other HR HPV B	HR HPV Detected	
HPV18; Other HR HPV A; Other HR HPV B	HR HPV Detected	
HPV45; Other HR HPV A; Other HR HPV B	HR HPV Detected	
HPV16; HPV18; HPV45; Other HR HPV A	HR HPV Detected	
HPV16; HPV18; HPV45; Other HR HPV B	HR HPV Detected	
HPV16; HPV18; Other HR HPV A; Other HR HPV B	HR HPV Detected	
HPV16; HPV45; Other HR HPV A; Other HR HPV B	HR HPV Detected	
HPV18; HPV45; Other HR HPV A; Other HR HPV B	HR HPV Detected	
HPV16; HPV18; HPV45; Other HR HPV A; Other HR HPV B	HR HPV Detected	

Flags, Results Codes, and Message Codes

Some results may contain information in the Flags and Codes fields. For a description of the flags and result codes that may appear in these fields, refer to the Alinity m System Operations Manual, Section 5.

For a description of message codes, refer to the Alinity m System Operations Manual, Section 10.

LIMITATIONS OF THE PROCEDURE

- Optimal performance of this test requires appropriate specimen collection and handling (refer to the **SPECIMEN COLLECTION AND PREPARATION FOR ANALYSIS** section of this package insert).
- Clinician-collected cervical specimens collected with the Alinity m Cervi-Collect Specimen Collection Kit, collected in ThinPrep PreservCyt Solution, or SurePath Preservative Fluid may be used with the Alinity m HR HPV assay. Self-collected vaginal specimens collected with the simpli-COLLECT HPV Collection Kit and Evalyn Brush in a clinical or non-clinical setting may be used with the Alinity m HR HPV assay. Performance with other specimen types or collection devices has not been evaluated.
- The instruments and assay procedures reduce the risk of contamination by amplification product. However, nucleic acid contamination from the positive controls or specimens must be controlled by good laboratory practice and careful adherence to the procedures specified in this package insert.
- If the HPV results are inconsistent with clinical evidence, additional testing is suggested to confirm the result.
- As with any diagnostic test, results from the Alinity m HR HPV assay should be interpreted in conjunction with other clinical and laboratory findings.

SPECIFIC PERFORMANCE CHARACTERISTICS

Clinical Sensitivity and Specificity in Screening Population

The clinical sensitivity and specificity for detection of ≥CIN2 among a screening population (age ≥ 30 years) were determined for Alinity m HR HPV in comparison with hc2 High-Risk HPV DNA Test (hc2) and Abbott RealTi*m*e High Risk (HR) HPV (**Table 1**). All specimens were collected in ThinPrep PreservCyt Solution.

Table 1. Clinical Sensitivity and Specificity in Screening Population

	Sensitivity (%)		Specificity (%)	
Assay	**Estimate (95% CI)**	**n/N[a]**	**Estimate (95% CI)**	**n/N[b]**
Alinity m HR HPV	100.0 (94.7, 100.0)	68/68	93.2 (92.2, 94.0)	2768/2971
hc2	95.6 (87.8, 98.5)	65/68	92.9 (91.9, 93.7)	2759/2971
Abbott RealTi*m*e HR HPV	100.0 (94.7, 100.0)	68/68	94.2 (93.3, 95.0)	2794/2967

[a] n represents the number of ≥ CIN2 specimens detected. N represents the number of ≥ CIN2 specimens tested.

[b] n represents the number of disease negative specimens that were not detected. N represents the number of disease negative specimens that were tested. Negative disease status is defined as either < CIN2 histology or negative cytology when histology result is unknown.

Among the 68 ≥ CIN2 specimens, 34 were ≥ CIN3. The clinical sensitivity for detection of ≥ CIN3 was 100.0% (34/34; 95% CI 89.8% to 100.0%) for Alinity m HR HPV, 97.1% (33/34; 95% CI 85.1% to 99.5%) for hc2, and 100.0% (34/34; 95% CI 89.8% to 100.0%) for Abbott RealTi*m*e HR HPV.

Clinical Sensitivity in ASC-US Population

The clinical sensitivity for detection of ≥ CIN2 among patients with ASC-US cytology was determined for Alinity m HR HPV in comparison with hc2 and Abbott RealTi*m*e HR HPV (**Table 2**). All specimens were collected in ThinPrep PreservCyt Solution.

Table 2. Clinical Sensitivity in ASC-US Population

Assay	**Estimate (95% CI)**	**n/N[a]**
Alinity m HR HPV	96.8 (83.8, 99.4)	30/31
hc2	93.5 (79.3, 98.2)	29/31
Abbott RealTi*m*e HR HPV	96.8 (83.8, 99.4)	30/31

[a] n represents the number of ≥ CIN2 specimens detected. N represents the number of ≥ CIN2 specimens tested.

Clinical Specificity in Screening Population with Normal Cytology

The clinical specificity in a screening population (age ≥ 30 years) with normal cytology was determined for Alinity m HR HPV in comparison with hc2 and Abbott RealTi*m*e HR HPV (**Table 3**). All specimens were collected in ThinPrep PreservCyt Solution.

Table 3. Clinical Specificity in Screening Population with Normal Cytology

Assay	**Estimate (95% CI)**	**n/N[a]**
Alinity m HR HPV	92.8 (91.8, 93.7)	2762/2976
hc2	92.5 (91.5, 93.4)	2753/2976
Abbott RealTi*m*e HR HPV	93.8 (92.9, 94.6)	2788/2972

[a] n represents the number of specimens that were not detected. N represents the number of specimens tested.

Accuracy in Identification of HPV 16 and/or HPV 18 in Women with Cervical Disease

The performance of Alinity m HR HPV in identification of HPV 16 and/or HPV 18 in ≥ CIN2 was evaluated based on the results from a screening population (age ≥ 30 years) and an ASC-US population (**Table 4**). Out of 68 ≥ CIN2 specimens from the screening population, 68 had an interpretation of "HR HPV Detected" from both Alinity m HR HPV and Abbott RealTi*m*e HR HPV. Thirty-five specimens were detected as HPV 16 and/or HPV 18 by both assays. Thirty-three specimens were detected as non-HPV 16/18 by both assays. The overall agreement for detection of HPV 16 and/or HPV 18 between Alinity m HR HPV and Abbott RealTi*m*e HR HPV was 100.0% (68/68).

Table 4. Genotyping Accuracy for HPV 16 and/or HPV 18 in Screening Population

	Abbott RealTi*m*e HR HPV	
Alinity m HR HPV	**HPV 16 and/or HPV 18 Detected[a]**	**Non-HPV 16/18 High Risk Genotype(s) Detected[b]**
HPV 16 and/or HPV 18 Detected[a]	35	0
Non-HPV 16/18 High Risk Genotype(s) Detected[b]	0	33

[a] These specimens were detected for HPV 16 and/or HPV 18 signal(s) with or without non-HPV 16/18 HR HPV signal detected.

[b] These specimens were not detected for HPV 16 or HPV 18 signal and detected for non-HPV 16/18 HR HPV signal.

Out of 31 ≥ CIN2 specimens from the ASC-US population, 30 had an interpretation of "HR HPV Detected" from both Alinity m HR HPV and Abbott RealTi*m*e HR HPV (**Table 5**). Twenty two specimens were detected as HPV 16 and/or HPV 18 by both assays. Eight specimens were detected as non-HPV 16/18 by both assays. The overall agreement for detection of HPV 16 and/or HPV 18 between Alinity m HR HPV and Abbott RealTi*m*e HR HPV was 100.0% (30/30).

Table 5. Genotyping Accuracy for HPV 16 and/or HPV 18 in ASC-US Population

	Abbott RealTi*m*e HR HPV	
Alinity m HR HPV	**HPV 16 and/or HPV 18 Detected[a]**	**Non-HPV 16/18 High Risk Genotype(s) Detected[b]**
HPV 16 and/or HPV 18 Detected[a]	22	0
Non-HPV 16/18 High Risk Genotype(s) Detected[b]	0	8

[a] These specimens were detected for HPV 16 and/or HPV 18 signal(s) with or without non-HPV 16/18 HR HPV signal detected.

[b] These specimens were not detected for HPV 16 or HPV 18 signal and detected for non-HPV 16/18 HR HPV signal.

Estimate of Relative Disease Risk Associated with Different Genotype Results

The relative risks of having cervical disease (≥ CIN2) were estimated, by calculating the ratio of absolute risks, for HPV 16 and/or HPV 18 Detected vs. Non-HPV 16/18 HR HPV Detected results in a screening population (age ≥ 30 years) and an ASC-US Population (**Table 6**). The relative risk was 2.3 in screening population, and 2.1 in ASC-US population.

Table 6. Relative Risk of Cervical Disease Associated with Different Genotype Results (HPV 16 and/or HPV 18 Detected vs Non-HPV 16/18 HR HPV Detected)

Population	**Relative Risk**	**95% CI**
Screening	2.3	(1.6, 3.5)
ASC-US	2.1	(1.1, 4.1)

Genotype Inclusivity and Partial Genotyping

The ability of Alinity m HR HPV to detect 14 HR HPV genotypes (HPV 16, 18, 31, 33, 35, 39, 45, 51, 52, 56, 58, 59, 66, and 68) and to specifically identify HPV genotypes 16, 18 and 45 while reporting the concurrent detection of the other high-risk genotypes (Other HR HPV A: 31/33/52/58; Other HR HPV B: 35/39/51/56/59/66/68) was evaluated. Forty samples containing HPV DNA targets from 14 genotypes, individually and in combinations, were tested as listed in **Table 7**. Results from all samples including 14 with single genotype, 10 with 2 genotypes, 10 with 3 genotypes, 5 with 4 genotypes and 1 with 5 genotypes were reported accurately. The presence or absence of HPV DNA for each designated signal, HPV 16, HPV 18, HPV 45, Other HR HPV A and Other HR HPV B, was accurately determined in each case.

Table 7. Genotype Detection and Partial Genotyping Capability

Sample No.	Genotype(s)	Reported Result
1	HPV 16	HPV 16
2	HPV 18	HPV 18
3	HPV 31	Other HR HPV A
4	HPV 33	Other HR HPV A
5	HPV 35	Other HR HPV B
6	HPV 39	Other HR HPV B
7	HPV 45	HPV 45
8	HPV 51	Other HR HPV B
9	HPV 52	Other HR HPV A
10	HPV 56	Other HR HPV B
11	HPV 58	Other HR HPV A
12	HPV 59	Other HR HPV B
13	HPV 66	Other HR HPV B
14	HPV 68	Other HR HPV B
15	HPV 16 and HPV 18	HPV 16; HPV 18
16	HPV 16 and HPV 45	HPV 16; HPV 45
17	HPV 16 and HPV 58	HPV 16; Other HR HPV A
18	HPV 16 and HPV 39	HPV 16; Other HR HPV B
19	HPV 18 and HPV 45	HPV 18; HPV 45
20	HPV 18 and HPV 58	HPV 18; Other HR HPV A
21	HPV 18 and HPV 39	HPV 18; Other HR HPV B
22	HPV 45 and HPV 58	HPV 45; Other HR HPV A
23	HPV 45 and HPV 39	HPV 45; Other HR HPV B
24	HPV 58 and HPV 39	Other HR HPV A; Other HR HPV B
25	HPV 16, HPV 18, and HPV 45	HPV 16; HPV 18; HPV 45
26	HPV 16, HPV 18, and HPV 58	HPV 16; HPV 18; Other HR HPV A
27	HPV 16, HPV 18, and HPV 39	HPV 16; HPV 18; Other HR HPV B
28	HPV 16, HPV 45, and HPV 58	HPV 16; HPV 45; Other HR HPV A
29	HPV 16, HPV 45, and HPV 39	HPV 16; HPV 45; Other HR HPV B
30	HPV 16, HPV 58, and HPV 39	HPV 16; Other HR HPV A; Other HR HPV B
31	HPV 18, HPV 45, and HPV 58	HPV 18; HPV 45; Other HR HPV A
32	HPV 18, HPV 45, and HPV 39	HPV 18; HPV 45; Other HR HPV B
33	HPV 18, HPV 58, and HPV 39	HPV 18; Other HR HPV A; Other HR HPV B
34	HPV 45, HPV 58, and HPV 39	HPV 45; Other HR HPV A; Other HR HPV B
35	HPV 16, HPV 18, HPV 45, and HPV 58	HPV 16; HPV 18; HPV 45; Other HR HPV A
36	HPV 16, HPV 18, HPV 45, and HPV 39	HPV 16; HPV 18; HPV 45; Other HR HPV B
37	HPV 16, HPV 18, HPV 58, and HPV 39	HPV 16; HPV 18; Other HR HPV A; Other HR HPV B
38	HPV 16, HPV 45, HPV 58, and HPV 39	HPV 16; HPV 45; Other HR HPV A; Other HR HPV B
39	HPV 18, HPV 45, HPV 58, and HPV 39	HPV 18; HPV 45; Other HR HPV A; Other HR HPV B
40	HPV 16, HPV 18, HPV 45, HPV 58, and HPV 39	HPV 16; HPV 18; HPV 45; Other HR HPV A; Other HR HPV B

Limit of Detection for High Risk HPV Genotypes

Limit of detection (LoD) of Alinity m HR HPV was determined by testing plasmids for 14 HR HPV genotype sequences (16, 18, 31, 33, 35, 39, 45, 51, 52, 56, 58, 59, 66, and 68) in ThinPrep PreservCyt Solution containing an HPV negative human cell line (C33A) background. In addition, LoD was determined by testing HPV positive cell lines, SiHa (HPV 16) and HeLa (HPV18), in ThinPrep PreservCyt Solution containing C33A cell line background. Four hundred microliters of sample is used per assay. Each plasmid or cell line was diluted to 4 concentrations, including at, below and above the expected LoD levels, and was tested with 2 lots of amplification reagents. For each plasmid or cell line, a total of 72 replicates were tested across all concentrations (ie, 4 concentrations, 6 replicates per day over 3 days per concentration) with each amplification reagent lot. The LoD was defined as a concentration having a ≥95% detection rate with all higher concentrations having a ≥95% detection rate. The LoD was 40 cells per assay for SiHa (HPV 16) and HeLa (HPV 18); 240 copies per assay for HPV 16 and 18; 500 copies per assay for HPV 45; 2000 copies per assay for HPV 33, 35, 51, 52, and 59; and 5000 copies per assay for HPV 31, 39, 56, 58, 66, and 68.

To evaluate the LoD for vaginal collection devices, plasmids for the 14 HR HPV genotype sequences and HPV positive cell lines SiHa (HPV 16) and HeLa (HPV 18) were prepared at LoD in Specimen Buffer containing an HPV negative human cell line background. Testing was performed using 1 lot of amplification reagent.

100% detection was observed at 40 cells per assay for SiHa (HPV16) and HeLa (HPV18) cells, 240 copies per assay for HPV 16 and 18, 500 copies per assay for HPV 45, 2000 copies per assay for HPV 33, 35, 51, and 59, 4000 copies per assay for HPV 52, and 5000 copies per assay for HPV 31, 39, 56, 58, 66, and 68.

Reproducibility

A total of 581 specimens were tested to evaluate the reproducibility of Alinity m HR HPV within the same laboratory. Each of the specimens was tested twice by two operators in the same laboratory. The overall percent agreement between the two tests (**Table 8**) was 97.9% (569/581; 95% CI: 96.4% to 98.8%), with average positive agreement of 96.9% (370/382; 95% CI: 94.9% to 98.5%) and average negative agreement of 98.5% (768/780; 95% CI: 97.5% to 99.2%).

Table 8. Intra-laboratory Reproducibility

		Second Test	
		HR HPV Detected	**Not Detected**
First Test	**HR HPV Detected**	185	5
	Not Detected	7	384

A total of 560 specimens were tested to evaluate the reproducibility of Alinity m HR HPV between two laboratories at Abbott using different Alinity m Systems. The overall percent agreement between the two tests (**Table 9**) was 97.5% (546/560; 95% CI: 95.8% to 98.5%), with average positive agreement of 96.1% (342/356; 95% CI: 93.7% to 97.9%) and average negative agreement of 98.2% (750/764; 95% CI: 97.1% to 99.0%).

Table 9. Inter-laboratory Reproducibility

		Second Laboratory	
		HR HPV Detected	**Not Detected**
First Laboratory	**HR HPV Detected**	171	9
	Not Detected	5	375

Analytical Specificity – Potential Cross-Reactants

The analytical specificity of Alinity m HR HPV was evaluated with a panel of microorganisms (**Table 10**) in HPV negative samples and HR HPV positive samples (containing HPV at 3 times the limit of detection). The panel included low-risk HPV, bacteria, viruses, protozoan, yeast, and human cellular DNA. No cross-reactivity or interference in Alinity m HR HPV performance was observed in the presence of the tested microorganisms.

Table 10. Microorganisms Tested

Low Risk HPV	Bacteria	Virus
HPV 6	*Bacteroides fragilis*	Adenovirus
HPV 11	*Bacteroides ureolyticus*	Cytomegalovirus (CMV)
HPV 13	*Bifidobacterium adolescentis*	Epstein Barr Virus (EBV)
HPV 26	*Chlamydia trachomatis*	Hepatitis B virus (HBV)
HPV 30	*Clostridium perfringens*	Herpes simplex virus I
HPV 32	*Corynebacterium genitalium*	Herpes simplex virus II
HPV 34	*Entercoccus faecalis*	Human Herpes virus 3
HPV 40	*Enterobacter cloacae*	Hepatitis C virus (HCV)
HPV 42	*Escherichia coli*	Human immunodeficiency virus (HIV-1)
HPV 43	*Fusobacterium necrophorum*	
HPV 44	*Gardnerella vaginalis*	**Protozoan**
HPV 53	*Haemophilus ducreyi*	Trichomonas vaginalis
HPV 54	*Klebsiella pneumoniae ss ozaenae*	
HPV 55B	*Lactobacillus acidophilus*	**Yeast**
HPV 57	*Mycoplasma genitalium*	Candida albicans
HPV 61	*Mycoplasma hominis*	
HPV 67	*Neisseria gonorrhoeae*	**Other**
HPV 69	*Neisseria meningitidis Serogroup A*	Human Cellular DNA
HPV 70	*Peptostreptococcus anaerobius*	
HPV 73	*Proteus mirabilis*	
HPV 82	*Pseudomonas aeruginosa*	
HPV 85	*Staphylococcus aureus*	
	Staphylococcus epidermidis	
	Streptococcus agalactiae	
	Streptococcus pneumoniae	
	Streptococcus pyogenes	
	Trepenoma pallidum	
	Ureaplasma urealyticum	

Analytical Specificity – Potentially Interfering Substances

The effect of potentially interfering endogenous and exogenous substances that may be present in cervical specimens on Alinity m HR HPV performance was assessed by testing HPV negative samples and HPV positive samples (SiHa and HeLa cell lines at 3 times the limit of detection) in ThinPrep PreservCyt Solution containing C33A cell line background. Blood was evaluated at a concentration of 10% (v/v), mucus at 5% (v/v), and peripheral blood mononuclear cells (PBMC) at approximately 1×10^6 cells/mL. The exogenous interference substances were evaluated at 0.5% (w/v) by spiking into the sample. No interference in Alinity m HR HPV performance was observed in the presence of the tested substances (**Table 11**).

Table 11. Substances Tested

Mucus	Up & Up Lubricating Liquid
PBMC	KY Jelly
Whole Blood	VCF Contraceptive Gel
Norforms Deodorant Suppositories	Conceptrol Vaginal Contraceptive Gel
Clotrimazole Vaginal Cream	Hydrocortisone
Terazol-3 Vaginal Cream	Zovirax
Monistat 3	Up & Up Povidone - Iodine
Metrogel-Vaginal	Sigma Acetic Acid
KY Warming Liquid	

Carryover

The carryover rate for Alinity m HR HPV assay was evaluated in 3 studies. In study 1, the sample input rack and sample processing unit carryover rate was determined by analyzing 265 replicates of HPV negative samples processed from alternating positions in the sample rack with high concentration HPV positive samples (representative of cervical specimens) at 10,000,000 copies/mL, across multiple runs. HPV was not detected in any HPV negative sample, resulting in an overall carryover rate of 0.0% (95% CI: 0.0% to 1.4%).

In study 2, the sample input rack and sample processing unit carryover rate for vaginal collection devices was determined by analyzing 240 replicates of HPV negative samples processed from alternating positions in the sample rack with high concentration HPV positive sample prepared in Specimen Buffer at 10,000,000 copies/mL, across multiple runs. HPV was detected in 2 HPV negative samples, resulting in an overall carryover rate of 0.8% (95% CI: 0.2% to 3.0%).

In study 3, the AMP tray carryover rate was determined by analyzing 285 replicates of HPV negative samples processed from alternating positions on the AMP tray with high concentration HPV positive samples at >10,000,000 copies/mL, across multiple runs. HPV was not detected in any HPV negative sample, resulting in an overall carryover rate of 0.0% (95% CI: 0.0% to 1.3%).

Agreement Between Specimen Types

Specimens collected in ThinPrep PreservCyt Solution and with the Alinity m Cervi-Collect Specimen Collection Kit from the same 277 patients were tested with Alinity m HR HPV. The overall percent agreement between the Alinity m HR HPV interpretations of the two specimen types (**Table 12**) was 94.6% (262/277; 95% CI: 91.3% to 96.7%), with average positive agreement of 93.4% (214/229; 95% CI: 89.7% to 96.5%) and average negative agreement of 95.4% (310/325; 95% CI: 92.7% to 97.6%).

Table 12. Agreement between Cervi-Collect and ThinPrep PreservCyt Specimens

		Cervi-Collect	
		HR HPV Detected	**Not Detected**
ThinPrep PreservCyt	**HR HPV Detected**	107	8
	Not Detected	7	155

Specimens collected in SurePath Preservative Fluid and ThinPrep PreservCyt Solution from the same 276 patients were tested with Alinity m HR HPV. The overall percent agreement between the Alinity m HR HPV interpretations of the two specimen types (**Table 13**) was 93.8% (259/276; 95% CI: 90.4% to 96.1%), with average positive agreement of 91.5% (184/201; 95% CI: 87.2% to 95.1%) and average negative agreement of 95.2% (334/351; 95% CI: 92.6% to 97.3%).

Table 13. Agreement between SurePath and ThinPrep PreservCyt Specimens

		SurePath	
		HR HPV Detected	**Not Detected**
ThinPrep PreservCyt	**HR HPV Detected**	92	10
	Not Detected	7	167

Agreement Between ThinPrep PreservCyt Pre-Cytology and Post-Cytology Samples

The aliquots of 119 ThinPrep PreservCyt specimens that were removed both prior to and after cytological processing (ie, pre-cytology and post-cytology samples) were tested with Alinity m HR HPV. The overall percent agreement between the Alinity m HR HPV interpretations of the pre-cytology and post-cytology samples (**Table 14**) was 97.5% (116/119; 95% CI: 92.8% to 99.1%), with average positive agreement of 97.1% (102/105; 95% CI: 93.2% to 100.0%) and average negative agreement of 97.7% (130/133; 95% CI: 94.7% to 100.0%).

Table 14. Agreement between Pre-Cytology and Post-Cytology ThinPrep PreservCyt Samples

		Post-Cytology	
		HR HPV Detected	**Not Detected**
Pre-Cytology	**HR HPV Detected**	51	3
	Not Detected	0	65

Agreement Between SurePath Pre-Cytology and Post-Cytology Samples

The aliquots of 112 SurePath specimens that were removed both prior to and after cytological processing (ie, pre-cytology and post-cytology samples) were tested with Alinity m HR HPV.[33] The overall percent agreement between the Alinity m HR HPV interpretations of the pre-cytology and post-cytology samples (**Table 15**) was 92.9% (104/112; 95% CI: 86.5% to 96.3%), with average positive agreement of 90.5% (76/84; 95% CI: 83.4% to 96.3%) and average negative agreement of 94.3% (132/140; 95% CI: 89.6% to 97.8%).

Table 15. Agreement between Pre-Cytology and Post-Cytology SurePath Samples

		Post-Cytology	
		HR HPV Detected	**Not Detected**
Pre-Cytology	**HR HPV Detected**	38	7
	Not Detected	1	66

Agreement Between Self-Collected simpli-COLLECT Vaginal Specimens and Clinician-Collected Cervical Specimens

A comparison of Alinity m HR HPV assay results from self-collected vaginal specimens and clinician-collected cervical specimens was performed using paired specimens from study participants who were 25 years or older presenting for routine cervical cancer screening. Each participant collected a vaginal specimen using the simpli-COLLECT HPV Collection Kit (ie, simpli-COLLECT) in a simulated home setting. Following the self-collection of the vaginal specimen, a cervical specimen was collected from each participant by the clinician and placed in ThinPrep PreservCyt Solution (ie, PreservCyt) per standard of care.

968 participants with valid results from paired clinician-collected cervical specimen and self-collected vaginal specimen using the simpli-COLLECT Kit were evaluated. For 85 subjects with positive cervical results, 81 had a positive result for the self-collected vaginal specimen with the simpli-COLLECT Kit (ie, PPA 95.3%). For 883 subjects with negative cervical results, 794 had a negative result for the self-collected vaginal specimen with simpli-COLLECT Kit (ie, NPA 89.9%). Refer to **Table 16** for the positive agreement, negative agreement, and overall percent agreement.

Table 16. Agreement between Self-Collected Vaginal Specimens Using simpli-COLLECT and Clinician-Collected Cervical PreservCyt Specimens

	Estimate (95% CI)	n/N [a]
Positive Percent Agreement	95.3 (88.5, 98.2)	81/85
Negative Percent Agreement	89.9 (87.8, 91.7)	794/883
Overall Percent Agreement	90.4 (88.4, 92.1)	875/968

[a] n represents the number of subjects with self-collected vaginal specimen results in agreement with clinician-collected cervical specimen results. N represents the number of subjects.

Agreement Between Self-Collected Evalyn Brush Vaginal Specimens and Clinician-Collected Cervical Specimens

A comparison of Alinity m HR HPV assay results from self-collected vaginal specimens and clinician-collected cervical specimens was performed using paired specimens from study participants who were 25 years or older presenting for routine cervical cancer screening. Each participant collected a vaginal specimen using an Evalyn Brush (Rovers Medical Devices) in a simulated home setting. Following the self-collection of the vaginal specimen, a cervical specimen was collected from each participant by the clinician and placed into PreservCyt per standard of care.

960 participants with valid results from paired clinician-collected cervical specimen and self-collected vaginal specimen using Evalyn Brush were evaluated. For 84 subjects with positive cervical results, 80 had a positive result for the self-collected vaginal specimen with Evalyn Brush (ie, PPA 95.2%). For 876 subjects with negative cervical results, 808 had a negative result for the self-collected vaginal specimen with Evalyn Brush (ie, NPA 92.2%). Refer to **Table 17** for the positive agreement, negative agreement, and overall percent agreement.

Table 17. Agreement between Self-Collected Vaginal Specimens Using Evalyn Brush and Clinician-Collected Cervical PreservCyt Specimens

	Estimate (95% CI)	n/N [a]
Positive Percent Agreement	95.2 (88.4, 98.1)	80/84
Negative Percent Agreement	92.2 (90.3, 93.8)	808/876
Overall Percent Agreement	92.5 (90.7, 94.0)	888/960

[a] n represents the number of subjects with self-collected vaginal specimen results in agreement with clinician-collected cervical specimen results. N represents the number of subjects.

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KEY TO SYMBOLS

REF	Reference Number
IVD	In Vitro Diagnostic Medical Device
LOT	Lot Number
In Vitro Test	In Vitro Test
AMP TRAY	AMP TRAY
ACT TRAY	ACT TRAY
UNIT	Unit
	Health Hazard
	Exclamation Mark
	Consult Instructions for Use
	Temperature Limit
	Use By Date
	Contains sufficient for <n> tests
EC REP	Authorized Representative in the European Community
	Manufacturer

TECHNICAL ASSISTANCE

For technical assistance, call Abbott Technical Services at 1-800-553-7042 (within the US) or +49-6122-580 (outside the US), or visit the Abbott website at www.molecular.abbott.

Abbott Molecular Inc. is the legal manufacturer of the Alinity m HR HPV AMP Kit.

SUMMARY OF SAFETY AND PERFORMANCE STATEMENT

A summary of safety and performance (SSP) for this device is available at https://ec.europa.eu/tools/eudamed. This is the SSP location after the launch of European Database on Medical Devices. Search for device using UDI-DI provided on the outer packaging of the device.

The Alinity m HR HPV AMP Kit is imported into the European Union by Abbott Diagnostics GmbH, located at Max-Planck-Ring 2, 65205 Wiesbaden, Germany.

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EC REP

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53-608488/R1
April 2024

Abbott

Alinity m

Specimen Buffer Kit II

en

REF 09R03-050

53-608399/R2

Created August 2024

REF 09R03-050

53-608399/R2

PN MD2361

9PIMD2361rev00

CUSTOMER SERVICE: 1-800-553-7042
CUSTOMER SERVICE INTERNATIONAL: CALL YOUR ABBOTT REPRESENTATIVE

Instructions must be carefully followed. Reliability of assay results cannot be guaranteed if there are any deviations from these instructions.

NOTICE TO USER

If a serious incident occurs in relation to this device, the incident should be reported to the manufacturer and to the appropriate competent authority of the member state in which the user and/or the patient is established. To report to the manufacturer, see the contact information provided in the customer service or technical assistance section of these instructions.

NAME

Alinity m Specimen Buffer Kit II

INTENDED USE

The Alinity m Specimen Buffer Kit II contains bottles of bulk buffer solution intended for the resuspension of specimens for testing on the automated Alinity m System; refer to the appropriate Alinity m assay package inserts for additional information.

INTENDED USER

The intended users for the Alinity m Specimen Buffer Kit II are laboratory and healthcare professionals.

REAGENTS

Kit Contents

Alinity m Specimen Buffer Kit II List No. 09R03-050

The Alinity m Specimen Buffer Kit II contains the following:

- Alinity m Specimen Buffer II bottles
  Each bottle contains guanidine thiocyanate in Tris buffer.

Reagent	Quantity
Alinity m Specimen Buffer II	4 bottles × 237 mL

WARNINGS AND PRECAUTIONS

IVD

For In Vitro Diagnostic Use

Safety Precautions

Wear disposable gloves while handling specimens and wash hands thoroughly afterward. Use of protective eyewear is recommended.

CAUTION: This product requires the handling of human specimens. It is recommended that all human sourced materials be considered potentially infectious and handled with appropriate biosafety practices.[1,2]

The following warnings and precautions apply to:	
Alinity m Specimen Buffer II	
Hazard-determining components of labeling: Guanidine thiocyanate	
EUH032	Contact with acids liberates very toxic gas.
Disposal	
P501	Dispose of contents / container in accordance with local regulations.

Important information regarding the safe handling, transport and disposal of this product is contained in the Safety Data Sheet.

Safety Data Sheets are available from your Abbott Representative.

For a detailed discussion of safety precautions during system operation, refer to the Alinity m System Operations Manual; Section 8.

Reagent Shipping

	Shipment Condition
Alinity m Specimen Buffer Kit II	15°C to 30°C

Reagent Storage

	Storage Temperature	Maximum Storage Time
Unopened	15°C to 30°C	Until expiration date

Reagent Handling

- Do not use reagents that have been damaged.
- Do not use past expiration date.
- Alinity m Specimen Buffer Kit II is shipped at 15°C to 30°C and is stored at 15°C to 30°C upon arrival. If reagents arrive in a condition contrary to this recommendation or are damaged, immediately contact your Abbott Representative.

PROCEDURE

Materials Provided

09R03-050 Alinity m Specimen Buffer Kit II

Instructions for Use

Refer to the appropriate Alinity m assay Package Insert for the Alinity m Specimen Buffer Kit II instructions for use.

QUALITY CONTROL PROCEDURES

Refer to the **QUALITY CONTROL PROCEDURES** section of the appropriate Alinity m assay Package Insert.

BIBLIOGRAPHY

1. Clinical and Laboratory Standards Institute (CLSI). *Protection of Laboratory Workers From Occupationally Acquired Infections; Approved Guideline—Fourth Edition*. CLSI Document M29-A4. CLSI; 2014.
2. US Environmental Protection Agency. *EPA Guide for Infectious Waste Management*. US Environmental Protection Agency; 1986:1-1–5-5, R1-R3, A1-A24. Publication No. EPA/530-SW-86-014.

KEY TO SYMBOLS

REF	Reference Number
IVD	In Vitro Diagnostic Medical Device
LOT	Lot Number
PN	Part Number
In Vitro Test	In Vitro Test
SPECIMEN BUFFER II	Specimen Buffer II
	Consult Instructions for Use or Consult Electronic Instructions for Use
	Temperature Limit
For In Vitro Diagnostic Use	For In Vitro Diagnostic Use
	Use By Date
EC REP	Authorized Representative in the European Community/ European Union
	Manufacturer

Abbott

TECHNICAL ASSISTANCE

For technical assistance, call Abbott Technical Services at 1-800-553-7042 (within the US) or +49-6122-580 (outside the US), or visit the Abbott website at www.molecular.abbott.

The Alinity m Specimen Buffer Kit II is manufactured for Abbott Molecular Inc. by Promega Corporation, Madison, WI 53711 USA.

Abbott Molecular Inc. is the legal manufacturer of the Alinity m Specimen Buffer Kit II.

The Alinity m Specimen Buffer Kit II is imported into the European Union by Abbott Diagnostics GmbH, located at Max-Planck-Ring 2, 65205 Wiesbaden, Germany.

Abbott Molecular Inc.
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Des Plaines, IL 60018 USA

EC REP Abbott GmbH
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53-608399/R2
August 2024

Abbott

Alinity m

en

REF 09R03-060

53-608469/R1

Specimen Buffer Kit III

Created April 2024

REF 09R03-060

53-608469/R1

CUSTOMER SERVICE: 1-800-553-7042
CUSTOMER SERVICE INTERNATIONAL: CALL YOUR ABBOTT REPRESENTATIVE

Instructions must be carefully followed. Reliability of assay results cannot be guaranteed if there are any deviations from these instructions.

NOTICE TO USER

If a serious incident occurs in relation to this device, the incident should be reported to the manufacturer and to the appropriate competent authority of the member state in which the user and/or the patient is established. To report to the manufacturer, see the contact information provided in the customer service or technical assistance section of these instructions.

NAME

Alinity m Specimen Buffer Kit III

INTENDED USE

The Alinity m Specimen Buffer Kit III contains transport tubes filled with buffer solution intended for the resuspension of specimens for testing on the automated Alinity m System; refer to the appropriate Alinity m assay package inserts for additional information.

INTENDED USER

The intended users for the Alinity m Specimen Buffer Kit III are laboratory and healthcare professionals.

REAGENTS

Kit Contents

Alinity m Specimen Buffer Kit III List No. 09R03-060

The Alinity m Specimen Buffer Kit III contains the following:

- Transport tubes with pierceable cap containing 2.95 mL Alinity m Specimen Buffer III (guanidine thiocyanate in Tris buffer)

Reagent	Quantity
Alinity m Specimen Buffer III	36 tubes

WARNINGS AND PRECAUTIONS

IVD

For In Vitro Diagnostic Use

Safety Precautions

Wear disposable gloves while handling specimens and wash hands thoroughly afterward. Use of protective eyewear is recommended.

CAUTION: This product requires the handling of human specimens. It is recommended that all human sourced materials be considered potentially infectious and handled with appropriate biosafety practices.[1,2]

The following warnings and precautions apply to:	
Alinity m Specimen Buffer III	
Hazard-determining components of labeling: Guanidine thiocyanate	
EUH032	Contact with acids liberates very toxic gas.
Disposal	
P501	Dispose of contents / container in accordance with local regulations.

Important information regarding the safe handling, transport and disposal of this product is contained in the Safety Data Sheet.

Safety Data Sheets are available from your Abbott Representative.

For a detailed discussion of safety precautions during system operation, refer to the Alinity m System Operations Manual; Section 8.

Reagent Shipping

	Shipment Condition
Alinity m Specimen Buffer Kit III	15°C to 30°C

Reagent Storage

	Storage Temperature	Maximum Storage Time
Unopened	15°C to 30°C	Until expiration date

Reagent Handling

- Do not use reagents that have been damaged.
- Do not use past expiration date.
- Alinity m Specimen Buffer Kit III is shipped at 15°C to 30°C and is stored at 15°C to 30°C upon arrival. If reagents arrive in a condition contrary to this recommendation or are damaged, immediately contact your Abbott Representative.
- Alinity m Specimen Buffer Kit III contains single-use tubes with pierceable caps. Avoid contamination or damage to the caps after removal from their original packaging.
- Specimen labels, including barcodes, must be placed below the blue ring present on the tube. Blue ring must remain entirely visible after label placement.

PROCEDURE

Materials Provided

09R03-060 Alinity m Specimen Buffer Kit III

Instructions for Use

Refer to the appropriate Alinity m assay Package Insert for the Alinity m Specimen Buffer Kit III instructions for use.

QUALITY CONTROL PROCEDURES

Refer to the **QUALITY CONTROL PROCEDURES** section of the appropriate Alinity m assay Package Insert.

BIBLIOGRAPHY

1. Clinical and Laboratory Standards Institute (CLSI). *Protection of Laboratory Workers From Occupationally Acquired Infections; Approved Guideline—Fourth Edition*. CLSI Document M29-A4. CLSI; 2014.
2. US Environmental Protection Agency. *EPA Guide for Infectious Waste Management*. US Environmental Protection Agency; 1986:1-1–5-5, R1-R3, A1-A24. Publication No. EPA/530-SW-86-014.

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KEY TO SYMBOLS

REF	Reference Number
IVD	In Vitro Diagnostic Medical Device
LOT	Lot Number
In Vitro Test	In Vitro Test
For In Vitro Diagnostic Use	For In Vitro Diagnostic Use
SPECIMEN BUFFER III	Specimen Buffer III
PRODUCED BY	Produced by
QTY	Quantity
	Consult Instructions for Use
	Temperature Limit
	Use By Date
EC REP	Authorized Representative in the European Community
	Manufacturer

TECHNICAL ASSISTANCE

For technical assistance, call Abbott Technical Services at 1-800-553-7042 (within the US) or +49-6122-580 (outside the US), or visit the Abbott website at www.molecular.abbott.

The Alinity m Specimen Buffer Kit III is manufactured for Abbott Molecular Inc. by MML Diagnostics Packaging, Inc., Troutdale, OR 97060 USA.

Abbott Molecular Inc. is the legal manufacturer of the Alinity m Specimen Buffer Kit III.

The Alinity m Specimen Buffer Kit III is imported into the European Union by Abbott Diagnostics GmbH, located at Max-Planck-Ring 2, 65205 Wiesbaden, Germany.

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53-608469/R1
April 2024

Abbott

simpli-COLLECT™ HPV Collection Kit

en

REF 09R03-030

53-608547/R1

Created November 2024

REF 09R03-030

53-608547/R1

CUSTOMER SERVICE: 1-800-553-7042
CUSTOMER SERVICE INTERNATIONAL: CALL YOUR ABBOTT REPRESENTATIVE

Instructions must be carefully followed. Reliability of results cannot be guaranteed if there are any deviations from these instructions.

NOTICE TO USER

If a serious incident occurs in relation to this device, the incident should be reported to the manufacturer and to the appropriate competent authority of the member state in which the user and/or the patient is established. To report to the manufacturer, see the contact information provided in the Customer Service section or Technical Assistance section of these instructions.

NAME

simpli-COLLECT™ HPV Collection Kit

INTENDED USE

The simpli-Collect HPV Collection Kit is intended for the self-collection and transport of vaginal swab specimens for testing with the Alinity m HR HPV assay. Swab specimens may be collected and prepared for transport in a healthcare or non-healthcare environment by a lay user.

The collected specimens are intended to be tested on the automated Alinity m System; refer to the Alinity m HR HPV assay package insert for additional information.

INTENDED USER

The intended users for the simpli-COLLECT HPV Collection Kit are lay users, and laboratory and healthcare professionals.

SUMMARY AND EXPLANATION OF THE TEST

The simpli-COLLECT HPV Collection Kit allows patients to self-collect vaginal swab specimens without supervision. The kit and patient instructions for use are given or sent to the patient. The patient collects and transfers the specimen to the Alinity m Sample Tube before returning it to the laboratory for analysis.

CONTENTS

Case Contents

Component	Quantity
simpli-COLLECT HPV Collection Kit	40 individually-wrapped simpli-COLLECT HPV Collection Kits and 40 patient instructions for use per box, 10 boxes per case

simpli-COLLECT HPV Collection Kit Contents

Each non-reusable simpli-COLLECT HPV Collection Kit includes the following:

- 1 Alinity m Sample Tube
- 1 Specimen Collection Swab

WARNINGS AND PRECAUTIONS

IVD

For In Vitro Diagnostic Use

Safety Precautions

- Follow all instructions in this package insert.
- Do not send the simpli-COLLECT HPV Collection Kit to the patient if the kit is damaged. Discard unused or damaged kits in accordance with local, regional, and national regulations.[1,2]
- Do not send the simpli-COLLECT HPV Collection Kit to the patient if the kit is beyond its expiration date.
- Wear disposable gloves while handling specimens and wash hands thoroughly afterward. Use of protective eyewear is recommended.
- Decontaminate and dispose of all specimens, reagents, and other potentially contaminated materials in accordance with local, regional, and national regulations.[1,2]

CAUTION: This product requires the handling of human specimens. It is recommended that all human sourced materials be considered potentially infectious and handled with appropriate biosafety practices.[1,2]

Storage

	Storage Temperature	Maximum Storage Time
Unopened	15°C to 30°C	Until expiration date

PROCEDURE

Materials Provided (per case)

- 10 boxes, each box contains 40 simpli-COLLECT HPV Collection Kits and 40 patient instructions for use

Specimen Collection, Storage, and Transport

Provide the simpli-COLLECT HPV Collection Kit along with the Patient Instructions for Use to the patient. Specimens must include identification information, including the date of collection. Specimens should be transported at ambient temperature. Refer to the Alinity m HR HPV (List No. 09N15-092) package insert for information on specimen storage.

For domestic and international shipments, specimens should be packaged and labeled in compliance with applicable local, national, and international regulations covering the transport of clinical, diagnostic, or biological specimens.

LIMITATIONS OF THE PROCEDURE

- Optimal performance of this kit requires appropriate specimen collection, handling, preparation, and storage. Refer to the Alinity m HR HPV package insert for additional information.
- This kit should only be used to collect vaginal swab samples. Refer to the patient instructions for use and the Alinity m HR HPV (List No. 09N15-092) package insert for additional information.
- Pregnant women should not use the simpli-COLLECT HPV Collection Kit.

BIBLIOGRAPHY

1. Clinical and Laboratory Standards Institute (CLSI). *Protection of Laboratory Workers From Occupationally Acquired Infections; Approved Guideline—Fourth Edition*. CLSI Document M29-A4. Wayne, PA: CLSI; 2014.
2. US Environmental Protection Agency. *EPA Guide for Infectious Waste Management*. US Environmental Protection Agency, 1986:1-1–5-5, R1-R3, A1-A24. Publication No. EPA/530-SW-86-014.

Abbott

KEY TO SYMBOLS

REF	Reference Number
LOT	Lot Number
IVD	In Vitro Diagnostic Medical Device
In Vitro Test	In Vitro Test
STORE AT	Store At
UNIT	Unit
SWAB	Swab
SAMPLE TUBE	Sample Tube
GTIN	Global Trade Item Number
PRODUCED BY	Produced By
	Do Not Use if Package is Damaged
	Do Not Reuse
	Temperature Limit
	Expiration Date
	Plain Paper
	Ethylene-vinyl acetate (EVA)
	Consult Instructions for Use or Electronic Instructions for Use
EC REP	Authorized Representative in the European Community/European Union
	Manufacturer

TECHNICAL ASSISTANCE

For technical assistance, call Abbott Technical Services at 1-800-553-7042 (within the US) or +49-6122-580 (outside the US), or visit the Abbott website at www.molecular.abbott.

Abbott Molecular Inc. is the legal manufacturer of the simpli-COLLECT™ HPV Collection Kit.

simpli-COLLECT™ HPV Collection Kit is manufactured for Abbott Molecular Inc. by MML Diagnostics Packaging, Inc., Troutdale, OR 97060 USA.

The simpli-COLLECT™ HPV Collection Kit is imported into the European Union by Abbott Diagnostics GmbH, located at Max-Planck-Ring 2, 65205 Wiesbaden, Germany.

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CE

53-608547/R1

November 2024

Abbott

EN INTENDED USE

The simpli-COLLECT™ HPV Collection Kit is intended for the self-collection and transport of vaginal swab specimens for testing with the Alinity m HR HPV assay. Swab specimens may be collected and prepared for transport in a healthcare or non-healthcare environment by a lay user.

DE VERWENDUNGSZWECK

Der simpli-COLLECT™ HPV Collection Kit dient der Selbstentnahme und dem Transport von Vaginalabstrichen zur Testung mit dem Alinity m HR HPV Assay. Abstriche können von einer Laienanwenderin in oder außerhalb einer Gesundheitseinrichtung entnommen und für den Transport vorbereitet werden.

FR DOMAINE D'APPLICATION

Le simpli-COLLECT™ HPV Collection Kit est destiné à l'auto-prélèvement et au transport d'échantillons vaginaux sur écouvillon destinés au test Alinity m HR HPV. Les échantillons sur écouvillon peuvent être prélevés et préparés pour le transport dans un environnement médical ou non médical par une utilisatrice non initiée.

ES FINALIDAD DE USO

simpli-COLLECT™ HPV Collection Kit se utiliza para la recogida y el envío por parte de la paciente de especímenes de frotis vaginales para el análisis con el ensayo Alinity m HR HPV. Usuarios no profesionales pueden recoger y preparar los especímenes de frotis para el envío en un entorno sanitario o no sanitario.

IT FINALITÀ D'USO

simpli-COLLECT™ HPV Collection Kit è indicato per l'autoraccolta e il trasporto di campioni di tamponi vaginali da testare con il dosaggio Alinity m HR HPV. I campioni di tamponi possono essere raccolti e preparati per il trasporto in un contesto sanitario o non sanitario da un utente non professionista.

PT FINALIDADE DE USO

O simpli-COLLECT™ HPV Collection Kit destina-se à autocolheita e transporte de amostras de zaragatoas vaginais para serem analisadas com o ensaio Alinity m HR HPV. As amostras de zaragatoas podem ser colhidas e preparadas para transporte em ambiente de cuidados de saúde ou fora dele, por um utilizador leigo.

DA ANVENDELSE

simpli-COLLECT™ HPV Collection Kit er beregnet til egenindsamling og transport af vaginale podningsprøver til testning med Alinity m HR HPV-analysen. Podningsprøver kan indsamles og klargøres til transport i eller uden for sundhedsvæsenet af en lægperson.

SV ANVÄNDNINGSOMRÅDE

simpli-COLLECT™ HPV Collection Kit är avsett för självprovtagning och transport av vaginala prover på provtagningspinne för analys med Alinity m HR HPV-analysen. Prover på provtagningspinne kan tas och prepareras för transport på en vårdinrättning eller på annan plats av en lekman.

FI KÄYTTÖTARKOITUS

simpli-COLLECT™ HPV -keruupakkaus on tarkoitettu emättimen näytteiden keräämiseen ja kuljettamiseen Alinity m HR HPV -testillä testaamista varten. Maallikkokäyttäjä voi kerätä näytteitä ja valmistaa ne kuljetettaviksi terveydenhuollon ympäristössä tai muussa ympäristössä.

NO BRUKSOMRÅDE

simpli-COLLECT™ HPV Collection Kit er beregnet for selvprøvetaking og transport av vaginale prøver tatt med prøvetakingspinne for testing med Alinity m HR HPV-analysen. Prøver på prøvetakingspinne kan tas og klargjøres for transport innen helsevesenet eller på et annet sted av en legperson.

NL BEOOGD GEBRUIK

De simpli-COLLECT™ HPV-afnamekit is bedoeld voor het zelf afnemen en vervoeren van vaginale uitstrijkjes voor testen met het Alinity m HR HPV-testsysteem. Uitstrijkjes kunnen door een onervaren gebruiker in een zorgomgeving of niet-zorgomgeving voor verzending worden afgenomen en voorbereid.

CS POUŽITÍ

Odběrová souprava simpli-COLLECT™ HPV Collection Kit je určena k samoodběru a přepravě vzorků vaginálních výtěrů k testování metodou Alinity m HR HPV. Vzorky výtěrů mohou být odebrány a připraveny k přepravě ve zdravotnickém zařízení nebo mimo zdravotnické zařízení laickým uživatelem.

ET KASUTUSOTSTARVE

Komplekt simpli-COLLECT™ HPV Collection Kit on ette nähtud tupekaape proovide iseseisvaks kogumiseks ja transportimiseks, et testida neid analüüsiga Alinity m HR HPV. Tavakasutaja võib kaapeproove koguda ja transportimiseks ette valmistada tervishoiuasutuses või väljaspool seda.

PL PRZEWIDZIANE ZASTOSOWANIE

Zestaw do pobrań simpli-COLLECT™ HPV Collection Kit służy do samodzielnego pobierania i transportowania wymazów z pochwy do przeprowadzenia testu Alinity m HR HPV. Wymazy mogą być pobierane i przygotowywane do transportu w placówce służby zdrowia lub w warunkach domowych przez samą pacjentkę.

ZHHK 預期用途

simpli-COLLECT™ HPV 採集套裝用於自行採集和運送陰道拭子樣本，以便進行 Alinity m 高危型人類乳頭瘤病毒 (HR HPV) 檢測。拭子樣本可由一般使用者在醫療或非醫療環境中採集並準備，以作運送用途。

EN LIMITATIONS OF THE PROCEDURE

- This kit should only be used to collect vaginal swab specimens.
- Pregnant women should not use the kit.

DE GRENZEN DES VERFAHRENS

- Diesen Kit nur zur Entnahme von Vaginalabstrichen verwenden.
- Schwangere sollten den Kit nicht verwenden.

FR LIMITES DE LA METHODE

- Ce kit doit uniquement être utilisé pour prélever des échantillons vaginaux sur écouvillon.
- Les femmes enceintes ne doivent pas utiliser le kit.

ES LIMITACIONES DEL PROCEDIMIENTO

- Este kit se debe utilizar exclusivamente para recoger especímenes de frotis vaginales.
- Las mujeres embarazadas no deben utilizar este kit.

IT LIMITI DEL METODO

- Questo kit deve essere utilizzato esclusivamente per raccogliere campioni di tamponi vaginali.
- Le donne incinte non devono utilizzare il kit.

PT LIMITAÇÕES DO PROCEDIMENTO

- Este kit só deve ser utilizado para colher amostras de zaragatoas vaginais.
- As grávidas não devem utilizar o kit.

DA PROCEDUREBEGRÆNSNINGER

- Dette sæt bør kun anvendes til indsamling af vaginale skrab.
- Gravide kvinder bør ikke anvende sættet.

SV ANALYSMETODENS BEGRÄNSNINGAR

- Provtagningskitet får endast användas för att ta vaginala prover på provtagningspinne.
- Gravida kvinnor bör inte använda detta provtagningskit.

FI TOIMENPITEEN RAJOITUKSET

- Tätä pakkausta tulee käyttää vain emättimen näytteiden keräämiseen.
- Raskaana olevien naisten ei tule käyttää pakkausta.

NO PROSEDYRENS BEGRENSNINGER

- Denne pakken skal kun brukes til å ta vaginale prøver med prøvetakingspinne.
- Gravide kvinner skal ikke bruke pakken.

NL BEPERKINGEN AAN DE PROCEDURE

- Deze kit mag alleen worden gebruikt voor de afname van vaginale uitstrijkjes.
- Zwangere vrouwen mogen de kit niet gebruiken.

CS OMEZENÍ METODY

- Tato souprava by se měla používat pouze k odběru vzorků vaginálních výtěrů.
- Tuto soupravu by neměly používat těhotné ženy.

ET PROTSEDUURI PIIRANGUD

- Seda komplekti tuleks kasutada ainult tupekaape proovide kogumiseks.
- Rasedad naised ei tohiks komplekti kasutada.

PL OGRANICZENIA PROCEDURY

- Zestaw stosować wyłącznie do pobierania wymazów z pochwy.
- Zestawu nie powinny stosować kobiety w ciąży.

ZHHK 程序限制

- 本套裝僅應用於採集陰道拭子樣本。
- 孕婦不應使用本套裝。

EN WARNINGS AND PRECAUTIONS

- IVD For In Vitro Diagnostic Use
- **FOLLOW ALL INSTRUCTIONS** in the Instructions for Use. If you do not follow the instructions, your result may be incorrect.
- Keep out of reach of children.
- Only use the swab provided.
- **DO NOT USE** if **PREGNANT.**
- **DO NOT USE** if the kit is beyond its **EXPIRATION DATE.**
- **DO NOT USE** if the kit is damaged or if the seal is broken. **DISCARD UNUSED OR DAMAGED KITS** in accordance with national, regional and local ordinances.

DE VORSICHTSMASSNAHMEN

- IVD Zur Verwendung als In-vitro-Diagnostikum
- **ALLE ANWEISUNGEN** in dieser Gebrauchsanweisung **BEFOLGEN**. Wenn Sie die Anweisungen nicht befolgen, ist Ihr Ergebnis möglicherweise nicht korrekt.
- Außerhalb der Reichweite von Kindern aufbewahren.
- Nur den mitgelieferten Tupfer verwenden.
- **NICHT VERWENDEN**, wenn Sie **SCHWANGER** sind.
- Den Kit **NICHT VERWENDEN**, wenn er das **VERFALLSDATUM** überschritten hat.
- Den Kit **NICHT VERWENDEN**, wenn er beschädigt ist oder die Versiegelung durchtrennt wurde. **NICHT VERWENDETE ODER BESCHÄDIGTE KITS** gemäß den geltenden Vorschriften entsorgen.

FR MISES EN GARDE ET PRECAUTIONS

- IVD Dispositif médical de diagnostic in vitro
- **SUIVEZ TOUTES LES INSTRUCTIONS** de cette notice d'utilisation. Si vous ne suivez pas les instructions, vos résultats pourraient être incorrects.
- Gardez hors de la portée des enfants.
- Utilisez uniquement l'écouvillon fourni.
- **N'UTILISEZ PAS** le kit si vous êtes **ENCEINTE.**
- **N'UTILISEZ PAS** le kit si sa **DATE DE PEREMPTION** est dépassée.
- **N'UTILISEZ PAS** le kit s'il est endommagé ou ouvert. **JETEZ LES KITS NON UTILISES OU ENDOMMAGES** conformément à la réglementation nationale, régionale et locale.

ES ADVERTENCIAS Y PRECAUCIONES

- IVD Para uso en diagnóstico *in vitro*
- **SIGA TODAS LAS INDICACIONES** incluidas en las instrucciones de uso. Si no se siguen las instrucciones, se pueden obtener resultados incorrectos.
- Manténgase fuera del alcance de los niños.
- Utilice exclusivamente el hisopo suministrado.
- **NO UTILICE** si **ESTÁ EMBARAZADA.**
- **NO UTILICE** el kit una vez transcurrida **LA FECHA DE CADUCIDAD.**
- **NO UTILICE** el kit si está dañado o el sello está roto. **DESECHE LOS KITS NO UTILIZADOS O DAÑADOS** según las normativas vigentes.

IT AVVERTENZE E PRECAUZIONI

- IVD Per uso diagnostico *in vitro*
- **ATTENERSI A TUTTE LE ISTRUZIONI** riportate nelle Istruzioni per l'uso. Se non ci si attiene alle istruzioni, il risultato potrebbe non essere corretto.
- Tenere lontano dalla portata dei bambini.
- Usare esclusivamente il tampone fornito.
- **NON USARE** in caso di **GRAVIDANZA.**
- **NON USARE** se il kit ha superato la **DATA DI SCADENZA.**
- **NON USARE** se il kit è danneggiato oppure se il sigillo è rotto. **ELIMINARE I KIT NON UTILIZZATI O DANNEGGIATI** conformemente alle ordinanze nazionali, regionali e locali.

PT AVISOS E PRECAUÇÕES

- IVD Para utilização em diagnóstico *in vitro*
- **SEGUIR TODAS AS INDICAÇÕES** das instruções de utilização. Caso as instruções não sejam seguidas, o seu resultado pode ser incorreto.
- Manter fora do alcance de crianças.
- Utilizar apenas a zaragatoa fornecida.
- **NÃO UTILIZAR** se **ESTIVER GRÁVIDA.**
- **NÃO UTILIZAR** se o kit tiver ultrapassado o respetivo **PRAZO DE VALIDADE.**
- **NÃO UTILIZAR** se o kit estiver danificado ou se o selo estiver quebrado. **ELIMINAR KITS NÃO UTILIZADOS OU DANIFICADOS** em conformidade com as determinações locais, regionais e nacionais.

DA VIGTIGE FORHOLDSREGLER

- IVD Til in vitro-diagnostisk brug
- **FØLG ALLE INSTRUKTIONER** i brugsanvisningen. Hvis anvisningerne ikke følges, kan resultatet blive forkert.
- Opbevares utilgængeligt for børn.
- Anvend kun den medfølgende podepind.
- **ANVEND IKKE** ved **GRAVIDITET.**
- **ANVEND IKKE** efter sættets **UDLØBSDATO.**
- **ANVEND IKKE**, hvis sættet er beskadiget, eller hvis sættets forsegling er brudt. **BORTSKAF UBRUGTE ELLER BESKADIGEDE SÆT** i henhold til lokale og nationale retningslinjer.

SV SÄKERHETSFÖRESKRIFTER

- IVD För diagnostisk användning in vitro
- **FÖLJ ALLA ANVISNINGAR** i bruksanvisningen. Om du inte följer anvisningarna kan resultatet bli felaktigt.
- Förvaras utom räckhåll för barn.
- Använd endast den medföljande provtagningspinnen.
- Får **INTE ANVÄNDAS** om du är **GRAVID.**
- Får **INTE ANVÄNDAS** om förpackningen har passerat **SISTA FÖRBRUKNINGSDAG.**
- Får **INTE ANVÄNDAS** om förpackningen är skadad eller förseglingen är bruten. **KASSERA OANVÄNDA ELLER SKADADE FÖRPACKNINGAR** i enlighet med gällande bestämmelser.

FI VAROITUKSET JA VAROTOIMET

- IVD In vitro -diagnostiikkaa varten
- **NOUDATA KAIKKIA** käyttöohjeessa olevia ohjeita. Jos et noudata ohjeita, tuloksesi voi olla virheellinen.
- Säilytä lasten ulottumattomissa.
- Käytä vain tarjottua näytteenottotikkua.
- **ÄLÄ KÄYTÄ,** jos olet **RASKAANA.**
- **ÄLÄ KÄYTÄ,** jos pakkauksen **VANHENEMISPÄIVÄ ON MENNYT.**
- **ÄLÄ KÄYTÄ,** jos pakkaus on vaurioitunut tai jos pakkauksen sinetti on murtunut. **HÄVITÄ KÄYTTÄMÄTTÖMÄT TAI VAHINGOITTUNEET PAKKAUKSET** kansallisten, alueellisten ja paikallisten määräysten mukaisesti.

NO ADVARSLER OG FORHOLDSREGLER

- IVD Til bruk ved in vitro-diagnostikk
- **FØLG ALLE INSTRUKSJONENE** i bruksanvisningen. Hvis instruksjonene ikke følges, kan resultatet bli feil.
- Oppbevares utilgjengelig for barn.
- Bruk kun prøvetakingspinnen som følger med.
- **MÅ IKKE BRUKES** hvis **DU ER GRAVID.**
- **IKKE BRUK** pakken etter **UTLØPSDATOEN.**
- **IKKE BRUK** pakken hvis den er skadet eller forseglingen er brutt. **KAST UBRUKTE ELLER SKADDE PAKKER** i samsvar med nasjonale, regionale og lokale bestemmelser.

NL WAARSCHUWINGEN EN VOORZORGSMAATREGELEN

- IVD Voor in-vitro diagnostisch gebruik
- **VOLG ALLE INSTRUCTIES** in de gebruiksaanwijzing. Als u de instructies niet opvolgt, kan het resultaat onjuist zijn.
- Buiten bereik van kinderen houden.
- Gebruik alleen het meegeleverde wattenstaafje.
- Gebruik de kit **NIET** als **U ZWANGER BENT.**
- Gebruik de kit **NIET** na de **VERVALDATUM.**
- Gebruik de kit **NIET** als de verpakking is beschadigd of de verzegeling is verbroken. **WERP ONGEBRUIKTE OF BESCHADIGDE KITS WEG** overeenkomstig de nationale, regionale en lokale voorschriften.

CS VAROVÁNÍ A BEZPEČNOSTNÍ OPATŘENÍ

- IVD Pro diagnostické účely in vitro
- **DODRŽUJTE VŠECHNY POKYNY** uvedené v návodu k použití. Pokud nedodržíte pokyny, váš výsledek může být nesprávný.
- Uchovávejte mimo dosah dětí.
- Používejte pouze dodaný tampon.
- **NEPOUŽÍVEJTE,** pokud **JSTE TĚHOTNÁ.**
- **NEPOUŽÍVEJTE,** pokud je souprava po **DATU EXPIRACE.**
- **NEPOUŽÍVEJTE,** pokud je souprava poškozená nebo pokud je narušená plomba. **NEPOUŽITÉ NEBO POŠKOZENÉ SOUPRAVY ZLIKVIDUJTE** v souladu s platnými předpisy.

ET HOIATUSED JA ETTEVAATUSABINÕUD

- IVD In vitro diagnostikas kasutamiseks
- **JÄRGIGE KÕIKI JUHISEID** kasutusjuhendis. Vastasel korral võib saada valesid tulemusi.
- Hoidke lastele kättesaamatus kohas.
- Kasutage ainult komplektis olevat tampooni.
- **ÄRGE KASUTAGE RASEDUSE AJAL.**
- **ÄRGE KASUTAGE KOMPLEKTI** pärast selle **KÕLBLIKKUSAJA LÕPPU.**
- **ÄRGE KASUTAGE KAHJUSTATUD EGA AVATUD KOMPLEKTI. KASUTAMATA VÕI KAHJUSTUNUD KOMPLEKTID KÕRVALDAGE** kooskõlas riiklike, piirkondlike ja kohalike eeskirjadega.

PL OSTRZEŻENIA I ŚRODKI OSTROŻNOŚCI

- IVD Do diagnostyki in vitro
- **NALEŻY POSTĘPOWAĆ ZGODNIE ZE WSZYSTKIMI WYTYCZNYMI** opisanymi w niniejszej instrukcji używania. Niezastosowanie się do tych wytycznych może skutkować uzyskaniem błędnego wyniku.
- Przechowywać w miejscu niedostępnym dla dzieci.
- Stosować wyłącznie dostarczone wymazówki.
- **NIE STOSOWAĆ** w czasie **CIĄŻY.**
- **NIE STOSOWAĆ ZESTAWU** po upływie **DATY WAŻNOŚCI.**
- **NIE STOSOWAĆ ZESTAWU** w przypadku jego uszkodzenia lub naderwania zabezpieczenia. **ZESTAWY NIEZUŻYTE LUB USZKODZONE** usuwać zgodnie z ogólnokrajowymi i miejscowymi przepisami.

ZHHK 警告及預防措施

- IVD 僅供體外診斷使用
- **請按照使用說明中的所有指示操作**。如果您未有按照指示操作，測試結果可能有誤。
- 請將本產品放在兒童接觸不到的地方。
- 僅使用隨附拭子。
- **懷孕**期間**請勿使用**。
- 如果套裝已過**有效日期**，**請勿使用**。
- 如果套裝損壞或封口破損，**請勿使用**。請根據國家、地區及當地法令**棄置未使用或受損的套裝**。

EN SUMMARY AND EXPLANATION OF THE TEST

This kit allows you to self-collect vaginal swab specimens without supervision. You will collect and transfer the specimen to the sample tube and return it to the laboratory for analysis.

DE ZUSAMMENFASSUNG UND ERLÄUTERUNG DES TESTS

Mit diesem Kit können Vaginalabstriche ohne Beaufsichtigung selbst entnommen werden. Sie entnehmen eine Probe, transferieren sie in ein Probenröhrchen und senden sie zur Analyse an das Labor zurück.

FR RESUME ET EXPLICATION DU TEST

Ce kit vous permet de prélever vous-même des échantillons vaginaux sur écouvillon sans supervision. Vous prélèverez l'échantillon, le transférerez dans le tube échantillon puis le renverrez au laboratoire pour analyse.

ES RESUMEN Y EXPLICACIÓN DE LA PRUEBA

Este kit le permite recoger especímenes de frotis vaginales sin supervisión. Usted recoge el espécimen, lo transfiere al tubo de muestra y, a continuación, lo remite al laboratorio para su análisis.

IT RIASSUNTO E SPIEGAZIONE DEL TEST

Questo kit consente di raccogliere autonomamente campioni di tamponi vaginali senza supervisione. È possibile raccogliere il campione e trasferirlo nella provetta da inviare al laboratorio per essere analizzato.

PT RESUMO E EXPLICAÇÃO DO TESTE

Este kit permite a autocolheita de amostras de zaragatoas vaginais sem supervisão. Irá colher e transferir a amostra para o tubo de amostra e devolvê-la ao laboratório para análise.

DA RESUME OG ANALYSEFORKLARING

Dette sæt gør det muligt selv at tage vaginale skrab uden overvågning. Du skal indsamle prøven og overføre den til prøverøret og returnere det til laboratoriet til analyse.

SV SAMMANFATTNING OCH FÖRKLARING AV ANALYSEN

Med detta provtagningskit kan du ta vaginala prover på provtagningspinne själv utan övervakning. Du samlar in och överför provet till provröret och skickar det till laboratoriet för analys.

FI TESTIN YHTEENVETO JA KUVAUS

Pakkaus mahdollistaa emätinpuikkonäytteiden keräämisen itse ilman valvontaa. Sen avulla voit ottaa ja siirtää näytteen näyteputkeen ja palauttaa sen laboratorioon analysoitavaksi.

NO SAMMENDRAG OG ANALYSEFORKLARING

Med denne pakken kan du selv ta vaginale prøver med prøvetakingspinne uten tilsyn. Du tar prøven selv, overfører den til prøverøret og sender prøven til laboratoriet for analysering.

NL SAMENVATTING EN UITLEG VAN DE TEST

Met deze kit kunt u in uw eigen tijd zelf vaginale uitstrijkjes afnemen. U neemt het monster af, brengt het over naar het monsterbuisje en retourneert het voor analyse naar het laboratorium.

CS SHRNUTÍ A VYSVĚTLENÍ TESTU

Tato souprava vám umožňuje odebrat vzorky vaginálních výtěrů samostatně bez dohledu. Po odběru a převedení vzorku do vzorkové zkumavky zašlete vzorek do laboratoře k analýze.

ET KOKKUVÕTE JA ANALÜÜSIMEETODI KIRJELDUS

See komplekt võimaldab järelevalveta iseseisvalt koguda tupekaape proove. Kogute proovimaterjali ja panete selle proovikatsutisse ning tagastate seejärel analüüsimiseks laborisse.

PL WPROWADZENIE I OPIS TESTU

Zestaw pozwala na samodzielne pobranie wymazu z pochwy bez nadzoru. Po pobraniu i włożeniu wymazówki do probówki należy ją dostarczyć do laboratorium w celu analizy pobranego materiału.

ZHHK 測試概述及說明

本套裝可讓您在無需監督的情況下自行採集陰道拭子樣本。您會採集樣本並將其轉移到樣本試管內，然後將試管返還到實驗室以作分析。

PRODUCED BY
MML Diagnostics Packaging, Inc., Troutdale, OR 97060 USA

Abbott Molecular Inc.
1300 East Touhy Avenue
Des Plaines, IL 60018 USA

EC REP Abbott GmbH
Max-Planck-Ring 2
65205 Wiesbaden, Germany

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Max-Planck-Ring 2
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CE

22 PAP

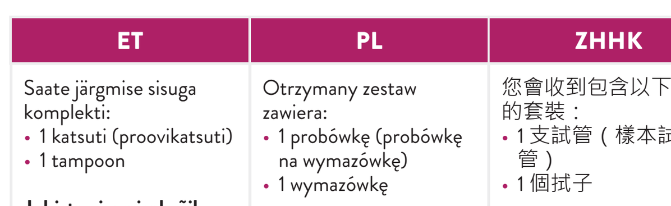
REF 09R03-030
53-608546/R2
NOTE: Changes Highlighted

Abbott

simpli-COLLECT™ HPV Collection Kit

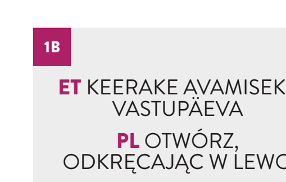
www.molecular.abbott/int/en/simpli-collect-hpv

ET ENNE KASUTAMIST / PL PRZED ROZPOCZĘCIEM / ZHHK 開始之前

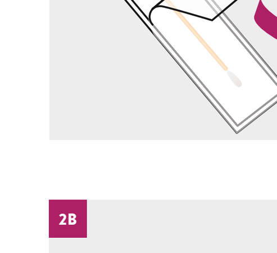
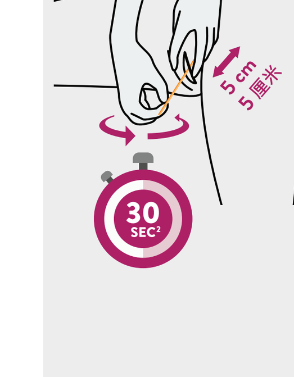


ET	PL	ZHHK
Saate järgmise sisuga komplekti: • 1 katsuti (proovikatsuti) • 1 tampoon **Juhiste eiramisel võib saada valesid tulemusi.** • Säilitage komplekti enne ja pärast kasutamist toatemperatuuril (vahemikus 15 °C kuni 30 °C). • Tagastage proov 24 tunni jooksul. • **Ärge kasutage** raseduse ajal. • **Ärge** puhastage suguelundite piirkonda vahetult enne proovi võtmist. • **Ärge kasutage** komplekti pärast **KÕLBLIKKUSAJA LÕPPU,** mis on trükitud komplekti pakendile. ¹ Tunnid	Otrzymany zestaw zawiera: • 1 probówkę (probówkę na wymazówkę) • 1 wymazówkę **Niezastosowanie się do tych wytycznych może skutkować uzyskaniem błędnego wyniku.** • Przed i po użyciu przechowuj zestaw w temperaturze pokojowej (15 °C do 30 °C). • Pobrany materiał dostarcz do laboratorium w ciągu 24 godzin. • **Nie** stosuj w czasie ciąży. • **Nie** przemywaj okolic narządów płciowych bezpośrednio przed pobraniem wymazu. • **Nie** stosuj zestawu po upływie **DATY WAŻNOŚCI** wydrukowanej na opakowaniu. ¹ godz.	您會收到包含以下內容的套裝： • 1 支試管（樣本試管） • 1 個拭子 **如果您未有按照指示操作，測試結果可能有誤。** • 使用前和使用後，應將套裝儲存在室溫環境（15°C 至 30°C）。 • 請在 24 小時內返還樣本。 • **請勿**在懷孕期間使用。 • **請勿**於清潔生殖器部位後立即採樣。 • **請勿**在套裝包裝上所印的**有效日期**後使用本套裝。 ¹ 小時
ℹ ÄRGE puudutage tampooni valget otsa ega asetage tampooni maha. Kui puudutate valget otsa või asetate tampooni maha või see kukub maha, ei pruugi tulemused olla õiged. Peate küsima uue komplekti simpli-COLLECT HPV Collection Kit.	ℹ NIE dotykaj białej końcówki wymazówki ani nie odkładaj jej. Dotknięcie białej końcówki lub odłożenie czy upuszczenie wymazówki mogą skutkować uzyskaniem niedokładnych wyników. W takich przypadkach użyj nowego zestawu simpli-COLLECT HPV Collection Kit.	ℹ 請勿觸碰拭子的白色尖端或將拭子平放。如果您觸碰白色尖端或將拭子平放或掉落，測試結果可能有誤。您需要申請新的 simpli-COLLECT HPV 採集套裝。
Testitulemuste/diagnoosi kohase teabe saamiseks või uue komplekti hankimiseks võtke ühendust oma tervishoiuteenuse osutajaga. Lisateave: www.molecular.abbott/int/en/simpli-collect-hpv	Skontaktuj się z pracownikiem służby zdrowia w przypadku pytań dotyczących wyników testu/diagnozy lub chcąc otrzymać nowy zestaw do pobrań. Dodatkowe informacje dotyczące produktu można znaleźć na stronie: www.molecular.abbott/int/en/simpli-collect-hpv	如對測試結果/診斷有疑問，或需要協助取得新套裝，請聯絡醫療服務提供者。 如需更多產品支援，請瀏覽： www.molecular.abbott/int/en/simpli-collect-hpv

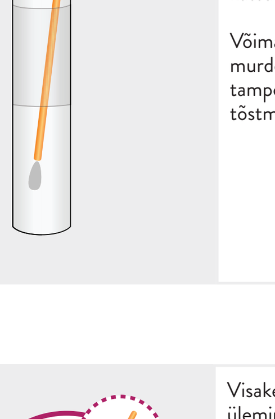
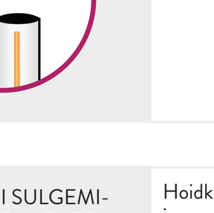
1 ET ETTEVALMISTUSED / PL PRZYGOTOWANIE / ZHHK 準備工作

	ET	PL	ZHHK
1A 	Peske ja kuivatage käed.	Umyj ręce i wytrzyj je do sucha.	清洗並擦乾雙手。
1B **ET** KEERAKE AVAMISEKS VASTUPÄEVA **PL** OTWÓRZ, ODKRĘCAJĄC W LEWO **ZHHK** 逆時針扭開管蓋 	Avage katsutit sisaldav komplekt. Eemaldage katsuti ja tampooni pakend. Asetage komplekti pakend tasasele pinnale. Hoidke katsutit püsti ja eemaldage kork. Asetage avatud katsuti ja kork tagasi komplekti pakendisse.	Otwórz zestaw zawierający probówkę. Wyjmij probówkę i blister z wymazówką. Połóż opakowanie zestawu na płaskiej powierzchni. Trzymając probówkę w pozycji pionowej, zdejmij zakrętkę. Umieść otwartą probówkę i zakrętkę z powrotem w opakowaniu zestawu.	打開裝有試管的套裝。取出試管和拭子包裝。將套裝包裝放在平坦的表面上。 垂直握住試管，並取下管蓋。將打開的試管和管蓋放回套裝包裝中。

2 ET PROOVI VÕTMINE / PL POBIERANIE WYMAZU / ZHHK 採集樣本

	ET	PL	ZHHK
2A **ET** HOIDKE ORANŽIST PULGAST **PL** TRZYMAJ ZA POMARAŃCZOWY TRZONEK **ZHHK** 握住橙色手柄 	Avage tampooni pakend ja hoidke seda oranžist pulgast. ℹ Ärge puudutage valget otsa. Tampooni kasutamise ajal proovige tampooni valge otsaga mitte puudutada midagi peale tupe sisemuse.	Otwórz blister z wymazówką i przytrzymaj ją za pomarańczowy trzonek. ℹ Nie dotykaj białej końcówki. Stosując wymazówkę, staraj się, by jej biała końcówka dotykała wyłącznie wnętrza pochwy.	撕開拭子包裝，並握住橙色拭子手柄。 ℹ 請勿觸碰白色尖端。 使用拭子時，請儘量避免讓拭子的白色尖端接觸除陰道內部以外的任何地方。
2B 	Leidke mugav asend, kust pääsete lihtsalt ligi tupeavale. Hoidke tampooni ühe käega. Liigutage teise käega häbememokad eest ära, et pääseda ligi tupeavale. Sisestage tampooni valge ots õrnalt umbes 5 cm sügavusele tuppe. Pöörake tampooni õrnalt **15-30 sekundit** (veenduge, et tampoon puudutaks tupe seinu). Eemaldage tampoon ettevaatlikult. **Ärge asetage tampooni maha!** ² Sekundid	Przyjmij wygodną pozycję, zapewniającą łatwy dostęp do wejścia do pochwy. Trzymaj wymazówkę jedną ręką. Drugą ręką rozsuń wargi sromowe, aby uzyskać dostęp do wejścia do pochwy. Delikatnie wprowadź do pochwy białą końcówkę wymazówki na głębokość około 5 cm. Delikatnie obracaj wymazówką przez **15-30 sekund** (upewnij się, że wymazówka dotyka ścianek pochwy). Ostrożnie wyjmij wymazówkę. **Nie odkładaj wymazówki!** ² sek.	選擇一個舒適的姿勢，以便拭子進入陰道口。 單手握住拭子。用另一隻手撥開皮膚皺褶（陰唇），以便拭子進入陰道口。 將拭子的白色尖端輕輕插入陰道約 5 厘米。 輕輕轉動拭子 **15 至 30 秒**（確保拭子接觸到陰道壁）。 小心取出拭子。**請勿放下拭子！** ² 秒

3 ET TRANSPORDITAMPOON / PL PRZEKAZANIE WYMAZU DO BADANIA / ZHHK 轉移拭子

	ET	PL	ZHHK
3A **ET** MURDKE **PL** ODŁAM TRZONEK **ZHHK** 折斷 	Hoidke katsutit püsti. Asetage tampoon katsutisse nii, et valge ots on suunatud alla. Murdke tampooni oranž pulk, painutades seda murdejoone juures vastu katsutit. Võimalik, et peate murdejoone leidmiseks tampooni veidi üles tõstma.	Przytrzymaj probówkę w pozycji pionowej. Włóż wymazówkę skierowaną białą końcówką do dołu do probówki. Odłam część pomarańczowego trzonka wymazówki, wyginając go o bok probówki wzdłuż zaznaczonej linii. W razie potrzeby nieznacznie przesuń wymazówkę do góry, aby znaleźć zaznaczenie.	垂直握住試管。白色尖端朝下，將拭子放入試管。 在折斷線處，將橙色的拭子手柄抵住試管彎曲折斷。 您可能需要稍微提起拭子以找出折斷線。
3B 	Visake see tampooni ülemine osa ära! **Tampooni ots jääb katsutisse.**	Wyrzuć górną część trzonka wymazówki! **Dolna część wymazówki ma pozostać w probówce.**	請丟棄拭子手柄的頂部部分！ **拭子的底部將留在試管中。**
3C **ET** KORGI SULGEMISEKS KEERAKE SEDA PÄRIPÄEVA **PL** ZAMKNIJ, PRZEKRĘCAJĄC W PRAWO **ZHHK** 順時針扭緊管蓋	Hoidke katsutit püsti ja eemaldage kork seda vastupäeva keerates. Kui tunnete vastupanu, keerake veel veerand pööret, kuni kork enam ei liigu.	Trzymając probówkę w pozycji pionowej, zamknij ją, obracając zakrętkę w prawo. Po napotkaniu oporu przekręć zakrętkę jeszcze o około jedną czwartą obrotu, aż zostanie ona całkowicie unieruchomiona.	垂直握住試管，順時針扭緊管蓋。 當您感到阻力時，繼續轉動約四分之一圈，直到管蓋不再轉動。
3D	Peske ja kuivatage käed.	Umyj ręce i wytrzyj je do sucha.	清洗並擦乾雙手。
	**Tagastage proov 24 tunni jooksul, järgides eraldi antud juhiseid.**	**Dostarcz wymaz do laboratorium w ciągu 24 godzin, stosując się do podanych osobno wytycznych.**	**請按照另有提供的說明，在 24 小時內返還您的樣本。**

EN KEY TO SYMBOLS / ES SÍMBOLOS UTILIZADOS / DA SYMBOLFORKLARING / NO SYMBOLFORKLARING / ET KASUTATUD SÜMBOLID / DE ERLÄUTERUNG DER SYMBOLE / IT LEGENDA DEI SIMBOLI / SV SYMBOLFÖRKLARING / NL BETEKENIS VAN DE SYMBOLEN / PL OBJAŚNIENIA SYMBOLI / FR LEGENDE DES SYMBOLES / PT LEGENDA DOS SÍMBOLOS / FI SYMBOLIEN SELITE / CS VYSVĚTLENÍ SYMBOLŮ / ZHHK 標誌說明

IVD	**EN** In Vitro Diagnostic Medical Device / **DE** In-vitro-Diagnostikum / **FR** Dispositif médical de diagnostic *in vitro* / **ES** Producto sanitario para diagnóstico *in vitro* / **IT** Dispositivo medico-diagnostico *in vitro* / **PT** Dispositivo médico para diagnóstico *in vitro* / **DA** Medicinsk udstyr til in vitro-diagnostik / **SV** Medicinteknisk produkt för in vitro-diagnostik / **FI** In vitro -diagnostinen lääketieteellinen laite / **NO** Medisinsk utstyr for in vitro-diagnostikk / **NL** Medisch hulpmiddel voor in-vitrodiagnostiek / **CS** Diagnostické zdravotnické prostředky in vitro / **ET** In vitro diagnostika meditsiiniseade / **PL** Wyrób medyczny do diagnostyki in vitro / **ZHHK** 體外診斷醫療儀器
In Vitro Test	**EN** In Vitro Test / **DE** In-vitro-Test / **FR** Test *in vitro* / **ES** Prueba *in vitro* / **IT** Test *in vitro* / **PT** Teste *in vitro* / **DA** In vitro-test / **SV** In vitro-analys / **FI** In vitro -testi / **NO** In vitro-test / **NL** In-vitrotest / **CS** Test in vitro / **ET** In vitro test / **PL** Test in vitro / **ZHHK** 體外測試
REF	**EN** Reference Number / **DE** Bestellnummer / **FR** Référence / **ES** Número de referencia / **IT** Numero di riferimento / **PT** Número de referência / **DA** Bestillingsnummer / **SV** Listnummer / **FI** Tuotenumero / **NO** Bestillingsnummer / **NL** Referentienummer / **CS** Katalogové číslo / **ET** Referentsnumber / **PL** Numer katalogowy / **ZHHK** 參考編號
	EN Do Not Reuse / **DE** Nicht wiederverwenden / **FR** Ne pas réutiliser / **ES** No reutilizar / **IT** Non riutilizzare / **PT** Não reutilizar / **DA** Må ikke genbruges / **SV** Får ej återanvändas / **FI** Kertakäyttöinen / **NO** Må ikke gjenbrukes / **NL** Niet hergebruiken / **CS** Nepoužívejte opakovaně / **ET** Mitte korduskasutada / **PL** Nie stosować ponownie. / **ZHHK** 請勿重複使用
	EN Temperature Limit / **DE** Temperaturgrenze / **FR** Limites de température / **ES** Límite de temperatura / **IT** Limiti di temperatura / **PT** Restrições de temperatura / **DA** Temperaturbegrænsning / **SV** Temperaturbegränsning / **FI** Lämpötilaraja / **NO** Temperaturgrense / **NL** Temperatuurgrens / **CS** Teplotní limit / **ET** Temperatuuripiirang / **PL** Ograniczenie dopuszczalnej temperatury / **ZHHK** 溫度限制
	EN Expiration Date / **DE** Verfallsdatum / **FR** Date de péremption / **ES** Fecha de caducidad / **IT** Data di scadenza / **PT** Prazo de validade / **DA** Udløbsdato / **SV** Sista förbrukningsdag / **FI** Viimeinen käyttöpäivä / **NO** Utløpsdato / **NL** Vervaldatum / **CS** Datum expirace / **ET** Kõlblikkusaja lõpp / **PL** Data ważności / **ZHHK** 有效日期
	EN Consult Instructions for Use / **DE** Gebrauchsanweisung beachten / **FR** Consulter les instructions d'utilisation / **ES** Consultar las instrucciones de uso / **IT** Consultare le istruzioni per l'uso / **PT** Consultar as instruções de utilização / **DA** Se brugsanvisningen / **SV** Läs tillhörande dokumentation / **FI** Lue käyttöohjeet / **NO** Se pakningsvedlegg / **NL** Raadpleeg de gebruiksaanwijzing / **CS** Viz návod k použití / **ET** Vt kasutusjuhendit / **PL** Zajrzyj do instrukcji używania. / **ZHHK** 請查閱使用說明
	EN Peel Open Here / **DE** Zum Öffnen hier ziehen / **FR** Ouvrir ici / **ES** Tirar de aquí para abrir / **IT** Per aprire tirare qui / **PT** Abrir aqui / **DA** Åbnes her / **SV** Öppna här / **FI** Avaa tästä / **NO** Åpnes her / **NL** Hier opentrekken / **CS** Zde odtrhněte / **ET** Avada siit / **PL** Tu otwierać. / **ZHHK** 於此處撕開
	EN Do Not Use If Package Is Damaged / **DE** Nicht verwenden, wenn die Verpackung beschädigt ist / **FR** Ne pas utiliser si l'emballage est endommagé / **ES** No utilizar si el envase está dañado / **IT** Non utilizzare se la confezione è danneggiata / **PT** Não utilizar se a embalagem estiver danificada / **DA** Må ikke anvendes, hvis pakken er beskadiget / **SV** Får inte användas om förpackningen är skadad / **FI** Ei saa käyttää, jos pakkaus on vahingoittunut / **NO** Må ikke brukes hvis pakningen er skadet / **NL** Niet gebruiken als de verpakking is beschadigd / **CS** Nepoužívejte, pokud je obal poškozený / **ET** Ärge kasutage, kui pakend on kahjustunud / **PL** Nie stosować, jeśli opakowanie jest uszkodzone. / **ZHHK** 如包裝破損，請勿使用
ℹ	**EN** Important Information / **DE** Wichtige Information / **FR** Informations importantes / **ES** Información importante / **IT** Informazioni importanti / **PT** Informação importante / **DA** Vigtige oplysninger / **SV** Viktig information / **FI** Tärkeää tietoa / **NO** Viktig informasjon / **NL** Belangrijke informatie / **CS** Důležité informace / **ET** Oluline teave / **PL** Ważne informacje / **ZHHK** 重要資訊
SWAB	**EN** Swab / **DE** Tupfer / **FR** Ecouvillon / **ES** Hisopo / **IT** Tampone / **PT** Zaragatoa / **DA** Podepind / **SV** Provtagningspinne / **FI** Wattenstaafje / **NO** Prøvetakingspinne / **NL** Wattenstaafje / **CS** Tampon / **ET** Tampoon / **PL** Wymazówka / **ZHHK** 拭子
SAMPLE TUBE	**EN** Sample Tube / **DE** Probenröhrchen / **FR** Tube échantillon / **ES** Tubo de muestra / **IT** Provetta per campione / **PT** Tubo de amostra / **DA** Prøverør / **SV** Provrör / **FI** Näyteputki / **NO** Prøverør / **NL** Monsterbuisje / **CS** Vzorková zkumavka / **ET** Proovikatsuti / **PL** Probówka na wymazówkę / **ZHHK** 樣本試管
PRODUCED BY	**EN** Produced By / **DE** Produziert von / **FR** Produit par / **ES** Producido por / **IT** Prodotto da / **PT** Produzido por / **DA** Produceret af / **SV** Tillverkas av / **FI** Tuottanut / **NO** Produseres av /**NL** Geproduceerd door / **CS** Vyrobeno společností / **ET** Valmistaja / **PL** Wyprodukowano przez / **ZHHK** 製造商
LOT	**EN** Lot Number / **DE** Chargenbezeichnung / **FR** Numéro de lot / **ES** Número de lote / **IT** Numero di lotto / **PT** Número de lote / **DA** Lotnummer / **SV** Lotnummer / **FI** Eränumero / **NO** Lotnummer / **NL** Partijnummer / **CS** Číslo šarže / **ET** Partiinumber / **PL** Numer partii / **ZHHK** 批號
STERILE R	**EN** Sterilized Using Irradiation / **DE** Steril durch Bestrahlung / **FR** Stérilisé par irradiation / **ES** Esterilizado mediante radiación / **IT** Sterilizzato tramite irradiazione / **PT** Esterilizado por radiação / **DA** Steriliseret ved brug af stråling / **SV** Steriliseras genom strålning / **FI** Steriloitu säteilyttämällä / **NO** Sterilisert ved bestråling / **NL** Gesteriliseerd met behulp van straling / **CS** Sterilizováno zářením / **ET** Steriliseeritud kiiritusega / **PL** Sterylizowane radiacyjnie / **ZHHK** 已使用輻射滅菌
SPECIMEN COLLECTION SWAB	**EN** Specimen Collection Swab / **DE** Tupfer für die Probenentnahme / **FR** Ecouvillon de prélèvement d'échantillon / **ES** Hisopo de recogida de especímenes / **IT** Tampone per la raccolta del campione / **PT** Zaragatoa para colheita de amostras / **DA** Podepind til udtagning / **SV** Provtagningspinne / **FI** Näytteenottotikku / **NO** Prøvetakingspinne til prøver / **NL** Wattenstaafje voor monsterafname / **CS** Tampon pro odběr vzorku / **ET** Proovi kogumise tampoon / **PL** Wymazówka do pobierania próbek / **ZHHK** 樣本採集拭子
STORE AT	**EN** Store At / **DE** Lagerung bei / **FR** Conserver à / **ES** Almacenar a / **IT** Conservare a / **PT** Conservar a / **DA** Opbevares ved / **SV** Förvaras i / **FI** Säilytettävä / **NO** Oppbevares ved /**NL** Bewaren bij /**CS** Skladujte při / **ET** Säilitusjuhised / **PL** Przechowywać w temp. / **ZHHK** 儲存條件
NOTE: Changes Highlighted	**EN** NOTE: Changes Highlighted / **DE** HINWEIS: Änderungen sind hervorgehoben / **FR** REMARQUE : Faire attention aux modifications / **ES** NOTA: Modificaciones marcadas / **IT** NOTA: fare attenzione alle modifiche / **PT** NOTA: Alterações assinaladas / **DA** BEMÆRK: Ændringer er markeret / **SV** Observera markerade ändringar / **FI** HUOMAUTUS: Muutokset korostettu / **NO** MERK: Endringer er markert / **NL** OPMERKING: Wijzigingen gemarkeerd / **CS** POZNÁMKA: Změny zvýrazněny / **ET** MÄRKUS: muudatused on esile tõstetud / **PL** UWAGA: Zmiany wyróżniono kolorem szarym. / **ZHHK** 備註：已突顯變更部分
EC REP	**EN** Authorized Representative in the European Community / European Union / **DE** Bevollmächtigter in der Europäischen Gemeinschaft / Europäischen Union / **FR** Mandataire au sein de la Communauté européenne / de l'Union européenne / **ES** Representante autorizado en la Comunidad Europea/Unión Europea /**IT** Mandatario nella Comunità europea / Unione europea / **PT** Mandatário na Comunidade Europeia/União Europeia / **DA** Autoriseret repræsentant i EF / EU / **SV** Auktoriserad representant inom Europeiska gemenskapen/Europeiska unionen / **FI** Valtuutettu edustaja Euroopan yhteisössä / **NO** Autorisert representant i Det europeiske fellesskap / EU / **NL** Gemachtigd vertegenwoordiger in de Europese Gemeenschap/Europese Unie / **CS** Zplnomocněný zástupce v zemích Evropského společenství / Evropské unie / **ET** Volitatud esindaja Euroopa Ühenduses / Euroopa Liidus / **PL** Upoważniony przedstawiciel w krajach Wspólnoty Europejskiej / **ZHHK** 歐洲共同體/歐盟授權代表
	EN Importer / **DE** Importeur / **FR** Importateur / **ES** Importador / **IT** Importatore / **PT** Importador / **DA** Importør / **SV** Importör / **FI** Maahantuoja / **NO** Importør / **NL** Importeur / **CS** Dovozce / **ET** Importija / **PL** Importer / **ZHHK** 進口商
	EN Manufacturer / **DE** Hersteller / **FR** Fabricant / **ES** Fabricante / **IT** Fabbricante / **PT** Fabricante / **DA** Fabrikant / **SV** Tillverkare / **FI** Valmistaja / **NO** Produsent / **NL** Fabrikant / **CS** Výrobce / **ET** Tootja / **PL** Producent / **ZHHK** 製造商

	EN WASTE COLLECTION GUIDELINES: Paper and Plastic Collection	DE RICHTLINIEN ZUR ABFALLSAMMLUNG: Papier- und Kunststoffsammlung	FR INDICATIONS CONCERNANT LA COLLECTE DE DECHETS : Collecte de papier et collecte de plastique
22 PAP / 7 OTHER	Sample Tube Packaging: Plain Paper and Ethylene-vinyl acetate (EVA)	Probenröhrchenverpackung: Einfaches Papier und Ethylen-Vinylacetat (EVA)	Emballage du tube échantillon : papier ordinaire et éthylène-acétate de vinyle (EVA)
22 PAP	Swab Packaging and Instructions for Use: Plain Paper	Tupferverpackung und Gebrauchsanweisung: Einfaches Papier	Emballage de l'écouvillon et instructions d'utilisation : papier ordinaire
	Items with the recyclable symbol can be recycled. Follow your national, regional, and local ordinances accordingly for waste disposal regulations.	Artikel mit dem Recycling-Symbol können recycelt werden. Bitte befolgen Sie die geltenden gesetzlichen Bestimmungen zur Abfallentsorgung.	Les éléments avec le symbole de recyclage peuvent être recyclés. Suivez les réglementations nationales, régionales et locales sur l'élimination des déchets.

	ES INDICACIONES PARA LA ELIMINACIÓN DE RESIDUOS: Eliminación de papel y plástico	IT LINEE GUIDA PER LA RACCOLTA DEI RIFIUTI: Raccolta carta e plastica	PT DIRETRIZES DE RECOLHA DE RESÍDUOS: Recolha de papel e de plástico
22 PAP / 7 OTHER	Envase del tubo de muestra: papel y etilvinilacetato (EVA)	Imballaggio della provetta per campione: carta ed etilene vinil acetato (EVA)	Embalagem do tubo de amostra: Papel normal e etileno-acetato de vinilo (EVA)
22 PAP	Envase del hisopo e instrucciones de uso: papel	Imballaggio del tampone e istruzioni per l'uso: carta	Embalagem da zaragatoa e instruções de utilização: Papel normal
	Los artículos que tienen el símbolo de reciclaje se pueden reciclar. Siga las normativas vigentes para la eliminación de residuos.	Gli articoli con il simbolo del riciclaggio possono essere riciclati. Attenersi alle normative nazionali, regionali e locali relative allo smaltimento dei rifiuti.	Os itens com o símbolo de reciclável podem ser reciclados. Seguir as determinações nacionais, regionais e locais em conformidade com os regulamentos de eliminação de resíduos.

	DA RETNINGSLINJER FOR AFFALDSHÅNDTERING: Håndtering af papir og plastik	SV RIKTLINJER FÖR AVFALLSINSAMLING: insamling av papper och plast	FI JÄTTEIDEN KERÄYSOHJEET: Paperi- ja muovikeräys
22 PAP / 7 OTHER	Prøverørets indpakning: Almindeligt papir og ethylen-vinylacetat (EVA)	Provrörsförpackning: papper och etylenvinylacetat (EVA)	Näyteputken pakkaus: Tavallinen paperi ja etyleenivinyyliasetaatti (EVA)
22 PAP	Podepindens indpakning og brugsanvisning: Almindeligt papir	Förpackning för provtagningspinne samt bruksanvisning: papper	Tikun pakkaus ja käyttöohjeet: Tavallinen paperi
	Elementer med genbrugssymbolet kan genbruges. Følg de lokale og nationale retningslinjer for bortskaffelse af affald.	Artiklar med återvinningssymbolen kan återvinnas. Följ gällande bestämmelser för kassering av avfall.	Kierrätyssymbolilla varustetut tuotteet voidaan kierrättää. Noudata kansallisia, alueellisia ja paikallisia jätteenkäsittelymääräyksiä.

	NO RETNINGSLINJER FOR AVFALLSHÅNDTERING: Innsamling av papir og plast	NL RICHTLIJNEN VOOR AFVALINZAMELING: Inzameling van papier en plastic	CS POKYNY PRO SBĚR ODPADU: Sběr papíru a plastů
22 PAP / 7 OTHER	Emballasje til prøverør: Vanlig papir og etylenvinylacetat (EVA)	Verpakking van monsterbuisjes: Gewoon papier en ethyleenvinylacetaat (EVA)	Balení vzorkové zkumavky: Běžný papír a ethylen-vinylacetát (EVA)
22 PAP	Emballasje til prøvetakingspinne og bruksanvisning: Vanlig papir	Verpakking en gebruiksaanwijzing wattenstaafje: Gewoon papier	Balení tamponu a návod k použití: Běžný papír
	Deler med resirkuleringssymbolet kan resirkuleres. Følg nasjonale, regionale og lokale bestemmelser for avfallshåndtering.	Items met het recyclingsymbool kunnen worden gerecycled. Houd u aan de nationale, regionale en lokale voorschriften voor afvalverwerking.	Položky označené symbolem recyklace lze recyklovat. Postupujte podle platných nařízení pro nakládání s odpady.

	ET JÄÄTMETE KOGUMISE SUUNISED: Paper and Plastic Collection	PL WYTYCZNE DOT. ZBIÓRKI ODPADÓW: Zbiórka papieru i tworzyw sztucznych	ZHHK 廢物收集指引：紙張和塑膠收集
22 PAP / 7 OTHER	Proovikatsuti pakend: Tavaline paber ja etüleen-vinüülatsetaat (EVA)	Opakowanie probówki na wymazówkę: zwykły papier i kopolimer etylenu i octanu winylu (EVA)	樣本試管包裝：普通紙張和乙烯–醋酸乙烯酯共聚物 (EVA)
22 PAP	Tampooni pakend ja kasutusjuhend: Paber	Opakowanie wymazówki i instrukcja używania: zwykły papier	拭子包裝及使用說明：普通紙張
	Ümbertöödeldava toote tähisega esemeid saab ringlusse võtta. Jäätmekäitluse eeskirjade puhul järgige riiklikke, piirkondlike ja kohalike eeskirju.	Elementy opatrzone symbolem recyklingu mogą być poddane recyklingowi. Należy postępować zgodnie z ogólnokrajowymi i miejscowymi regulacjami dotyczącymi gospodarowania odpadami.	帶有可回收標誌的物品可回收。請遵循國家、地區和當地相關的廢物處置法規。

EN BEFORE STARTING / DE VOR BEGINN / FR AVANT DE COMMENCER

24 HOURS[1]

EN	DE	FR
You will receive a kit containing the following: • 1 Tube (Sample Tube) • 1 Swab **If you do not follow the instructions, your result may be incorrect.** • Store kit before and after use at room temperature (between 15°C to 30°C). • Return your sample within 24 hours. • **Do not** use if you are pregnant. • **Do not** clean genital area immediately before collecting sample. • **Do not** use the kit beyond its **EXPIRATION DATE** printed on kit packaging. [1] Hours	Sie erhalten einen Kit mit folgendem Inhalt: • 1 Röhrchen (Probenröhrchen) • 1 Tupfer **Wenn Sie die Anweisungen nicht befolgen, ist Ihr Ergebnis möglicherweise nicht korrekt.** • Den Kit vor und nach Gebrauch bei Raumtemperatur lagern (zwischen 15 °C und 30 °C). • Senden Sie Ihre Probe innerhalb von 24 Stunden zurück. • **Nicht** verwenden, wenn Sie schwanger sind. • Reinigen Sie den Genitalbereich **nicht** unmittelbar vor der Probenentnahme. • Den Kit **nicht** über das auf der Kitverpackung aufgedruckte **VERFALLSDATUM** hinaus verwenden. [1] Stunden	Vous allez recevoir un kit contenant ce qui suit : • 1 tube (tube échantillon) • 1 écouvillon **Si vous ne suivez pas les instructions, vos résultats pourraient être incorrects.** • Conservez le kit à température ambiante (entre 15 °C et 30 °C) avant et après le prélèvement de l'échantillon. • Renvoyez votre échantillon dans les 24 heures. • **N'utilisez pas** le kit si vous êtes enceinte. • **Ne** nettoyez **pas** vos parties génitales juste avant de prélever l'échantillon. • **N'utilisez pas** le kit au-delà de la **DATE DE PEREMPTION** imprimée sur l'emballage du kit. [1] Heures
i DO NOT touch the white tip of the swab or lay the swab down. If the white tip is touched or the swab is laid down or dropped, your results may not be accurate. You need to request a new simpli-COLLECT HPV Collection Kit.	i Die weiße Spitze des Tupfers NICHT berühren und den Tupfer nicht ablegen. Wird die weiße Spitze berührt, der Tupfer abgelegt oder fallen gelassen, sind die Ergebnisse möglicherweise nicht zuverlässig. In diesem Fall einen neuen simpli-COLLECT HPV Collection Kit anfordern.	i NE touchez PAS l'embout blanc de l'écouvillon ou ne posez pas l'écouvillon. Si vous touchez l'embout blanc, si l'écouvillon est posé ou s'il tombe, vos résultats pourraient être incorrects. Vous devrez demander un nouveau kit de prélèvement simpli-COLLECT HPV.
Contact your healthcare provider with questions regarding test results/diagnosis or assistance with obtaining a new kit. For additional product support please visit: www.molecular.abbott/int/en/simpli-collect-hpv	Bitte wenden Sie sich bei Fragen zu den Testergebnissen/Diagnosen oder zum Bezug eines neuen Kits an Ihren Arzt. Bitte besuchen Sie für zusätzliche Produktunterstützung: www.molecular.abbott/int/en/simpli-collect-hpv	Contactez votre professionnel de santé si vous avez des questions concernant les résultats du test/le diagnostic, ou si vous avez besoin de recevoir un nouveau kit. Si vous avez besoin d'aide pour savoir comment utiliser ce produit, veuillez vous rendre sur : www.molecular.abbott/int/en/simpli-collect-hpv

1 EN SETTING UP / DE VORBEREITUNG / FR PREPARATION

	EN	DE	FR
1A	Wash and dry your hands.	Waschen und trocknen Sie Ihre Hände.	Lavez et séchez vos mains.
1B **EN** COUNTER CLOCKWISE TO UNCAP **DE** GEGEN DEN UHRZEIGERSINN ZUM ÖFFNEN **FR** DEVISSEZ LE BOUCHON	Open kit containing tube. Remove tube and swab packet. Place kit packaging on a flat surface. Hold tube upright and remove cap. Place open tube and cap back into kit packaging.	Öffnen Sie den Kit mit dem darin enthaltenen Röhrchen. Entnehmen Sie das Röhrchen und die Tupferpackung. Platzieren Sie die Kitverpackung auf einer ebenen Oberfläche. Halten Sie das Röhrchen aufrecht und entfernen Sie die Verschlusskappe. Platzieren Sie das offene Röhrchen und die Verschlusskappe wieder in der Kitverpackung.	Ouvrez le kit contenant le tube. Sortez le tube et l'écouvillon du paquet. Placez l'emballage du kit sur une surface plane. Tenez le tube à la verticale et dévissez le bouchon. Replacez le tube ouvert et le bouchon dans l'emballage du kit.

2 EN COLLECTING YOUR SAMPLE / DE ENTNAHME DER PROBE / FR PRELEVEMENT DE VOTRE ECHANTILLON

	EN	DE	FR
2A **EN** HOLD BY ORANGE HANDLE **DE** AM ORANGEFARBENEN TUPFERGRIFF HALTEN **FR** TENEZ PAR LA TIGE ORANGE	Peel open swab packet and hold by orange swab handle. i Do not touch white tip. While using the swab, try not to touch the white tip of the swab to anything except the inside of your vagina.	Öffnen Sie die Tupferverpackung und halten Sie den Tupfer am orangefarbenen Tupfergriff fest. i Die weiße Spitze nicht berühren. Versuchen Sie, während der Verwendung des Tupfers nur die Innenseite Ihrer Vagina mit der weißen Spitze des Tupfers zu berühren.	Ouvrez l'emballage de l'écouvillon et tenez par la tige orange de l'écouvillon. i Ne touchez pas l'embout blanc. Lors de l'utilisation de l'écouvillon, faites en sorte que l'embout blanc de l'écouvillon ne rentre en contact qu'avec l'intérieur de votre vagin.
2B 5 cm 30 SEC[2]	Find a comfortable position to easily access the opening of your vagina. Hold swab with one hand. With the other hand, move the folds of skin (labia) out of the way to access the opening of your vagina. Gently insert white tip of swab about 5 cm into your vagina. Gently rotate swab for **15-30 seconds** (make sure swab touches the walls of your vagina). Carefully remove swab. **Do not set swab down!** [2] Seconds	Nehmen Sie eine bequeme Position ein, in der Sie die Öffnung Ihrer Vagina ungehindert erreichen können. Halten Sie den Tupfer mit einer Hand. Bewegen Sie mit der anderen Hand die Hautfalten (Schamlippen) zur Seite, um an die Öffnung Ihrer Vagina zu gelangen. Führen Sie die weiße Spitze des Tupfers vorsichtig etwa 5 cm in Ihre Vagina ein. Drehen Sie den Tupfer behutsam **15 - 30 Sekunden** lang (stellen Sie sicher, dass der Tupfer dabei die Seiten Ihrer Vagina berührt). Entfernen Sie den Tupfer vorsichtig. **Den Tupfer nicht ablegen!** [2] Sekunden	Trouvez une position confortable pour accéder facilement à l'orifice de votre vagin. Tenez l'écouvillon d'une main. De l'autre main, écartez les lèvres pour accéder à l'orifice de votre vagin. Insérez doucement l'embout blanc de l'écouvillon d'environ 5 cm dans votre vagin. Tournez doucement l'écouvillon pendant **15 à 30 secondes** (assurez-vous que l'écouvillon touche les parois de votre vagin). Retirez doucement l'écouvillon. **Ne posez pas l'écouvillon !** [2] Secondes

3 EN TRANSFER SWAB / DE TRANSFER DES TUPFERS / FR TRANSFERT DE L'ECOUVILLON

	EN	DE	FR
3A **EN** SNAP **DE** ABBRECHEN **FR** CRAC	Hold tube upright. With the white tip pointed down, put the swab into the tube. Snap the orange swab handle by bending the handle against the tube at the break line. You may need to lift the swab slightly to find the break line.	Halten Sie das Röhrchen aufrecht. Führen Sie den Tupfer mit der weißen Spitze nach unten in das Röhrchen ein. Brechen Sie den orangefarbenen Tupfergriff ab, indem Sie ihn an der Bruchlinie gegen das Röhrchen biegen. Möglicherweise müssen Sie den Tupfer leicht anheben, um die Bruchlinie zu finden.	Tenez le tube à la verticale. Avec l'embout blanc pointé vers le bas, placez l'écouvillon dans le tube. Cassez la tige orange de l'écouvillon en pliant la tige contre le tube au niveau du point de rupture. Vous devrez peut-être soulever légèrement l'écouvillon pour trouver le point de rupture.
3B	Throw this top piece of the swab handle away! **The bottom of the swab will remain in the tube.**	Entsorgen Sie das obere Endstück des Tupfergriffs! **Der untere Teil des Tupfers verbleibt im Röhrchen.**	Jetez la partie supérieure de la tige de l'écouvillon ! **La partie inférieure de l'écouvillon restera dans le tube.**
3C **EN** CLOCKWISE TO RECAP **DE** IM UHRZEIGERSINN ZUM VERSCHLIESSEN **FR** VISSEZ LE BOUCHON	Hold tube upright and recap the tube by screwing the cap clockwise. When you feel resistance, keep turning about another quarter turn until cap no longer moves.	Halten Sie das Röhrchen aufrecht und schrauben Sie den Verschluss im Uhrzeigersinn wieder auf das Röhrchen. Wenn Sie einen Widerstand spüren, drehen Sie den Verschluss noch etwa eine Vierteldrehung weiter, bis er sich nicht mehr bewegt.	Tenez le tube à la verticale et rebouchez le tube en vissant le bouchon dans le sens des aiguilles d'une montre. Lorsque vous sentez une résistance, continuez à tourner encore d'un quart de tour jusqu'à ce que le bouchon ne bouge plus.
3D	Wash and dry your hands.	Waschen und trocknen Sie Ihre Hände.	Lavez et séchez vos mains.
✓	**Return your sample within 24 hours following the instructions provided separately.**	**Senden Sie Ihre Probe innerhalb von 24 Stunden gemäß den separat zur Verfügung gestellten Anweisungen zurück.**	**Renvoyez votre échantillon dans les 24 heures en suivant les instructions fournies séparément.**

ES ANTES DE EMPEZAR / IT PRIMA DI INIZIARE / PT ANTES DE COMEÇAR

24 HOURS[1]

ES	IT	PT
Recibirá un kit que contiene lo siguiente: • 1 tubo (tubo de muestra) • 1 hisopo **Si no se siguen las instrucciones, se pueden obtener resultados incorrectos.** • Almacene el kit a temperatura ambiente (entre 15 °C y 30 °C) antes y después del uso. • Remita la muestra en un plazo de 24 horas. • **No** utilice este producto si está embarazada. • **No** lave la zona genital inmediatamente antes de recoger la muestra. • **No utilice** el kit una vez transcurrida la **FECHA DE CADUCIDAD** impresa en el envase del kit. [1] Horas	Riceverai un kit contenente quanto segue: • 1 provetta (provetta per campione) • 1 tampone **Se non ci si attiene alle istruzioni, il risultato potrebbe non essere corretto.** • Conservare il kit prima e dopo l'uso a temperatura ambiente (tra 15°C e 30°C). • Il campione deve essere spedito entro 24 ore. • **Non** usare in caso di gravidanza. • **Non** lavare l'area genitale poco prima di raccogliere il campione. • **Non** usare il kit oltre la **DATA DI SCADENZA** stampata sulla confezione del kit. [1] ore	Irá receber um kit contendo o seguinte: • 1 tubo (tubo de amostra) • 1 zaragatoa **Caso as instruções não sejam seguidas, o seu resultado pode ser incorreto.** • Conserve o kit antes e depois da sua utilização à temperatura ambiente (entre 15°C e 30°C). • Devolva a sua amostra no prazo de 24 horas. • **Não** utilize se estiver grávida. • **Não** limpe a zona genital imediatamente antes da colheita da amostra. • **Não** utilize o kit depois do respetivo **PRAZO DE VALIDADE** impresso na embalagem do kit. [1] Horas
i NO toque la punta blanca del hisopo o apoye el hisopo en ninguna superficie. Si toca la punta blanca o el hisopo se apoya sobre alguna superficie o se cae, los resultados obtenidos podrían no ser exactos. Tiene que pedir un nuevo simpli-COLLECT HPV Collection Kit.	i NON toccare il puntale bianco del tampone o appoggiare il tampone. Se il puntale bianco viene toccato o se il tampone viene appoggiato o fatto cadere, i risultati potrebbero non essere accurati. È necessario richiedere un nuovo simpli-COLLECT HPV Collection Kit.	i NÃO toque na ponta branca da zaragatoa nem a pouse em nenhuma superfície. Caso a ponta branca toque em alguma coisa ou a zaragatoa seja pousada em alguma superfície ou deixada cair, os resultados podem não ser exatos. Irá necessitar de pedir um novo simpli-COLLECT HPV Collection Kit.
Contacte con su profesional sanitario si tiene dudas sobre los resultados o el diagnóstico de la prueba, o si necesita ayuda para obtener un kit nuevo. Para obtener más información sobre el producto consulte: www.molecular.abbott/int/en/simpli-collect-hpv	Contattare il proprio operatore sanitario per domande relative ai risultati del test/alla diagnosi, oppure per assistenza su come ottenere un nuovo kit. Per ulteriori informazioni sul prodotto, visitare: www.molecular.abbott/int/en/simpli-collect-hpv	Contacte o seu prestador de cuidados de saúde caso tenha questões relativas ao envio da amostra, aos resultados de teste/diagnóstico ou para pedir ajuda para obter um novo kit. Para suporte adicional ao produto, por favor consulte: www.molecular.abbott/int/en/simpli-collect-hpv

1 ES PREPARACIÓN / IT PREPARATIVI / PT PREPARAÇÃO

	ES	IT	PT
1A	Lávese y séquese las manos.	Lavare e asciugare le mani.	Lave e seque as mãos.
1B **ES** GIRE EN SENTIDO ANTIHORARIO PARA ABRIR EL TAPÓN **IT** SVITARE IN SENSO ANTIORARIO **PT** RODE NO SENTIDO CONTRÁRIO AO DOS PONTEIROS DO RELÓGIO PARA DESAPERTAR	Abra el kit que contiene el tubo. Extraiga el tubo y el envase con el hisopo. Coloque el envase del kit en una superficie lisa. Sostenga el tubo en posición vertical y quite el tapón. Vuelva a meter el tubo abierto y el tapón en el envase del kit.	Aprire il kit contenente la provetta. Rimuovere la provetta e la confezione del tampone. Posizionare la confezione del kit su una superficie piana. Tenere la provetta in posizione verticale e rimuovere il tappo. Rimettere la provetta aperta e il tappo nella confezione del kit.	Abra o kit contendo o tubo. Retire o tubo e o pacote da zaragatoa. Coloque a embalagem do kit numa superfície plana. Segure o tubo na vertical e retire a tampa. Coloque o tubo aberto e a tampa de volta na embalagem do kit.

2 ES RECOGIDA DE LA MUESTRA / IT RACCOLTA DEL CAMPIONE / PT COLHER A AMOSTRA

	ES	IT	PT
2A **ES** SUJETAR POR LA VARILLA NARANJA **IT** TENERE PER IL MANICO ARANCIONE **PT** SEGURE PELA PEGA COR DE LARANJA	Abra el envase del hisopo y sosténgalo por la varilla naranja. i No toque la punta blanca. Mientras utiliza el hisopo, procure no tocar nada con la punta blanca, excepto el interior de la vagina.	Aprire l'imballaggio del tampone e tenere il tampone per il manico arancione. i Non toccare il puntale bianco Mentre si usa il tampone, cercare di non far toccare altro al puntale bianco del tampone se non l'interno della vagina.	Abra o pacote da zaragatoa e segure pela pega da zaragatoa cor de laranja. i Não toque na ponta branca. Ao utilizar a zaragatoa, tente não tocar em nada com a ponta branca da zaragatoa, com exceção do interior da sua vagina.
2B 5 cm 30 SEC[2]	Adopte una postura cómoda para acceder fácilmente a la abertura de la vagina. Sostenga el hisopo con una mano. Con la otra mano, separe los pliegues de piel (labios) para acceder a la abertura de la vagina. Introduzca en la vagina con cuidado la punta blanca del hisopo aproximadamente 5 cm. Gire suavemente el hisopo durante **15-30 segundos** (asegúrese de que el hisopo toca las paredes vaginales). Extraiga el hisopo con cuidado. **¡No apoye el hisopo en ninguna superficie!** [2] Segundos	Trovare una posizione comoda per accedere facilmente all'apertura vaginale. Tenere il tampone con una mano. Con l'altra mano spostare le pliche cutanee (le piccole labbra) dall'apertura della vagina. Inserire delicatamente il puntale del tampone nella vagina per circa 5 cm. Ruotare delicatamente il tampone per **15-30 secondi** (assicurarsi che il tampone tocchi le pareti vaginali). Estrarre il tampone con cautela. **Non appoggiare il tampone.** [2] secondi	Encontre uma posição confortável para aceder facilmente à abertura da sua vagina. Segure na zaragatoa com uma mão. Com a outra mão, afaste as pregas de pele (lábios) para aceder à abertura da sua vagina. Insira cuidadosamente a ponta branca cerca de 5 cm na sua vagina. Rode cuidadosamente a zaragatoa durante **15-30 segundos** (assegure-se que a zaragatoa toca nas paredes da sua vagina). Retire cuidadosamente a zaragatoa. **Não pouse a zaragatoa!** [2] Segundos

3 ES TRANSFERENCIA DEL HISOPO / IT TRASFERIRE IL TAMPONE / PT TRANSFERIR A ZARAGATOA

	ES	IT	PT
3A **ES** ROMPER **IT** SPEZZARE **PT** PARTIR	Sostenga el tubo en posición vertical. Con la punta blanca apuntando hacia abajo, introduzca el hisopo en el tubo. Rompa la varilla naranja del hisopo doblándola contra el tubo por la línea de rotura. Es posible que deba elevar ligeramente el hisopo para encontrar la línea de rotura.	Tenere la provetta in posizione verticale. Collocare il tampone nella provetta, con il puntale bianco rivolto verso il basso. Spezzare il manico arancione del tampone piegandolo contro la provetta nel punto di rottura. Per trovare il punto di rottura potrebbe essere necessario sollevare leggermente il tampone.	Segure o tubo na vertical. Com a ponta branca virada para baixo, coloque a zaragatoa no tubo. Parta a pega da zaragatoa cor de laranja dobrando a pega contra o tubo pela linha de quebra. Pode ser necessário levantar ligeiramente a zaragatoa para encontrar a linha de quebra.
3B	¡Deseche la parte superior del hisopo! **La parte inferior del hisopo permanecerá dentro del tubo.**	Gettare la parte superiore del manico del tampone! **La parte inferiore del tampone rimarrà nella provetta.**	Elimine a parte superior da pega da zaragatoa! **A parte inferior da zaragatoa irá permanecer no tubo.**
3C **ES** GIRE EN SENTIDO HORARIO PARA CERRAR EL TAPÓN **IT** AVVITARE IN SENSO ORARIO **PT** RODE NO SENTIDO DOS PONTEIROS DO RELÓGIO PARA VOLTAR A TAPAR	Sostenga el tubo en posición vertical y ciérrelo girando el tapón en sentido horario. Cuando note resistencia, siga girando el tapón otro cuarto de vuelta hasta que no gire más.	Tenere la provetta in posizione verticale e ritapparla avvitando il tappo in senso orario. Quando si avverte una certa resistenza, continuare a girare per un altro quarto di giro fino a quando il tappo non si muove più.	Segure o tubo na vertical e volte a tapar o tubo enroscando a tampa no sentido dos ponteiros do relógio. Quando sentir resistência, continue a rodar mais um quarto de volta até que a tampa já não se mexa.
3D	Lávese y séquese las manos.	Lavare e asciugare le mani.	Lave e seque as mãos.
✓	**Remita la muestra en un plazo de 24 horas según se indica en las instrucciones suministradas separadamente.**	**Spedire il campione entro 24 ore seguendo le istruzioni fornite separatamente.**	**Devolva a sua amostra no prazo de 24 horas, seguindo as instruções fornecidas separadamente.**

DA FØR START / SV INNAN DU BÖRJAR / FI ENNEN ALOITTAMISTA

24 HOURS[1]

DA	SV	FI
Du modtager et sæt med følgende indhold: • 1 rør (prøverør) • 1 podepind **Hvis anvisningerne ikke følges, kan resultatet blive forkert.** • Opbevar sættet ved stuetemperatur (mellem 15 °C og 30 °C) før og efter prøvetagning. • Returner prøven inden for 24 timer. • Anvend **ikke**, hvis du er gravid. • Vask **ikke** kønsorganerne umiddelbart før prøvetagning. • Anvend **ikke** sættet efter den **UDLØBSDATO**, som er angivet på indpakningen. [1] Timer	Du kommer att erhålla en förpackning som innehåller följande: • 1 provrör (rör) • 1 provtagningspinne **Om du inte följer anvisningarna kan resultatet bli felaktigt.** • Förvara förpackningen i rumstemperatur (mellan 15 °C och 30 °C) före och efter användning. • Skicka provet inom 24 timmar. • Får **inte** användas om du är gravid. • Rengör **inte** underlivet omedelbart före provtagningen. • Provtagningskitet får **inte** användas om den **SISTA FÖRBRUKNINGSDAG** som anges på förpackningen har passerat. [1] timmar	Saat pakkauksen, jossa on • 1 putki (näyteputki) • 1 näytteenottotikku **Jos et noudata ohjeita, tuloksesi voi olla virheellinen.** • Säilytä pakkausta käyttöä ennen ja sen jälkeen huoneenlämmössä (15–30 °C). • Palauta näyte 24 tunnin sisällä. • **Älä** käytä, jos olet raskaana. • **Älä** puhdista genitaalialuetta välittömästi ennen näytteen ottamista. • **Älä** käytä pakkausta pakkaukseen tulostetun **VANHENEMISPÄIVÄN** jälkeen. [1] Tuntia
i Rør IKKE ved podepindens hvide spids, og læg IKKE podepinden fra dig. Hvis den hvide spids berøres, eller podepinden lægges ned eller tabes, kan resultaterne blive unøjagtige. Du skal anmode om et nyt simpli-COLLECT HPV Collection Kit.	i Du får INTE vidröra den vita spetsen på provtagningspinnen eller lägga ned provtagningspinnen. Om du vidrör den vita spetsen eller lägger ned eller tappar provtagningspinnen kan resultaten bli felaktiga. Du måste då begära en ny förpackning av simpli-COLLECT HPV Collection Kit.	i ÄLÄ kosketa tikun valkoista kärkeä tai laita tikkua alustalle. Jos valkoista kärkeä kosketetaan tai tikku laitetaan alustalle tai pudotetaan, tulokset eivät ehkä ole tarkkoja. Sinun on pyydettävä uutta simpli-COLLECT HPV -keruupakkausta.
Kontakt din læge for spørgsmål om testresultater/diagnose eller hjælp til at få et nyt sæt. For yderligere produktsupport se venligst: www.molecular.abbott/int/en/simpli-collect-hpv	Kontakta din vårdgivare vid frågor om analysresultat/diagnos, eller för hjälp med att få ett nytt provtagningskit. Ytterligare information om produkten finns här: www.molecular.abbott/int/en/simpli-collect-hpv	Ota yhteyttä terveydenhuollon tarjoajaasi, jos sinulla on kysyttävää testituloksista/diagnoosista tai tarvitset apua uuden pakkauksen hankinnassa. Lisää tuotetukea saadaksesi vieraile osoitteessa: www.molecular.abbott/int/en/simpli-collect-hpv

1 DA KLARGØRING / SV FÖRBEREDELSER / FI VALMISTELU

	DA	SV	FI
1A	Vask og tør hænderne.	Tvätta och torka händerna.	Pese ja kuivaa kätesi.
1B **DA** MOD URET FOR AT SKRUE HÆTTEN AF **SV** VRID MOTURS FÖR ATT TA AV LOCKET **FI** VASTAPÄIVÄÄN KORKIN AVAAMISEKSI	Åbn sættet med røret. Fjern røret og pakken med podepinden. Anbring pakken med sættet på en flad overflade. Hold røret oprejst, og skru hætten af. Læg det åbne rør og hætten tilbage i sættets indpakning.	Öppna förpackningen som innehåller provröret. Plocka ur provröret och förpackningen med provtagningspinnen. Placera förpackningen på en plan yta. Håll provröret upprätt och ta bort locket. Placera det öppnade provröret och locket i förpackningen igen.	Avaa pakkaus, jossa putki on. Poista putki ja tikun pakkaus. Aseta näytepakkaus tasaiselle alustalle. Pidä putkea pystyasennossa ja poista korkki. Laita avoin putki ja korkki näytepakkaukseen.

2 DA PRØVETAGNING / SV SAMLA IN PROVET / FI NÄYTTEEN KERÄÄMINEN

	DA	SV	FI
2A **DA** HOLD I DET ORANGE SKAFT **SV** HÅLL I DET ORANGEFÄRGADE HANDTAGET **FI** PIDÄ KIINNI ORANSSISTA VARRESTA	Åbn pakken med podepinden, og tag fat i det orange skaft. i Rør ikke ved den hvide spids. Ved brug af podepinden skal du prøve at undgå, at podepindens hvide spids rører ved andet end indersiden af din vagina.	Öppna förpackningen med provtagningspinnen och håll i det orangefärgade handtaget. i Vidrör inte den vita spetsen. Försök att inte låta den vita spetsen vidröra något annat än insidan av vaginan när du använder provtagningspinnen.	Avaa näytteenottopaketti ja pidä kiinni näytteenottotikun oranssista varresta. i Älä koske valkoiseen kärkeen. Kun käytät näytteenottotikkua, yritä olla koskettamatta näytteenottotikun valkoista kärkeä minnekään muualle kuin emättimen sisäosaan.
2B 5 cm 30 SEC[2]	Find en behagelig stilling, så der er nem adgang til din vaginalåbning. Hold podepinden med én hånd. Spred dine kønslæber (labia) med den anden hånd, så der er adgang til din vaginalåbning. Stik forsigtigt podepindens hvide spids cirka 5 cm ind i din vagina. Drej forsigtigt podepinden i **15-30 sekunder** (sørg for, at indersiden af din vagina berøres af podepinden). Fjern forsigtigt podepinden. **Læg ikke podepinden fra dig!** [2] Sekunder	Hitta en bekväm position så att du enkelt kommer åt vaginalöppningen. Håll provtagningspinnen med ena handen. Med den andra handen särar du på hudvecken (blygdläpparna) för att komma åt vaginalöppningen. För försiktigt in den vita spetsen på provtagningspinnen cirka 5 cm i vaginan. Rotera försiktigt provtagningspinnen i **15-30 sekunder** (se till att provtagningspinnen vidrör vaginans väggar). Ta försiktigt ut provtagningspinnen. **Lägg inte ned provtagningspinnen!** [2] sekunder	Hakeudu mukavaan asentoon päästäksesi helposti käsiksi emättimen aukkoosi. Pidä näytteenottotikkua toisessa kädessä. Siirrä toisella kädellä ihopoimut (labia) pois tieltä päästäksesi käsiksi emättimen aukkoon. Työnnä varovasti näytetikun valkoinen kärki noin 5 cm emättimeen. Pyöritä näytteenottotikkua varovasti **15-30 sekuntia** (varmista, että näytteenottotikku koskettaa emättimen seinämiä). Poista näytteenottotikku varovasti. **Älä laske näytepuikkoa alas!** [2] Sekuntia

3 DA OVERFØRSEL AF SKRAB / SV ÖVERFÖRA PROVET TILL PROVRÖRET / FI SIIRRÄ TIKKU

	DA	SV	FI
3A **DA** KNÆK **SV** BRYT **FI** NAPSAUTA	Hold røret oprejst. Stik podepinden ned i røret med den hvide spids nedad. Knæk det orange skaft ved at trykke det ind imod røret ved knæklinjen. Du skal muligvis løfte podepinden lidt for at finde knæklinjen.	Håll provröret upprätt. Rikta den vita spetsen nedåt och placera provtagningspinnen i provröret. Bryt av det orangefärgade handtaget på provtagningspinnen genom att böja handtaget mot provröret vid brytskåran. Du kan behöva lyfta upp provtagningspinnen lite för att hitta brytskåran.	Pidä putkea pystyssä. Aseta tikku putkeen siten, että valkoinen kärki osoittaa alaspäin. Napsauta oranssi näytteenottotikku kahtia taivuttamalla vartta putkea vasten murtoviivan kohdalta. Sinun on ehkä nostettava näytteenottotikkua hieman löytääksesi katkoviivan.
3B	Kassér den øverste del af podepindens skaft! **Den nederste del af podepinden forbliver i røret.**	Släng den övre delen av provtagningspinnens handtag! **Den nedre delen av provtagningspinnen ska vara kvar i provröret.**	Heitä tämä näytteenottotikun varren yläosa pois! **Näytteenottotikun alaosa pysyy putkessa.**
3C **DA** MED URET FOR AT SKRUE HÆTTEN PÅ **SV** VRID MEDURS FÖR ATT ÅTERFÖRSLUTA **FI** ORKIN KIERRETÄÄN MYÖTÄPÄIVÄÄN	Hold røret oprejst, og sæt hætten på igen ved at dreje den med uret. Når der mærkes modstand, skal der drejes endnu en kvart omgang, indtil hætten ikke kan bevæges.	Håll provröret upprätt och sätt tillbaka locket genom att skruva på det medurs. När du känner att det tar emot fortsätter du att skruva ytterligare ungefär ett kvarts varv tills locket inte rör sig längre.	Pidä putkea pystyasennossa ja sulje putki uudelleen kiertämällä korkkia myötäpäivään. Kun tunnet vastustusta, jatka kiertämistä noin neljänneskierros, kunnes korkki ei enää liiku.
3D	Vask og tør hænderne.	Tvätta och torka händerna.	Pese ja kuivaa kätesi.
✓	**Send prøven til laboratoriet inden for 24 timer i henhold til separat vejledning.**	**Skicka provet inom 24 timmar genom att följa de anvisningar som erhållits separat.**	**Palauta näyte 24 tunnin sisään erikseen tarjottujen ohjeiden mukaisesti.**

NO FØR DU STARTER / NL VOORDAT U BEGINT / CS PŘED ZAHÁJENÍM

24 HOURS[1]

NO	NL	CS
Du mottar en pakke som inneholder følgende: • 1 rør (prøverør) • 1 prøvetakingspinne **Hvis du ikke følger instruksjonene, kan resultatet bli feil.** • Oppbevar pakken ved romtemperatur (mellom 15 °C og 30 °C) før og etter bruk. • Send prøven din innen 24 timer. • **Må ikke** brukes hvis du er gravid. • **Ikke** rengjør området rundt kjønnsorganet like før prøvetaking. • **Ikke** bruk pakken etter **UTLØPSDATOEN** som er trykt på pakningsemballasjen. [1] timer	U ontvangt een kit met het volgende: • 1 buisje (monsterbuisje) • 1 wattenstaafje **Als u de instructies niet opvolgt, kan het resultaat onjuist zijn.** • Bewaar de kit voor en na gebruik bij kamertemperatuur (tussen 15 °C en 30 °C). • Stuur uw monster binnen 24 uur terug. • Gebruik de kit **niet** als u zwanger bent. • U mag het genitale gebied **niet** reinigen vlak voordat u het monster afneemt. • Gebruik de kit **niet** na de **VERVALDATUM** die op de verpakking van de kit staat vermeld. [1] uur	Dodaná souprava obsahuje následující: • 1 zkumavka (vzorková zkumavka) • 1 tampon **Pokud nedodržíte pokyny, váš výsledek může být nesprávný.** • Před a po použití soupravu uchovávejte při pokojové teplotě (mezi 15 °C až 30 °C). • Vzorek odešlete zpět do 24 hodin. • **Nepoužívejte**, pokud jste těhotná. • **Nečistěte** oblast genitálií bezprostředně před odběrem vzorku. • **Nepoužívejte** soupravu po **DATU EXPIRACE** vytištěném na balení soupravy. [1] Hodin
i IKKE berør den hvite tuppen på prøvetakingspinnen eller legg fra deg prøvetakingspinnen. Hvis du berører den hvite tuppen, legger fra deg prøvetakingspinnen eller mister den, kan resultatene dine bli unøyaktige. Du må be om å få en ny simpli-COLLECT HPV Collection Kit.	i Raak de witte punt van het wattenstaafje NIET aan en leg het wattenstaafje NIET neer. Als u de witte punt aanraakt of het wattenstaafje neerlegt of laat vallen, zijn uw resultaten mogelijk niet nauwkeurig. U moet dan een nieuwe simpli-COLLECT HPV-afnamekit aanvragen.	i NEDOTÝKEJTE se bílé špičky tamponu a nepokládejte tampon. Pokud se bílá špička něčeho dotkne nebo tampon položíte či upustíte, mohou být získané výsledky nepřesné. V takovém případě si vyžádejte novou soupravu simpli-COLLECT HPV Collection Kit.
Kontakt legen din hvis du har spørsmål vedrørende testresultater/diagnose eller trenger hjelp til å få en ny pakke. Hvis du ønsker mer produkthjelp, gå til: www.molecular.abbott/int/en/simpli-collect-hpv	Neem contact op met uw zorgverlener als u vragen hebt over de testresultaten/diagnose of hulp bij het verkrijgen van een nieuwe kit. Ga voor aanvullende productondersteuning naar: www.molecular.abbott/int/en/simpli-collect-hpv	Pokud máte dotazy týkající se výsledků testů / diagnózy nebo potřebujete pomoci se získáním nové soupravy, kontaktujte svého poskytovatele zdravotní péče. Další informace o produktu naleznete na: www.molecular.abbott/int/en/simpli-collect-hpv

1 NO KLARGJØRING / NL VOORBEREIDEN / CS PŘÍPRAVA

	NO	NL	CS
1A	Vask og tørk hendene.	Was en droog uw handen.	Umyjte a osušte si ruce.
1B **NO** MOT KLOKKEN FOR Å TA KORKEN AV **NL** DRAAI LINKSOM OM DE DOP TE VERWIJDEREN **CS** PRO UVOLNĚNÍ OTOČTE PROTI SMĚRU HODINOVÝCH RUČIČEK	Åpne pakken som inneholder røret. Ta ut røret og pakningen med prøvetakingspinnen. Sett pakningsemballasjen på et jevnt underlag. Hold røret loddrett og fjern korken. Sett det åpne røret og korken tilbake i pakningsemballasjen.	Open de kit met het buisje. Verwijder het buisje en de verpakking met het wattenstaafje. Plaats de verpakking van de kit op een vlakke ondergrond. Houd het buisje rechtop en verwijder de dop. Plaats het open buisje en de dop terug in de kitverpakking.	Otevřete soupravu obsahující zkumavku. Vyjměte zkumavku a balení tamponu. Položte balení soupravy na rovný povrch. Držte zkumavku ve svislé poloze a sejměte víčko. Vložte otevřenou zkumavku a víčko zpět do balení soupravy.

2 NO PRØVETAKING / NL MONSTERAFNAME / CS ODBĚR VAŠEHO VZORKU

	NO	NL	CS
2A **NO** HOLD I DET ORANSJE HÅNDTAKET **NL** HOUD VAST AAN HET ORANJE STOKJE **CS** DRŽTE ZA ORANŽOVOU TYČINKU	Åpne pakken med prøvetakingspinnen, og hold i det oransje håndtaket på prøvetakingspinnen. i Ikke berør den hvite tuppen. Når du bruker prøvetakingspinnen, må du forsøke å unngå at den hvite tuppen kommer i kontakt med andre ting enn innsiden av skjeden.	Trek de verpakking van het wattenstaafje open en houd dit vast aan het oranje wattenstaafstokje. i Raak de witte punt niet aan. Probeer tijdens gebruik van het wattenstaafje de witte punt van het wattenstaafje niet aan te raken, behalve de binnenkant van uw vagina.	Odlepte fólii balení tamponu a uchopte oranžovou tyčinku tamponu. i Nedotýkejte se bílé špičky. Při používání tamponu se snažte nedotýkat se bílou špičkou tamponu čehokoli kromě vnitřku pochvy.
2B 5 cm 30 SEC[2]	Finn en behagelig stilling hvor du lett får tilgang til skjedeåpningen. Hold prøvetakingspinnen i den ene hånden. Bruk den andre hånden til å skyve hudfoldene (kjønnsleppene) til side, slik at du får tilgang til skjedeåpningen. Før forsiktig den hvite tuppen på prøvetakingspinnen omtrent 5 cm inn i skjeden. Drei prøvetakingspinnen forsiktig rundt i **15–30 sekunder** (pass på at prøvetakingspinnen er i kontakt med skjedeveggen). Trekk prøvetakingspinnen forsiktig ut. **Ikke legg fra deg prøvetakingspinnen!** [2] sekunder	Ga in een comfortabele houding staan om goed bij de opening van de vagina te kunnen komen. Houd het wattenstaafje met één hand vast. Doe met de andere hand de huidplooien (schaamlippen) opzij om toegang te krijgen tot de opening van de vagina. Steek de witte punt van het wattenstaafje voorzichtig ongeveer 5 cm in de vagina. Draai het wattenstaafje gedurende **15-30 seconden** voorzichtig rond (zorg dat het wattenstaafje de wanden van uw vagina raakt). Verwijder het wattenstaafje voorzichtig. **Leg het wattenstaafje niet neer!** [2] seconden	Najděte si pohodlnou polohu pro snadný přístup k otvoru vaší pochvy. Jednou rukou držte tampon. Druhou rukou odsuňte záhyby kůže (stydké pysky), abyste získala přístup k otvoru vaší pochvy. Jemně zasuňte bílou špičku tamponu asi 5 cm do pochvy. Jemně tamponem otáčejte po dobu **15-30 sekund** (ujistěte se, že se tampon dotýká stěn vaší pochvy). Opatrně tampon vyjměte. **Tampon nepokládejte!** [2] Sekund

3 NO OVERFØRE PRØVETAKINGSPINNEN / NL BRENG HET WATTENSTAAFJE OVER / CS PŘENOS TAMPONU

	NO	NL	CS
3A **NO** KNEKK **NL** AFBREKEN **CS** ZLOM	Hold røret loddrett. La den hvite tuppen peke ned, og plasser prøvetakingspinnen i røret. Knekk det oransje håndtaket på prøvetakingspinnen ved å bøye håndtaket mot røret ved bruddlinjen. Det kan hende du må løfte litt på prøvetakingspinnen for å finne bruddlinjen.	Houd het buisje rechtop. Plaats het wattenstaafje met de witte punt naar beneden in het buisje. Breek het oranje wattenstaafstokje door het stokje bij de breukstreep tegen het buisje te buigen. Mogelijk moet u het wattenstaafje iets omhoog brengen om de breukstreep te vinden.	Zkumavku držte svisle. Vložte tampon do zkumavky bílou špičkou dolů. Odlomte oranžovou tyčinku tamponu ohnutím proti zkumavce v místě zlomu. Možná budete muset tampon mírně zvednout, abyste našla místo zlomu.
3B	Kast den øvre delen av prøvetakingshåndtaket! **Den nedre delen av prøvetakingspinnen blir værende igjen i røret.**	Gooi dit bovenste deel van het wattenstaafstokje weg! **Het onderste deel van het wattenstaafje blijft achter in het buisje.**	Tuto horní část tyčinky tamponu vyhoďte! **Spodní část tamponu zůstane ve zkumavce.**
3C **NO** MED KLOKKEN FOR Å SETTE KORKEN PÅ IGJEN **NL** DRAAI RECHTSOM OM DE DOP TERUG TE PLAATSEN **CS** PRO UZAVŘENÍ VÍČKA OTOČTE VE SMĚRU HODINOVÝCH RUČIČEK	Hold røret loddrett, og sett korken på røret igjen ved å skru korken med klokken. Når du merker motstand, skal du fortsette å dreie en kvart omgang til, inntil korken ikke kan beveges mer.	Houd het buisje rechtop en sluit het buisje weer af door de dop rechtsom te draaien. Als u weerstand voelt, draai dan nog een kwartslag tot de dop niet meer beweegt.	Držte zkumavku ve svislé poloze a uzavřete ji zašroubováním víčka ve směru hodinových ručiček. Když ucítíte odpor, otáčejte o další čtvrt otáčky, dokud se víčko nepřestane pohybovat.
3D	Vask og tørk hendene.	Was en droog uw handen.	Umyjte a osušte si ruce.
✓	**Send prøven din innen 24 timer, og følg instruksjonene som gis separat.**	**Stuur uw monster binnen 24 uur terug volgens de apart meegeleverde instructies.**	**Odešlete vzorek zpět do 24 hodin podle samostatně uvedených pokynů.**