WHO Prequalification of In Vitro Diagnostics
PUBLIC REPORT

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

Alinity m HR HPV with product codes 09N15-090 and 09N15-080, 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 prequalification assessment for the Alinity m HR HPV

	Date	Outcome
Prequalification listing	27 March 2025	listed
Abridged Dossier assessment	26 March 2025	MR
Site inspection of the quality management system	21 September 2021	MR
Product performance evaluation	06 December 2024	MR

MR: Meets Requirements

Intended use

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 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."

Assay description
According to the claim of the assay description from Abbott Molecular Inc., *"The Alinity m HR HPV assay requires 2 separate assay specific kits:*

- *Alinity m HR HPV AMP Kit (09N15-090) 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 specimens collected with the Alinity m Cervi-Collect Specimen Collection Kit or specimens collected in ThinPrep PreservCyt Solution or SurePath Preservative Fluid. 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.
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."

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

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 must be stored at 2 °C to 8 °C.
The Alinity m HR HPV CTRL Kit must be stored at -25 to -15 °C.

Shelf-life upon manufacture:
24 months.

Warnings/limitations:
Refer to the current version of the manufacturer's instructions for use attached to this public report.

Prioritisation for prequalification
Based on the established criteria, the Alinity m HR HPV was given priority for WHO prequalification assessment.

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.

Manufacturing site inspection

At the time of considering the product application for Prequalification, the Manufacturer of the product had a well-established quality management system and manufacturing practices in place that would support the manufacture of a product of consistent quality. Routine inspections of the Manufacturing site will be conducted with copies of the WHO Public Inspection Report (WHOPIR) published on the WHO Prequalification web page as per Resolution WHA57.14 of the World Health Assembly. Note that a WHOPIR reflects the information on the most current assessment performed at a manufacturing site for in vitro diagnostic products and summarises the assessment findings.

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

All published WHOPIRs are with the agreement of the manufacturer.

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

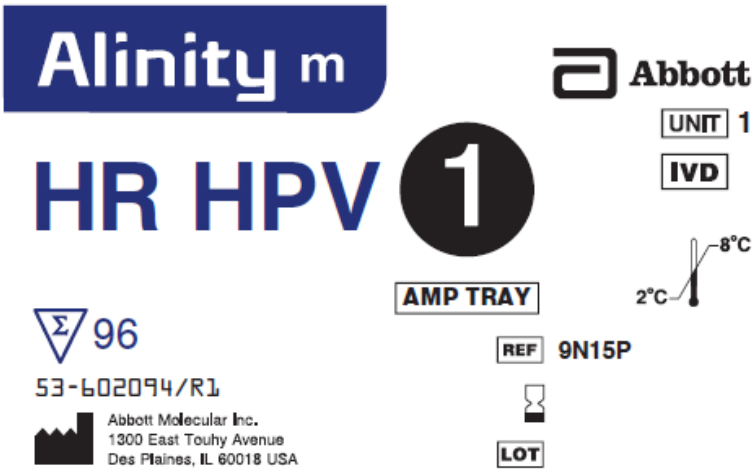
1. **Labels**
2. **Instructions for use**

1. Labels

Alinity m HR HPV AMP Kit Labels

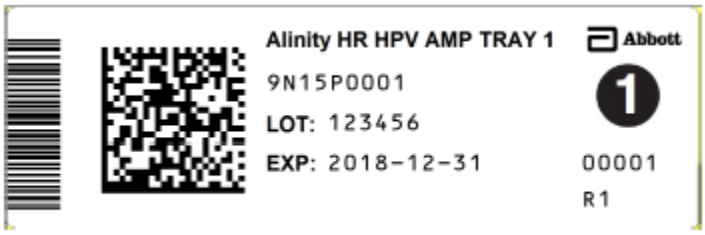
1.1 Alinity m HR HPV AMP Kit (List No. 09N15-090 [Label No. 53-602095])

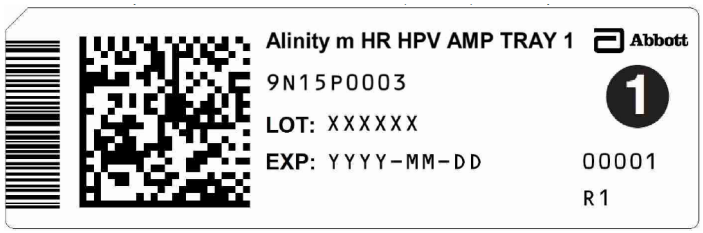
1.2 Alinity m HR HPV AMP Pouch (Label No. 53-602094)



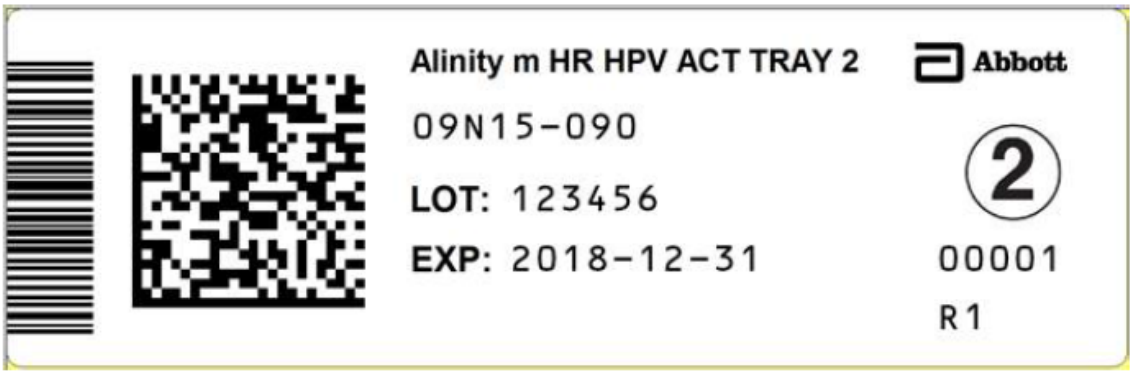
1.3 Alinity m HR HPV ACT Pouch (Label No. 53-602093)

1.4 Alinity m HR HPV AMP TRAY 1





1.5 Alinity m HR HPV ACT TRAY 2

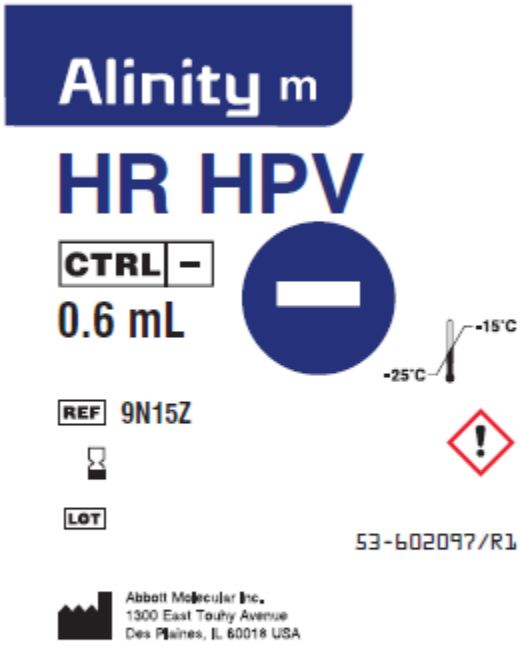


1.6 Example Kit Label Containing Lot, Expiration, and UDI Information

1.7 Alinity m HR HPV CTRL Kit

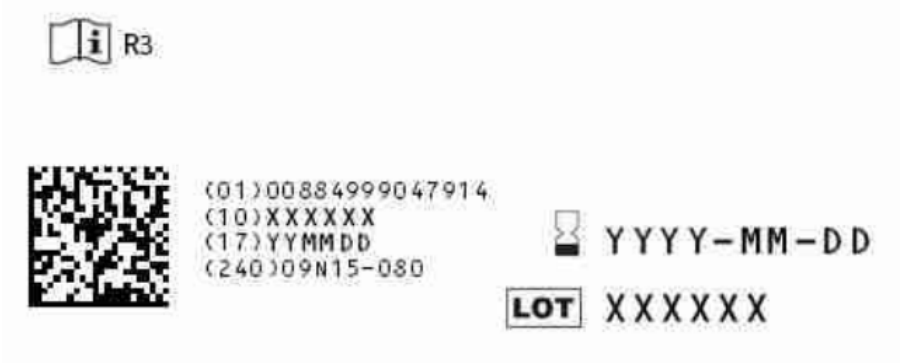
Alinity m HR HPV CTRL Kit (List No. 09N15-080 [Label No. 53-602096])

1.8 Alinity m HR HPV Negative CTRL (Label No.53-602097)



1.9 Alinity m HR HPV Positive CTRL (Label No.53-602098)

1.10 Example Kit Label Containing Lot, Expiration, and UDI Information



2. Instructions for use[1]

[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

Revised May 2024

REF 09N15-090
53-608076/R7

Note: Changes Highlighted

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 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.

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 in cervical cells 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 that amplifies and detects HR HPV DNA in cervical cells collected in liquid media. The detection of 14 HR HPV genotypes (HPV 16, 18, 31, 33, 35, 39, 45, 51, 52, 56, 58, 59, 66, and 68) is achieved through a primer mix targeting a conserved region of the HPV genomes and single stranded DNA probes. The assay can differentiate between HPV 16, HPV 18, HPV 45 and non-HPV 16/18/45 genotypes [(31/ 33/ 52/ 58) and (35/ 39/51/ 56/ 59/ 66/ 68)].

BIOLOGICAL PRINCIPLES OF THE PROCEDURE

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

- Alinity m HR HPV AMP Kit (09N15-090) 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 specimens collected with the Alinity m Cervi-Collect Specimen Collection Kit or specimens collected in ThinPrep® PreservCyt® Solution or SurePath™ Preservative Fluid. 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.

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. 09N15-090

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.[31] 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.[32]

Decontaminate and dispose of all potentially infectious materials in accordance with local, state and federal regulations.[29]

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).

Specimen Types

Specimens collected in ThinPrep PreservCyt Solution or SurePath Preservative Fluid, or collected with the Alinity m Cervi-Collect Specimen Collection Kit (List No. 09N29-001) 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

[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
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

[a] Avoid more than 4 freeze-thaw cycles for Alinity m Cervi-Collect Specimens.

Specimen Shipping

Ship specimens according to the recommended storage temperature and time listed in the Specimen Storage section. 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

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).

PROCEDURE

Materials Provided

09N15-090 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
- 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 vial. 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.

From the Create Order screen, select the assay (HR HPV) 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.

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	09N49-011	ThinPrep: 0.55 mL SurePath: 0.50 mL	Capped or Uncapped
Alinity m Pierceable Cap	09N49-012		
Alinity m Labeled Tube with Pierceable Cap	09N65-050	ThinPrep: 0.55 mL SurePath: 0.50 mL	Capped or Uncapped

[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.

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.
- Cervical specimens collected with the Alinity m Cervi-Collect Specimen Collection Kit and collected in ThinPrep PreservCyt Solution or SurePath Preservative Fluid 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 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.

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*	**Yeast**
HPV 55B	*Lactobacillus acidophilus*	Candida albicans
HPV 57	*Mycoplasma genitalium*	**Other**
HPV 61	*Mycoplasma hominis*	Human Cellular DNA
HPV 67	*Neisseria gonorrhoeae*	
HPV 69	*Neisseria meningitidis Serogroup A*	
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 x10^6 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 was determined by analyzing 265 replicates of HPV negative samples processed from alternating positions with high concentration HPV positive samples at 10,000,000 copies/mL, from more than 10 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%).

Agreement Between Specimen Types

Specimens collected in ThinPrep PreservCyt Solution and with the Alinity Cervi-Collect Specimen Collection Kit and 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

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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
PRODUCT OF USA	Product of USA
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.

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

53-608076/R7
May 2024

Abbott

Alinity m

en

REF 09N15-080
53-608077/R4

HR HPV CTRL Kit

Revised May 2024

REF 09N15-080
53-608077/R4

NOTE: Changes Highlighted

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 CTRL Kit

INTENDED USE

The Alinity m HR HPV controls are for validity determination of the qualitative Alinity m HR HPV assay on the automated Alinity m System. These controls are intended to be used with the Alinity m HR HPV assay; refer to the assay package insert for additional information.

INTENDED USER

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

REAGENTS

Kit Contents

Alinity m HR HPV Negative CTRL (List No. 9N15Z) contains beta globin plasmid DNA in a buffer solution with carrier DNA. Preservatives: Sodium azide and 0.087% ProClin® 950.

Alinity m HR HPV Positive CTRL (List No. 9N15W) contains less than 0.01% noninfectious HPV16, HPV18, HPV39, HPV45, HPV58, and beta globin plasmid DNA in a buffer solution with carrier DNA. Preservatives: Sodium azide and 0.087% ProClin 950.

Control	Quantity
Alinity m HR HPV Negative CTRL	12 tubes x 0.6 mL
Alinity m HR HPV Positive CTRL	12 tubes x 0.6 mL

WARNINGS AND PRECAUTIONS

IVD

- **For In Vitro Diagnostic Use**
- The Alinity m HR HPV Negative and Positive Controls are intended to monitor for substantial reagent failure. The Positive Control should not be used as an indicator for cut-off precision and only ensures reagent functionality. Quality control requirements must be performed in conformance with local, state and/or federal regulations or accreditation requirements and your laboratory's standard Quality Control procedures.

Safety Precautions

The following warnings and precautions apply to:
Alinity m HR HPV Negative CTRL and Positive CTRL.

WARNING	Contains 2-Methyl-4-isothiazolin-3-one and Sodium azide.
H317	May cause an allergic skin reaction.
EUH032	Contact with acids liberates very toxic gas.
Prevention	
P261	Avoid breathing mist / vapours / spray.
P272	Contaminated work clothing should not be allowed out of the workplace.
P280	Wear protective gloves / protective clothing / eye protection.
Response	
P302+P352	IF ON SKIN: Wash with plenty of water.
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.

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, Sections 7 and 8.

Reagent Shipment

	Shipment Condition
Alinity m HR HPV CTRL Kit	On dry ice

Reagent Storage

	Storage Temperature	Maximum Storage Time
Unopened	-25°C to -15°C	Until expiration date
Onboard	System Temperature	Discard after 4 hours

Reagent Handling

- Alinity m HR HPV control reagents are contained in single-use tubes with pierceable caps. Avoid any contamination or damage to the caps after removal from the tube's original packaging.
- The Alinity m System will track onboard storage of the Alinity m assay controls. Onboard storage time begins when the control tubes are loaded on the Alinity m System. The Alinity m System will not allow the use of Alinity m assay controls that have exceeded the maximum onboard storage time.
- For a detailed discussion of handling controls during system operations, refer to the Alinity m System Operations Manual, Section 5.

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Indications of Reagent Deterioration

- Deterioration of the reagents may be indicated when a control error occurs or a value is out of the specified range.
- Reagents are shipped on dry ice and are stored at -25°C to -15°C upon arrival. If you receive reagents that are in a condition contrary to this recommendation, or that are damaged, immediately contact your Abbott Representative.
- For troubleshooting information, refer to the Alinity m System Operations Manual, Section 10.

PROCEDURE

Materials Provided

09N15-080 Alinity m HR HPV CTRL Kit

Instructions for Use

Lot-specific values for assay controls are available via: Abbott Mail, the Abbott customer portal www.molecular.abbott/portal, and from your Abbott Representative.

When a control test order is created:

- Lot-specific values can be automatically imported to the Alinity m System via Abbott Mail upon scanning the control tube barcodes (HR HPV NEG CTRL and HR HPV POS CTRL).
- Lot-specific values can also be obtained from the Abbott customer portal or provided by your Abbott Representative and imported to the Alinity m System via a USB drive.

For instructions on creating a test order and loading controls on the instrument, refer to the Alinity m System Operations Manual, Section 5.

The Alinity m HR HPV Negative CTRL and Alinity m HR HPV Positive CTRL tubes are intended for single-use only.

- Thaw assay controls at 15°C to 30°C or at 2°C to 8°C.
- Once thawed, assay controls can be stored at 2°C to 8°C for up to 24 hours before use.
- This product may be used immediately after removal from 2°C to 8°C storage.
- Prior to loading onto the Alinity m System, vortex each assay control 3 times for 2 to 3 seconds. Ensure that the contents of each tube are at the bottom after vortexing by tapping the tubes on the bench to bring liquid to the bottom of the tube.
- Load the control tubes onto the Alinity m Universal Sample Rack (sample rack); the tubes should remain capped.

QUALITY CONTROL PROCEDURES

Refer to the **QUALITY CONTROL PROCEDURES** section of the Alinity m HR HPV AMP Kit package insert.

KEY TO SYMBOLS

REF	Reference Number
IVD	In Vitro Diagnostic Medical Device
LOT	Lot Number
In Vitro Test	In Vitro Test
PRODUCT OF USA	Product of USA
CTRL −	Control Negative
CTRL +	Control Positive
	Exclamation Mark
	Consult Instructions for Use
	Temperature Limit
	Use By Date
EC REP	Authorized Representative in the European Community
	Manufacturer

TECHNICAL ASSISTANCE

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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

53-608077/R4

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