WHO Prequalification of In Vitro Diagnostics
PUBLIC REPORT

Product: Asanté HIV-1/2 Oral Fluid Test
WHO reference number: PQDx 0661-265-00

Asanté HIV-1/2 Oral Fluid Test with product code 1502-100, manufactured by Sedia Biosciences Corporation, was accepted for the WHO list of prequalified in vitro diagnostics and was listed on 29 April 2025.

Summary of WHO Prequalification Assessment for the Asante HIV-1/2 Oral Fluid Test

	Date	Outcome
Prequalification listing	**29 April 2025**	listed
Dossier assessment	**19 September 2024**	MR
Site inspection(s) of quality management system	**04 March 2024**	MR
Product performance evaluation	**3rd and 4th Quarter of 2024**	MR

MR: Meets Requirements

Intended use

According to the intended use claim from Sedia Biosciences Corporation, "*The Asanté HIV-1/2 Oral Fluid Test is a single use, qualitative, manually performed immunoassay device for the detection of antibodies to Human Immunodeficiency Virus Type 1 (HIV-1) and Type 2 (HIV-2) in oral fluid specimens. The Asanté HIV-1/2 Oral Fluid Test is intended for rapid testing by medical professionals at the point-of-care as an aid in the diagnosis of HIV-1 and HIV-2 infections. No specific training is needed other than following the Instructions for Use. The Asanté HIV-1/2 Oral Fluid Test is intended for in vitro diagnostic use with patients 18 years or older at risk for HIV infection. The test is not intended for use in screening blood, plasma, cell, or tissue donors.*"

Assay description

According to the claim of assay description from Sedia Biosciences Corporation, "*The Asanté HIV-1/2 Oral Fluid Test is a manual point-of-care, visually read immunoassay for the qualitative detection of antibodies to HIV-1 and HIV-2 in human oral fluid (i.e., oral mucosal transudate). Results can be obtained in as little as 20 minutes. The Asanté test is comprised of an Oral Swab, a tube containing a pre-measured volume of Sample Buffer and a pouched Test Strip. The Test Strip itself is composed of several materials which in combination can detect HIV antibodies when those antibodies are added to the tube of Sample Buffer.*

After the oral fluid specimen has been collected and mixed with the Sample Buffer according to the instructions, the Test Strip is placed into the specimen/Sample Buffer mixture and the liquid is absorbed into the absorbent pad at the end of the Test Strip. The mixture migrates up the Test Strip by wicking action until it encounters a dehydrated reagent composed of Protein A conjugated to a colloidal gold reagent ("conjugate"), which is rehydrated by the liquid. The conjugate confers a red-purple coloration to the reagent which is important for visualizing and interpreting Test Strip results. The Protein A component of the conjugate will bind to HIV-specific (if any) and other endogenous IgG and IgM antibodies that are present in the liquid containing the specimen.
The buffer mixture continues to wick up the strip onto a nitrocellulose membrane, which contains two invisible reagent lines (a Test and Control Line) where the test results are read. Once the buffer mixture starts to appear on the membrane, the user will see a red-purple cloud migrate up the strip with the liquid containing Protein A conjugate bound to antibodies in the sample. The buffer mixture will continue to be drawn up to the top of the strip until the red-purple cloud on the membrane has cleared 20 minutes after the start of the test.
As the liquid containing antibodies bound to the conjugate crosses the membrane, it first encounters the Test Line, which consists of recombinant HIV proteins bound to the membrane that will bind with any HIV IgG and IgM antibodies present in the specimen. Since these HIV antibodies are also bound to the conjugate, the red-purple colored reagent will accumulate on the Test Line by means of the capture of the HIV antibodies by HIV viral proteins. A red-purple line will form, indicative of the presence of HIV antibodies.

The liquid specimen mixture will continue to wick up the strip, next encountering the Control Line. The Control Line consists of goat antibody fragments reactive to human antibodies ("goat anti-human Ab"), which will bind human antibodies present in the liquid regardless of whether those antibodies are specific to HIV. If specimen has been collected and the test is run correctly, antibodies present in the liquid will have bound to the conjugate and remain captured on the Control Line, yielding a visible redpurple Control Line. The color intensity of the Control Line and/or the Test Line does not necessarily correlate to the amount of antibody captured or to the severity of HIV infection if present.

The results of the test are to be interpreted no sooner than 20 minutes, but no later than 45 minutes after adding the Test Strip to the Sample Buffer containing the specimen. At this time, the antibodies in the specimen will have had adequate time to migrate up the entire strip. The Test Line, if visible (when a valid Control Line is also present), indicates that HIV antibodies are present and represents a presumed positive for HIV antibodies in the specimen. If the Test Line is not visible (when a valid Control Line is present), then HIV antibodies are not present, and the result is negative for the presence of HIV antibodies in the specimen."

Test kit contents

Component	PN 2502 (100 tests/kit)
Product insert (LN 6263)	1
Oral Swabs (PN 3094)	100
capped tubes containing Sample Buffer (PN 3099)	100
Test Strips sealed in foil pouches with desiccant (PN 3092)	100
Reusable foam tube holder (PN 7122)	1

Items required but not provided

- Timer or watch,
- Disposable gloves, for use by a professional performing the test,
- Indelible marker to label the Sample Buffer Tube with a patient identifier,
- Biohazard bag to safely dispose of potentially infectious materials.

Storage

The test kit must be stored at 2-30 °C.

Shelf-life upon manufacture

18 months.

Warnings/limitations

Please refer to the current version of the manufacturer's Instructions for Use (IFU) attached to this public report.

Prioritization for Prequalification Assessment

Based on the established criteria, the Asanté HIV-1/2 Oral Fluid Test was given priority for the WHO prequalification assessment.

Dossier assessment

Sedia Biosciences Corporation submitted a product dossier for the Asanté HIV-1/2 Oral Fluid Test 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 discrepancies found during dossier screening and assessment findings were accepted on 19 September 2024.

Based on the product dossier screening and assessment findings, the product dossier for Asanté HIV-1/2 Oral Fluid Test 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 Asanté HIV-1/2 Oral Fluid Test meets WHO prequalification requirements.

Product performance evaluation

Asanté HIV-1/2 Oral Fluid Test (Sedia Biosciences Corporation) was evaluated by the Central Public Health Laboratories (CPHL), Uganda on behalf of WHO in the 3rd and 4th quarters of 2024, according to protocol IVD/PR/4/P4, version 4.2.

Clinical performance evaluation

In this limited laboratory-based evaluation of clinical performance characteristics, a panel of 650 oral fluid specimens was used, including 200 from HIV-positive individuals not on ART, 50 from HIV-positive individuals on ART and 400 from HIV-negative individuals. Plasma specimens collected simultaneously were characterized using the following reference algorithm: AiD anti-HIV 1+2 ELISA (Beijing Wantai Biological Pharmacy Enterprise Co., Ltd) and Murex HIV Ag/Ab Combination (DiaSorin); followed by INNO-LIA HIV I/II Score (Fujirebio). In addition, false-negative results on the test under evaluation from HIV-positive individuals self-reporting not being on ART were further investigated for HIV-1 viral load using cobas HIV-1 quantitative nucleic acid test for use on cobas 5800/6800/8800 systems (Roche Molecular Systems Inc.).

The main analysis of sensitivity was done on HIV-positive individuals not on ART (based on self reporting). As specified in the protocol, sensitivity was recalculated after exclusion of HIV-positive specimens with viral load below 1000 copies/mL, as these were considered to suggest that the individuals may be on ART.

Specimens from HIV-positive individuals on ART were not included in the main analysis and are described separately.

Clinical performance characteristics in comparison with an agreed reference standard	
Sensitivity % (95% CI) on HIV-positive individuals not on ART (self-reporting) (N=200)	98.0% (95.0-99.5%)
Sensitivity % (95% CI) After exclusion of 3 HIV-positive individuals with VL ≤1000 cp/mL (N=197)	99.5% (97.2-100%)
Specificity % (95% CI) (N= 400)	100% (99.1-100%)
Invalid rate % (N= 650)	0%
Inter-reader variability % (N= 600)	0.2%
Sensitivity % (95% CI) on HIV-positive individuals on ART (N=50)	96.0% (86.3-99.5%)

Analytical performance evaluation

Commercial panels used in this analytical evaluation contain plasma specimens. These plasma specimens were diluted into assay buffer at dilutions 1:250 and 1:1000, based on expected antibody concentration in oral fluid compared to plasma.

Analytical performance characteristics	
Sensitivity during seroconversion on 5 seroconversion panels in comparison with a benchmark test (AiD anti-HIV 1+2 ELISA (Beijing Wantai Biological Pharmacy Enterprise Co., Ltd))	Of a total of 34 specimens, 7 were detected by the test under evaluation at dilution 1:250 and 6 were detected by the test under evaluation at dilution 1:1000; versus 10 specimens detected by the benchmark test on undiluted plasma.
Analytical sensitivity on a mixed titer panel (0800-0436, SeraCare)	At both dilution factors, all 20 specimens were correctly classified.
Analytical sensitivity on a low titer panel (0800-0457, SeraCare)	At dilution 1:250, 16 of 20 specimens were correctly classified. At dilution 1:1000, 15 of 20 specimens were correctly classified.
Analytical sensitivity on WHO reference preparation panel (NIBSC code 02/210)	At dilution 1:250, all subtypes except HIV-1 group O were detected. At dilution 1:1000, all subtypes except HIV-1 subtype B and HIV-1 group O were detected.
Analytical sensitivity on subtype specimen panel(s) (HIV-2: 0315-0028 (batch n° 10431586, 10566397, 10597285), 0315-0031; HIV-1 Subtype CRF01_AE: 0315-0064; HIV-1 Subtype CRF02_AG: 0315-0067 (SeraCare); HIV-1 group O clinical specimen (ITM)	At dilution 1:250, all HIV-1 and HIV-2 specimens were detected. At dilution 1:1000, 2 of 3 HIV-1 specimens were detected and 4 of 4 HIV-2 specimens were detected. The HIV-1 group O clinical specimen was detected at dilution 1:250, but not detected at dilution 1:1000.
Lot to lot variation on a dilution panel	Lot to lot variation was within +/- 1 two-fold dilutions for 10 dilution series.

Operational characteristics and ease of use

The assay was found easy to use by the operators performing the evaluation.

However, a high proportion of very weak lines was found (26.5% of the reactive lines) and operators reported anomalies on 96 tests (mostly incomplete clearing and red background).

Key operational characteristics	
Number of steps*	3 steps in total 0 steps with precision pipetting
Time to result	20 minutes
Endpoint stability (interval)	25 minutes (the test can be read between 20 and 45 minutes after addition of the strip to the tube containing the buffer and specimen)
Internal QC	Yes, specimen addition control

** Definition: each action required to obtain a result (excluding specimen collection, device preparation – opening the pouch), e.g. for RDTs: add specimen, add buffer (2 steps).*

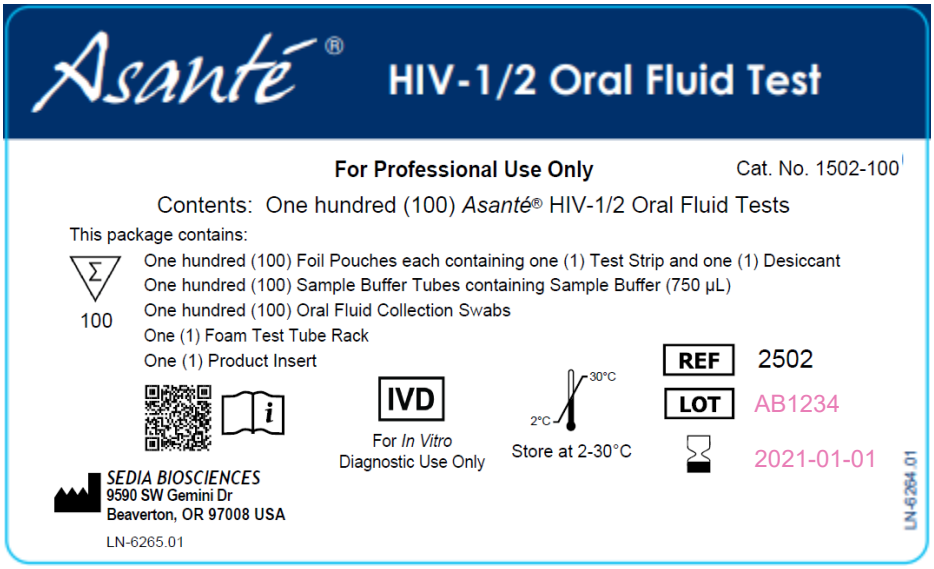
Based on these results, the performance evaluation for Asanté HIV-1/2 Oral Fluid Test meets the WHO prequalification requirements for HIV rapid diagnostic tests for professional use.

Labelling

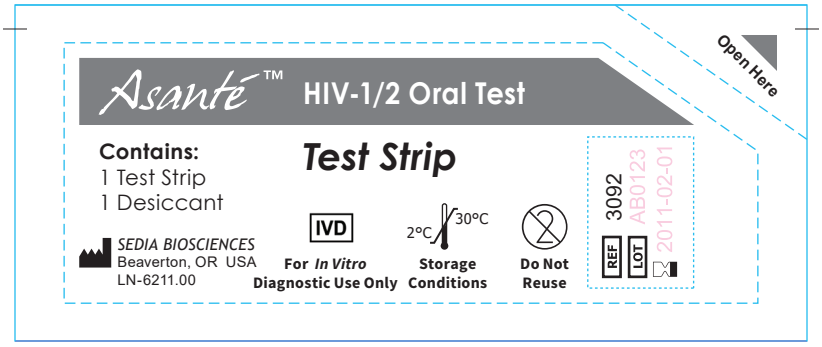
1. **Labels**
2. **Instructions for use**

1. Labels

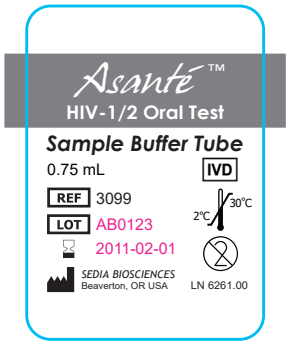
LN-6265, Primary Kit Label



LN-6211, Pouched Test Strip Labeling



LN-6261, Sample Buffer Tube Label



LN-6217, Paper Wrapped Oral Fluid Collection Swab Labeling

2. Instructions for use[1]

[1] English version of the IFU was the one that was assessed by WHO. It is the responsibility of the manufacturer to ensure correct translation into other languages.

Cat. No.
1502-100

REF 2502

Asanté®

HIV-1/2 Oral Fluid Test

For Professional Use Only

NAME AND INTENDED USE

The *Asanté*® HIV-1/2 Oral Fluid Test is a single use, qualitative, manually performed immunoassay device for the detection of antibodies to Human Immunodeficiency Virus Type 1 (HIV-1) and Type 2 (HIV-2) in oral fluid specimens. The *Asanté*® HIV-1/2 Oral Fluid Test is intended for rapid testing by medical professionals at the point-of-care as an aid in the diagnosis of HIV-1 and HIV-2 infections. No specific training is needed other than following the Instructions for Use. The *Asanté*® HIV-1/2 Oral Fluid Test is intended for *in vitro* diagnostic use with patients 18 years or older at risk for HIV infection. The test is not intended for use in screening blood, plasma, cell, or tissue donors.

SUMMARY AND EXPLANATION OF THE TEST

The Human Immunodeficiency Virus (HIV) causes Acquired Immune Deficiency Syndrome (AIDS).[1,2] HIV transmission occurs predominantly through exposure by sexual contact, exposure to blood, including shared usage of contaminated needles and syringes, and exposure to contaminated blood products. Transmission may also occur via mother-to-child transmission during the prenatal period and/or during birth. When individuals are infected with HIV, their body produces antibodies to HIV viral proteins. The presence of these antibodies in various body fluids, including blood and oral fluid, are indicative of exposure to the HIV virus and their detection can be used as an aid in the diagnosis of HIV infection when considered in the context of other clinical evaluation. There are, however, situations where HIV antibodies may be absent even though an infection is present. The development of antibodies to HIV (i.e., "seroconversion") in a person exposed to the virus may take several weeks to months during which time the person may be infected and capable of transmitting the virus. Conversely, the presence of HIV antibodies in neonates does not necessarily indicate HIV infection, but rather may reflect acquisition of maternal antibodies.

BIOLOGICAL PRINCIPLES OF THE TEST

The *Asanté*® HIV-1/2 Oral Fluid Test is a manual point-of-care, visually read immunoassay for the qualitative detection of antibodies to HIV-1 and HIV-2 in human oral fluid (i.e., oral mucosal transudate). Results can be obtained in as little as 20 minutes. The *Asanté*® test is comprised of an Oral Swab, a tube containing a pre-measured volume of Sample Buffer and a pouched Test Strip. The Test Strip itself is composed of several materials which in combination can detect HIV antibodies when those antibodies are added to the tube of Sample Buffer.

After the oral fluid specimen has been collected and mixed with the Sample Buffer according to the instructions, the Test Strip is placed into the specimen/Sample Buffer mixture and the liquid is absorbed into the absorbent pad at the end of the Test Strip. The mixture migrates up the Test Strip by wicking action until it encounters a dehydrated reagent composed of Protein A conjugated to a colloidal gold reagent ("conjugate"), which is rehydrated by the liquid. The conjugate confers a red-purple coloration to the reagent which is important for visualizing and interpreting Test Strip results. The Protein A component of the conjugate will bind to HIV-specific (if any) and other endogenous IgG and IgM antibodies that are present in the liquid containing the specimen.

The buffer mixture continues to wick up the strip onto a nitrocellulose membrane, which contains two invisible reagent lines (a Test and Control Line) where the test results are read. Once the buffer mixture starts to appear on the membrane, the user will see a red-purple cloud migrate up the strip with the liquid containing Protein A conjugate bound to antibodies in the sample. The buffer mixture will continue to be drawn up to the top of the strip until the red-purple cloud on the membrane has cleared 20 minutes after the start of the test.

As the liquid containing antibodies bound to the conjugate crosses the membrane, it first encounters the Test Line, which consists of recombinant HIV proteins bound to the membrane that will bind with any HIV IgG and IgM antibodies present in the specimen. Since these HIV antibodies are also bound to the conjugate, the red-purple colored reagent will accumulate on the Test Line by means of the capture of the HIV antibodies by HIV viral proteins. A red-purple line will form, indicative of the presence of HIV antibodies.

The liquid specimen mixture will continue to wick up the strip, next encountering the Control Line. The Control Line consists of goat antibody fragments reactive to human antibodies ("goat anti-human Ab"), which will bind human antibodies present in the liquid regardless of whether those antibodies are specific to HIV. If specimen has been collected and the test is run correctly, antibodies present in the liquid will have bound to the conjugate and remain captured on the Control Line, yielding a visible red-purple Control Line. The color intensity of the Control Line and/or the Test Line does not necessarily correlate to the amount of antibody captured or to the severity of HIV infection if present.

The results of the test are to be interpreted no sooner than 20 minutes, but no later than 45 minutes after adding the Test Strip to the Sample Buffer containing the specimen. At this time, the antibodies in the specimen will have had adequate time to migrate up the entire strip. The Test Line, if visible (when a valid Control Line is also present), indicates that HIV antibodies are present and represents a presumed positive for HIV antibodies in the specimen. If the Test Line is not visible (when a valid Control Line is present), then HIV antibodies are not present, and the result is negative for the presence of HIV antibodies in the specimen. (Refer to the Interpretation of Results on visual Step-by-Step Instructions for Use page).

WARNINGS

For *in vitro* diagnostic use

1. Read this product insert completely before performing the *Asanté*® HIV-1/2 Oral Fluid Test. It is important to follow the instructions carefully to avoid obtaining inaccurate results.
2. Tests are to be performed on individuals 18 years and older.
3. Do not perform the test on a subject who is taking antiretroviral therapy (ART) or pre-exposure prophylaxis (PrEP), as the test may produce a false non-reactive result.
4. This product is intended only for use with oral fluid specimens. Testing with any other specimen type will not give accurate results. Oral fluid specimens must be collected and tested using the procedure described herein, using only the materials provided with this test. Use of other collection swabs may not give accurate results.
5. During specimen collection and testing, handle the Oral Swab and Sample Buffer as if they could transmit infection. Before performing testing, professional test administrators must read and understand Universal Precautions for Prevention of Transmission of Human Immunodeficiency Virus, Hepatitis B Virus and other Blood Borne Pathogens in Health Care Settings.[3]
6. This test is to be performed at ambient temperature (i.e., 15-37°C, 59-99°F). If test components are stored refrigerated, remove them from the refrigerator and allow them to reach ambient temperature (15-37°C, 59-99°F) before opening the component packaging.
7. Subjects must not eat, drink, use tobacco or similar products, or use oral care products for 60 minutes before testing or it may cause a false result.
8. It is illegal to test another person using an HIV test without their consent.
9. Interpret all faint Test Lines with a visible Control Line as a presumptive positive result and refer the subject to a clinic for a follow-up confirmatory HIV test.

PRECAUTIONS

Safety Precautions

1. Wipe all spills thoroughly with disinfectant or household bleach. Do not autoclave solutions that contain bleach.
2. Do not eat, drink, or smoke in areas where specimens or test reagents are being handled.
3. Professional test administrators should wear gloves when collecting oral fluid samples and performing testing. Wash hands thoroughly after each oral fluid test and after any contact with oral fluid.

Handling Precautions

1. Each *Asanté*® HIV-1/2 Oral Fluid Test component (Test Strip, Sample Buffer and Oral Swab) is intended for a single use. **Do not use more than once**. If a test must be repeated, use all new components for the retest and wait at least 1 hour (preferably longer) before collecting a new oral fluid specimen.
2. Check the expiration date of the kit and each dated component (Test Strip and Sample Buffer) prior to use. Do not use any materials after the expiration date printed on the material package labeling.
3. Do not use the test if any of the test components are damaged.
4. Do not use if the desiccant is missing from the Test Strip package or if the desiccant is pink in color. Discard the affected Test Strip and use a new Test Strip.
5. Test Strips and Sample Buffer tubes are matched to function with each other in each kit. Do not interchange or use Test Strips and Sample Buffer from different kit lots.
6. Avoid excessive handling of kit components to avoid microbial contamination. Do not handle the swab end of the Oral Swab or handle the Test Strip's read area (i.e., membrane region with Test and Control Lines).
7. Once the collected oral fluid sample is added to the Sample Buffer, it must be tested immediately and cannot be stored.
8. Perform the test and read the results using adequate lighting to ensure accurate results.

MATERIALS PROVIDED

The *Asanté*® HIV-1/2 Oral Fluid Test (PN 2502) is packaged as a 100-count test configuration (Catalog #1502-100) including a product insert (LN 6263). Each box contains 100 Oral Swabs (PN 3094), 100 capped tubes containing Sample Buffer (PN 3099), and 100 Test Strips sealed in foil pouches with desiccant (PN 3092). A reusable foam tube holder (PN 7122) is also included for performing up to 12 tests concurrently.

MATERIALS REQUIRED BUT NOT PROVIDED

- Timer or watch
- Disposable gloves, for use by a professional performing the test
- Indelible marker to label the Sample Buffer Tube with patient identifier
- Biohazard bag to safely dispose of potentially infectious materials

STORAGE CONDITIONS

- Unused *Asanté*® HIV-1/2 Oral Fluid Tests may be stored unopened at 2-30°C (36-86°F) until the product expiration date. Store in a dry location not to exceed 85% humidity.
- Do not open the Test Strip pouch or other component outer packaging until ready to perform a test.
- If the test is stored refrigerated, remove it from the refrigerator and allow it to reach ambient temperature (15-37°C, 59-99°F) before opening the component packaging.

DISPOSAL

After using an individual test, dispose of all used components and packaging in accordance with local regulations.

INSTRUCTIONS FOR USE

***See* Visual Step-by-Step Instruction on Last Page**

1. Label Sample Buffer Tube with unique patient identifier using indelible ink.
2. Place Sample Buffer Tube upright in provided foam tube holder. Twist off gray cap.
3. Tear open blue swab packaging where indicated. Remove swab, holding it by the handle.
4. Press swab against the subject's upper gum. Rub swab head back and forth across the gum.
5. Flip swab over. Repeat for the bottom gum.
6. Hold Sample Buffer Tube in the tube holder and press the swab firmly against the tube opening. The swab will bend and fit tightly in the tube.
7. Gently slide swab into tube and press all the way to the bottom.
8. Move swab up and down at least 2 times to mix with fluid. Then press swab against the side of the tube, remove swab and discard. Keep tube in the tube holder.
9. If interrupted after collecting the oral fluid specimen in buffer, place Test Strip in the Sample Buffer Tube within 30 minutes or use a new test.
10. Open Test Strip packaging and remove strip.
11. Place Test Strip in the tube with the gray label and arrow pointing down.
12. Wait at least 20 minutes (but no longer than 45 minutes) for the test to run. Do not read the result after 45 minutes.
13. Remove the Test Strip from the Sample Buffer Tube, place the strip next to the images on the last page of this product insert and compare against the patient's results.

LIMITATIONS OF THE TEST

1. The *Asanté*® HIV-1/2 Oral Fluid Test must be used according to the instructions in this product insert to obtain accurate results.
2. Results must be read no earlier than 20 minutes nor later than 45 minutes after inserting the Test Strip into the specimen/Sample Buffer mixture.
3. This test is intended for use only with oral fluid specimens. Oral fluid specimens collected following procedures other than those specified in this product insert may yield erroneous results.
4. Specimens collected from individuals infected with HIV but who are on antiretroviral therapy (ART) may produce false negative results.
5. A reactive Test Line combined with a reactive Control Line using the *Asanté*® HIV-1/2 Oral Fluid Test indicates the presence of HIV-1 and/or HIV-2 antibodies in the specimen. The *Asanté*® HIV-1/2 Oral Fluid Test should not be used alone to form a diagnosis of HIV but used as an aid in such diagnosis. Confirmation of test results should be obtained using an approved test algorithm.
6. The intensity of either the Test Line or Control Line does not necessarily correlate with the levels of any antibodies that may be present in the specimen or with the severity of presumptive disease.
7. A non-reactive result does not exclude the possibility of exposure to HIV or the presence of HIV infection. In response to recent HIV exposure, antibody levels may take several weeks to several months to reach detectable levels.
8. The presence of HIV-1 or HIV-2 antibodies is presumed to be an indication of a viral infection. However, individuals who have participated in HIV vaccine studies may have antibodies present as a result of vaccination but may not be infected with HIV.
9. In contrived oral fluid studies, individual specimens with Tuberculosis and Trypanosomiasis infection produced false-reactive results. If these conditions are suspected, additional confirmation testing for affected patients is recommended.
10. In contrived oral fluid studies, Visceral Leishmaniasis, Tick-borne Encephalitis, HTLV-II, and Trypanosomiasis specimens enriched to be weakly HIV-positive yielded false-nonreactive results. If these conditions are suspected, additional confirmation testing for affected patients is recommended.
11. A single contrived HIV-positive specimen was observed to be false-nonreactive when enriched with high concentrations of Secretory IgA (200 µg/mL). Determination of S-IgA in oral fluid is difficult, however if elevated levels are suspected, additional confirmation testing for affected patients is recommended.

PERFORMANCE CHARACTERISTICS

HIV-1 SEROCONVERSION STUDY

A nonclinical seroconversion sensitivity study was conducted by testing 31 commercially available seroconversion panels, containing 187 unique serum or plasma specimens, sourced from SeraCare Life Sciences and ZeptoMetrix Corporation. Serum/plasma specimens were contrived to mimic a conservative dilution of antibodies in true oral fluid specimens relative to their matched serum or plasma counterparts. A conservative dilution of 1:2500 in Sample Buffer was used to simulate an oral fluid specimen for this study, however Sedia has data indicating the appropriate dilution factor is more likely 1:1000. Panel members were each tested with three unique *Asanté*® HIV-1/2 Oral Fluid Test lots, producing a calculated mean Seroconversion Sensitivity Index Score of 0.7 (i.e., the *Asanté*® HIV-1/2 Oral Fluid Test detected infections a mean 0.7 bleeds later than reference rapid diagnostic tests (RDT)). The relevant time period between seroconversion bleeds in panels important to RDTs in this study typically represent a difference of only 2-5 days. One kit lot was marginally more sensitive than the other two kit lots, yielding a Seroconversion Sensitivity Score Index of 0.4 while the other two lots produced Index Scores of 0.9. Results are provided in Table 1, Table 2, and Table 3.

Table 1: Seroconversion Sensitivity Study, Summary Results vs. EIA

Asanté® HIV-1/2 Oral Fluid Test	Number of Panels[1] (n = 31)
Detected the earliest bleed that was detected by an EIA	6[2]
Within 1 bleed of the earliest bleed that was detected by an EIA	3
No bleeds detected by *Asanté* HIV-1/2 Oral Fluid Test or reference EIA	11
Unknown	8[3]

Table 2: Seroconversion Sensitivity Study, Summary Results vs. RDT

Asanté® HIV-1/2 Oral Fluid Test	Number of Panels[1] (n = 31)
Detected the earliest bleed that was detected by an RDT	7[2]
Within 1 bleed of the earliest bleed that was detected by an RDT	2
No bleeds detected by *Asanté* HIV-1/2 Oral Fluid Test or reference RDT	11
Unknown	8[3]

Table 3: HIV-1 Seroconversion Sensitivity Study Results by Panel

Seroconversion Panel ID	No. Panel Bleeds	No. Bleeds Detected by *Asanté*® OFT	No. Bleeds Detected by Serum EIA	No. Bleeds Detected by Serum RDTs
0600-0250	10	2	4	2
0600-0251	10	1	3	3
0600-0270	4	0	2	1
0600-0237	4	0	1	N/A[4]
0600-0230	4	0	0	1
0600-0232	4	0/0/1[5]	1	N/A[2]
0600-0227	4	0	0	N/A[2]
0600-0252	4	0/0/1[3]	2	1
0600-0253	4	0	1	0
0600-0261	4	0	0	0
0600-0262	4	0	1	1
0600-0256	4	0	1	0
0600-0258	4	0	0	0
0600-0239	5	0	1	N/A[2]
0600-0240	5	0	0	N/A[2]
0600-0260	5	0	0	0
0600-0272	6	0/0/1[3]	2	1
0600-0244	6	0	0	0
0600-0249	6	1	3	2
0600-0246	6	0	0	0
0600-0238	7	0	1	N/A[2]
0600-0245	7	0	0	0
0600-0263	7	0	0	0
0600-0271	8	4/3/4[3]	4	3
0600-0265	9	0	0	0
0600-0243	9	0	0	0
HIV9096	6	2	2	2
HIV12007	9	2/3/4[3]	3	2
HIV12008	13	2	2	2
HIV9081	4	2	3	3
HIV9014	5	4	3	3

[1] HIV-1 Seroconversion Panels: (SeraCare) 0600-0250, 0600-0251, 0600-0270, 0600-0237, 0600-0230, 0600-0232, 0600-0227, 0600-0252, 0600-0253, 0600-0261, 0600-0262, 0600-0256, 0600-0258, 0600-0239, 0600-0240, 0600-0260, 0600-0272, 0600-0244, 0600-0249, 0600-0246, 0600-0238, 0600-0245, 0600-0263, 0600-0271, 0600-0265, 0600-0243, (ZeptoMetrix) HIV9096-1, HIV12007-1, HIV12008-1, HIV9081-1, HIV9014-1.

[2] Only kit lot 4 detected the final bleed in panels 0600-0252 and 0600-0272. Lots 1 and 4 detected the last four bleeds of panel 0600-0271, while lot 3 detected the last three bleeds in the panel. For panel HIV12007-1, lot 2 detected the last two bleeds, lot 3 detected the last three bleeds, and lot 4 detected the last four bleeds in the panel.

[3] Four panels did not contain RDT reference data. For panels 0600-0237, 0600-0230, 0600-0253, 0600-0262, 0600-0256, 0600-0239, and 0600-0238, the *Asanté*® HIV-1/2 Oral Fluid Test did not detect any bleeds in the panel, while the reference EIA or RDT detected at least one bleed.

[4] No RDT reference data available.

[5] Results for different kit lots.

CLINICAL SENSITIVITY AND SPECIFICITY

Clinical studies were conducted using the *Asanté*® HIV-1/2 Oral Fluid Test in regional clinical sites in South Africa and Senegal. Oral fluid specimens from 2150 consenting participants across all studies were collected and tested by trained healthcare professionals. For these studies, the *Asanté*® HIV-1/2 Oral Fluid Test achieved a 99.1% pooled sensitivity (95% CI: 97.5% - 99.7%) and 99.9% specificity (95% CI: 99.5% - 100%) relative to ELISA confirmatory test results. The Senegalese Study included eight HIV-2 only subjects and two HIV-1/2 coinfections correctly identified by the *Asanté*® HIV-1/2 Oral Fluid Test. Summary data from the professional user trials are provided in Table 4.

Table 4: Trained User Pooled Clinical Sensitivity and Specificity

		ELISA Confirmatory Test Result			
		-	+	Indeterminate	Total
Asanté® HIV-1/2 Oral Fluid Test	-	1683	4	0	1687
	+	2	461	0	463
	Total	1685	465	0	2150

HIV Sensitivity: 461/465 or 99.1% (95% CI: 97.5% - 99.7%)

HIV Specificity: 1683/1685 or 99.9% (95% CI: 99.5% - 100%)

HIV-2 SENSITIVITY

To supplement low HIV-2 prevalence, *Asanté*® HIV-1/2 Oral Fluid Test sensitivity to HIV-2 antibodies was evaluated with a nonclinical laboratory study contracted through Ezintsha, a subdivision of Wits Reproductive Health and HIV Institute in South Africa. The study incorporated testing of 119 HIV-2 specimens characterized by an FDA-approved HIV-1/HIV-2 antibody differentiation assay to have antibodies to HIV-2 viral proteins. A cohort of specimens positive for HIV-2 antibodies, characterized as HIV-2 only, HIV-2 and HIV-1 indeterminate, and HIV-2 with HIV-1 cross-reactivity, were included in the study as coinfection with HIV-1 and the misclassification of HIV-2 infection are recognized diagnostic complications. This serum and plasma panel was obtained from Boca Biolistics, with each specimen contrived to simulate an oral fluid specimen using a conservative dilution factor of 1:2500. The *Asanté*® HIV-1/2 Oral Fluid Test produced 119 concordant positive results using one lot tested in singlicate. Table 5 provides HIV-2 sensitivity data calculated as 100% (95% CI: 96.9% - 100%).

Table 5: HIV-2 Sensitivity Laboratory Study Results

		FDA-approved HIV-1/2 Ab Differentiation Assay			
		-	+	Indeterminate	Total
Asanté® HIV-1/2 Oral Fluid Test	-	0	0	0	0
	+	0	119	0	119
	Total	0	0	0	119

HIV-2 Sensitivity: 119/119 or 100% (95% CI: 96.9% - 100%)

HIV-1 GENOTYPE PERFORMANCE STUDY

The *Asanté*® HIV-1/2 Oral Fluid Test was assessed for its ability to detect anti-HIV antibodies with various HIV-1 genotypes and common-to-rare circulating recombinant forms (CRF) by testing a panel of 106 unique serum and plasma specimens with verified HIV-1 genotypes obtained from repositories or commercial vendors and prepared as contrived oral fluid specimens using a conservative 1:2500 dilution factor. As presented in Table 6, one borderline CR01-AE specimen was consensus negative with all three kit lots employed for the study. Contrived HIV-1 subtype O specimens challenged the test; however, consensus reactivity was observed in over half of the subtype O specimens tested.

Table 6: Device Results for HIV-1 Genotype Performance Study

Viral Subtype	Subtype Class	No. Specimens Tested	Reactive Results	False Non-Reactive Results
A1	Common	10	10	0
B	Common	12	12	0
C	Common	12	12	0
D	Rare	2	2	0
G	Common	10	10	0
CRF01-AE	Common	12	11	1
CRF02-AG	Common	11	11	0
CRF07-BC	Common	10	10	0
CRF08-BC	Rare	2	2	0
CRF19_cpx	Rare	2	2	0
CRF20_BG	Rare	1	1	0
CRF26_AU	Rare	1	1	0
CRF45_cpx	Rare	2	2	0
BF	Common	1	1	0
F1	Rare	5	5	0
URF BF1	Rare	3	3	0
K	Rare	1	1	0
H	Rare	1	1	0
CPX2	Rare	1	1	0
O	Rare	7	4	3
Total		106	102	4

UNRELATED CONDITIONS AND INTERFERING SUBSTANCES

A nonclinical cross-reactivity study was conducted by testing 102 contrived oral fluid specimens with unrelated medical conditions (i.e., Cross-Reactive Panel) formulated using a high concentration of sera/plasma at a 1:500 dilution to challenge the *Asanté*® HIV-1/2 Oral Fluid Test's specificity. Potentially cross-reactive specimens were tested across three production lots both with and without enrichment from a plasma specimen confirmed positive for low-avidity HIV-1 antibodies to investigate the potential for false non-reactive and false-reactive results, respectively. Additionally, a cohort of three HIV-1 positive and three HIV-negative specimens was enriched with 15 potentially interfering substances, grouped into 11 enrichment conditions (Interference Panel). These panel members were also each tested with three unique *Asanté*® HIV-1/2 Oral Fluid Test lots. The results indicate there is limited diagnostically important cross-reactivity, as only one specimen yielded false-reactive results on all three kit lots, even after subsequent dilution to a 1:2500 level. Similarly, no common medication or elevated endogenous substance tested in the Interference Panel produced false reactive results. Contrived oral fluid specimens with unrelated medical conditions, enriched to be weakly HIV-reactive at a 5:1 ratio of panel member to enrichment specimen were more variable, creating borderline results and some false non-reactive results. Importantly, no condition demonstrated false non-reactivity across all kit lots using a very challenging study design. Results are provided in Tables 7a and 7b.

Table 7a: Unrelated Medical Conditions and Interfering Substances – HIV-Negative Results

Unrelated Medical Condition (n = 102)	*Asanté*® HIV-1/2 Oral Fluid Test Consensus Results	
	Reactive	Non-Reactive
Hepatitis A	0	5
Hepatitis B	0	5
Hepatitis C	0	5
Cytomegalovirus	0	5
Epstein-Barr Virus	0	6
Varicella Zoster Virus	0	4
Yellow Fever Virus	0	3
Measles (Rubeola)	0	6
Rubella	0	1
Influenza	0	3
Tick-borne Encephalitis	0	3
HTLV-I	0	5
HTLV-II	0	5
Malaria	0	4
Visceral Leishmaniasis	0	3
Tuberculosis	1[1]	3
Trypanosomiasis	0[2]	3
Influenza Vaccine Recipient	0	4
Vaccine-Induced Seropositivity	0	3
Syphilis	0	5
Herpes Simplex Virus	0	5
COVID-19	0	3
Candida	0	3
Auto-Immune Disorders	0	6
Dengue Fever	0	3
Potentially Interfering Substances (n = 33)		
Ibuprofen, Aspirin, Pseudoephedrine, Acetaminophen	0	3
Bilirubin	0	3
Cholesterol, Triglycerides	0	3
Tetracycline	0	3
Quinidine	0	3
Ethambutol	0	3
Albumins	0	3
Whole Blood	0	3
S-IgA	0	3
IgG	0	3
IgM	0	3

[1] One Tuberculosis specimen produced false-reactive results on all three kit lots.
[2] One Trypanosomiasis specimen produced a false-reactive result on one kit lot.

A specimen from each of two conditions, Visceral Leishmaniasis and Tick-borne Encephalitis, generated consensus false non-reactive results (i.e., with two kit lots). No other conditions or substances yielded false non-reactive results on more than a single specimen and kit lot.

Table 7b: Unrelated Medical Conditions and Interfering Substances – HIV-Positive Results

Unrelated Medical Condition (n = 102)	*Asanté*® HIV-1/2 Oral Fluid Test Consensus Results	
	Reactive	Non-Reactive
Hepatitis A	5	0
Hepatitis B	5	0
Hepatitis C	5	0
Cytomegalovirus	5	0
Epstein-Barr Virus	6	0
Varicella Zoster Virus	4	0
Yellow Fever Virus	3	0
Measles (Rubeola)	6	0
Rubella	1	0
Influenza	3	0
Tick-borne Encephalitis	2[1]	1
HTLV-I	5	0
HTLV-II	5[2]	0
Malaria	4	0
Visceral Leishmaniasis	2[3]	1
Tuberculosis	4	0
Trypanosomiasis	3[4]	0
Influenza Vaccine Recipient	4	0
Vaccine-Induced Seropositivity	3	0
Syphilis	5	0
Herpes Simplex Virus	5	0
COVID-19	3	0
Candida	3	0
Auto-Immune Disorders	6	0
Dengue Fever	3	0
Potentially Interfering Substances (n = 33)		
Ibuprofen, Aspirin, Pseudoephedrine, Acetaminophen	3	0
Bilirubin	3	0
Cholesterol, Triglycerides	3	0
Tetracycline	3	0
Quinidine	3	0
Ethambutol	3	0
Albumins	3	0
Whole Blood	3	0
S-IgA	3[5]	0
IgG	3	0
IgM	3	0

[1] One Tick-borne Encephalitis specimen produced false non-reactive results on two kit lots.
[2] One HTLV-II specimen produced a false non-reactive result on a single kit lot.
[3] One Visceral Leishmaniasis specimen produced false non-reactive results on two kit lots.
[4] One Trypanosomiasis specimen produced a false non-reactive result on a single kit lot.
[5] One S-IgA enriched HIV-positive specimen produced a false non-reactive result on a single kit lot.

POTENTIALLY INTERFERING SUBSTANCES – CLINICAL ORAL FLUID SPECIMENS

An additional investigational study was conducted on true oral fluid specimens collected under clinical research protocol from both HIV-positive and HIV-negative consenting community volunteers. The HIV status of these subjects was confirmed by Sedia clinical research staff upon study enrollment using an RDT approved by a stringent regulatory authority. Oral fluid specimens were collected using the *Asanté*® HIV-1/2 Oral Fluid Test's Oral Fluid Specimen Collection Swab and eluted in Sample Buffer prior to testing with the *Asanté*® HIV-1/2 Oral Fluid Test. The majority of specimens were collected within 18 minutes of the potentially interfering activity, with the exception of tobacco usage, which occurred between 6 and 117 minutes prior to specimen collection. Of the 48 HIV-positive participants, all but three disclosed use of at least one antiretroviral therapy (ART) medication as treatment for their HIV infection. Testing results for one subject suggest that cold beverages or alcoholic mouthwash may have interfered with the assay's ability to function as intended; however, the results do not definitively indicate interference, as these false non-reactive results occurred with different specimens collected from the same individual. Instead, the false non-reactive results could be attributed to seroreversion, a decline in antibody titer in response to diminishing viral load, which may result from the therapeutic effects of effective ART. None of the other oral fluid specimens collected under these same conditions exhibited similar putative impacts on device performance. Study results are summarized in Table 7c below.

Table 7c: Interfering Substances and Unrelated Medical Conditions, Clinically Collected Oral Fluid Specimens

Substance/Condition	*Asanté*® HIV-1/2 Oral Fluid Test, Concordance	
	# of HIV+ Specimens	# of HIV- Specimens
Concomitant Medications / No Interfering Substances	5/5	4/4
Tobacco Use (Smoking)	4/4	2/2
Periodontal Disease	3/3	0
Dentures	1/1	0
Caffeine	5/5[1]	5/5[1]
Oral Hygiene: Teeth Brushing	5/5	8/8
Oral Hygiene: Mouthwash with Alcohol	6/7[2]	7/7
Oral Hygiene: Mouthwash without Alcohol	5/5	3/3
Consumption of Food	5/5	7/7
Consumption of Hot Beverages	6/6	8/8
Consumption of Cold Beverages	6/7[2]	8/8
Consumption of Acidic Beverages	6/6	5/5
Total Unique Specimens	54/56	54/54

[1] Three each HIV positive and negative participants are included from the Hot Beverage condition, as the hot beverage selected contained caffeine.
[2] False non-reactive results were observed in specimens from the same individual, collected on different dates.

REPRODUCIBILITY AND REPEATABILITY

A nonclinical reproducibility and repeatability study was conducted by testing a panel comprised of one HIV-negative, two HIV-1 positive (borderline and moderate reactivity), and two HIV-2 positive (borderline and moderate reactivity) contrived oral fluid specimens. Study panels were manufactured from sera diluted in Sample Buffer to reflect the anti-HIV antibody reactivity observed in true oral fluid specimens. The borderline HIV-1 panel member was formulated using sera confirmed to be an early HIV infection with low avidity antibodies. Each discrete panel contained five blinded replicates of each specimen, for a total of 25 specimens per panel. For each *Asanté*® HIV-1/2 Oral Fluid Test assay performed, operators utilized the device's Oral Swab to transfer contrived specimen from the panel member's aliquot tube to the kit's Sample Buffer Tube, mimicking oral fluid collection described in the Instructions for Use. The Test Strip was used and interpreted as intended. Testing was performed by multiple operators at three different testing locations over five days, with three unique *Asanté*® HIV-1/2 Oral Fluid Test kit lots tested each day. Summary results are provided in Tables 8a and 8b. Operators at Sedia Biosciences were instructed to assign numerical visual interval scores according to internal test methods, rather than simply assigning a binary score (i.e., +/-). However, in the intended use-case, any visual reactivity on the Test Line is considered a positive result. Therefore, in the summary tables below, Sedia visual scoring indicating faintly reactive Test Lines are represented as a positive result.

Table 8a: Summary of Reproducibility and Repeatability Testing Results, All Testing Sites

Panel Member	Negative	Positive	Criteria	Percent Concordance	Invalid
HIV-1/2 Negative	220	3	Negative	98.7%	2
HIV-1 Low Positive	5	220	Positive	97.8%	0
HIV-1 Medium Positive	0	224[1]	Positive	100%	0
HIV-2 Low Positive	2	223	Positive	99.1%	0
HIV-2 Medium Positive	0	225	Positive	100%	0

[1] One test not performed by one laboratory.

Table 8b: Summary of Reproducibility and Repeatability Testing Results per Testing Site

Panel Member	Testing Site 1[1]		Testing Site 2		Testing Site 3	
	Negative	Positive	Negative	Positive	Negative	Positive
HIV-1/2 Negative	70	3	75	0	75	0
HIV-1 Low Positive	4	71	1	74	0	75
HIV-1 Medium Positive	0	75	0	75	0	74
HIV-2 Low Positive	1	74	1	74	0	75
HIV-2 Medium Positive	0	75	0	75	0	75

[1] Sedia Biosciences

ASSAY MEASURING RANGE, PROZONE EFFECT

A nonclinical study was conducted to evaluate the potential for a prozone (i.e., "hook") effect by testing 20 highly reactive HIV-1 positive serum specimens, sourced from Dx Biosamples and Tennessee Blood Services, and 20 highly reactive HIV-2 positive specimens, sourced from Boca Biolistics. Individual specimens were selected for their high reactivity, as determined by an FDA-approved EIA. These serum specimens were used in combination with Sample Buffer to formulate contrived oral fluid specimens at two dilutions, 1:2500 and 1:250. A dilution factor of 1:2500 corresponds to a conservative level of HIV antibodies found in oral fluid. The 1:250 factor was used to assess how excess analyte affects *Asanté*® HIV-1/2 Oral Fluid Test results. Contrived oral fluid specimens were tested at both dilutions, in triplicate, with components from one lot of *Asanté*® HIV-1/2 Oral Fluid Test. No diagnostically important difference was observed between Test Line results produced by specimens contrived at 1:250, relative to results produced by specimens contrived at 1:2500.

FLEX Studies intended to mitigate risk of adversity demonstrated the *Asanté*® HIV-1/2 Oral Fluid Test is robust in use under a variety of challenging environmental conditions outside of recommended use.

REFERENCES

1. Gallo R., Salahuddin S., Popovic M., et al. Frequent detection and isolation of cytopathic retroviruses (HTLV III) from patients with AIDS and at risk for AIDS. Science 1984, **224(4648)**:500-503.
2. Curran, J., Morgan, W., Hardy A., et al. The epidemiology of AIDS: current status and future prospects. 1985, **229(4720)**: 1352-1357.
3. Centers for Disease Control and Prevention (CDC). Universal Precautions for Prevention of Transmission of Human Immuno-Deficiency Virus, Hepatitis B Virus and other Blood Borne Pathogens in Health Care Settings. MMWR 1988; **37(24)**: 377-388.

SYMBOLS

The following symbols appear in the *Asanté*® HIV-1/2 Oral Fluid Test product labeling:

IVD	*In Vitro* Diagnostic Device		Do Not Reuse
REF	Part Number (Reference)		Manufacturer
LOT	Lot Number (Batch Code)		StorageTemperature Limitation
	Use by (Expiration Date)		Consult Instructions for Use
	Warning, Important		Number of Tests

Asanté® HIV-1/2 Oral Fluid Test

Manufactured by:

SEDIA BIOSCIENCES CORPORATION
9590 SW Gemini Drive
Beaverton, OR 97008-7166 USA
Ph: +1 503-459-4159
FAX: +1 503-459-4168
Webpage: www.sediabio.com
Email: customerservice@sediabio.com

Cat. No.
1502-100

REF 2502

Asanté®

HIV-1/2 Oral Fluid Test

INSTRUCTIONS FOR USE

For Professional Use Only

For self-testing, use the *Asanté*® HIV-1/2 Oral Self-Test

- Read **all** instructions and procedures before using test.
- Perform test in a clean, well-lit area and ensure you have all contents before beginning the test.

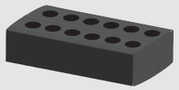
Warnings

- Subjects **must not** eat, drink, use tobacco or similar products, or use oral care products for 1 hour before testing or it may cause a false result.
- **Do not use** the test if today's date is past the expiration date listed on the test kit's box or on any of its components.
- **Do not use** if any of the test contents are missing or damaged.
- **Do not use** if the desiccant is missing from the test strip package or if the desiccant materials are pink in color.

Limitations

- Tests are to be performed on individuals 18 years and older.
- Do not perform the test on a subject who is taking HIV therapy (i.e., antiretroviral therapy (ART) or pre-exposure prophylaxis (PrEP)), or it may lead to a false test result.
- The *Asanté*® HIV-1/2 Oral Fluid Test may not detect HIV infections that have occurred within the last 3 months.

PACKAGE CONTENTS



Foam Tube Holder (1 ea.)
REF 7122

Instructions for Use (1 ea.)
REF LN-6263

Sample Buffer Tubes (100 ea.)
REF 3099

Pouched Test Strips (100 ea.)
REF 3092
(each contains)

Desiccant
(**DO NOT USE**)

Test Strip

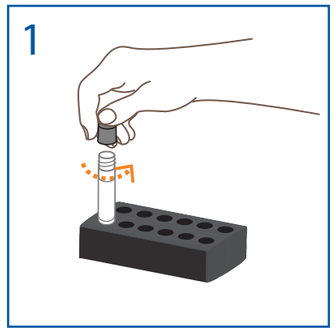
Oral Swabs (100 ea.)
REF 3094

Manufactured By:

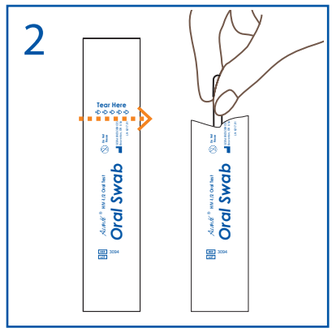
SEDIA BIOSCIENCES CORPORATION
9590 SW Gemini Drive, Beaverton, OR 97008 USA
Ph: +1 503 459 4159 FAX: +1 503 459 4168
Webpage: www.sediabio.com Email: customerservice@sediabio.com

TEST PROCEDURE

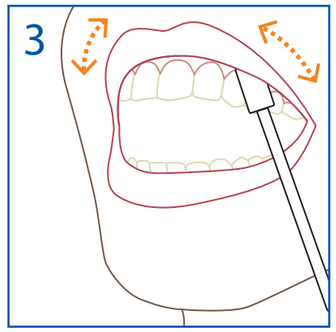
Scan with smartphone for additional information.
sediabio.com



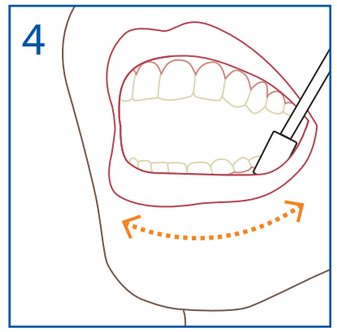
Label Sample Buffer Tube with unique patient identifier using indelible ink. Place tube upright in tube holder. Twist off cap.



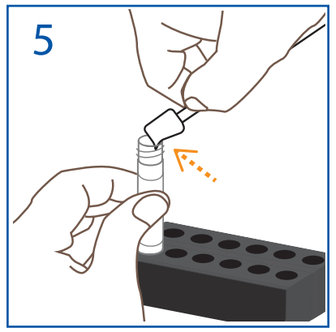
Tear open **blue** swab packaging as shown. Remove swab, holding it by the handle.



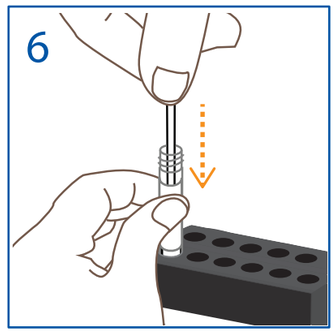
Press swab against the upper gum. Rub swab head back and forth across the gum.



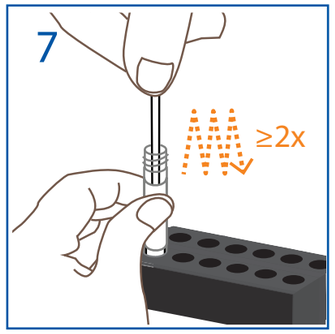
Flip swab over. Repeat for the bottom gum.



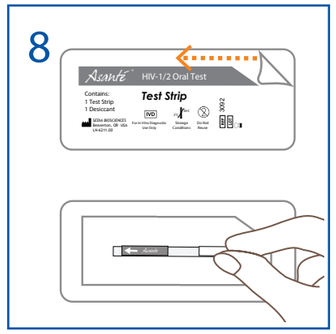
Hold tube in the holder and press the swab firmly against the tube opening as shown above. The swab will bend and then fit tightly in the tube.



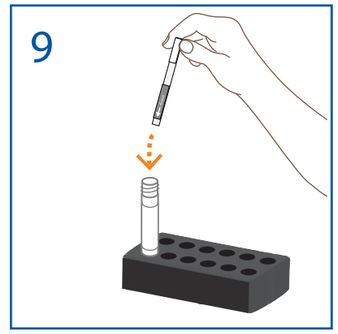
Gently slide swab into tube and press all the way to the bottom.



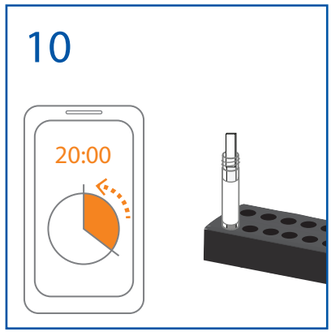
Move swab up and down **at least 2 times** to mix with fluid. Then press swab against the side of the tube, remove swab and discard. Keep tube in holder.



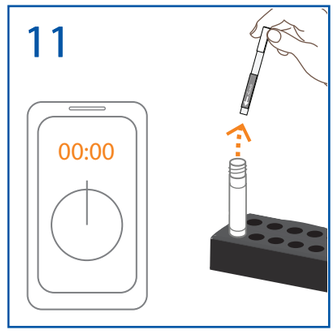
Open test strip packaging and remove strip as shown.



Place test strip in tube with gray label and **arrow pointing down**.



Wait at least 20 minutes (but no longer than 45 minutes) for the test to run. Do not read the result after 45 minutes.



Remove the test, place the strip next to the images at right and compare the results.

INTERPRETATION OF RESULTS

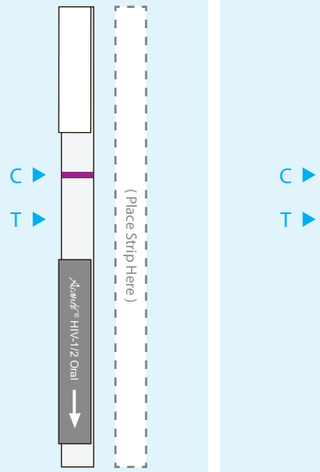
If the test result is NEGATIVE:

As with many tests, there is a chance for a false result. Be sure to use the test as instructed to reduce the chance of false results. If the subject has recently been involved in an activity with increased HIV risk, recommend testing again in 3 months.

If the test result is POSITIVE:

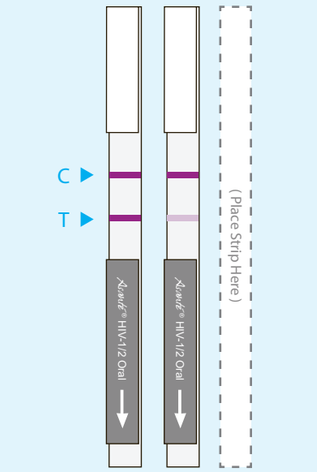
The presence of HIV-1 or HIV-2 antibodies is presumed to be an indication of a viral infection. **Positive results from the test must be confirmed following the national HIV testing algorithm.**

False-positive results are rare but possible. One subject with tuberculosis and no HIV infection produced a false-positive result.



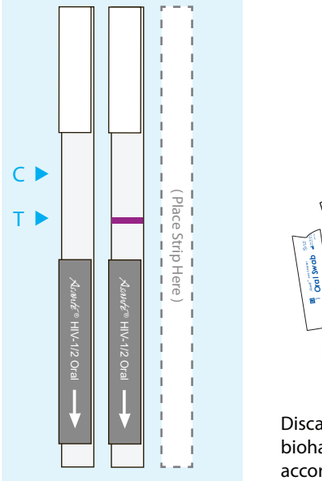
NEGATIVE

If only the C line appears, the test result is negative. If appropriate, testing should be repeated again in 3 months.



POSITIVE

If both lines have color, the subject probably has HIV. **Even a faint color on the T line is a positive diagnosis**. **Positive results must be confirmed following the national HIV testing algorithm.**

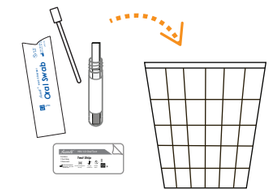


INVALID

If the C line does not appear, the test did not work. Retest with a new kit. Contact the distributor or manufacturer if an invalid test result persists.

DISPOSAL

Do Not Reuse



Discard used test items in biohazard waste container or according to local regulation.

EXPLANATION OF SYMBOLS

The following symbols appear in *Asanté*® HIV-1/2 Oral Fluid Test labeling:

IVD *In Vitro* Diagnostic Device
REF Part Number (Reference)
Use by (Expiration Date)
Do Not Reuse
Number of Tests
Temperature Limitation
LOT Lot number (Batch Code)
Warning, Important
Manufacturer
Consult Instructions for Use