Aptima Specimen Transfer Kit

For *in vitro* diagnostic use.

For US export only.

Intended Use

The Aptima Specimen Transfer Kit consists of transfer tubes containing specimen transport medium (STM) and is intended for use with Aptima assays for the testing of gynecological specimens collected in ThinPrep™ Pap Test vials containing PreservCyt™ solution. The Aptima Specimen Transfer Kit may also be used to transfer other liquid specimen medias for use with Aptima assays and other Hologic products. Refer to the appropriate product package insert for the indicated uses of the Aptima Specimen Transfer Kit for each Hologic product.

Reagents

Materials Provided

Aptima Specimen Transfer Kit (Cat. No. 301154C)

Aptima Specimen Transfer Kit — printable (Cat. No. PRD-05110)

Component	Quantity	Description
Aptima Specimen Transfer tubes	100 tubes	1 tube x 2.9 mL STM.

Materials Required But Available Separately

Materials available from Hologic have catalog numbers listed, unless otherwise specified.

Pipettor and tips capable of pipetting 1000 µL

Bleach, 5% to 7% (0.7M to 1.0M) sodium hypochlorite solution

Test tube rack

Plastic-backed absorbent laboratory bench covers

Fisherbrand BloodBloc Super Absorbency Wipes (available from Fisher Scientific)

Lint-free disposable wipes

Optional Materials

Gyn TransCyt™ Filters (clear) for use with the ThinPrep 2000 System

Kit Storage Requirements

Store specimen transfer tubes at room temperature (15°C to 30°C) prior to use.

Do not use reagent beyond the expiration date indicated on the vials.

Warnings and Precautions

A. For handling ThinPrep liquid cytology specimens, refer to the ThinPrep 2000 System, ThinPrep 5000 Processor or ThinPrep 5000 Processor with AutoLoader (ThinPrep 5000 Systems), or ThinPrep Genesis Processor instructions for use.

B. If the Aliquot Removal procedure will be used, refer to the ThinPrep 2000 System, ThinPrep 5000 Systems, or ThinPrep Genesis Processor instructions on aliquot removal.

C. Use the Aptima Specimen Transfer Kit with Aptima assays or other Hologic products only. Performance has not been evaluated with non-Hologic products.

D. Do not apply the Aptima specimen transport medium directly to skin or mucous membranes or take internally.

E. Use only supplied or specified disposable laboratory ware.

F. Use routine laboratory precautions. Do not eat, drink or smoke in designated work areas. Wear disposable, powderless gloves, protective eye wear, and laboratory coats when handling specimens and reagents. Wash hands thoroughly after handling specimens and reagents.

G. Specimens may be infectious. Use Universal Precautions when handling specimens. Only laboratory personnel adequately trained in handling infectious materials should perform the procedures described in this package insert.

H. Take care to avoid cross-contamination during the specimen handling steps. Specimens may contain high levels of organisms. Change gloves frequently and always change gloves when they come in contact with specimen. Discard used materials without passing over open containers. Avoid specimen contact with one another.

I. Work surfaces, pipettes and other equipment must be regularly decontaminated with 0.5% sodium hypochlorite solution, made with deionized (DI) water. If DI water is not used in the 0.5% sodium hypochlorite solution, the effectiveness of the solution may be compromised. The pH of tap water varies from lab to lab. Alkaline water can decrease the available chlorine making the sodium hypochlorite less effective for decontaminating equipment. Refer to *ThinPrep Liquid Cytology Specimen Procedural Notes* and *Decontamination Instructions*. The effect of the ThinPrep 2000 System decontamination procedure was not assessed for its impact on cytology results. Prior to implementing the decontamination procedure, laboratories should validate that the decontamination procedure does not impact cytology results.

J. Only pipette tips with hydrophobic plugs should be used to transfer specimens to the transfer tubes.

K. Do not use this kit after its expiration date.

L. Maintain proper temperature conditions during specimen shipping and storage to ensure the integrity of the specimen. Refer to the appropriate Aptima assay or Hologic product package insert for specific shipping and storage conditions.

M. Dispose of unused residual clinical specimens, unused reagents, and waste in accordance with local regulations.

N. If testing gynecological specimens processed with the ThinPrep 2000 System, a specific procedure has been validated to mitigate the potential for cross-contamination during cytology processing. Two important steps of the procedure include: (1) soaking the filter cap in 0.5% sodium hypochlorite solution for 1 minute between samples and (2) mandating that the operator change gloves between the handling of each sample. Refer to *ThinPrep Liquid Cytology Specimen Procedural Note C* for a detailed protocol.

O. Some reagents of this kit may be labeled with risk and safety symbols.

Note: *For hazard communication information, refer to the Safety Data Sheet Library at www.hologicsds.com.*

Specimen Performance

Gynecological Specimens

The assay performance characteristics of gynecologic specimens collected in ThinPrep liquid cytology vials are provided in the appropriate Aptima assay package insert. The Aptima assay package inserts may be referenced online at www.hologic.com. The table below identifies the acceptable aliquot procedure for each of the Aptima assays.

Aptima Assay for	Pre-Processed Aliquot	Post-Processed Aliquot		
		ThinPrep 2000 System	ThinPrep 5000 Systems	ThinPrep Genesis Processor
Chlamydia trachomatis and *Neisseria gonorrhoeae* (Aptima Combo 2™ assay)	Yes	Yes	Yes	No
Chlamydia trachomatis (Aptima CT assay)		Yes	No	No
Neisseria gonorrhoeae (Aptima GC assay)		Yes	No	No
Human papillomavirus (Aptima HPV assay)		Yes	Yes	Yes
Human papillomavirus (Aptima HPV 16 18/45 Genotype assay)		Yes	Yes	Yes
Trichomonas vaginalis (Aptima Trichomonas vaginalis assay)		No	No	No

VTM Lesion Swab Specimens or Other Liquid Media Specimens

The performance characteristics of VTM lesion swab specimens or other liquid media specimens are provided in the appropriate Aptima assay or other Hologic product package insert. The Aptima assay and Hologic product package inserts may be referenced online at www.hologic.com.

Specimen Transport and Storage

Note: *Refer to the appropriate Aptima assay or Hologic product package insert for complete storage and handling information.*

Note: *Specimens must be shipped in accordance with applicable national and international transportation regulations.*

ThinPrep Liquid Cytology Specimens

Gynecological specimens may be stored in the ThinPrep liquid cytology vials for at least 30 days at 2°C to 30°C prior to transfer to Aptima Specimen Transfer tubes. Refer to the appropriate Aptima assay package insert for additional storage and handling information. ThinPrep liquid cytology specimens transferred to the Aptima Specimen Transfer tube may be stored for at least 14 days at 2°C to 30°C prior to testing. Refer to the appropriate Aptima assay package insert for additional storage and handling information.

VTM Lesion Swab Specimens

Lesion swab specimens may be stored for 3 days in the VTM tube at 2°C to 8°C prior to transfer to the Aptima Specimen Transfer tubes. Refer to the appropriate Aptima assay package insert for additional storage and handling information. VTM lesion swab specimens transferred to the Aptima Specimen Transfer tube may be stored for up to 30 days at 2°C to 30°C prior to testing. If longer storage is needed, freeze the VTM lesion swab specimen in the Aptima Specimen Transfer tube for up to 90 days at ≤ –20°C.

Other Liquid Media Specimens

Refer to the appropriate Aptima assay or other Hologic product package insert for acceptable specimen transport and storage information.

ThinPrep Liquid Cytology Specimen Procedural Notes

Note: *If the ThinPrep aliquot removal procedure will be used before processing using the ThinPrep 2000 System or ThinPrep 5000 Systems, refer to the ThinPrep 2000 System, or ThinPrep 5000 System instructions for use on aliquot removal and follow the Hologic Specimen Transfer Procedure as defined Procedural Note B.*

If the ThinPrep aliquot removal procedure will be used before processing using the ThinPrep Genesis processor, refer to the ThinPrep Genesis Processor instructions for use on aliquot removal.

Note: *If ThinPrep liquid cytology specimens will be transferred into Aptima Specimen Transfer tubes after processing using the ThinPrep 2000 System, perform ThinPrep 2000 System processing according to the instructions in Procedural Note C and Procedural Note D.*

Note: *If ThinPrep liquid cytology specimens will be transferred into Aptima Specimen Transfer tubes after processing using either of the ThinPrep 5000 Systems, perform ThinPrep 5000 Systems processing according to the ThinPrep 5000 Systems instructions in ThinPrep Liquid Cytology Specimen Procedural Note A and ThinPrep Liquid Cytology Specimen Procedural Note D.*

Note: *If ThinPrep liquid cytology specimens will be transferred into Aptima Specimen Transfer tubes after processing using the ThinPrep Genesis Processor, perform ThinPrep Genesis Processor processing according to the ThinPrep Genesis Processor instructions using "Aliquot Only" mode, or if manually transferring the aliquot follow the instructions in ThinPrep Liquid Cytology Specimen Procedural Note A and ThinPrep Liquid Cytology Specimen Procedural Note D.*

A. Preparation of the Specimen Transfer Area

1. Put on clean gloves.
2. Wipe down work surfaces and pipettors with 0.5% sodium hypochlorite solution. (Use DI water to dilute 5% to 7% (0.7M to 1.0M) sodium hypochlorite solution. A prepared batch of 0.5% sodium hypochlorite solution will be effective for 1 week if it is properly stored.)
3. Allow the sodium hypochlorite to contact work surfaces and pipettors for at least 1 minute, then follow with a water rinse. Dry the surfaces with paper towels.
4. Cover the bench with clean, plastic-backed, absorbent laboratory bench covers.
5. In the specimen transfer area, place a test tube rack containing a sufficient number of Aptima Specimen Transfer tubes corresponding to the number of ThinPrep liquid cytology specimens being tested.
6. Label each Aptima Specimen Transfer tube with the accession number or specimen ID number.

B. Specimen Transfer Procedure for ThinPrep Liquid Cytology Specimen Aliquots Removed Before Processing with the ThinPrep 2000 System or ThinPrep 5000 Systems

1. Put on clean gloves and transfer specimens to be tested to the specimen transfer area.
2. Uncap the Aptima Specimen Transfer tube, placing the cap on the bench with the threads facing up.
3. Vortex the tube containing the removed aliquot of ThinPrep liquid cytology specimen for 3 to 10 seconds. Uncap the tube, placing the cap on the bench with the threads facing up.
4. Within 1 minute of vortexing, transfer 1 mL of the ThinPrep liquid cytology specimen into the Aptima Specimen Transfer tube.
5. Dispose of the pipette tip in an appropriate biohazard container.
6. Recap the Aptima Specimen Transfer tube tightly. Gently invert the tube 2 to 3 times to ensure complete mixture of the specimen.
7. Recap the tube containing the removed aliquot of ThinPrep liquid cytology specimen for storage for up to 30 days at 2°C to 30°C, if desired.
8. Put on clean gloves and repeat steps 1 through 7 above for the transfer of subsequent specimens. To reduce the risk of contaminating other specimens, work with one ThinPrep liquid cytology specimen at a time.
9. Proceed to the *Test Procedure* section.

C. Processing ThinPrep Liquid Cytology Specimens Using the ThinPrep 2000 System

Refer to the ThinPrep 2000 System instructions for use to perform standard cytology processing steps and the maintenance of the O-rings at the base of the filter cap.

Note: *The following cleaning procedures on the ThinPrep 2000 System are not required for the Aptima HPV assays. See ThinPrep Liquid Cytology Specimen Contamination Study for the Aptima HPV Assay below for more information.*

1. Put on clean gloves.
2. Clean 2 filter caps by soaking them in 0.5% sodium hypochlorite solution for at least 1 minute, rinse the caps in DI water and dry them thoroughly with a lint-free, disposable wipe. Dispose of the wipe.

   Note: *Using 2 filter caps enables the work flow to continue while 1 filter cap is soaking.*
3. Place a clean filter cap on a BloodBloc Super Absorbency Wipe.
4. Place the fixative bath into the ThinPrep 2000 System.
5. Create a filter assembly by placing a new Gyn TransCyt Filter in a clean filter cap and insert the filter assembly into the ThinPrep 2000 System. Refer to the ThinPrep 2000 System instructions for use for details on performing this step.
6. Put a slide in the slide holder. Refer to the ThinPrep 2000 System instructions for use for details on performing this step.
7. Uncap the ThinPrep Pap Test vial, placing the cap on the bench with the threads facing up. Ensure that the bench is clean, with no bleach residue or foreign particles.
8. Load the ThinPrep Pap Test vial into the ThinPrep 2000 System. From the ThinPrep system main menu, select “4-GYN” by pressing **4** on the keypad.
9. Put on clean gloves.
10. After the slide preparation is finished, open the door, remove the ThinPrep Pap Test vial and recap the vial.
11. Remove the fixative bath and place the slide in a 95% ethanol bath.
12. Return the fixative bath to the system.
13. Remove the filter assembly from the system using one hand to grasp the filter cap and, using a lint-free, disposable wipe as a barrier, separate the filter from the filter cap. Discard the filter, gloves, and disposable wipe. **Do not discard the filter cap**.
14. Place the filter cap in a container of 0.5% sodium hypochlorite solution for at least 1 minute.
15. With clean gloves, rinse the filter cap in DI water, then dry it thoroughly with a lint-free disposable wipe. Dispose of the wipe.
16. Repeat the process for each specimen starting with step 3 of this processing procedure, changing gloves between each specimen, until all of the specimens are processed.

D. Specimen Transfer Procedure for ThinPrep Liquid Cytology Specimens After Processing with the ThinPrep 2000 System, ThinPrep 5000 Systems. or ThinPrep Genesis Processor

1. Put on clean gloves and transfer specimens to be tested to the specimen transfer area.
2. Uncap the Aptima Specimen Transfer tube, placing the cap on the bench with the threads facing up.
3. Vortex the ThinPrep Pap Test vial for 3 to 10 seconds. Uncap the vial, placing the cap on the bench with the threads facing up.
4. Within 1 minute of vortexing, transfer 1 mL of the processed ThinPrep liquid cytology specimen into the Aptima Specimen Transfer tube.
5. Dispose of the pipette tip in an appropriate biohazard container.
6. Recap the Aptima Specimen Transfer tube tightly. Gently invert the tube 2 to 3 times to ensure complete mixture of the specimen.
7. Recap the ThinPrep Pap Test vial for storage, if desired.

8. Put on clean gloves and repeat steps 1 through 7 above for the transfer of subsequent specimens. To reduce the risk of contaminating other specimens, work with one processed ThinPrep liquid cytology specimen at a time.
9. Proceed to the *Test Procedure* section.

VTM Lesion Swab Specimen Procedural Notes

A. Preparation of the Specimen Transfer Area

1. Put on clean powderless gloves.
2. Wipe down work surfaces and pipettors with 2.5% to 3.5% (0.35 M to 0.5 M) sodium hypochlorite solution.
3. Allow the sodium hypochlorite solution to contact work surfaces and pipettors for at least 1 minute, then follow with a DI water rinse. Dry the surfaces with clean paper towels.
4. Cover the bench with clean, plastic-backed, absorbent laboratory bench covers.
5. In the specimen transfer area, place a test tube rack containing a sufficient number of Aptima Specimen Transfer tubes corresponding to the number of VTM specimens being tested.
6. Label each Aptima Specimen Transfer tube with the accession number or specimen ID.

B. Specimen Transfer Procedure

1. To reduce the risk of contaminating other specimens, work with one VTM specimen at a time.
2. Put on clean powderless gloves and place specimens to be tested in the specimen transfer area.
3. Obtain one VTM specimen. Uncap the corresponding Aptima Specimen Transfer tube, placing the cap on the bench with the threads facing up.
4. Vortex the VTM specimen for 3 to 10 seconds. Uncap the tube, placing the cap on the bench with the threads facing up.
5. Within 1 minute of vortexing, pipet 0.5 mL of the VTM specimen into the Aptima Specimen Transfer tube containing 2.9 mL of specimen transport medium.
6. Dispose of the pipette tip in an appropriate biohazard container.
7. Recap the Aptima Specimen Transfer tube tightly. Gently invert the tube 2 to 3 times to ensure complete mixture of the specimen.
8. Recap the tube containing the leftover VTM specimen for storage at ≤ –70°C if desired.
9. Repeat steps 3 through 8 above for the transfer of subsequent specimens. Change powderless gloves often and especially if they come in contact with specimen.

Other Liquid Media Specimen Procedural Notes

Refer to the appropriate Hologic product package insert for the specimen transfer procedure.

Test Procedure

Test the ThinPrep liquid cytology, VTM lesion swab, or other liquid media specimens from the Aptima Specimen Transfer tube according to the instructions in the appropriate Aptima assay or other Hologic product package insert.

Decontamination Instructions

Note: *If ThinPrep liquid cytology specimens are transferred into Aptima Specimen Transfer tubes after processing using the ThinPrep 2000 System, the ThinPrep 2000 System must be decontaminated after 8 hours of use.*

- It is important to clean the system from the top of the machine to the bottom and to change gloves as instructed in order to prevent recontamination of cleaned surfaces.
- Avoid touching the internal instrumentation wiring throughout this process.
- Only use 0.5% sodium hypochlorite solution to decontaminate the ThinPrep 2000 System.

A. Decontamination of the ThinPrep 2000 System

1. Put on clean gloves.
2. Wet a lint-free disposable wipe with 0.5% sodium hypochlorite solution.
3. Open the sample door, wipe down the slide holder with the disposable wipe, and dispose of the wipe.
4. Close the sample door.
5. Move the internal workings of the system into the maintenance position by pressing **7** then **2** and **Enter** on the keypad.
6. Open the sample door.
7. Put on clean gloves.
8. Wet a lint-free disposable wipe with 0.5% sodium hypochlorite solution and wipe down the surfaces from top to bottom. Be sure to thoroughly clean surfaces that are handled during processing such as the slide holder, fixative bath holder, and sample vial holder. Also be sure to clean the cap seal and the inside of the system's door. Dispose of the wipe.
9. Change gloves. Using a lint-free disposable wipe moistened with 0.5% sodium hypochlorite solution, clean the exterior of the system from top to bottom paying close attention to the door handle and the keypad. Dispose of the wipe.
10. Allow the 0.5% sodium hypochlorite solution to sit on the equipment for 5 minutes.
11. Return the system to the working position by closing the sample door and pressing **Enter** on the keypad.
12. Change gloves and wipe down the slide holder with a lint-free, disposable wipe soaked in DI water. Dispose of the wipe.
13. Close the sample door and enter **7** then **2** and **Enter** on the keypad to return the system to the maintenance position.
14. Open the sample door and, working from top to bottom, wipe the interior with a lint-free, disposable wipe soaked in DI water, being sure to thoroughly remove the 0.5% sodium hypochlorite solution from the cap seal. Dispose of the wipe.
15. Repeat steps 1 through 14 to ensure that decontamination is complete.

B. Lab Contamination Monitoring Protocol

There are many laboratory-specific factors that may contribute to contamination, including testing volume, workflow, disease prevalence, and various other laboratory activities. These factors should be taken into consideration when contamination monitoring frequency is being established. Intervals for contamination monitoring should be established based on each laboratory's practices and procedures. Each cytology lab must coordinate with an Aptima assay testing site in order to test samples collected for monitoring contamination and receive the sample results.

To monitor for laboratory contamination, the following procedure may be performed using the Aptima Unisex Swab Specimen Collection Kit for Endocervical and Male Urethral Swab Specimens:

1. Label the swab transport tubes with numbers corresponding to the areas of the lab that will be tested.
2. Remove the specimen collection swab (blue shaft swab with green printing) from its packaging, wet the swab in the swab transport medium and swab the numbered area using a circular motion.
3. Immediately insert the swab into the corresponding transport tube.
4. Carefully break the swab shaft at the score line. Avoid splashing the contents.
5. Re-cap the swab transport tube tightly.
6. Repeat steps 2 to 5 for all areas to be swabbed.
7. Test the swab using instructions found in the *Test Procedure* section of the appropriate assay package insert.

If the results are positive or equivocal (see the *Test Interpretation* section of the appropriate assay package insert), the surface may be contaminated and should be decontaminated by treating with 0.5% sodium hypochlorite solution as recommended in the appropriate Operator’s Manual and/or assay package insert.

Contamination Studies

ThinPrep Liquid Cytology Specimen Contamination Study for the Aptima Combo 2 Assay

To demonstrate that soaking the filter cap in 0.5% sodium hypochlorite solution (“bleaching”) is effective in reducing contamination, 200 negative and 200 high titer (>1x10^6 CFU/mL) GC positive samples were alternately processed first without the bleaching steps and, subsequently, with the bleaching steps. The GC positive samples were generated by spiking the liquid cytology sample with cell equivalents of >5x10^6 fg GC rRNA. Note that the operators changed gloves between handling each sample for both the first and second stages of the study. The same filter cap was used with all 400 samples. After processing on the ThinPrep 2000 System, 1 mL of the remaining ThinPrep liquid cytology sample was transferred to an Aptima Specimen Transfer tube (this is now referred to as the processed liquid cytology sample) then run in the Aptima Combo 2 assay. These conditions replicate the processes that are expected to be conducted in a typical clinical setting.

Additionally, an aliquot was removed from each sample prior to processing on the ThinPrep 2000 System as a control sample. This aliquot was tested when a sample produced a false positive result to determine if the contamination occurred prior to sample processing. Further, an additional 20 negative ThinPrep liquid cytology samples were added at the end of the second stage to determine if a build up of cells on the system (potentially due to the creation of aerosols) could contaminate negative samples.

Without the bleach step there were 24 false positives and 17 equivocal results among the ThinPrep liquid cytology samples for a false positive frequency of 20.5%. When the filter cap was bleached between samples the false positive frequency was 1.4% (3 false positives out of 220 negative samples). None of the pre-processed aliquots from the samples producing false results were GC-positive. This is consistent with the notion that the contamination was not introduced prior to processing the sample on the ThinPrep 2000 System; rather, contamination was likely introduced during the cytology processing.

These studies demonstrate that incorporation of a contamination mitigation protocol decreases the potential for cross-contamination introduced by the processing steps of the ThinPrep 2000 System by > 14 fold.

ThinPrep Liquid Cytology Specimen Contamination Study for the Aptima HPV Assay

ThinPrep 2000 System Study

A study was conducted to determine the false positive rate observed with the Aptima HPV assay when ThinPrep liquid cytology specimens containing a high concentration of spiked HPV-positive cells, were alternately processed with HPV-negative specimens on the ThinPrep 2000 System.

Negative samples were created by spiking 20 mL of PreservCyt solution with 3 x 10^5 HPV negative cultured cells. Prior to processing on the ThinPrep 2000 System, 1 mL of each negative sample was transferred to an Aptima Specimen Transfer tube which served as a ‘pre-processed’ negative control. High titer HPV-positive samples were created by spiking 7.5 x 10^4 HPV 16-positive cultured cells and 2.25 x 10^5 HPV-negative cultured cells into 20 mL of PreservCyt solution. HPV-positive then HPV-negative samples were alternately processed on the ThinPrep 2000 System according to the ThinPrep 2000 System instructions for use. One set of HPV-positive and HPV-negative samples were processed following the filter cap cleaning procedure (described above in *Procedural Note C*) and one set were processed without following the filter cap cleaning procedure. An aliquot of each sample was removed after processing on the ThinPrep 2000 System (post-processed samples) and transferred to an Aptima Specimen Transfer tube. The pre- and post-processed samples were tested with the Aptima HPV assay.

The false positive rate for the pre-processed negative control samples, as well as both sets of post-processed negative samples (with cleaning procedure and without) was calculated, as well as the 2-sided 95% Score confidence interval. Of the post-processed negative samples for which the cleaning procedure was followed, one false positive was observed out of the 120 tested, which resulted in a false positive rate of 0.8% (95% CI 0.1%-4.6%, 99.2% specificity). For the post-processed negative samples for which the cleaning procedure was not followed, a total of 2 false positives out of 119 negative samples tested were observed, resulting in a false positive rate of 1.7% (95% CI 0.5%-5.9%, 98.3% specificity). All three samples with false results were negative for the pre-processed negative control sample. The difference in false positive rates was not significant; -0.85% difference (95% confidence interval: -5.16% to 3.00%).

ThinPrep 5000 Processor with Autoloader (ThinPrep 5000 System) Study

A study was conducted to determine the false positive rate observed with the Aptima HPV assay when ThinPrep liquid cytology specimens containing a high concentration of spiked HPV-positive cells, were alternately processed with HPV-negative specimens on the ThinPrep 5000 System.

Residual, HPV-negative, ThinPrep liquid cytology specimens were pooled to create HPV-negative samples. HPV-positive samples were prepared by first combining residual ThinPrep liquid cytology specimens into five large negative pools. HPV 16-positive cells (SiHa) and HPV 18-positive cells (HeLa) were spiked together into the pools to achieve a concentration of 1 x 10^4 cells/mL for each cell line. HPV-positive then HPV-negative samples were alternately processed on the ThinPrep 5000 System according to the ThinPrep 5000 System instructions for use. An aliquot of each sample was removed after processing on the ThinPrep 5000 System (post-processed samples) and transferred to an Aptima Specimen Transfer tube. The pre- and post-processed samples were tested with the Aptima HPV assay.

The false positive rate for the pre- and post-processed negative samples was calculated. The pre- and post-processed negative samples each resulted in one false positive (1/250, 0.4%).

ThinPrep Genesis Processor Study

A study was conducted to determine the false positive rate observed with the Aptima HPV and Aptima HPV 16, 18/45 assays when ThinPrep liquid cytology specimens containing a high concentration of spiked HPV-positive cells, were alternately processed with HPV-negative specimens on the ThinPrep Genesis Processor.

Residual HPV-negative ThinPrep liquid cytology specimens were pooled to create HPV-negative samples. HPV-positive samples were prepared by combining residual HPV-negative ThinPrep liquid cytology specimens which were then spiked with HPV 16-positive cells (SiHa) and HPV 18-positive cells (HeLa) to achieve a concentration of 1 x 104 cells/mL for each cell line.

As a control, Manual aliquots were prepared from HPV negative samples and HPV positive samples. Then HPV-positive and HPV-negative samples were alternately processed on the ThinPrep Genesis Processor according to the "Aliquot and Slide" (aliquot prepared before cytology) option outlined in the ThinPrep Genesis Processor instructions for use. The HPV positive and HPV negative samples were then alternately processed again on the ThinPrep Genesis Processor according to the "Aliquot Only" option (aliquot prepared after cytology) Aliquots tested with the HPV 16, 18/45 Genotype assay testing yielded negative aliquot positivity rates of 0.7% [2/299], 0.3% [1/299], and 0.0% [0/299] for the Manual Control, Genesis pre-cytology and Genesis post-cytology, respectively.

Results from the Aptima HPV assay testing yielded negative aliquot positivity rates of 2.7% [8/299], 4.0% [12/299], and 2.7% [8/299] for the Manual control, Genesis pre-cytology, and Genesis post-cytology, respectively. The observed positivity rates were consistent for the three aliquots tested. This indicates the presence of low level HPV positivity in the negative clinical specimen pool. The observed positivity rate was not impacted as a result of processing specimens on the ThinPrep Genesis Processor.

Limitations

A. ThinPrep liquid cytology samples processed on the ThinPrep 5000 Systems or the ThinPrep Genesis Processor have not been evaluated for use with the Aptima GC and Aptima CT assays.

B. There is no data supporting the use of post-processed ThinPrep liquid cytology specimens with the Aptima Trichomonas vaginalis assay.

C. The Aptima Specimen Transfer Kit was evaluated using ThinPrep liquid cytology specimens collected with either broom-type or endocervical brush/spatula collection devices. The use of other collection devices was not evaluated for use in Aptima assays.

D. The effect of the ThinPrep 2000 System decontamination procedure was not assessed for its impact on cytology results. Prior to implementing the decontamination procedure, laboratories should validate that the decontamination procedure does not impact cytology results.

E. Use of these products is limited to personnel who have been trained in the use of the Aptima Specimen Transfer Kit.

F. Hologic Bleach Enhancer has not been validated for the ThinPrep 2000 System decontamination procedure.

G. If a liquid cytology specimen has small amounts of cellular material, uneven distribution of this material may occur, which may affect the ability to detect target organisms in the collected material. If negative results from the specimen do not fit with the clinical impression, a new specimen may be necessary. When compared to direct sampling with the Aptima swab transport medium, the additional volume of PreservCyt solution results in greater dilution of the sample material.

H. Test results may be affected by improper specimen collection, storage or specimen processing.


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