

Wyoming Public Health Laboratory

Combined Laboratories Facility
208 South College Drive
Cheyenne, WY 82002
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CHLAMYDIA/GONORRHEA COLLECTION PROTOCOL

The Aptima Combo 2 nucleic acid amplification test requires specimen collection with a specific collection kit dependent on the specimen collection site to be tested. Follow the criteria described for the specimen type: Female endocervical swab, male urethral swab, urines, rectal and pharyngeal swabs, and female self-collected vaginal swabs. Accurate testing is directly related to adequate collection.

DO NOT CONTAMINATE THE OUTSIDE AND SILVER TOP OF THE TUBES DURING COLLECTION. Do not pour out transport liquid in collection tube.

CRITERIA FOR REJECTION: Specimens may be rejected for expired collection tubes, incorrect specimen tube for specimen type, over or under filled urine tube, improper swab used, no swab or two swabs in tube, unlabeled tube, leaked in transit, specimen too old.

SPECIMEN SHIPMENT: Collect specimens following specific directions below. DO NOT CONTAMINATE THE OUTSIDE AND SILVER TOP OF THE TUBES DURING COLLECTION. Do not pour out transport liquid in collection tube. Label tubes with patient name. Store and transport collected specimens at 2-30° C. Complete WPHL test request form.

If using WPHL mailing containers, place specimen in the biohazard bag with absorbent paper and put into the aluminum container. Wrap the completed WPHL test request form around the outside of the aluminum container and insert this into the cardboard mailing container.

If not using the WPHL mailing containers, place the specimen in the biohazard bag with absorbent paper and insert the completed WPHL test request form into the outside pocket of the bag. Then place into an approved shipping container.

Ship as diagnostic specimen following postal or carrier shipping regulations.

<http://www.health.wyo.gov/phsd/lab/index.html>

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SPECIMEN COLLECTIONS:

FEMALE ENDOCERVICAL SWAB – blue unisex swab kit

Remove excess mucus from cervical os and surrounding mucosa using WHITE SWAB provided. DISCARD SWAB. Insert BLUE UNISEX COLLECTION SWAB from kit into endocervical canal. Rotate swab clockwise for 10-30 seconds. Withdraw swab carefully, avoiding contact with vaginal mucosa. Insert swab into transport tube and break off at score line. Cap tightly and label tube.

MALE URETHRAL SWAB – blue unisex swab kit

PATIENT SHOULD NOT HAVE URINATED FOR AT LEAST 1 HOUR PRIOR TO COLLECTION. Insert BLUE UNISEX COLLECTION SWAB from kit 2-4 cm into urethra. Gently rotate swab clockwise 2-3 seconds to ensure adequate sampling. Withdraw swab and insert into transport tube. Break off at score line. Cap tightly and label tube.

URINES FOR MALE OR FEMALE– yellow urine collection kit

PATIENT SHOULD NOT HAVE URINATED FOR AT LEAST 1 HOUR PRIOR TO COLLECTION. DO NOT CLEAN area prior to collection. Direct patient to collect 20-30 ml of INITIAL URINE STREAM in urine cup. Larger volumes will dilute specimen and reduce test sensitivity. The disposable kit pipette has a 2 ml mark at the base of the bulb. Squeeze the bulb and DRAW UP 2ml URINE from the cup. Dispense into the urine transport tube. The resulting liquid level will be BETWEEN THE TWO BOLD LINES in the middle of view window on the side of the tube. DO NOT over or under fill the tube. Cap tightly and label tube.

DO NOT send urine in specimen cup. Dispose of urine cup and pipette. DO NOT reuse. Female urine testing is not intended to replace cervical exams and endocervical samples.

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MALE OR FEMALE RECTAL or PHARYNGEAL SWAB – blue unisex collection kit

These specimen types are not FDA-approved for use with the APTIMA Combo 2 assay. However, the WPHL has performed a validation study which meets CLIA requirements and demonstrates the APTIMA Combo 2 assay is acceptable for testing rectal and pharyngeal specimens at our facility. Results will include a disclaimer.

Submission criteria for rectal and pharyngeal specimens: Please complete a thorough health history to determine these risk categories before performing any rectal or pharyngeal testing. Testing criteria should include MSM and heterosexuals with a history of anal intercourse or oral sex WITH a high index of suspicion of infection.

RECTAL SPECIMEN: Insert the blue unisex swab approximately 3-5 cm into the rectum and rotate against the rectal wall several times (at least 3). Swabs that are grossly contaminated with feces should be discarded and the collection repeated. Insert the swab into the blue transport tube. Break off at score line. Cap tightly and label tube.

PHARYNGEAL SPECIMEN: Insert the blue unisex swab and rotate against the back wall of the pharynx several times (at least 3). Insert the swab into the blue transport tube. Break off at score line. Cap tightly and label tube.

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VAGINAL SELF COLLECTED SPECIMEN: orange swab collection kit

Vaginal swabs are used to obtain a self-collected specimen by the patient.

Accuracy is dependent on understanding and following the collection instructions. The following includes both diagrams and instructions for the patient. A set of instructions and helpful tips is also included for the provider and clinic. Please review all instructions with the patient before collection.

Provider/Clinic instructions:

In the restroom, loosen cap and place silver-side down on a clean paper towel.

Place open collection tube in a tube rack.

Instruct patient about importance of holding the swab with the THUMB AND FINGER OVER THE GRAY LINE on the middle of the swab shaft for collection, placing swab into open tube - soft tip down, and breaking swab shaft without spilling tube contents.

Explain how to screw cap on without touching inside edges or the silver top.

Clean restroom after each patient by using a 50/50 bleach solution to wipe down the toilet handle, faucet handles, light switch and door knobs.

Keep an extra orange vaginal swab out as an example. Show patient the GRAY LINE in the middle of the swab shaft. Stress the importance of holding the swab with the THUMB AND FINGER OVER THE GRAY LINE on the middle of the swab shaft for collection. The score in the middle of the swab has been known to break during collection!

Vaginal collection kit should only to be used at the clinic. Do not send home with the patient.

If patient drops the cap, use a new one. If she drops the swab, have her recollect with a new kit. ONLY use swabs provided in the kit.

Self collected vaginal collection can occur less than 1 hour since last void.

Continued

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Keep in mind that contamination can occur, so clean restroom after each patient use.

“The performance of vaginal swab specimens has not been evaluated in pregnant women” - from Gen-Probe APTIMA package insert.

Note: Spanish versions of the small instructions are available from Gen-Probe.

Patient instructions:

Remove cap from test tube without touching the inside of the cap or tube. Set cap silver-side down on clean paper towel. Set open tube in test tube rack as shown in Figure 1. If cap is dropped, please notify clinic staff.

Partially open the swab package as shown in Figure 2.

Remove the swab but do not touch the soft tip or lay the swab down. Hold swab between thumb and finger in the middle of the swab shaft as shown in Figure 3.

Insert the swab into your vagina about 2 inches and gently rotate the swab for 10-30 seconds as shown in Figure 4.

Withdraw the swab without touching the skin. Place the swab into the test tube so that the tip of the swab is visible below the tube label as shown in Figure 5.

Break the swab shaft against the side of the tube at the “gray score-line” as shown in Figure 6. Be careful not to splash the contents of the tube. If tube is dropped, contents spilled, or if the swab flips out of the tube, please notify clinic staff.

Re-cap the tube tightly without touching the inside of the cap or the silver top as shown in Figure 7.

DIAGRAMMED INSTRUCTIONS FOLLOW

<http://www.health.wyo.gov/phsd/lab/index.html>

Directions for Self-collected Vaginal Swab

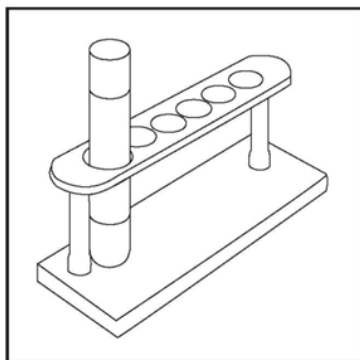


Figure 1.

Remove cap from test tube without touching the inside of the cap or tube. Set cap silver-side down on clean paper towel. Set the open tube in test tube rack as shown in Figure 1. If cap is dropped, please notify clinic staff.

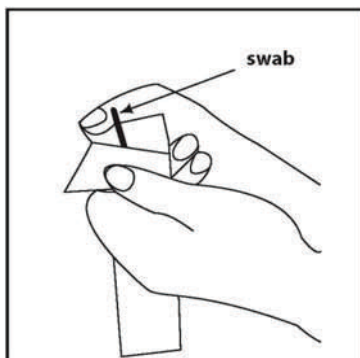


Figure 2.

Partially open the swab package as shown in Figure 2.

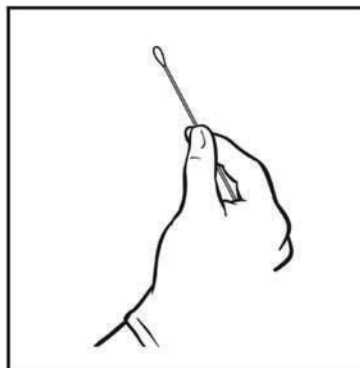


Figure 3.

Remove the swab but do not touch the soft tip or lay the swab down. Hold the swab with the THUMB AND FINGER OVER THE GRAY LINE on the middle of the swab shaft as shown in Figure 3.



Figure 4.

Insert the swab into your vagina about 2 inches and gently rotate the swab for 10-30 seconds as shown in Figure 4.

Directions for Self-collected Vaginal Swab

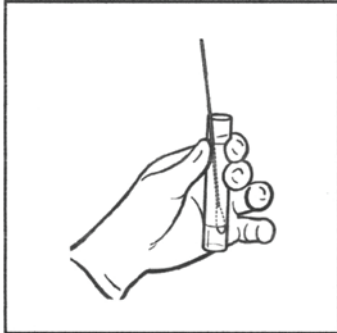


Figure 5.

Withdraw the swab without touching the skin. Place the swab into the test tube so that the tip of the swab is visible below the tube label as shown in Figure 5.

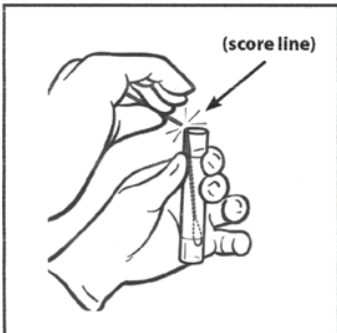


Figure 6.

Break the swab shaft against the side of the tube as shown in Figure 6. Be careful not to splash the contents of the tube. If tube is dropped, contents spilled, or if the swab flips out of the tube, please notify clinic staff.

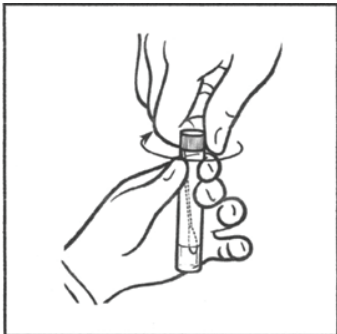


Figure 7.

Re-cap the tube tightly without touching the inside of the cap or the silver top as shown in Figure 7.