Instructions for collection and submission of urine for *N. gonorrhoeae, C. trachomatis or T. vaginalis* testing using GEN-PROBE[®] APTIMA[®] urine collection kit

I. Collection kit

- A. Unit 2-U (IATA Category B)-collection kit for urine specimens (yellow-labeled tube).
- B. Check the expiration date. Do not use an expired collection kit.

II. Patient preparation and sample collection

- A. Make sure the patient has not urinated for at least 1 hour prior to specimen collection. Female patient should not cleanse the labial area prior to providing the specimen.
- B. Mark the 20–30 ml fill line on a clean, preservative-free container such as a paper or plastic disposable cup.
- C. Instruct the patient to collect the first 20-30ml (**NOT MIDSTREAM**) of the urine stream in a sterile cup without preservatives. If a larger amount is collected, it may affect testing.

D. Transport tube

- 1. Put on gloves and remove the cap from the transport tube. <u>Do not pour off the liquid</u> <u>preservative contents from the tube.</u>
- 2. Use the disposable pipette (provided) to transfer 2ml of the urine sample into the transport tube. The correct volume of urine has been added when the fluid level in the tube is between the two black lines marked "Fill Area".

NOTE: If the fluid level is not between the two black lines, the specimen will not be tested.

- 3. Screw the cap on the transport tube as evenly and tightly as possible. Tape or Para-film® around the cap, but **DO NOT** put tape over the top of the cap.
- 4. Dispose of the pipette and the container used to collect the urine as medical waste.

III. Labeling

- A. Label the transport tube with the complete patient name and at least 1 unique identifier (For example: specimen number, date of birth, medical record number, etc.)
- B. Verify the patient's identity at the time of collection. Best practice is to ask patient to spell their first and last name
- C. Enter the required information on the test requisition form (DCH-0583). The patient name and unique identifier on the form must be entered **exactly** the same as the information on the tube.
- D. If there are multiple specimens from the same patient, use a separate test requisition and collection kit for each specimen.

IV. Packaging and Shipping

- A. Specimens should be sent to MDHHS immediately after collection.
- B. Specimens can be shipped at ambient temperature.
- C. Insert the specimen and absorbent pad into the small plastic bag provided. Make sure it is sealed. Place in the large plastic bag with the Biohazard symbol (Bio-Bag).
- D. Place the completed MDHHS test requisition (DCH-0583) in the outside pocket of the Bio-Bag. Seal the bag.

Michigan Department of Health and Human Services DCH - 0975 May 13, 2022

- E. Close the box and secure with sealing tape on both sides of the flap.
- F. Attach the completed address label with the UN3733 label included in the kit.
- G. Send to the Michigan Department of Health and Human Services, Lansing laboratory as soon as possible (e.g. courier or United Parcel Service (UPS), etc.).
- H. Instructions are also available by visiting, <u>http://www.Michigan.gov/mdhhslab</u>
- I. The specimen will NOT be tested if:
 - 1. The specimen container is received leaking.
 - 2. The specimen is not properly labeled or the test requisition not completed.
 - 3. The specimen label does not match the test requisition.
 - 4. The specimen was collected using an expired collection kit.
 - 5. The urine was collected more than 30 days ago.
 - 6. The specimen is collected with the wrong collection device.
- V. Packaging and shipping are the responsibility of the shipper. Please be sure it is in compliance with shipping regulations.



Unit 2-U-Chlamydia & Gonorrhea Amplified Test-Urine Tube