PROGRAM Standard Operating Procedure – Laboratory Services	
Title: MIC10350 – OSOM *Trichomonas* Rapid Test	Policy Number: 15-147-V1
Program Name: Laboratory Services	
Applicable Domain: Lab, DI and Pharmacy Services	
Additional Domain(s): NA	
Effective Date: 18/03/2024	Next Review Date: 18/03/2026
Issuing Authority: Director, Laboratory and Diagnostic Imaging Services	Date Approved: 18/03/2024
Accreditation Canada Applicable Standard: NA	

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GUIDING PRINCIPLE:
The OSOM *Trichomonas* Rapid Test is intended for the qualitative detection of *Trichomonas vaginalis* antigens from genital swabs. This test is intended for use in patients with symptoms of vaginosis/vaginitis or suspected exposure to the *Trichomonas* pathogen.

PURPOSE/RATIONALE:
This standard operating procedure describes the OSOM *Trichomonas* Rapid Test.

SCOPE/APPLICABILITY:
This standard operating procedure applies to Medical Laboratory Technologists (MLTs) processing genital specimens for *Trichomonas* testing using the OSOM *Trichomonas* Rapid Test.

SAMPLE INFORMATION:

Type	Swab • Amie's with or without charcoal
Source	• Cervix • Vagina • Urethra
Stability	If the sample is received in the laboratory and processed greater than 48 hours from collection: • Add specimen quality comment: "Delayed transport may adversely affect pathogen recovery"
Storage Requirements	Room temperature or refrigerated

Criteria for rejection	1. Unlabeled/mislabeled samples 2. Sample container label does not match patient identification on requisition

SUPPLIES:
- OSOM *Trichomonas* Rapid Test kit

EQUIPMENT:
- Timer

ENVIRONMENTAL CONTROLS:
- Store Test Sticks and reagents tightly capped at 15°C to 30°C
- Do not freeze test components

SPECIAL SAFETY PRECAUTIONS:
Containment Level 2 facilities, equipment, and operational practices for work involving infectious or potentially infectious materials or cultures:
- Ensure that appropriate hand hygiene practices be used
- Lab gown must be worn when performing activities with potential pathogens
- Gloves must be worn when direct skin contact with infected materials is unavoidable
- Eye protection must be used when there is a known or potential risk of exposure of splashes
- All procedures that may produce aerosols, or involve high concentrations or large volumes should be conducted in a biological safety cabinet (BSC)
- The use of needles, syringes and other sharp objects should be strictly limited

All patient specimens are assumed to be potentially infectious. Routine Practices must be followed. Since viable micro-organisms are used, all cultures must be handled with appropriate precautions. All equipment in contact with cultures should be decontaminated by appropriate methods.

QUALITY CONTROL:
- <u>Internal Controls:</u>
  1. The appearance of the red control line in the result window indicates that adequate sample volume was present, and that adequate capillary migration of the sample has occurred. It also verifies proper assembly of the Test Stick. If a red control line does not appear, then the test is invalid.
  2. The clearing of the background in the results area is an internal negative control and also serves as an additional capillary flow control. At read time the background should appear white to light grey and not interfere with the reading of the test. The test is invalid if the background fails to clear and hides the appearance of a distinct control line.

- External Control:
  1. The test kit includes a positive control swab for external quality control testing. Run the positive control when opening a new kit, and record results in TQC.
  2. To perform a positive control test, complete the steps under Procedure Instructions, starting at step #2.

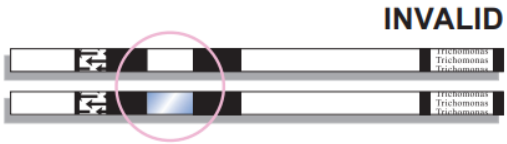
PROCEDURE INSTRUCTIONS:

Step	Action
Processing swabs for *Trichomonas* Rapid Test	
1	Make a smear for the BV screen before performing the *Trichomonas* rapid test if requested.
2	Label a plastic test tube included in the kit with the media label.
3	Using the dropper, add 0.5mL of Sample Buffer to the test tube by filling the dropper to the line and expelling the entire contents into the tube.
4	Place the swab into the tube. Vigorously mix the solution by rotating the swab forcefully against the side of the tube at least 10 times (while submerged). Allow the swab to soak in the solution for 1 minute.
5	Squeeze out as much liquid as possible from the swab by pinching the side of the test tube while removing the swab. Discard swab into a biohazard bin.
6	Remove a Test Stick from the canister and place Stick (with arrows pointing down) into the solution in the tube. Recap the canister immediately.
7	Read results at 10 minutes. (Some positive results may be seen earlier).

INTERPRETATION OF RESULTS:

Step	Action
1	The appearance of a red control line, with or without a blue test line indicates a valid result. A blue or red line that appears uneven in colour shading is still considered a valid line. In cases of moderate or high positive specimens, some colour behind the test line may be seen. As long as the test line and the control line are visible, the results are valid.
2	Positive result: A blue test line and a red control line is a positive result for *Trichomonas* antigen. **NOTE:** The red and blue lines can be any shade of that colour
3	Negative result: A red control line but no blue test line is a negative result. A negative result means that no *Trichomonas* antigen was detected, or that the level of the antigen in the sample was below the detection limit of the assay.
4	Invalid result: If no red control line appears, or background colour makes reading the red control line impossible, the result is invalid. If this occurs, repeat the test on a new specimen.

REPORTING INSTRUCTIONS:

IF	REPORT
A red Control Line but no blue Test Line 	**NEGATIVE**
A red Control Line and a blue Test Line 	**POSITIVE**
If no red Control line appears, or background colour makes reading the red control line impossible 	**INVALID** • From the keypad add key R to add repeat sample collection comment

LIMITATIONS:

1. The test is intended for use in patients with symptoms of vaginosis / vaginitis or suspected exposure to the *Trichomonas* antigen.
2. The test does not differentiate between viable and non-viable organisms. Results must be used only as an adjunct to other information available to the physician.
3. A negative result may be obtained if the specimen collection is inadequate or if antigen concentration is below the sensitivity of the test.
4. Specimens contaminated with preparations containing iodine or by the immediate prior use of vaginal lubricants are not recommended.

REFERENCES:

1. SEKISUI DIAGNOSTICS. (11/2021). *OSOM Trichomonas Rapid Test* package insert, revision: 3084-2

APPROVAL:

March 18, 2024
Date

REVISION HISTORY:

REVISION	DATE	Description of Change	REQUESTED BY
1.0	13 Jul 23	Initial Release	L. Steven
2.0	14 Feb 24	Procedure reviewed	L. Steven