SAMPLE PROCEDURE

This “Sample Procedure” is not intended as a substitute for your facility’s Procedure Manual or reagent labeling, but rather as a model for your use in customizing for your laboratory’s needs.

Space has been provided within the document to allow you to update this template with information specific to your facility. It is suggested that a current version of the manufacturer’s directional insert be maintained as a supplement.

PROCEDURE

Title: Sekisui Diagnostics OSOM® Trichomonas Rapid Test

Procedure #:

Institution: _____

Prepared by: _____ Date:_____

Title: _____

Accepted by: _____ Date adopted: _____

Title: _____

Reviewed by:_____ Date:_____

_____ _____

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_____ _____

_____ _____

Discontinued by:_____ Date:_____

I. TEST NAME

OSOM® Trichomonas Rapid Test
CLIA Complexity: Waived

II. INTENDED USE

The OSOM® Trichomonas Rapid Test is intended for the qualitative detection of *Trichomonas vaginalis* ("Trichomonas") antigens from vaginal swabs or from the saline solution prepared when making wet mounts from vaginal swabs. This test is intended for use in patients with symptoms of vaginosis/vaginitis or suspected exposure to the Trichomonas pathogen.

III. SUMMARY AND EXPLANATION OF TEST

Trichomonas infection is responsible for the most common, non-viral sexually transmitted disease (vaginitis or trichomoniasis) worldwide. Trichomoniasis is a significant cause of morbidity among all infected patients[1,2]. Effective diagnosis and treatment of Trichomonas infections have been shown to eliminate symptoms[2]. Conventional identification procedures for Trichomonas from vaginal swabs or vaginal washes involve the isolation and subsequent identification of viable pathogens by wet mount microscopy or by culture[3], a process that can take 24–120 hours. Wet mount microscopy has a reported sensitivity of 58% versus culture[4]. The OSOM® Trichomonas Rapid Test is an immunochromatographic assay that detects pathogen antigens directly from vaginal swabs. Results are rapid, occurring within approximately 10 minutes.

IV. PRINCIPLES OF TEST

The OSOM® Trichomonas Rapid Test uses color immunochromatographic, capillary flow, "dipstick" technology. The test procedure requires the solubilization of Trichomonas proteins from a vaginal swab by mixing the swab in Sample Buffer. The OSOM® Trichomonas Rapid Test Stick is then placed in the sample mixture and the mixture migrates along the membrane surface. If Trichomonas is present in the sample, it will form a complex with the primary anti-Trichomonas antibody conjugated to colored particles (blue). The complex will then be bound by a second anti-Trichomonas antibody coated on the nitrocellulose membrane. The appearance of a visible blue test line along with the red control line will indicate a positive result.

V. KIT CONTENTS AND STORAGE

25 Test Sticks
25 Sterile Swabs
25 Test tubes
1 Sample Buffer vial, 25 ml (saline buffer with 0.01% sodium azide)
1 Sample Buffer dropper top
1 Positive control swab (contains sodium azide and a desiccant tablet)
1 Workstation
1 Directional Insert
Note: Extra components (tubes, swabs) have been provided for your convenience.
Warning: Contains Sodium Azide

STORAGE CONDITIONS

- Store Test Sticks and reagents tightly capped at room temperature 15°-30°C (59°-86°F).
- Do not freeze
- Do not use Test Sticks and reagents after expiration date.
- Discard unused Test Sticks that have been removed from the canister after 1 hour.

At this facility, kits are stored: _____.

VI. MATERIALS REQUIRED BUT NOT PROVIDED

A timer or a watch.

VII. WARNINGS AND PRECAUTIONS

- For *in vitro* diagnostic use only.
- Follow your clinical and/or laboratory safety guidelines in the collecting, handling, storaging, and disposing of patient specimens, and all items exposed to patient specimens. Swabs, test tubes, and Test Sticks are for single use only.
- The Sample Buffer contains a saline solution with a preservative (sodium azide) and a detergent at low concentrations. If solution comes in contact with the skin or eyes, flush with lots of water.
- Solutions that contain sodium azide may react explosively with lead or copper plumbing. Use large quantities of water to flush discarded solutions down a sink.
- Do not use or mix components from different kit lots.

VIII. PATIENT PREPARATION & SPECIMEN COLLECTION

This facility's procedure for patient preparation is: _____.

_____.

This facility's procedure for sample labeling is: _____.

_____.

Specimen Collection and Handling:

- Collect specimens from the vaginal cavity with a sterile rayon swab supplied in the kit.
- Use of the swabs supplied in the kit or BD BBL™ CultureSwab™ (sterile or with Liquid Stuarts Media) is recommended. Swabs from other suppliers have not been validated. Swabs with cotton tips or wooden shafts are not recommended.
- Process the swab as soon as possible after collecting the specimen. Specimens may be held at room temperature for no longer than 24 hours. Swabs may also be stored at 4° C or -20° C for up to 36 hours.
- To transport patient samples place swab in a clean, dry container such as a plastic or glass tube.
- The solution remaining in the test tube used for the wet mount may also be used as the sample for the OSOM® test. **To use this sample type, soak a new kit swab in this solution. Using this swab, perform the complete test procedure detailed below.** There must be enough solution left after the wet mount to soak the new swab completely. These saline specimens may be held at room temperature for no longer than 24 hours. These specimens may also be stored at 4° C or -20° C for up to 36 hours.
- To run a culture as well as the OSOM® Test, separate swabs must be collected because the Sample Buffer will kill Trichomonas organisms.

This facility's procedure for transporting specimens is: _____.

_____.

This facility's procedure for rejected specimens is: _____.

_____.

IX. QUALITY CONTROL & ASSURANCE

The OSOM Trichomonas Rapid Test provides two methods of control for the assay: internal controls to aid in determining test validity, and external controls to demonstrate proper test function.

Internal Procedural Controls
Several controls are incorporated into each Test Stick for routine quality checks.

1. The appearance of the control band in the results window is an internal positive procedural control:

   ***Test System*:** The appearance of the control line assures that adequate sample volume was present. It also assures that adequate capillary migration of the sample has occurred. It also verifies proper assembly of the Test Stick.

   ***Operator*:** The appearance of the control line indicates that an adequate volume of sample was present for capillary migration to occur. If the control line does not appear at the read time, the test is invalid.

2. The clearing of the background in the results area may be documented as an internal negative procedural control. It also serves as an additional capillary flow control. At the 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 band. If any background color does not clear and interferes with the test result, the test may be invalid. Call Sekisui Diagnostics Technical Service at (800) 332-1042 if you experience a problem.

External Quality Control Testing
OSOM® Test kits include a Positive Control Swab for external quality control testing. Kit swabs may be used as negative controls. Additional Positive Control Swabs may be purchased separately. The Trichomonas Positive Control Kit is catalog number 182. Use the Controls to ensure that the Test Sticks are functioning properly. Also, the Controls may be used to demonstrate proper performance by the test operator. Quality Control requirements should be established in accordance with local, state and federal regulations or accreditation requirements. Minimally, Sekisui Diagnostics recommends that positive and negative external controls be run with each new lot, and with each new untrained operator.

QC Testing Procedures
The Positive Control Swab is impregnated with sufficient Trichomonas antigen to produce a visible positive test result. To perform a positive or negative control test, complete the steps in the Test Procedure section treating the control swab in the same manner as a specimen swab.

QC Testing Frequency and Documentation
For this facility, External QC is run: _____

_____

Results of External QC and action(s) taken when control results are unacceptable are documented:

_____

_____

X. TEST PROCEDURE

When opening kit for the first time, unscrew the cap from the Sample Buffer bottle and replace it with the dropper top included in the kit. Discard the original Sample Buffer cap.

STEP 1: ADD SAMPLE BUFFER
Using the supplied dropper top, add 0.5 mL of Sample Buffer to each test tube. Fill the dropper to the line indicated on the barrel of the dropper top and expel entire contents into tube. **Note: Add Sample Buffer to the tube before putting in the specimen swab to prevent contaminating the Sample Buffer vial.**

STEP 2: MIX SWAB IN BUFFER
Put the specimen swab into the tube. Vigorously mix the solution by rotating the swab forcefully against the side of the tube at least ten times (while submerged). Best results are obtained when the specimen is vigorously mixed in the solution. Allow the swab to soak in the Sample Buffer for one minute prior to Step 3.

STEP 3: SQUEEZE LIQUID FROM SWAB
Squeeze out as much liquid as possible from the swab by pinching the side of the flexible test tube as the swab is removed. At least 1/4" of Sample Buffer solution must remain in the tube for adequate capillary migration to occur. Discard the swab in a suitable biohazardous waste container.

STEP 4: ADD TEST STICK AND INCUBATE
Remove the OSOM® Test Stick from the canister package. Recap the canister immediately. Place the absorbent end (indicated with arrows, see picture) of the Test Stick into the Sample Buffer solution in the tube. Unused sticks removed from the canister should be discarded after 1 hour.

STEP 5: READ RESULTS
Read results at 10 minutes (some positive results may be seen earlier). See interpretation of results section. Test is invalid beyond the stated read time. **Note: To see the Result Window clearly, remove the Test Stick from the test tube while reading results.**
Discard used test tubes and Test Sticks in suitable biohazardous waste container.

For this facility, sample swabs, used test tubes and Test Sticks are disposed:_____

XI. INTERPRETATION OF RESULTS

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 color shading is still considered a valid line. In cases of moderate or high positive specimens, some color behind the Test Line may be seen. As long as the Test Line and the Control Line are visible, the results are valid.

Positive
A blue Test Line and a red Control Line is a positive result for the detection of Trichomonas antigen. Note that the red and blue lines can be any shade of that color and can be lighter or darker than the line in the picture.

Negative
A red Control Line but no blue Test Line is a presumptive 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.

Invalid
If no red Control Line appears or background color makes reading the red Control Line impossible, the result is invalid. If this occurs, repeat the test on a new Test Stick or contact Sekisui Diagnostics' Technical Service.

In the event this test becomes inoperable, this facility's course of action for patient samples is: ____

_____

XII. RESULT REPORTING

This facility's procedure for patient result reporting is: _____

_____

_____

_____

XIII. LIMITATIONS

- The OSOM® Trichomonas Rapid Test is only for the qualitative detection of *T. vaginalis* antigen from vaginal swabs and the saline solution remaining from a wet mount of a vaginal swab.
- The performance of the OSOM® Trichomonas Rapid Test with specimens other than vaginal fluid or the saline solution remaining from a wet mount of a vaginal swab has not been established.
- The results obtained with this kit yield data that must be used only as an adjunct to other information available to the physician.
- This test does not differentiate between viable and non-viable organisms.
- This test does not differentiate between individuals that are carriers and individuals that have an acute infection.
- Patients with vaginitis/vaginosis symptoms may have mixed infections. Therefore a test indicating the presence of *T. vaginalis* does not rule out the presence of Candida vulvovaginitis or Bacterial vaginosis.
- A negative result may be obtained if the specimen collection is inadequate or if antigen concentration is below the sensitivity of the test. A negative OSOM® Trichomonas Rapid Test result may warrant additional patient follow up.
- Women with vaginal discharge should be evaluated for risk factors of cervicitis and pelvic inflammatory disease and for other organisms including *Neisseria gonorroeae* and *Chlamydia trachomatis*.
- Samples contaminated with preparations containing iodine or by the immediate prior use of vaginal lubricants are not recommended.
- *Staphylococcus aureus* in specimens at concentrations higher than $1x10^8$ organisms per mL may interfere with the test results in negative samples. These concentrations of *S. aureus* are higher than would be expected to be present in normal patient samples[5].

XIV. EXPECTED RESULTS

Studies have shown that the incidence of Trichomonas infections by culture in women presenting to STD clinics is between 8-37%[1,2]. In a clinical trial involving the OSOM® Trichomonas Rapid Test at seven sites, including STD clinics, hospital emergency departments, and public health clinics, the prevalence of Trichomonas Infections detected by culture or wet mount ranged from 13% to 29%. Up to 50% of women infected with Trichomonas may not be aware of symptomology. The highest incidence of this disease is found in women with at-risk factors that predispose them to acquiring

sexually transmitted diseases. Trichomoniasis also has a high likelihood of co-infection with other STDs, including those that also result in symptoms of vaginitis.

XV. CROSS REACTIVITY

The OSOM® Trichomonas Rapid Test has been shown to be non-reactive with normal vaginal flora and infectious agents (including *Gardnerella vaginalis* and Candida species).

Positive and negative control samples were tested against the following potential interferents with no affect on the performance of the OSOM® Trichomonas Rapid test:

Organisms

Bacteriodes merdae	*Mobuluncus curtsii*
Candida albicans	*Monella choleraesuis*
Chlamydia trachomatis	*Salmonella typhimurium*
Escherichia coli	*Shigella flexneri*
Gardnerella vaginalis	*Staphylococcus aureus*
Tritrichomonas foetus	*Streptococcus agalactiae*
Neisseria gonorrhoeae	

T. foetus, C. trachomatis, and *C. albicans* samples tested at approximately 0.5 x 10^5 . All other samples tested at approximately 1x10^8 organisms/mL. *Staphylococcus aureus* in specimens at concentrations higher than 1x10^8 organisms per mL may interfere with the test results in negative samples. These concentrations of *S. Aureus* are higher than would be expected to be present in normal patient samples[5].

Other Substances

Condoms, with spermicide	Human blood
Douche (vinegar)	TYM Culture Medium
HeLa cells	Vaginal yeast treatment (Monistat® brand)
HVEC cells	

Samples contaminated with preparations containing douche medicated with iodine may interfere with negative samples (please refer to Limitations section).

XVI. PERFORMANCE CHARACTERSITICS & POL STUDIES

Refer to directional insert – OSOM® Trichomonas Rapid Test

XVI. REFERENCES

Refer to directional insert – OSOM® Trichomonas Rapid Test

XVII. ASSISTANCE

For technical assistance contact Sekisui Diagnostics Technical Service at (800) 332-1042.