OSOM® Trichomonas Rapid Test
CLIA Waived

Genzyme Diagnostics
Point of Care Diagnostic Products
Welcome to the Genzyme OSOM® Trichomonas Rapid Test Waived Testing Handbook. This packet has been put together as an aid in meeting many of the regulations surrounding waived testing. The Genzyme OSOM® Trichomonas Rapid Test kit has a CLIA complexity of WAIVED.

Within this packet you will find:

✧ Some information you may find useful
✧ CLSI formatted procedure (also available via email upon request)
✧ Patient and QC Log Sheets
✧ Competency Exam, Answer Key, and Training Certificate
✧ Material Safety Data Sheets (MSDS)
✧ Regulatory Information and Accrediting Agencies
✧ Proficiency Test Information and Providers

OSOM® is a registered trademark of Genzyme Corporation.
CLIA Complexity: Waived

CPT Code: 87808QW (QW for reimbursement with Medicare or Medicaid only).

Kit Storage: Store Test Sticks and reagents tightly capped at 15°C - 30°C (59° - 86°F).

Specimen: 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.
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.

Specimen Storage: 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.

Quality Control: Several controls are incorporated into each OSOM® Trichomonas test device as routine quality checks. 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. 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.

Minimally, Genzyme Diagnostics recommends that positive and negative external controls be run with each new lot, and with each new untrained operator.
(Your laboratory may have additional local, state, federal or accreditation requirements).
Procedural Tips: Specimens and Test Sticks should be at Room Temperature.

Read the results at 10 minutes. Results are considered invalid beyond the stated read time.

Refer to the Package Insert for specific information and additional procedural notes.

Expected Results: Studies have shown that the incidence of Trichomonas infections by culture in women presenting to STD clinics is between 8-37%. 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.

For further assistance, please call the Genzyme Technical Marketing Hotline at:

TELEPHONE: 800-332-1042 (US only)
FAX: 800-762-6311
WEB: www.genzymediagnostics.com
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.
PROCEEDURE

Title: Genzyme Diagnostics OSOM® Trichomonas Rapid Test

Procedure #:

Prepared by: _____________________________ Date: __________________________

Title:  ________________________________________________________________

Accepted by: _____________________________ Date: __________________________

Reviewed by: _____________________________ Date: __________________________

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2
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 trichomoniaisis) worldwide. Trichomoniaisis is a significant cause of morbidity among all infected patients. Effective diagnosis and treatment of Trichomonas infections have been shown to eliminate symptoms. 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, a process that can take 24–120 hours. Wet mount microscopy has a reported sensitivity of 58% versus culture. 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, storing, 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.
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 Genzyme 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, Genzyme 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
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 Genzyme 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 gonorrhoea* 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.

**XIV. EXPECTED RESULTS**

Studies have shown that the incidence of Trichomonas infections by culture in women presenting to STD clinics is between 8-37%. 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:

<table>
<thead>
<tr>
<th>Organisms</th>
</tr>
</thead>
<tbody>
<tr>
<td><em>Bacteriodes merdae</em></td>
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<tr>
<td><em>Candida albicans</em></td>
</tr>
<tr>
<td><em>Chlamydia trachomatis</em></td>
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<tr>
<td><em>Escherichia coli</em></td>
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<tr>
<td><em>Gardnerella vaginalis</em></td>
</tr>
<tr>
<td><em>Trichomonas foetus</em></td>
</tr>
<tr>
<td><em>Neisseria gonorrhoeae</em></td>
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</tbody>
</table>

*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.
<table>
<thead>
<tr>
<th>Other Substances</th>
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</thead>
<tbody>
<tr>
<td>Condoms, with spermicide</td>
</tr>
<tr>
<td>Douche (vinegar)</td>
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<tr>
<td>HeLa cells</td>
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<tr>
<td>HVEC cells</td>
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</tbody>
</table>

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

**XVI. PERFORMANCE CHARACTERISTICS & 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 Genzyme Diagnostics Technical Service at (800) 332-1042.
# OSOM® Trichomonas Patient Test Log

**Hospital/Clinic Name:** ________________________________  
**Received Date:** ______________  
**Date in Use:** ______________  
**Kit Lot #:** ___________________  
**Exp. Date:** ______________  

**EXTERNAL QC:** Refer to QC log for Positive and Negative control results  
**TEST RESULTS:**  
*Negative* = a red Control line only  
*Positive* = a blue Test line and a red Control line

<table>
<thead>
<tr>
<th>Date</th>
<th>Operator</th>
<th>Patient Name/ ID</th>
<th>Test Result (Neg/Pos)</th>
<th>Red Control Line Visible?</th>
<th>Clear Background?</th>
<th>Comments/Actions</th>
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<tbody>
<tr>
<td>1</td>
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<td>Positive Control</td>
<td>Exp. Date:</td>
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<td>2</td>
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<td>Negative Control</td>
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## OSOM® Trichomonas Patient Test Log (page 2)

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<tr>
<th>Date</th>
<th>Operator</th>
<th>Patient Name/ ID</th>
<th>Test Result (Neg/Pos)</th>
<th>Comments/Actions</th>
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### INTERNAL QUALITY CONTROL

<table>
<thead>
<tr>
<th>Red Control Line Visible?</th>
<th>Clear Background?</th>
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<tbody>
<tr>
<td>Y/ N</td>
<td>Y/ N</td>
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</table>

*IF "NO" ANSWERED ABOVE, TEST IS INVALID - REPEAT WITH NEW SAMPLE*
# OSOM® Trichomonas Quality Control Log

<table>
<thead>
<tr>
<th>Date</th>
<th>Operator</th>
<th>Kit Lot &amp; Exp. Date</th>
<th>Received Date</th>
<th>Positive Control Lot# &amp; Exp. Date</th>
<th>Result</th>
<th>Negative Control Lot# &amp; Exp. Date</th>
<th>Result</th>
<th>Internal QC OK? (√)</th>
<th>Reviewed</th>
</tr>
</thead>
</table>

**Hospital/Clinic Name** ____________________________

**External Control Material:** ______________________

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*Review Log181-v2 from CLIAwaived.com*
has been successfully trained on the following Genzyme products:

☐ OSOM® Strep A      ☐ OSOM® Ultra Strep A      ☐ OSOM® Mono      ☐ OSOM® hCG Combo
☐ OSOM® hCG Urine      ☐ OSOM® Card Pregnancy      ☐ OSOM® Influenza A&B
☐ OSOM® BVBLUE®      ☐ OSOM® Trichomonas      ☐ OSOM® ImmunoDip® Urinary Albumin
OSOM® Trichomonas Rapid Test - Operator Competency Exam

It is recommended that operator competency in performing this test is documented following initial training. Consult local, state and federal regulations and/or your accreditation agency for additional information on training requirements.

Operator Name (printed): ___________________________ Employee Number: ____________

Unit, Clinic, or Department: ___________________________ Training: ___________________________

(Initial, Annual, Re-Training)

Practical Training In-service:
- Procedural review, including control requirements
- Demonstration of the test procedure
- Successful performance of the OSOM® Trichomonas Rapid Test procedure (i.e. External Controls)
- Test interpretation and results

I have read and understood the complete OSOM® Trichomonas Rapid Test procedure, and have been trained in the test procedure.

Operator Signature: ___________________________ Date: ___________________________

Competency Exam:
The following exam is administered as proof of competency for personnel performing the waived OSOM® Trichomonas Rapid test using patient samples and external controls. Please circle your response to each question.

1. The OSOM® Trichomonas Rapid Test is for the detection of Trichomonas from which sample type(s)?
   A. Vaginal swabs only
   B. Vaginal swabs and the saline sample from a wet mount preparation
   C. Whole blood samples

2. The OSOM® Trichomonas Rapid Test will detect only live Trichomonas organisms.
   A. true
   B. false

3. The first step in running the test is to add ____ of Sample Buffer to the supplied test tube.
   A. 0.5 mL (the fill line on the dropper barrel)
   B. 1-2 drops

4. After dispensing the reagent, the specimen swab should be placed in the test tube, vigorously mixed with the reagent, and allowed to soak for _________ minute(s).
   A. one
   B. does not need to soak

5. Negative results from the OSOM® Trichomonas Rapid test stick must be read ________ .
   A. at one minute
   B. at ten minutes
   C. at any point after the appearance of the Control line
6. Interpret the following results:

The test stick below is showing a(n) _______ result:

#1                   A. Positive
                     B. Negative
                     C. Invalid

The test stick below is showing a(n) _______ result:

#2                   A. Positive
                     B. Negative
                     C. Invalid

The test stick below is showing a(n) _______ result:

#3                   A. Positive
                     B. Negative
                     C. Invalid

**For Program Administrator Use Only!**

Operator Score: ___________  Operator Status: __________________________________________
                        (Passed or Additional Training Required)

If additional training required:  Date scheduled: ___________
                                  Date completed: ___________ Operator Status: ___________

Program Administrator Signature: ___________________________  Date: ______________________
                        (or designee)

OSOM® is a registered trademark of Genzyme Corporation.
04Oct JAF
OSOM® Trichomonas Rapid Test - Operator Competency Exam Key

Competency Exam Answers:

1. The OSOM® Trichomonas Rapid Test is for the detection of *Trichomonas* from which sample type(s)?
   B. Vaginal swabs and the saline sample from a wet mount preparation

2. The OSOM® Trichomonas Rapid Test will detect only live *Trichomonas* organisms.
   B. false

3. The first step in running the test is to add ____ of Sample Buffer to the supplied test tube.
   A. 0.5 mL (the fill line on the dropper barrel)

4. After dispensing the reagent, the specimen swab should be placed in the test tube, vigorously mixed with the reagent, and allowed to stand for ______ minute(s).
   A. one

5. Negative results from the OSOM® Trichomonas Rapid test stick must be read _____.
   B. at ten minutes

6. Interpret the following results:

   The test stick below is showing a(n) _______ result:
   #1
   ![Test stick image]
   A. Positive

   The test stick below is showing a(n) _______ result:
   #2
   ![Test stick image]
   C. Invalid

   The test stick below is showing a(n) _______ result:
   #3
   ![Test stick image]
   B. Negative

*OSOM*® is a registered trademark of Genzyme Corporation.
### MATERIAL SAFETY DATA SHEETS

<table>
<thead>
<tr>
<th>Catalog Number:</th>
<th>Kit Name:</th>
</tr>
</thead>
<tbody>
<tr>
<td>181, 181E</td>
<td>OSOM® Trichomonas Rapid Test</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Item Number:</th>
<th>Component Name:</th>
</tr>
</thead>
<tbody>
<tr>
<td>1023</td>
<td>OSOM® Trichomonas Rapid Test Sample Buffer</td>
</tr>
</tbody>
</table>

Note: The page numbers on the following MSDS are specific to the document. There are a total of 8 pages including this cover sheet.

OSOM® Trichomonas Rapid Test Positive Control Swabs and OSOM® Trichomonas Rapid Test Sticks are “articles” and do not require an MSDS.

Effective Date: November 12, 2008
1. PRODUCT AND COMPANY IDENTIFICATION

Product Name: OSOM® Trichomonas Rapid Test Sample Buffer
Synonym(s): Sample Buffer
Product Use: Component of OSOM® Trichomonas Rapid Test kit (catalog # 181 & 181E). For use in the qualitative detection of Trichomonas vaginalis antigens. For In Vitro Diagnostic Use Only.

Description: Aqueous solution containing salts, detergent and bactericide.

Corporate Headquarters
Genzyme Corporation
500 Kendall Street
Cambridge, MA 02142
USA
Phone: 617-252-7500

Manufacturer/Distributor
Genzyme Diagnostics
6659 Top Gun Street
San Diego, CA 92121
USA
Phone: 858-452-3198

Distributor
Genzyme Diagnostics
50 Gibson Drive
Kings Hill, West Malling
Kent, ME19 4AF
UK
Phone: 44 (0) 1732 220022

Emergency Telephone Numbers
Genzyme (U.S.): 617-562-4555
CHEMTREC (U.S.): 800-424-9300
CHEMTREC (Outside U.S.): 703-527-3887

2. HAZARDS IDENTIFICATION

Precautionary Statements:
The chemical, physical and toxicological properties of this preparation have not been thoroughly characterized. May be irritating to eyes and skin. Avoid contact with eyes and skin. Do not ingest or inhale. Preparation appearance: clear, colorless liquid.

Routes of Exposure:
Occupational exposure routes may include eye and skin contact.

Potential Health Effects:

<table>
<thead>
<tr>
<th>Route</th>
<th>Effect</th>
</tr>
</thead>
<tbody>
<tr>
<td>Inhalation</td>
<td>Aerosol inhalation may cause coughing and sore throat.</td>
</tr>
<tr>
<td>Eye</td>
<td>Eye exposure may cause irritation, redness and watering.</td>
</tr>
<tr>
<td>Skin</td>
<td>Skin contact may cause irritation, dryness and redness.</td>
</tr>
<tr>
<td>Ingestion</td>
<td>No data available.</td>
</tr>
<tr>
<td>Chronic Effects</td>
<td>No data available.</td>
</tr>
<tr>
<td>Target Organs</td>
<td>Unknown.</td>
</tr>
</tbody>
</table>

Regulatory Status:

None of the components present in this preparation at concentrations equal to or greater than 0.1% are listed by IARC, NTP, OSHA or ACGIH as a carcinogen.
MATERIAL SAFETY DATA SHEET
OSOM® Trichomonas Rapid Test Sample Buffer

Potential Environmental Effects:
Unknown.

3. COMPOSITION / INFORMATION ON INGREDIENTS

<table>
<thead>
<tr>
<th>Ingredient Name</th>
<th>CAS #</th>
<th>EC #</th>
<th>% (wt/wt)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Water</td>
<td>7732-18-5</td>
<td>231-791-2</td>
<td>&gt; 96</td>
</tr>
<tr>
<td>Sodium chloride</td>
<td>7647-14-5</td>
<td>231-598-3</td>
<td>&lt; 3</td>
</tr>
<tr>
<td>Ethoxylated octylphenol (Triton X-100)</td>
<td>9002-93-1</td>
<td>Not Assigned</td>
<td>&lt; 1</td>
</tr>
<tr>
<td>Sodium azide</td>
<td>26628-22-8</td>
<td>247-852-1</td>
<td>0.01</td>
</tr>
</tbody>
</table>

EC R-Phrases:
- Water: None
- Sodium chloride: None
- Ethoxylated octylphenol (Triton X-100): R22, R36/38
- Sodium azide: R28, R32, R50, R53

EC Hazard Class:
- Sodium chloride: None
- Ethoxylated octylphenol (Triton X-100): Xn
- Sodium azide: T+, N

4. FIRST AID MEASURES

Inhalation:
If inhaled, move from exposure area to fresh air. Seek medical attention if breathing becomes difficult or if cough or other symptoms develop.

Eye Contact:
Immediately flush eyes with plenty of tepid water for 15 minutes while separating eyelids with fingers. Remove contact lenses if worn. Obtain medical attention if needed or if symptoms, such as redness or irritation persist.

Skin Contact:
In case of contact, flush skin with copious amounts of cool water and remove contaminated clothing. Obtain medical attention if needed or if irritation or other symptoms develop.

Ingestion:
In case of ingestion, contact a poison control center or physician for instructions.

5. FIRE FIGHTING MEASURES

Flammable Properties:
Dilute aqueous solution not considered a fire hazard.

Suitable Extinguishing Media:
Use extinguishing media suitable for surrounding fire, such as carbon dioxide, chemical foam, dry chemical or water spray.

Unsuitable Extinguishing Media:
Unknown.

Specific Hazards Arising from the Chemical:
None expected.

Standard Protective Equipment and Precautions for Firefighters:
Firefighters should wear NIOSH-approved or equivalent Self-Contained Breathing Apparatus and full protective gear.
6. ACCIDENTAL RELEASE MEASURES

Personal Precautions:
Wear Personal Protective Equipment (PPE) as indicated in Section 8. Avoid physical contact with material. Wash hands thoroughly after handling.

Environmental Precautions:
This preparation contains a small amount of sodium azide which can react with copper, lead, brass or solder in plumbing systems and form potentially explosive metal azides. Follow proper disposal procedures.

Methods and Materials for Containment and Clean-Up:
Absorb spill with inert material/sorbent. Decontaminate the spill site following standard procedures. Dispose of materials in accordance with all applicable federal, state, local and provincial environmental regulations, per Section 13.

7. HANDLING AND STORAGE

Handling:
Follow good laboratory hygiene practices. See Section 8, Engineering Controls. Minimize contact and contamination of personal clothing and skin. Wash hands thoroughly after handling.

Storage:
Store at room temperature, 15 to 30°C (59 to 86°F). Do not store with incompatible substances; see Section 10.

8. EXPOSURE CONTROLS / PERSONAL PROTECTION

Exposure Guidelines:
There are no ACGIH, NIOSH, OSHA or country-specific occupational exposure limits currently established for components present in this preparation at concentrations equal to or greater than 1% (0.1% if carcinogen).

Engineering Controls:
This preparation is aqueous and non-volatile and is not expected to require special ventilation measures. Facilities storing or using this preparation should be equipped with an eyewash fountain.

Personal Protective Equipment (PPE):

<table>
<thead>
<tr>
<th>Category</th>
<th>Protection</th>
</tr>
</thead>
<tbody>
<tr>
<td>Respiratory</td>
<td>A respirator is not required under normal conditions of use.</td>
</tr>
<tr>
<td>Eye/Face</td>
<td>Wear appropriate protective safety eye glasses or goggles.</td>
</tr>
<tr>
<td>Skin</td>
<td>Wear lab coat or other protective garments. Remove contaminated clothing promptly.</td>
</tr>
<tr>
<td>Gloves</td>
<td>Wear chemical resistant protective gloves.</td>
</tr>
<tr>
<td>General</td>
<td>Follow company-specific safety procedures.</td>
</tr>
</tbody>
</table>

9. PHYSICAL AND CHEMICAL PROPERTIES

<table>
<thead>
<tr>
<th>Property</th>
<th>Value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Appearance</td>
<td>Clear, colorless liquid</td>
</tr>
<tr>
<td>Odor</td>
<td>Not available</td>
</tr>
<tr>
<td>Boiling Point</td>
<td>Not available</td>
</tr>
<tr>
<td>Melting Point</td>
<td>Not applicable</td>
</tr>
<tr>
<td>Freezing Point</td>
<td>Not available</td>
</tr>
<tr>
<td>pH</td>
<td>7.4</td>
</tr>
<tr>
<td>Solubility</td>
<td>Water-soluble</td>
</tr>
<tr>
<td>Vapor Pressure</td>
<td>Not available</td>
</tr>
<tr>
<td>Partition Coefficient (n-octanol/water)</td>
<td>Not available</td>
</tr>
<tr>
<td>Vapor Density</td>
<td>Not available</td>
</tr>
</tbody>
</table>
10. STABILITY AND REACTIVITY

Chemical Stability:
Stable under ordinary conditions of use and storage. See Section 7.

Conditions to Avoid:
There are no physical conditions known to result in a hazardous situation.

Incompatible Materials:
Avoid strong oxidizers, strong acids and bases, heavy metals and their salts.

Hazardous Decomposition Products:
None expected under normal conditions of use.

Possibility of Hazardous Reactions:
Hazardous polymerization will not occur.

11. TOXICOLOGICAL INFORMATION

Acute Effects:
Toxicology Data - Selected LD50s and LC50s
Sodium chloride 7647-14-5 Inhalation LC50 Rat: >42 g/m3/1H; Oral LD50 Rat: 3 g/kg; Dermal LD50 Rabbit: >10 g/kg

Local Effects:
No data available.

Chronic Effects:
No data available.

Carcinogenicity:
No data available.

Mutagenicity:
No data available.

Teratogenicity:
No data available.

Reproductive Effects:
No data available.

Sensitization:
No data available.

12. ECOLOGICAL INFORMATION
Ecotoxicity:

Ecotoxicity - Freshwater Fish Species Data
Sodium chloride 7647-14-5 96 Hr LC50 Lepomis macrochirus: 9675 mg/L [flow-through]; 96 Hr LC50 Lepomis macrochirus: 12946 mg/L [static]; 96 Hr LC50 Pimephales promelas: 7650 mg/L [static]

Ecotoxicity - Water Flea Data
Sodium chloride 7647-14-5 48 Hr EC50 Daphnia magna: 1000 mg/L

Persistence and Degradability:
No data available.

Bioaccumulative Potential:
No data available.

Mobility in Environmental Media:
No data available.

13. DISPOSAL CONSIDERATIONS

Methods of Disposal:
This preparation contains a small amount of sodium azide which can react with copper, lead, brass or solder in plumbing systems and form potentially explosive metal azides. If preparation enters drain, flush with a large volume of water to prevent azide build-up. Dispose of unused product, spilled material and waste in accordance with all applicable federal, state, local and provincial environmental and hazardous waste regulations.

14. TRANSPORT INFORMATION

Basic Shipping Description:
Not classified as dangerous goods. Not regulated per IATA and DOT regulations.

15. REGULATORY INFORMATION

US Federal Regulations:
This preparation is a component of an FDA-regulated in vitro diagnostic device.

Inventory - United States - Section 8(b) Inventory (TSCA)
Sodium chloride 7647-14-5 Present
International Regulations:
If approved for European Communities use, this product is regulated under the In Vitro Diagnostic Medical Devices Directive (98/79/EC).

Canada - WHMIS - Classifications of Substances
Sodium chloride 7647-14-5 Uncontrolled product according to WHMIS classification criteria

Germany - Water Classification (VwWvS) - Annex 2 - Water Hazard Classes
Sodium chloride 7647-14-5 ID Number 270, hazard class 1 - low hazard to waters

Inventory - Australia - Inventory of Chemical Substances (AICS)
Sodium chloride 7647-14-5 Present

Inventory - Canada - Domestic Substances List (DSL)
Sodium chloride 7647-14-5 Present

Inventory - China
Sodium chloride 7647-14-5 Present

Inventory - European Union - European Inventory of Existing Commercial Chemical Substances (EINECS)
Sodium chloride 7647-14-5 231-598-3

Inventory - Japan Existing and New Chemical Substances (ENCS)
Sodium chloride 7647-14-5 1-236

Inventory - Korea - Existing and Evaluated Chemical Substances
Sodium chloride 7647-14-5 KE-31387

Canadian Hazardous Products:
WHMIS Status Exempt

European Communities Dangerous Substances/Preparations:
EC Hazard Class None
Risk Phrases None
Safety Phrases None

16. OTHER INFORMATION

Further Information:
This MSDS has been prepared in accordance with the ANSI Z400.1 format. Every effort has been made to adhere to the hazard criteria and content requirements of the U.S. OSHA Hazard Communication Standard, Canadian Controlled Products Regulation (CPR), UK Chemical Hazard Information and Packaging Regulations, European Communities REACH Regulation, and UN Globally Harmonized System of Classification and Labelling of Chemicals (GHS).

MSDS Origination Date: March 22, 2004
Version #: 4
Revision Date: November 12, 2008
Disclaimer:
The information above is provided in good faith. It is believed to be accurate and represents the best information currently available to us. HOWEVER, WE MAKE NO WARRANTY OF MERCHANTABILITY, FITNESS FOR A PARTICULAR PURPOSE OR OF ANY OTHER TYPE, EXPRESSED OR IMPLIED, WITH RESPECT TO PRODUCTS DESCRIBED OR DATA OR INFORMATION PROVIDED, AND WE ASSUME NO LIABILITY RESULTING FROM THE USE OF SUCH PRODUCTS, DATA OR INFORMATION. Users should make their own investigations to determine the suitability of the information for their particular purposes, and the user assumes all risk arising from their use of the material. The user is required to comply with all laws and regulations relating to the purchase, use, storage and disposal of the material, and must be familiar with and follow generally accepted safe handling procedures. In no event shall Genzyme be liable for any claims, losses, or damages of any individual or for lost profits or any special, indirect, incidental, consequential or exemplary damages, howsoever arising, even if Genzyme has been advised of the possibility of such damages.
Regulatory Information & Accrediting Agencies

Regulatory

The Centers for Medicare & Medicaid Services and the Clinical Laboratory Improvement Amendments Program:

In 1988, Congress passed the Clinical Laboratory Improvement Amendments (CLIA), to establish quality standards for all laboratory testing. CLIA applies to physician offices, clinics, laboratories, and any other settings that perform laboratory testing on human specimens for diagnosis, prevention, treatment or assessment. Any site performing this testing must have a certificate and obtain a CLIA number.

CLIA divides testing into three categories based on the complexity of the method - waived, moderate or high, with increasingly stringent requirements at each level. The standards involve quality assurance, quality control, proficiency testing, personnel, and patient/test management. Testing facilities must register to obtain a CLIA certificate at the appropriate complexity level.

The Centers for Medicare & Medicaid Services, (CMS, formerly the Health Care Financing Administration or HCFA), regulates all laboratory testing (except research) performed on humans in the U.S. The CMS, the state authority, or an accrediting agency with "deemed" status, such as the College of American Pathology (CAP), the Joint Commission on Accreditation of Healthcare Organizations (JCAHO), and the Commission on Office Laboratory Accreditation (COLA), may perform inspections of CLIA certified laboratories.


Accreditation

For laboratories, the granting of approval by an outside accrediting agency, after undergoing a rigorous inspection process to ensure adherence to stringent quality standards. The accrediting agency must have been granted “deemed” status from CMS. For an accreditation agency to achieve approved or “deemed” status, that agency must have standards that meet or exceed those established by CLIA. Examples of accrediting agencies include JCAHO, CAP, and COLA. Membership in accrediting agencies is voluntary and not required of a laboratory that performs testing on human specimens.

A list of CLIA approved accreditation organization follows.
List of Approved Accrediting Organizations under CLIA

JCAHO: Joint Commission on Accreditation of Healthcare Organizations
One Renaissance Boulevard
Oakbrook Terrace, Illinois 60181
(630) 792-5783

The Joint Commission, founded in 1951, evaluates and accredits nearly 18,000 health care organizations and programs in the United States. It is an independent, not-for-profit organization for standard setting and accreditation in healthcare. JCAHO has developed professionally based standards in consultation with health care experts and providers, measurement experts, purchasers and consumers, and evaluates the compliance of health care organizations against these benchmarks. To earn and maintain accreditation, an organization must undergo an on-site survey by a JCAHO survey team at least every three years. Laboratories must be surveyed every two years. When a JCAHO inspection is complete, it is made available to the public in the form of a percentage (the organization’s overall evaluation score) to inform the community of the organization’s performance. JCAHO accreditation is recognized nationwide as a symbol of quality that reflects an organization's commitment to meeting certain performance standards.

Information obtained from www.jcaho.org.

CAP: College of American Pathologists
325 Waukegan Road
Northfield, Illinois 60093-2750
Laboratory Accreditation Program
1-800-323-4040

The goal of the College's Laboratory Accreditation Program is to improve the quality of clinical laboratory services and to ensure the accuracy and reliability of test results through an educational and peer review inspection process. Inspectors are pathologists and other laboratory professionals who combine their extensive knowledge of the science of pathology with proper quality assurance procedures to determine whether a laboratory meets the standards for accreditation. In existence since 1962, the Laboratory Accreditation Program has had a long, stable history of providing support to the laboratory community and now accredits more than 6,000 laboratories in the US and abroad. Laboratories accredited by the College of American Pathologists meet exacting standards set by the College's Commission on Laboratory Accreditation and approved by the College's Board of Governors. Each laboratory is inspected to make sure it meets those standards and that it uses appropriate quality control and quality assurance procedures to benefit the patients it serves.

Information obtained from www.cap.org.

COLA: Commission on Office Laboratory Accreditation
9881 Broken Land Parkway, Suite 200
Columbia, Maryland 21046-1158
(410) 381-6581

Founded in 1998, COLA is a non-profit, physician-directed organization promoting quality and excellence in medicine and patient care through programs of voluntary education, achievement, and accreditation. In 1993, the Health Care Financing Administration (HCFA) granted COLA "deeming authority" under CLIA. COLA’s Laboratory Accreditation program includes voluntary self-assessment, on-site surveys, as well as a proficiency testing option. With successful completion of the program an accreditation certificate is issued, demonstrating that your site has met CLIA, JCAHO, and many state requirements.

Information obtained from www.cola.org.
AABB: American Association of Blood Banks
8101 Glenbrook Road
Bethesda, Maryland 20814-2749
Government Relations
(301) 907-6977

The AABB Accreditation Program strives to improve the quality and safety of collecting, processing, testing, distributing and administering blood and blood products. The program assesses the quality and operational systems in place within the facility. The basis for assessment includes compliance with Standards, Code of Federal Regulations and federal guidance documents. This independent assessment of a facility's operations helps the facility to prepare for other inspections and serves as a valuable tool to improve both compliance and operations.


AOA: American Osteopathic Association
142 East Ontario Street
Chicago, Illinois 60611
(312) 202-8070

The American Osteopathic Association's Healthcare Facilities Accreditation Program has been providing medical facilities with an objective review of their services since 1945. The program is recognized nationally by the federal government, state governments, insurance carriers and managed care organizations. In 1995 the AOA applied for and received deeming authority to accredit laboratories within AOA accredited hospitals under the Clinical Laboratory Improvement Amendments of 1988 (CLIA).


ASHI: American Society of Histocompatibility and Immunogenetics
P.O. Box 15804
Lenexa, Kansas 66285-5804
(913) 541-0009

With the objective of maintaining the highest standards of reliability and quality in Histocompatibility testing laboratories, ASHI established its accreditation program in 1974. In 1995, the ASHI Accreditation program achieved its deemed status with HCFA and CLIA. Its purpose is to evaluate laboratory personnel, procedures, and facilities to determine if they are in compliance with ASHI standards; to promote the educational aspects of the accreditation process, particularly in assisting laboratories in the correction of deficiencies; to provide expert advice and assistance to committees of the society; and to maintain the society's awareness of standard and novel procedures and methodologies. Laboratories will be evaluated for the technology utilized and, if applicable, the clinical services provided.

Information obtained from, www.ashi-hla.org

Proficiency Testing

Proficiency testing is an additional, documented measure of external quality control that can assist in demonstrating accuracy of results, assessing test methods, and verifying operator competency.

There are a number of CLIA approved Proficiency testing programs available. Most follow a similar protocol in which a number of “blind” or unknown samples are sent to your location at various times throughout the year. These survey specimens must be treated as a patient sample, and run by personnel responsible for performing the test at the site.

The results are sent to the proficiency agency to be evaluated and summarized into a report that is sent back to the site. The report compares your result to the accepted result and to other sites using the same methodology. Sites failing a “Proficiency Event” must document the cause, and any corrective or preventative actions taken to address a deficiency. Repeated failures of the same method may result in an inability to perform the test at that location.

At this time, sites performing only waived testing are not required to perform proficiency testing to comply with CLIA regulations. However, some states and most accreditation agencies are encouraging or requiring such testing. Proficiency testing for all tests performed at your site provides documentation of accuracy in the event of an inspection, and helps to ensure quality test results.
American Association of Bioanalysts (AAB)
Proficiency Testing Service
205 West Levee Street
Brownsville, Texas 78520-5596
(800)234-5315

American Academy of Family Physicians (AAFP)
11400 Tomahawk Creek Parkway
Leawood, Kansas 66211-7911
(800)274-7911

Accutest
P.O.Box 999
Westford, Massachusetts 01886-0031
(800)356-6788

American Proficiency Institute (API)
1159 Business Park Drive
Traverse City, Michigan 49686
(800)333-0958

California Thoracic Society (CTS)
202 Fashion Lane
Suite 219
Tustin, California 92780
(714)730-1944

The College of American Pathologists (CAP) – Surveys & EXCEL
325 Waukegan Road
Northfield, Illinois 60093-2750
(847)832-7000

Idaho Bureau of Laboratories
Proficiency Testing Program
2220 Old Penitentiary RD
Boise, Idaho 83712
(208)334-2235

Medical Laboratory Evaluation (MLE)
2011 Pennsylvania Avenue, NW
Suite 800
Washington, DC 20006-1834
(800)338-2746,(202)261-4500

New Jersey Department of Health and Senior Services
Proficiency Testing Program for Clinical Laboratories
Clinical Laboratory Improvement Service
P.O.Box 361
Trenton, New Jersey 08625-0360
(609)292-5605

Ohio Department of Health
1571 Perry Street
P.O.Box 2568
Columbus, Ohio 43216-2568
(614)466-2278
CLIA Approved Proficiency Testing Programs - continued

Commonwealth of Pennsylvania
Department of Health
Bureau of Laboratories
P.O. Box 500
Exton, Pennsylvania 19341-0500
(610)280-3464

Puerto Rico Department of Health
Laboratory Program
Department of Health of Puerto Rico
PO Box 70184
San Juan, Puerto Rico 00936-8184
(787)274-6827

Wisconsin State Laboratory of Hygiene
465 Henry Mall
Madison, Wisconsin 53706-1578
(800)462-5261

New York State Department of Health
State of New York
Department of Health
The Governor Nelson A. Rockefeller State Plaza
P.O. Box 509
Albany, New York 12201-0509
(518)474-8739