OSOM® BVBLUE® Test
CLIA Waived

Genzyme Diagnostics
Point of Care Diagnostic Products
Welcome to the Genzyme OSOM® BVBLUE® 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® BVBLUE® 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.
BVBLUE® is registered trademark of Gryphus Diagnostics, LLC.
Some information you may find useful:

**CLIA Complexity:** Waived

**CPT Code:** 87905QW (QW for reimbursement with Medicare or Medicaid only).

**Kit Storage:** Store Test Kits refrigerated when not in use (2°C - 8°C / 36°F - 46°F). Prior to testing patient samples or Controls, remove the kit from the refrigerator and allow it to come to room temperature before use.

**Specimen:** Collect specimens with a swab from the lower one-third of the vaginal wall. Collecting specimens from the cervix should be avoided because (a) it might increase risk to OB patients, and (b) cervical sialidase activity is usually higher than vaginal sialidase activity. Use of the swabs supplied in the kit is recommended. Swabs from other suppliers have not been validated.

To transport patient specimens, place each swab in a clean, dry container such as a plastic or glass tube. Do not use any transport media.

Do not use specimens from patients who have (a) used a vaginal cream or ointment product, (b) douched, or (c) used spermicides, vaginal lubricants or feminine sprays within 72 hours of testing.

If you do not collect enough sample or collect from a patient undergoing antimicrobial therapy the test may give a false negative result.

**Specimen Storage:** Test the patient specimen as soon as possible after collection.

If you do not perform the OSOM BVBLUE test immediately, store the swabs either at room temperature for up to 48 hours or refrigerated for up to 7 days.

**Quality Control:** The OSOM BVBLUE Test contains two types of internal quality control with each test run. For daily quality control, the manufacturer recommends documenting these controls on each day of testing:

- **Type 1 Control:** Before adding a patient specimen, inspect the BV Test Vessel. It should contain a colorless liquid without precipitates (sediment).
  
  If the testing vessel contains a precipitate, the test is invalid. Do not use the BV Test Vessel.

- **Type 2 Control:** The OSOM BVBLUE Test has a two-color result format: blue/green is positive, yellow is negative. After running the test according to the instructions for use, the appearance of either a uniform yellow, blue, or green color in the testing vessel or a blue or green color on the swab assures proper mixing of the reagent and sample has occurred.
  
  If the test fails to provide either a blue, green, or a yellow color result the test is invalid.

  Do not report patient results if either the Type 1 Control or the Type 2 Control does not produce expected results.
For CLIA Waived Labs:
You should follow the guidelines below for QC testing. The manufacturer recommends that external controls be run with each new lot, each new shipment and with each new untrained operator.

For CLIA Non-Waived Labs:
Quality Control requirements should be established in accordance with local, state and federal regulations or accreditation requirements. Minimally, the manufacturer recommends that external controls be run with each new lot, each new shipment and with each new untrained operator.

Procedural Tips: Specimens, Test Vessels, and Developer Solution should be at Room Temperature.

Read the results immediately after the addition of the Developer Solution to the Test Vessel.

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

Expected Results: The OSOM BVBLUE Test can show sialidase activity in vaginal fluid at levels of ≥ 7.8U. There are two possible results; positive or negative. If the test fails to provide a blue, green, or yellow color result, the test is invalid.

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
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: Genzyme Diagnostics OSOM® BVBLUE® Test

Procedure #: ___________________________

Institution: __________________________________________________________

Prepared by: ___________________________ Date: __________________________

Accepted by: ___________________________ Date adopted: _________________

Reviewed by: ___________________________ Date: __________________________

Discontinued by: _________________________ Date: ________________________
I. TEST NAME

OSOM® BVBLUE® Test
This is a CLIA Waived Test

For facilities in the US: A CLIA Certificate of Waiver is needed to perform testing in waived settings. Read all instructions carefully before use. If a laboratory modifies the following test instructions including Quality Control, the test will be considered High Complexity and no longer considered Waived.

II. INTENDED USE

The OSOM BVBLUE Test is an enzyme activity test for use in the detection of vaginal fluid specimens for sialidase activity, an enzyme produced by bacterial pathogens such as Gardnerella vaginalis, Bacteroides spp., Prevotella spp., and Mobiluncus spp.

The OSOM BVBLUE Test is indicated for use in women suspected of having Bacterial Vaginosis (BV) infection, e.g., women with vaginal discharge typical of BV and/or women with previous history of BV, as an aid in the diagnosis of BV infection. Test results should be considered in conjunction with other clinical and patient information (see Limitations of the Procedure).

For In Vitro Diagnostic Use Only. The OSOM BVBLUE Test is indicated for professional use only and may be used at the point of care and/or in physician's offices. It is not intended for home use.

III. SUMMARY AND EXPLANATION OF TEST

Vaginitis is one of the most common reasons that women visit obstetricians or gynecologists. BV is the most common form of infectious vaginitis. The causative agents of the infection are bacterial pathogens such as Gardnerella vaginalis, Bacteroides spp., Prevotella spp., and Mobiluncus spp.

Complications associated with BV include salpingitis, endometritis, post-hysterectomy infections recurrent UTI's and an increased risk of PID and HIV. BV represents a serious danger in women due to its significant association with placental infection, premature rupture of membranes, and preterm birth.

Studies have shown elevated sialidase activity in women with BV and an increased risk for preterm birth and low birth weight infants in patients exhibiting elevated sialidase activity.

The OSOM BVBLUE Test is designed to provide a clear, simple indication of elevated sialidase activity in patient vaginal fluid samples. The generation of a blue or green color indicates a positive test result; a yellow color indicates a negative test result.

IV. PRINCIPLES OF TEST

The OSOM BVBLUE Test contains a chromogenic substrate of bacterial sialidase. In the test procedure, a vaginal fluid sample is placed in the BV Test Vessel. The sample then reacts with the chromogenic substrate. A Developer Solution is added after the reaction.

If the sample has a high level of sialidase, a blue or green color will be seen in the BV Test Vessel or on the head of the swab. If the sample has no sialidase, or has very low levels, a yellow color will be seen in the BV Test Vessel.
V. REAGENTS / MATERIALS

IBX-4041 component (0.25 mg/test)
potassium acetate (24.5 mg/test)
sodium hydroxide (1.0 mg/test)

**Materials Provided:**
25 Test Vessels each containing 0.25 mg IBX-4041 component in 0.5 mL of an aqueous potassium acetate buffer solution (49 mg/mL; 0.5 M; pH 5.5–6.0).
1 Developer Solution Bottle containing 10.0 mL of an aqueous sodium hydroxide solution (40.0 mg/mL; 1.0 M; pH>11.0).
Sterile Swabs
1 Directional Insert

**Materials Required But Not Provided:**
OSOM BVBLUE Control Kit
Timer

VI. WARNINGS AND PRECAUTIONS

For *In Vitro* Diagnostic Use Only.
Do not use after the expiration date printed on the kit.
Do not store kit at temperatures above 26° C (79° F).
Do not store the kit in strong light.
Follow your laboratory safety guidelines in the collection, handling, storage and disposal of patient specimens and all items exposed to patient specimens.
Used tests should never be re-used.
This product is intended for vaginal fluid use only.

For this facility, sample swabs and used test tubes are disposed: __________________________

______________________________

VII. PATIENT PREPARATION, SPECIMEN COLLECTION & STORAGE

This facility’s procedure for patient preparation is: ________________________________

______________________________

This facility’s procedure for sample labeling is: ________________________________

______________________________

**Specimen Collection and Handling:**
• Collect specimens with a swab from the lower one-third of the vaginal wall. Collecting specimens from the cervix should be avoided because (a) it might increase risk to OB patients, and (b) cervical sialidase activity is usually higher than vaginal sialidase activity.

• Do not use specimens from patients who have (a) used a vaginal cream or ointment product, (b) douched, or (c) used spermicides, vaginal lubricants or feminine sprays within 72 hours of testing.

• Test the patient specimen as soon as possible after collection.

• If you do not perform the OSOM BVBLUE test immediately, store the swabs either at room temperature for up to 48 hours or refrigerated for up to 7 days. To transport patient specimens, place each swab in a clean, dry container such as a plastic or glass tube. Do not use any transport media.

• If you do not collect enough sample or collect from a patient undergoing antimicrobial therapy the test may give a false negative result.

This facility’s procedure for transporting specimens is: _______________________________

This facility’s procedure for rejected specimens is: _______________________________

<table>
<thead>
<tr>
<th>VIII. STORAGE AND STABILITY</th>
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<tbody>
<tr>
<td>Store the kit at controlled temperature, 2°C-26°C (36°F-79°F), out of direct sunlight. Store vessels inside the box. Kit contents are stable until the expiration date printed on the outer box.</td>
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</table>

NOTE: If temperatures in your facility may exceed 26°C (79°F), the kit should be refrigerated when not in use to ensure that the components remain stable until the expiration date printed on the packaging. **Allow the kit to come to room temperature before running the test.**

At this facility, kits are stored: _______________________________

<table>
<thead>
<tr>
<th>IX. INDICATIONS OF INSTABILITY</th>
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<tr>
<td>Signs of possible product instability include:</td>
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<tr>
<td>A blue color in a BV Test Vessel when one drop of Developer Solution is added to the BV Test Vessel in the absence of a patient specimen.</td>
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<tr>
<td>Positive control does not give expected results.</td>
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<tr>
<td>Negative control does not give expected results.</td>
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<tr>
<th>X. QUALITY CONTROL &amp; ASSURANCE</th>
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<tr>
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either a uniform yellow, blue, or green color in the testing vessel or a blue or green color on the swab assures proper mixing of the reagent and sample has occurred.

If the test fails to provide either a blue, green, or a yellow color result the test is invalid.

Do not report patient results if either the Type 1 Control or the Type 2 Control does not produce expected results.

2. External Quality Controls

External Controls (available from Genzyme), are used to test that the reagents are working properly. Also use the Controls to test that you are able to correctly perform the test procedure.

- A Control Kit that contains a positive control and a negative control is available from Genzyme Diagnostics and may be purchased separately, Catalog No. 184.
- Refer to the Control Kit Directional Insert for instructions on how to interpret the results of the controls.

If QC testing fails:
- Check expiration dates of the test kit and controls
- Ensure the instructions for testing were followed
- Repeat the test

If the controls still do not perform as expected contact Genzyme Technical Service at 1-800-332-1042.

2a. For CLIA Waived Labs

You should follow the guidelines below for QC testing. The manufacturer recommends that external controls be run with each new lot, each new shipment and with each new untrained operator.

2b. For CLIA Non-Waived Labs

Quality Control requirements should be established in accordance with local, state and federal regulations or accreditation requirements. Minimally, the manufacturer recommends that external controls be run with each new lot, each new shipment and with each new untrained operator.

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:

_________________________________________________________________

_________________________________________________________________

XI. LIMITATIONS

Do not use samples from the cervix.

Patients may have mixed infections. The OSOM BVBLUE Test shows that sialidase enzyme is active in the sample. The OSOM BVBLUE Test does not show if other organisms such as yeast and parasitic organisms are present in the sample.

Test results should be considered in conjunction with other clinical and patient information.

Test operators must follow all instructions to a) collect the sample, b) store the sample, and c) use the test procedure properly. If the instructions are not followed, the OSOM BVBLUE test may not give correct results.
**XII. EXPECTED VALUES**

The OSOM BVBLUE Test can show sialidase activity in vaginal fluid at levels of ≥7.8U. There are two possible results; positive or negative. If the test fails to provide a blue, green, or yellow color result, the test is invalid.

**XIII. INSTRUCTIONS FOR USE**

<table>
<thead>
<tr>
<th>STEP 1</th>
<th>Remove one BV Test Vessel and the Developer Solution Bottle from the kit prior to use. Remove the cap from the BV Test Vessel.</th>
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<tbody>
<tr>
<td>STEP 2</td>
<td>Collect a vaginal fluid sample with a swab. Contact the swab with the lower one-third of the vaginal wall. Collect as much fluid as possible.</td>
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<tr>
<td>NOTE:</td>
<td>Do not use samples from patients who have used vaginal cream products within 72 hours before testing. Do not touch or collect fluid near the cervix.</td>
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<tr>
<td>STEP 3</td>
<td>Put the swab into the BV Test Vessel. Gently swirl the mixture.</td>
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<tr>
<td>STEP 4</td>
<td>Let the BV Test Vessel containing the swab stand for 10 minutes between 17° and 37°C, (62.6°-98.6°F).</td>
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<tr>
<td>STEP 5</td>
<td>Add one drop of Developer Solution to the BV Test Vessel containing the swab. Gently swirl the mixture. <strong>Read the results immediately.</strong></td>
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<tr>
<td>CAUTION:</td>
<td>The Developer Solution is a dilute alkaline solution. This may cause skin and eye irritation. If the solution comes in contact with the skin or eyes, flush with large volumes of water.</td>
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</tbody>
</table>

**XIV. INTERPRETATION OF TEST RESULTS**

| There are two possible results: (a) positive result or (b) negative result. |
| a) **Positive Result:** A blue or green color in the BV Test Vessel or on the head of the swab. |
| b) **Negative Result:** A yellow color in the BV Test Vessel. |
| NOTE: You may need to remove the swab to read the test results. |
| A Positive Result shows a high level of sialidase activity. |
| A Negative Result shows a normal level of sialidase activity. |
| In the event this test becomes inoperable, this facility’s course of action for patient samples is: _____ |
XV. RESULT REPORTING

This facility’s procedure for patient result reporting is:

XVI. CROSS REACTIVITY

In all clinical studies, no evidence of interference was observed for menses (n=118); blood (n=620); semen (n=620); birth control methods (n=36) including birth control pills, Depo-Provera, Norplant, IUDs, condoms, or tubal ligation; or microorganisms (n=118) including Staphylococcus, Streptococcus, E. coli, Candida albicans, Lactobacillus, among others.

XVII. PERFORMANCE CHARACTERISTICS & POL STUDIES

Refer to directional insert – OSOM BVBLUE Test

XVIII. REFERENCES

Refer to directional insert – OSOM BVBLUE Test

XIX. ASSISTANCE

For technical assistance contact Genzyme Diagnostics Technical Service at (800) 332-1042.
OSOM® BVBlue® Patient Test Log

Kit Lot #:  

Exp. Date:  

Hospital/Clinic Name:  

Received Date:  

Date in Use:  

EXTERNAL QC:  Refer to QC log for Positive and Negative control results

TEST RESULT:  **Negative** = yellow color present in the testing vessel or on the head of the swab  

**Positive** = blue or green color present in the testing vessel

<table>
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<tr>
<th>Date</th>
<th>Operator</th>
<th>Patient Name/ ID</th>
<th>External QC OK? (✓)</th>
<th>Test Result (Neg/Pos)</th>
<th>Internal QC OK? (✓)</th>
<th>Comments/Actions</th>
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<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>
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</tr>
</tbody>
</table>
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

__________________________  ________________________
Trainer/ Title Date
OSOM® BVBLUE® Test - Operator Competency Exam

Minimally, regulations require 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.

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® BVBLUE® Test procedure (i.e. External Controls)
- Test interpretation and results

I have read and understood the complete OSOM® BVBLUE® 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 OSOM® BVBLUE® Test using patient samples and external controls. Please circle your response to each question.

1. What samples can be used with the OSOM® BVBLUE® Test?
   A. Serum samples
   B. Vaginal swabs

2. The OSOM® BVBLUE® Test detects sialidase activity, an enzyme produced by bacterial pathogens known to cause bacterial vaginosis infection.
   A. True
   B. False

3. After placing the specimen swab in the testing vessel, gently mix the swab in the solution and then ________.
   A. take the swab out and add the developer solution
   B. allow the vessel containing the swab to sit for 10 minutes

4. After adding one drop of the Developer solution to the testing vessel, results should be interpreted ________.
   A. immediately
   B. at any time after adding the Developer, the assay is not time dependant

5. The test kit should be stored between 2°- 8°C (36°- 46°F) when not in use. The kit must be removed from the refrigerator and allowed to come to room temperature before testing with Controls or patient samples.
   A. True
   B. False
6. Interpret the following results:

   a. The testing vessel at right is showing a(n) ______ result:
      A. Positive
      B. Negative

   b. The testing vessel at right is showing a(n) ______ result:
      A. Positive
      B. Negative

   c. The testing vessel at right is showing a(n) ______ result:
      A. Positive
      B. Negative

**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.
BVblue® is registered trademark of Gryphus Diagnostics, LLC.
OSOM® BVBLUE® Test - Operator Competency Exam Key

Competency Exam Answers:

1. What samples can be used with the OSOM® BVBLUE® Test?
   B. Vaginal swabs

2. The OSOM® BVBLUE® Test detects sialidase activity, an enzyme produced by bacterial pathogens known to cause bacterial vaginosis infection.
   A. True

3. After placing the specimen swab in the testing vessel, gently mix the swab in the solution and then ________.
   B. allow the vessel containing the swab to sit for 10 minutes

4. After adding one drop of the Developer solution to the testing vessel, results should be interpreted ________.
   A. immediately

5. The test kit should be stored between 2°- 8°C (36°- 46°F) when not in use. The kit must be removed from the refrigerator and allowed to come to room temperature before testing with Controls or patient samples.
   A. True

6. Interpret the following results:

   a. The testing vessel at right is showing a(n) ________ result:
      B. Negative

   b. The testing vessel at right is showing a(n) ________ result:
      A. Positive

   c. The testing vessel at right is showing a(n) ________ result:
      A. Positive
MATERIAL SAFETY DATA SHEETS

<table>
<thead>
<tr>
<th>Catalog Number:</th>
<th>Kit Name:</th>
</tr>
</thead>
<tbody>
<tr>
<td>183, 183E</td>
<td>OSOM® BVBLUE® Test</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Item Number:</th>
<th>Component Name:</th>
</tr>
</thead>
<tbody>
<tr>
<td>1086</td>
<td>OSOM® BVBLUE® Developer Solution</td>
</tr>
<tr>
<td>675</td>
<td>OSOM® BVBLUE® Testing Vessel</td>
</tr>
</tbody>
</table>

Note: The page numbers on the 2 individual MSDSs for this kit are specific to each document. There are a total of 15 pages including this cover sheet.
1. PRODUCT AND COMPANY IDENTIFICATION

Product Name: OSOM® BVBLUE® Developer Solution

Synonym(s): Developer Solution; 1M Sodium hydroxide solution

Product Use: Component of OSOM® BVBLUE® Test kit (catalog # 183 & 183E). For use in the detection of sialidase enzyme activity in vaginal fluid specimens, to aid in the diagnosis of Bacterial Vaginosis infection. For In Vitro Diagnostic Use Only.

Description: Alkaline solution.

2. HAZARDS IDENTIFICATION

Precautionary Statements:

WARNING! The chemical, physical and toxicological properties of this preparation have not been thoroughly characterized. Corrosive to the eyes, skin, and mucous membranes. Irritating to respiratory system. Avoid contact with eyes and skin. Do not ingest. Avoid aerosol or vapor inhalation. Based upon the small volume and packaging design, this preparation is considered unlikely to produce toxicity through the normal routes of occupational exposure. Preparation appearance: clear, colorless liquid.

Routes of Exposure:

Occupational exposure routes may include inhalation, eye and skin contact.

Potential Health Effects:

- **Inhalation**: Corrosive! Inhalation of mist can cause irritation, coughing, shortness of breath and wheezing. Substantial inhalation can cause build-up of fluid in the lungs (pulmonary edema), a medical emergency, with severe shortness of breath.

- **Eye**: Corrosive! Contact may cause irritation, severe burns, photophobia (light sensitivity), and permanent eye damage.

- **Skin**: Corrosive! Skin contact causes redness, pain, burns, and ulceration. Symptoms may be delayed. Skin contact may not necessarily be followed by an immediate sensation of irritation or pain. Skin burns from dilute solution may develop slowly from prolonged contact.

- **Ingestion**: Corrosive! Ingestion can cause difficulty swallowing, spontaneous vomiting, and pain and burns in the mouth, throat, and gastrointestinal tract. Symptoms may be delayed.

- **Chronic Effects**: Prolonged or repeated exposure through inhalation may damage the respiratory system.

- **Target Organs**: Eyes, respiratory system and skin.

Emergency Telephone Numbers

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

Phone: 858-452-3198

Distributor

Genzyme Diagnostics
6659 Top Gun Street
San Diego, CA 92121
USA

Phone: 617-252-7500

Distributor

Genzyme Diagnostics
50 Gibson Drive
Kings Hill, West Malling
Kent, ME19 4AF
UK

Phone: 44 (0) 1732 220022

Corporate Headquarters

Genzyme Corporation
500 Kendall Street
Cambridge, MA 02142
USA

Phone: 617-252-7500

Date Printed: November 12, 2008

Effective Date: November 12, 2008
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.

Potential Environmental Effects:
See Section 12.

### 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>96</td>
</tr>
<tr>
<td>Sodium hydroxide</td>
<td>1310-73-2</td>
<td>215-185-5</td>
<td>4</td>
</tr>
</tbody>
</table>

EC R-Phrases: None
EC Hazard Class: None

**4. FIRST AID MEASURES**

**Inhalation:**
If inhaled, immediately move from exposure area to fresh air. Seek immediate 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 immediate medical attention.

**Skin Contact:**
In case of contact, immediately flush skin with copious amounts of cool water and remove contaminated clothing. Avoid spreading material on unaffected skin. Watch for delayed symptoms. Seek medical attention for skin exposures that result in pain, burns, or noticeable redness or irritation.

**Ingestion:**
In case of ingestion, contact a poison control center and seek immediate medical attention. Do not induce vomiting.

**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 known.

**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:
Avoid physical contact with material and avoid aerosol inhalation. Wear Personal Protective Equipment (PPE) as indicated in Section 8. Ensure adequate ventilation. Wash hands thoroughly after handling. Change into clean clothes promptly if clothing has been contaminated.

Environmental Precautions:
Follow federal, state, local and provincial environmental regulations.

Methods and Materials for Containment and Clean-Up:
Absorb spill with inert material/sorbent or appropriate neutralizing agent. 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 2 - 8°C (36 - 46°F). Keep containers tightly closed in a dry, cool and well-ventilated place. Do not store with incompatible substances; see Section 10.

8. EXPOSURE CONTROLS / PERSONAL PROTECTION

Exposure Guidelines:

<table>
<thead>
<tr>
<th>ACGIH - Threshold Limits Values - Ceilings (TLV-C)</th>
<th>2 mg/m³ Ceiling</th>
</tr>
</thead>
<tbody>
<tr>
<td>Sodium hydroxide</td>
<td>1310-73-2</td>
</tr>
</tbody>
</table>

| Canada - Quebec - Occupational Exposure Limits - Ceilings |
|---|---|
| Sodium hydroxide | 1310-73-2 |

| Israel - Occupational Exposure Limits - Ceilings |
|---|---|
| Sodium hydroxide | 1310-73-2 |

| Japan - Recommended Exposure Limits - Ceiling Limits |
|---|---|
| Sodium hydroxide | 1310-73-2 |

| Korea - Occupational Exposure Limits - Ceilings |
|---|---|
| Sodium hydroxide | 1310-73-2 |

| U.S. - OSHA - Final PELs - Time Weighted Averages (TWAs) |
|---|---|
| Sodium hydroxide | 1310-73-2 |

Engineering Controls:
Minimize potential for aerosolization. Handle within a containment system, with local exhaust ventilation, or with dilution ventilation at a minimum. Facilities storing or using this preparation should be equipped with an eyewash fountain.

Personal Protective Equipment (PPE):

Respiratory
A respirator is not required under normal conditions of use. A respiratory protection program that meets U.S. Federal OSHA 29 CFR 1910.134 and ANSI Z99.2, European Standard CR 529, or other applicable regulatory standards should be followed whenever exposure limits may be exceeded (if applicable) and engineering controls are not feasible, or if insufficient ventilation or workplace conditions warrant the use of respiratory protection.

Eye/Face
Wear appropriate protective chemical safety goggles. If splashes are likely to occur, wear a face shield as well.
Personal Protective Equipment (PPE):

- **Skin**: Wear appropriate protective clothing, such as a lab coat or other long-sleeved garment over clothing to minimize contact and contamination of clothing. Select additional impervious protective clothing based on volume of material used and activity. Change into clean clothes promptly if clothing becomes contaminated.

- **Gloves**: Wear chemical resistant protective gloves.

- **General**: Follow company-specific safety procedures.

### 9. PHYSICAL AND CHEMICAL PROPERTIES

<table>
<thead>
<tr>
<th>Property</th>
<th>Value</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Appearance</strong></td>
<td>Clear, colorless liquid</td>
</tr>
<tr>
<td><strong>Odor</strong></td>
<td>Odorless</td>
</tr>
<tr>
<td><strong>pH</strong></td>
<td>13 - 14</td>
</tr>
<tr>
<td><strong>Solubility</strong></td>
<td>Miscible in water</td>
</tr>
<tr>
<td><strong>Specific Gravity</strong></td>
<td>1.02 - 1.05</td>
</tr>
<tr>
<td><strong>Boiling Point</strong></td>
<td>101 °C (213.8 °F) (approx.)</td>
</tr>
<tr>
<td><strong>Melting Point</strong></td>
<td>Not applicable</td>
</tr>
<tr>
<td><strong>Freezing Point</strong></td>
<td>Not available</td>
</tr>
<tr>
<td><strong>Flammability/Explosivity Limits in Air, Lower</strong></td>
<td>Not available</td>
</tr>
<tr>
<td><strong>Flammability/Explosivity Limits in Air, Upper</strong></td>
<td>Not available</td>
</tr>
<tr>
<td><strong>Auto-Ignition Temperature</strong></td>
<td>Not applicable</td>
</tr>
<tr>
<td><strong>Flash Point</strong></td>
<td>Not available</td>
</tr>
<tr>
<td><strong>Partition Coefficient</strong></td>
<td>Not available</td>
</tr>
<tr>
<td>(n-octanol/water)</td>
<td>Not available</td>
</tr>
<tr>
<td><strong>Vapor Pressure</strong></td>
<td>Not available</td>
</tr>
<tr>
<td><strong>Vapor Density</strong></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**: Unknown.
- **Incompatible Materials**: Physical Properties - Chemical Incompatibilities
  - Sodium hydroxide 1310-73-2 Water, acids, flammable liquids, organic halogens, metals: aluminum, tin, zinc; nitromethane and nitro compounds
- **Hazardous Decomposition Products**: None expected under normal conditions of use.
- **Possibility of Hazardous Reactions**: Hazardous polymerization will not occur.

### 11. TOXICOLOGICAL INFORMATION
Acute Effects:

The following irritation data is for sodium hydroxide:

Based on human data, concentrations of 0.5-4.0% were irritating to the skin. Eye irritation data are available for animals. The non-irritant level was 0.2-1.0%, while the corrosive concentration was 1.2% or higher.

Eye Irritation/Corrosion:
Rabbit, EPA Criteria, 0.1 mL dose, 0.004-0.2%: Not Irritating; 0.4%: Mildly Irritating; 1.2%: Corrosive.
Rabbit, Modified Draize Test, 0.1 and 0.3%: No conjunctivitis nor iritis; 1.0 and 3%: Conjunctivitis and iritis
Rabbit, OECD Guideline 405, 1%: Not Irritating; 2%: Irritating

Skin Irritation/Corrosion:
Human, Patch Test, 0.2 mL dose, 0.5%: Irritating for 55% of volunteers
Human, Patch Test, 0.2 mL, 0.5%: Irritating for 61% of volunteers
Human, Different Protocols, 1.0%: Irritating for ~50% of volunteers
Human, Filter Paper Discs, 0.5 and 1.0%: Irritating

Toxicology Data - Selected LD50s and LC50s
Sodium hydroxide 1310-73-2 Dermal LD50 Rabbit: 1350 mg/kg

Chronic Effects:
Prolonged or repeated exposure through inhalation may damage the respiratory system.

Carcinogenicity:
No data available.

Mutagenicity:
No evidence for mutagenic activity. (Sodium hydroxide)

Teratogenicity:
No risk for developmental toxicity. (Sodium hydroxide)

Reproductive Effects:
No risk for toxicity to reproduction. (Sodium hydroxide)

Sensitization:
Data indicates that sodium hydroxide is not a skin sensitizer.

Ecotoxicity:

Ecotoxicity - Freshwater Fish Species Data
Sodium hydroxide 1310-73-2 96 Hr LC50 Oncorhynchus mykiss: 45.4 mg/L [static]

Persistance and Degradability:
No data available.

Bioaccumulative Potential:
No data available.

Mobility in Environmental Media:
No data available.
13. DISPOSAL CONSIDERATIONS

Methods of Disposal:
Dispose of unused product, spilled material and waste in accordance with all applicable federal, state, local and provincial environmental and hazardous waste regulations.

Waste Classification:
U.S. - California - 22 CCR - Presumed Hazardous Wastes
Sodium hydroxide 1310-73-2 Toxic; Corrosive

14. TRANSPORT INFORMATION

DOT

<table>
<thead>
<tr>
<th>Proper Shipping Name</th>
<th>Sodium hydroxide solution</th>
</tr>
</thead>
<tbody>
<tr>
<td>Hazard Class</td>
<td>8</td>
</tr>
<tr>
<td>UN Number</td>
<td>UN1824</td>
</tr>
<tr>
<td>Packaging Group</td>
<td>III</td>
</tr>
</tbody>
</table>

Basic Shipping Description:
International Air Transport Association (IATA) Dangerous Goods Classification

UN Number: UN 3316
Proper Shipping Name: Chemical Kit
Hazard Class: 9
Hazard Label: Miscellaneous

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 hydroxide 1310-73-2 Present

U.S. - CERCLA/SARA - Hazardous Substances and their Reportable Quantities
Sodium hydroxide 1310-73-2 1000 lb final RQ; 454 kg final RQ

US State Regulations:
U.S. - California - 8 CCR Section 339 - Director's List of Hazardous Substances
Sodium hydroxide 1310-73-2 Present
MATERIAL SAFETY DATA SHEET
OSOM® BVBLUE® Developer Solution

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 hydroxide 1310-73-2 E (including 0.08%, 2%, 2.5%, 5%, 0.01 N, 0.04 N, 0.1 N, 10%, 16%, 1 N, 20%, 40%, 50%, 8.7N)

Canada - WHMIS - Ingredient Disclosure List
Sodium hydroxide 1310-73-2 1 %

EU - Dangerous Substances Directive (67/548/EEC) - Annex I - Classification
Sodium hydroxide 1310-73-2 C; R35

EU - Dangerous Substances Directive (67/548/EEC) - Annex I - Concentration Limits
Sodium hydroxide 1310-73-2 5%<=C: C; R35 2%<C<5%: C; R34 0.5%<=C<2%: Xi; R36/38

Sodium hydroxide 1310-73-2 S:1/2-26-37/39-45

Germany - Water Classification (VwVwS) - Annex 2 - Water Hazard Classes
Sodium hydroxide 1310-73-2 ID Number 142, hazard class 1 - low hazard to waters (footnote 8)

Inventory - Australia - Inventory of Chemical Substances (AICS)
Sodium hydroxide 1310-73-2 Present

Inventory - Canada - Domestic Substances List (DSL)
Sodium hydroxide 1310-73-2 Present

Inventory - China
Sodium hydroxide 1310-73-2 Present

Inventory - European Union - European Inventory of Existing Commercial Chemical Substances (EINECS)
Sodium hydroxide 1310-73-2 215-185-5

Inventory - Japan Existing and New Chemical Substances (ENCS)
Sodium hydroxide 1310-73-2 1-410; 2-1972

Inventory - Korea - Existing and Evaluated Chemical Substances
Sodium hydroxide 1310-73-2 KE-31487

Canadian Hazardous Products:
WHMIS Status Exempt

European Communities Dangerous Substances/Preparations:
EC Hazard Class C - Corrosive
Symbols

Risk Phrases
R34 Causes burns.

Safety Phrases
S26 In case of contact with eyes, rinse immediately with plenty of water and seek medical advice.
S37/39 Wear suitable gloves and eye/face protection.
S45 In case of accident or if you feel unwell, seek medical advice immediately (show the label where possible).

16. OTHER INFORMATION

Further Information:
BVBLUE® is a registered trademark of Gryphus Diagnostics, LLC.

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).
MATERIAL SAFETY DATA SHEET
OSOM® BVBLUE® Testing Vessel

1. PRODUCT AND COMPANY IDENTIFICATION

Product Name: OSOM® BVBLUE® Testing Vessel
Synonym(s): Testing Vessel
Product Use: Component of OSOM® BVBLUE® Test kit (catalog # 183 & 183E). For use in the detection of sialidase enzyme activity in vaginal fluid specimens, to aid in the diagnosis of Bacterial Vaginosis infection. For In Vitro Diagnostic Use Only.
Description: Aqueous salt solution containing a chromogenic substrate of the sialidase enzyme.

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

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

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 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>No data available.</td>
</tr>
<tr>
<td>Eye</td>
<td>No data available.</td>
</tr>
<tr>
<td>Skin</td>
<td>No data available.</td>
</tr>
<tr>
<td>Ingestion</td>
<td>Ingestion of potassium acetate produces a diuretic effect (increased urination).</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® BVBLUE® Testing Vessel

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>95</td>
</tr>
<tr>
<td>EC R-Phrases: None</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Potassium acetate</td>
<td>127-08-2</td>
<td>204-822-2</td>
<td>4.9</td>
</tr>
<tr>
<td>EC R-Phrases: None</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>IBX-4041 (chromogenic substrate compound)</td>
<td>Not Assigned</td>
<td>Not Assigned</td>
<td>0.05</td>
</tr>
<tr>
<td>EC R-Phrases: None</td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

EC Hazard Class:
Water: None
Potassium acetate: None
IBX-4041 (chromogenic substrate compound): Not Assigned

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 and avoid aerosol inhalation. Wash hands thoroughly after handling.

Environmental Precautions:
No information available.

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. Minimize contact and contamination of personal clothing and skin. See Section 8, Engineering Controls. Wash hands thoroughly after handling.

Storage:
Store at 2 - 8°C (36 - 46°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>Respiratory</th>
<th>A respirator is not required under normal conditions of use.</th>
</tr>
</thead>
<tbody>
<tr>
<td>Eye/Face</td>
<td>Wear appropriate protective chemical safety glasses.</td>
</tr>
<tr>
<td>Skin</td>
<td>Wear appropriate protective clothing, such as a lab coat or</td>
</tr>
<tr>
<td></td>
<td>other long-sleeved garment over clothing to minimize</td>
</tr>
<tr>
<td></td>
<td>contact and contamination of clothing. Change into clean</td>
</tr>
<tr>
<td></td>
<td>clothes promptly if clothing becomes contaminated.</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>Appearance:</th>
<th>Clear liquid</th>
</tr>
</thead>
<tbody>
<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>No available</td>
</tr>
<tr>
<td>pH:</td>
<td>5.5 - 6.0</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:
Unknown.

Incompatible Materials:
Unknown.

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
Potassium acetate 127-08-2 Oral LD50 Rat: 3250 mg/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
Potassium acetate 127-08-2 96 Hr LC50 Oncorhynchus mykiss: 6800 mg/L [semi-static]

Ecotoxicity - Water Flea Data
Potassium acetate 127-08-2 24 Hr EC50 Daphnia magna: 7170 mg/L
MATERIAL SAFETY DATA SHEET
OSOM® BVBLE® Testing Vessel

13. DISPOSAL CONSIDERATIONS

Methods of Disposal:
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:
International Air Transport Association (IATA) Dangerous Goods Classification

UN Number: UN 3316
Proper Shipping Name: Chemical Kit
Hazard Class: 9
Hazard Label: Miscellaneous

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)
Potassium acetate 127-08-2 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
Potassium acetate 127-08-2 Uncontrolled product according to WHMIS classification criteria

Germany - Water Classification (VwVwS) - Annex 2 - Water Hazard Classes
Potassium acetate 127-08-2 ID Number 757, hazard class 1 - low hazard to waters

Inventory - Australia - Inventory of Chemical Substances (AICS)
Potassium acetate 127-08-2 Present

Inventory - Canada - Domestic Substances List (DSL)
Potassium acetate 127-08-2 Present

Inventory - China
Potassium acetate 127-08-2 Present

Inventory - European Union - European Inventory of Existing Commercial Chemical Substances (EINECS)
Potassium acetate 127-08-2 204-822-2

Inventory - Japan Existing and New Chemical Substances (ENCS)
Potassium acetate 127-08-2 2-692

Inventory - Korea - Existing and Evaluated Chemical Substances
Potassium acetate 127-08-2 KE-29069
MATERIAL SAFETY DATA SHEET
OSOM® BVBLUE® Testing Vessel

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:
BVBLUE® is a registered trademark of Gryphus Diagnostics, LLC.

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: June 03, 2004
Version #: 5
Revision Date: November 12, 2008

Disclaimer:
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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.

More information is available at: http://www.cms.hhs.gov/

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](http://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](http://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](http://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.


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.
CLIA Approved Proficiency Testing Programs - 2008

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
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