

# CLIA Training Packet



## OSOM<sup>®</sup> Ultra Strep A Test CLIA Waived

**Genzyme Diagnostics**  
**Point of Care Diagnostic Products**

Distributed by: **CLIAwaived.com<sup>™</sup>**  
San Diego, CA 92121  
tel 858-481-5031  
toll free 888-882-7739  
[www.cliawaived.com](http://www.cliawaived.com)

## Genzyme Diagnostics CLIA Packet

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Welcome to the Genzyme OSOM<sup>®</sup> Ultra Strep A 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<sup>®</sup> Ultra Strep A 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

## Some information you may find useful:

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**CLIA Complexity:** Waived

**CPT Code:** 87880QW (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 with a sterile swab from the tonsils and /or the back of the throat. Take care to avoid the teeth, gums, tongue and cheek surfaces.

Use of sterile rayon swabs supplied with the kit is recommended. Swabs with transport tubes containing liquid media may also be used. Swabs from other suppliers have not been validated. Do not use swabs that have cotton tips or wooden shafts. Do not use calcium alginate swabs. Do not use a collection system that contains charcoal or a semisolid transport media.

**Specimen Storage:** Process the swab as soon as possible after collecting the specimen. You may store and transport swabs dry or in Stuart's Transport Media. If you do not perform the OSOM Ultra Strep A Test immediately, store the swabs at room temperature or refrigerate the swabs for up to 24 hours. The swabs and the test kit must be at room temperature before you perform the test.

**Quality Control:** Several controls are incorporated into each OSOM<sup>®</sup> Ultra Strep A test device as routine quality checks. For a test to be considered valid, a red visible line must be present at the Control ("C") position on the Test Stick within the specified read time. Additionally, the Test Stick's background must be clear.

Genzyme recommends that external positive and negative quality control samples be tested 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 5 minutes. Results are considered invalid beyond the stated read time.
- Refer to the Package Insert for specific information and additional procedural notes.

**Expected Results:** Approximately 19% of all upper respiratory tract infections are caused by Group A Streptococci. Streptococcal pharyngitis displays a seasonal variation and is most prevalent during winter and early spring. The highest incidence of this disease is found in crowded populations such as military bases and in school-age children.

**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](http://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.

CLIAwaived<sup>TM</sup>.com



## **I. TEST NAME**

OSOM<sup>®</sup> Ultra Strep A 50T  
CLIA: Waived

## **II. INTENDED USE**

The OSOM Ultra Strep A Test is a color immunochromatographic assay intended for the qualitative detection of Group A Streptococcal antigen directly from throat swab specimens.

## **III. SUMMARY AND EXPLANATION OF TEST**

Group A Streptococcus is one of the most important causes of acute upper respiratory tract infection. Early diagnosis and treatment of Group A Streptococcal pharyngitis has been shown to reduce the severity of symptoms and further complications such as rheumatic fever and glomerulonephritis. Conventional identification procedures for Group A Streptococcus from throat swabs involve the isolation and subsequent identification of viable pathogens by techniques that require 18 to 24 hours or longer. The OSOM Ultra Strep A Test detects either viable or nonviable organisms directly from a throat swab, providing results within 7 minutes.

## **IV. PRINCIPLES OF TEST**

The OSOM Ultra Strep A Test is a color immunochromatographic assay using Dual Label Technology (DLT). DLT uses antibody labeled color particles coated at two separate locations in the test device. DLT allows greater sensitivity than the conventional single label technology without sacrificing specificity. In the test procedure, a throat swab is subjected to a chemical extraction of a carbohydrate antigen unique to Group A Streptococcus. The Test Stick is then placed in the extraction mixture and the mixture migrates along the membrane. If Group A Streptococcus is present in the sample, it will form complexes with the anti-Group A Streptococcus antibody conjugated color particles located at two separate locations on the Test Stick. The complex will then be bound by the anti-Group A Streptococcus capture antibody and a visible blue Test Line will appear to indicate a positive result. A red Control Line will also appear to indicate the test is valid.

## **V. KIT CONTENTS AND STORAGE**

Contents:

50 Test Sticks Coated with Rabbit Anti-Group A Streptococcus

50 Test Tubes

50 Sterile Swabs

1 Reagent A (2 M Sodium Nitrite). Caution: Harmful if swallowed

1 Reagent B (0.3 M Acetic Acid). Warning: Severe eye irritant

1 Positive Control (Nonviable Group A Streptococci, 0.1% Sodium Azide)

1 Negative Control (Nonviable Group C Streptococci, 0.1% Sodium Azide)

1 Workstation

1 Directional Insert

Note: Extra components (swabs, tubes) have been provided for your convenience.

- Store Test Sticks and reagents tightly capped at 15°-30°C (59°-86°F).
- Do not use Test Sticks or reagents after expiration date.

At this facility, kits are stored: \_\_\_\_\_

<b>VI. MATERIALS REQUIRED BUT NOT PROVIDED</b>
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A timer or watch

<b>VII. PRECAUTIONS</b>
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- For *in vitro* diagnostic use
- Follow your laboratory safety guidelines in the collection, handling, storage and disposal of controls, patient specimens and all items exposed to patient specimens.
- Caution: The Reagent A contains Sodium Nitrite and may be harmful if swallowed. Do not taste or swallow. Wash thoroughly after handling.
- Warning: The Reagent B contains an acidic solution that will cause skin and eye irritation. If the solution comes in contact with the skin or eyes, flush with large volumes of water.
- The Positive and Negative Controls contain sodium azide which may react with lead or copper plumbing to form potentially explosive metal azide. Large quantities of water must be used to flush discarded control material down a sink.
- Do not interchange or mix components from different kit lots.

<b>VIII. PATIENT PREPARATION &amp; SPECIMEN COLLECTION</b>
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This facility's procedure for patient preparation is: \_\_\_\_\_

This facility's procedure for sample labeling is: \_\_\_\_\_

*Specimen Collection and Handling:*

Collect specimens with a sterile swab from the tonsils and/or the back of the throat. Take care to avoid the teeth, gums, tongue or cheek surfaces.

Use of sterile swabs supplied with the kit is recommended. Swabs from other suppliers have not been validated. Do not use swabs that have cotton tips or wooden shafts. Do not use calcium alginate swabs. Do not use a collection system that contains charcoal or semisolid transport media.

Process the swab as soon as possible after collecting the specimen. If your lab requires a culture result as well as the OSOM Ultra Strep A Test result, streak the culture plate with the swab before starting the OSOM Ultra Strep A Test procedure. The extraction reagents will cause the specimen to become nonviable.

Because the OSOM Ultra Strep A Test does not require live organisms for processing, you may store and transport the swabs dry or in Liquid Stuart's Transport Media. If you do not perform the OSOM Ultra Strep A Test immediately, store the swabs either at room or refrigerated temperature for up to 48 hours. The swabs and the test kit must be at room temperature before you perform the test.

This facility's procedure for transporting specimens is: \_\_\_\_\_

This facility's procedure for rejected specimens is: \_\_\_\_\_

## **IX. QUALITY CONTROL & ASSURANCE**

### **Internal Procedural Controls:**

The OSOM Ultra Strep A Test provides three levels of procedural controls with each test run:

- The color of the liquid changes from pink to light yellow after Reagent B is added to Reagent A and the extraction reagents are mixed. This is an internal extraction reagent control. The color change means you have mixed the extraction reagents properly. The color change also means that the reagents are functioning properly.
- The red Control Line is an internal positive procedural control. For the Test Stick to be working properly, capillary flow must occur. The Test Stick must absorb the proper amount of sample and the Test Stick must be working properly for the red Control Line to appear.
- A clear background is an internal background negative procedural control. If no interfering substances are in the specimen and the Test Stick is working properly, the background will clear. A discernible result will be seen.

If the red Control Line does not appear the test is invalid. If the background does not clear and interferes with the test result, the test is invalid. Call Genzyme Diagnostics Technical Service if you experience either of these problems.

### **External Quality Control Testing:**

Each kit contains Positive and Negative Control material. The controls are for external quality control testing. Use the Controls to test that the extraction reagents and the Test Sticks are working properly. Also use the Controls to test that you are able to correctly perform the test procedure, including the antigen extraction portion of the test procedure. If you choose, you may use Group A and non Group A Streptococcus ATCC reference strains as external controls. Some commercial controls may contain interfering additives. Therefore Genzyme Diagnostics recommends that you do not use commercial controls with the OSOM Ultra Strep A Test.

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 Procedure:*

- Follow the instructions in the TEST PROCEDURE section to dispense Reagents A and B into the Test Tube.
- Vigorously mix the Control material. Add 1 free falling drop of the Control from the dropper bottle into the Test Tube.
- Place a clean swab into the Test Tube.
- Follow the instructions in the TEST PROCEDURE section to test the 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: \_\_\_\_\_  
\_\_\_\_\_.

<b>X. TEST PROCEDURE</b>
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- Just before testing, add 3 drops Reagent A (pink) and 3 drops Reagent B to the Test Tube (the solution should turn light yellow).
- Immediately put the swab into the Tube.
- Vigorously mix the solution by rotating the swab forcefully against the side of the Tube at least ten (10) times. Best results are obtained when the specimen is vigorously extracted in the solution.
- Let stand for **2 minutes**.
- Express as much liquid as possible from the swab by squeezing the sides of the tube as the swab is withdrawn.
- Discard the swab.
- Remove the Test Stick(s) from the container; re-cap the container immediately.
- Place the Absorbent End of the Test Stick into the extracted sample.
- Read results at 5 minutes. Positive results may be read as soon as the red Control Line appears. Negative results must be confirmed at 5 minutes.

**Results are invalid after the read time. The use of a timer is recommended.**

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 TEST RESULTS**

**Positive:**

A blue Test Line and a red Control Line is a positive result. A positive result means that the assay detected Group A Streptococcus antigen in the specimen.

Note that the blue line can be any shade of blue and can be lighter or darker than the line in the picture.

**Negative:**

A red Control Line but no blue Test Line is a negative result. A negative result means that no Group A Streptococcus antigen was detected, or the levels of antigen in the specimen were below the detection level of the assay.

**Invalid:**

If after 5 minutes, 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 using a new sample or contact Genzyme Diagnostics Technical Service.

**Notes:**

A blue or red line that appears uneven in color density is still considered a valid line. In some cases, a trail of color may remain in the background; as long as the Test Line and Control Line are visible, the results are valid.

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**

As with all diagnostic assays, the results obtained by this test yield data that must be used only as an adjunct to other information available to the physician. The following factors must be considered to obtain reliable results:

- The OSOM Ultra Strep A Test is a qualitative test for the detection of Group A Streptococcal antigen. This test detects both viable and non-viable Group A Streptococci, and may yield a positive result in the absence of living organisms.
- The quality of the test depends on the quality of the sample; proper throat swab specimens must be obtained. Negative results can occur from inadequate specimen collection or antigen level, which is below the detection limit of the test.
- The OSOM Ultra Strep A Test should be used only with throat swab specimens. The use of swab specimens taken from other sites or the use of other samples such as saliva, sputum or urine has not been established.
- This test does not differentiate between carriers and acute infection.
- Pharyngitis may be caused by viral or bacterial pathogens other than Group A Streptococcus.
- If the test result is inconsistent with the clinical symptoms, a second throat swab should be collected for repeat testing.

The American Academy of Pediatrics states: "Several rapid diagnostic tests for GAS pharyngitis are available. .... The specificities of these tests generally are high, but the reported sensitivities vary considerably. As with throat cultures, the accuracy of these tests is most dependent on the quality of the throat swab specimen, which must contain pharyngeal and tonsillar secretions, and on the experience of the person who is performing the test. Therefore, when a patient suspected of having GAS pharyngitis has a negative rapid streptococcal test, a throat culture should be obtained to ensure that the patient does not have GAS infection." It also states: "Cultures that are negative for GAS infection after 24 hours should be incubated for a second day to optimize isolation of GAS."

### **XIV. EXPECTED RESULTS**

Approximately 19% of all upper respiratory tract infections are caused by Group A Streptococci. Streptococcal pharyngitis displays a seasonal variation and is most prevalent during winter and early spring. The highest incidence of this disease is found in crowded populations such as military bases and in school-age children.

## **XV. CROSS REACTIVITY**

The following organisms tested at levels of approximately  $1 \times 10^8$  organisms/test were all found to be negative when tested with the OSOM Strep A Test.

Streptococcus Group B	Staphylococcus aureus	Neisseria meningitis
Streptococcus Group C	Staphylococcus epidermidis	Neisseria gonorrhoea
Streptococcus Group F	Corynebacterium diphtheria	Neisseria sicca
Streptococcus Group G	Serratia marcescens	Neisseria subflava
Streptococcus pneumoniae	Candida albicans	Branhamella catarrhalis
Streptococcus sanguis	Klebsiella pneumoniae	Haemophilus influenza
Streptococcus mutans	Pseudomonas aeruginosa	
Enterococcus faecalis	Bordetella pertussis	

## **XVI. PERFORMANCE CHARACTERISTICS & POL STUDIES**

Refer to Directional Insert

## **XVII. REFERENCES**

Refer to Directional Insert

## **XVIII. ASSISTANCE**

For technical assistance, call Genzyme Diagnostics Technical Service at 800-332-1042.

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Diagnostics OSOM<sup>®</sup> Ultra Strep A Patient Test Log

Kit Lot #: \_\_\_\_\_ Exp. Date: \_\_\_\_\_

Hospital/Clinic Name: \_\_\_\_\_ Received Date: \_\_\_\_\_ Date in Use: \_\_\_\_\_

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

TEST RESULT: *Negative* = a red Control Line only. *Positive* = a blue Test Line and a red Control Line

	Date	Operator	Patient Name/ ID	Test Result (Neg/Pos)	INTERNAL QUALITY CONTROL			Comments/Actions
					3 drops each Reagent A & B Pink to Yellow? Y/N	Red Control Line Visible? Y/N	Clear Background? Y/N	
					IF "NO" ANSWERED ABOVE, TEST IS INVALID- REPEAT WITH NEW SAMPLE			
1			<b>Positive Control</b> Lot: _____ Exp. Date: _____					
2			<b>Negative Control</b> Lot: _____ Exp. Date: _____					
3								
4								
5								
6								
7								
8								
9								
10								



## OSOM<sup>®</sup> Ultra Strep A Patient Test Log (page 2)

	Date	Operator	Patient Name/ ID	Test Result (Neg/Pos)	INTERNAL QUALITY CONTROL			Comments/Actions
					3 drops each Reagent A & B Pink to Yellow? Y/N	Red Control Line Visible? Y/N	Clear Background? Y/N	
					IF "NO" ANSWERED ABOVE, TEST IS INVALID- REPEAT WITH NEW SAMPLE			
11								
12								
13								
14								
15								
16								
17								
18								
19								
20								
21								
22								
23								
23								

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Reviewed by: \_\_\_\_\_

Date: \_\_\_\_\_



# Certificate



Training Certification

CLIA Waived.com<sup>TM</sup>

\_\_\_\_\_  
Name

has been successfully trained on the following Genzyme products:

- |  |   |   |  |
|--|---|---|--|
| <input type="checkbox"/> OSOM <sup>®</sup> Strep A             | <input type="checkbox"/> OSOM <sup>®</sup> Ultra Strep A  | <input type="checkbox"/> OSOM <sup>®</sup> Mono                                   | <input type="checkbox"/> OSOM <sup>®</sup> hCG Combo |
| <input type="checkbox"/> OSOM <sup>®</sup> hCG Urine           | <input type="checkbox"/> OSOM <sup>®</sup> Card Pregnancy | <input type="checkbox"/> OSOM <sup>®</sup> Influenza A&B                          |  |
| <input type="checkbox"/> OSOM <sup>®</sup> BVBLUE <sup>®</sup> | <input type="checkbox"/> OSOM <sup>®</sup> Trichomonas    | <input type="checkbox"/> OSOM <sup>®</sup> ImmunoDip <sup>®</sup> Urinary Albumin |  |

\_\_\_\_\_  
Trainer/ Title

\_\_\_\_\_  
Date

# OSOM<sup>®</sup> Ultra Strep A Test (#149) - Operator Competency Exam

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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 Inservice:**

- Procedural review, including control requirements
- Demonstration of the test procedure
- Successful performance of the OSOM<sup>®</sup> Ultra Strep A test procedure
- Test interpretation and results

**I have read and understood the complete OSOM<sup>®</sup> Ultra Strep A test procedure, and have been trained in the above test and test procedure.**

**Operator Signature:** \_\_\_\_\_ **Date:** \_\_\_\_\_

## **Competency Exam:**

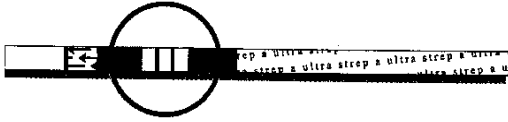
The following exam is administered as proof of competency for personnel performing the OSOM<sup>®</sup> Ultra Strep A test using patient swabs. Please circle your response to each question.

- Using the OSOM<sup>®</sup> Ultra Strep A test, how many drops of Reagent A and Reagent B should be added to the test tube?**
  - three of Reagent A and three of Reagent B
  - six of Reagent A and six of Reagent B
- After the addition of Reagents A & B to the test tube, the color of the solution should change from \_\_\_\_\_ to \_\_\_\_\_ as an internal control.**
  - pink to light yellow
  - light yellow to clear
- After dispensing the reagents, the swab should be placed in the test tube, vigorously mixed with the reagent, and allowed to stand for \_\_\_\_\_ minute(s).**
  - one
  - two
- Negative results from the OSOM<sup>®</sup> Ultra Strep A test strip must be read at \_\_\_\_\_ minute(s).**
  - one
  - two
  - five
  - any point after addition of test strip

5. Interpret the following results:

#1

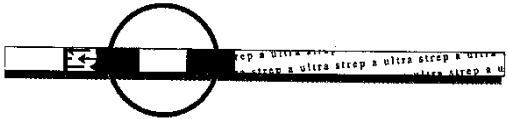
Device #1 is showing a(n) \_\_\_\_\_ result:



- A. Positive
- B. Negative
- C. Invalid

#2

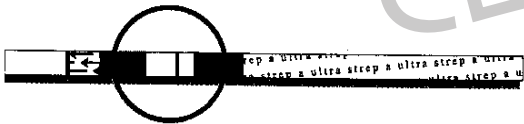
Device #2 is showing a(n) \_\_\_\_\_ result:



- A. Positive
- B. Negative
- C. Invalid

#3

Device #3 is showing a(n) \_\_\_\_\_ result:



- 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)

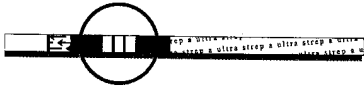
# OSOM<sup>®</sup> Ultra Strep A Test - Operator Competency Exam - ANSWER KEY

## Competency Exam Answers:

- Using the OSOM<sup>®</sup> Ultra Strep A test, how many drops of Reagent A and Reagent B should be added to the test tube?
  - three of Reagent A and three of Reagent B
- After the addition of Reagents A & B to the test tube, the color of the solution should change from \_\_\_\_\_ to \_\_\_\_\_ as an internal control.
  - pink to light yellow
- After dispensing the reagents, the swab should be placed in the test tube, vigorously mixed with the reagent, and allowed to stand for \_\_\_\_\_ minute(s).
  - two
- Negative results from the OSOM<sup>®</sup> Ultra Strep A test strip must be read at \_\_\_\_\_ minute(s).
  - five
- Interpret the following results:

#1

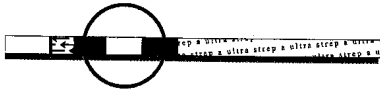
Device #1 is showing a(n) \_\_\_\_\_ result:



A. Positive

#2

Device #2 is showing a(n) \_\_\_\_\_ result:



C. Invalid

#3

Device #3 is showing a(n) \_\_\_\_\_ result:



B. Negative



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

**MATERIAL SAFETY DATA SHEETS**

Catalog Number:	Kit Name:
<b>149</b>	<b>OSOM<sup>®</sup> Ultra Strep A Test</b>

Item Number:	Component Name:
<b>1006</b>	<b>OSOM<sup>®</sup> Ultra Strep A Extraction Reagent A</b>
<b>1007</b>	<b>OSOM<sup>®</sup> Ultra Strep A Extraction Reagent B<sup>™</sup></b>
<b>1003</b>	<b>OSOM<sup>®</sup> Strep A Positive Control</b>
<b>1009</b>	<b>OSOM<sup>®</sup> Strep A Negative Control</b>

Note: The page numbers on the 4 individual MSDSs for this kit are specific to each document. There are a total of 30 pages including this cover sheet.

OSOM<sup>®</sup> Ultra Strep A Test Stick is an "article" and does not require an MSDS.



# MATERIAL SAFETY DATA SHEET

## OSOM® Ultra Strep A Extraction Reagent A

### 1. PRODUCT AND COMPANY IDENTIFICATION

**Product Name:** OSOM® Ultra Strep A Extraction Reagent A

**Synonym(s):** Ultra Strep A Extraction Reagent A

**Product Use:** Component of OSOM® Ultra Strep A Test kit (catalog # 149). For use in the qualitative detection of Group A Streptococcal antigen. For In Vitro Diagnostic Use Only.

**Description:** Aqueous solution containing color indicator and inorganic salt.

**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

**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:**

WARNING! The chemical, physical and toxicological properties of this preparation have not been thoroughly characterized. Avoid contact with eyes and skin. Do not ingest or inhale. Toxic by ingestion. Harmful by inhalation and in contact with skin. May cause severe eye irritation. Preparation appearance: clear, pink liquid.

**Routes of Exposure:**

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

**Potential Health Effects:**

- |                        |   |
|------------------------|---|
| <b>Inhalation</b>      | Substantial aerosol inhalation may result in symptoms similar to those specified for ingestion.   |
| <b>Eye</b>             | Eye exposure may cause severe irritation, redness, watering, swelling and burning.  |
| <b>Skin</b>            | Skin contact with sufficient chemical absorption may result in symptoms similar to those specified for ingestion.   |
| <b>Ingestion</b>       | Ingestion may cause gastric irritation, nausea, vomiting and abdominal pain. Significant exposure may result in a drop in blood pressure, headache, dizziness, rapid pulse and visual problems. Skin may be flushed and sweaty and then become cold. Skin and lips may turn blue. |
| <b>Chronic Effects</b> | Chronic effects from repeated or long-term occupational exposure to this preparation are unknown. Chronic exposure to nitrites may cause headaches, visual problems and decreased blood pressure.   |
| <b>Target Organs</b>   | Sodium nitrite: Cardiovascular and central nervous systems.   |

**Regulatory Status:**

This preparation is classified as hazardous under U.S. OSHA 29 CFR 1910.1200; E.C. Directive 1999/45/EC; Canadian R.S. 1985, c. H-3; U.K. CHIP 2002 No. 1689; and/or U.N. GHS ST/SG/AC 10/30. Refer to Sec. 15, Regulatory Information, for details regarding hazard classification.

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:**

May be harmful for the aquatic environment.

### 3. COMPOSITION / INFORMATION ON INGREDIENTS



## MATERIAL SAFETY DATA SHEET

### OSOM® Ultra Strep A Extraction Reagent A

Ingredient Name	CAS #	EC #	% (wt/wt)
Water	7732-18-5	231-791-2	84 - 88
EC R-Phrases: None	EC Hazard Class: None		
Sodium nitrite	7632-00-0	231-555-9	12 - 14
EC R-Phrases: R8, R25, R50	EC Hazard Class: T, O, N		
Phenol red, free acid	143-74-8	205-609-7	< 0.01
EC R-Phrases: None	EC Hazard Class: None		

#### 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 immediate medical attention.

**Skin Contact:**

In case of contact, immediately flush skin with 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:**

Not considered to be 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:**

When heated to decomposition, may produce carbon monoxide (CO), carbon dioxide (CO<sub>2</sub>), nitrogen oxides (NO<sub>x</sub>) and sulphur oxides (SO<sub>x</sub>).

**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. Ensure adequate ventilation. Wear Personal Protective Equipment (PPE) as indicated in Section 8. Wash hands thoroughly after handling.

**Environmental Precautions:**

Do not let product enter drains.



## MATERIAL SAFETY DATA SHEET

### OSOM® Ultra Strep A Extraction Reagent A

#### 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. Mixing Strep A Extraction Reagents A and B yields nitrous acid, which may immediately decompose into toxic nitrous gas, a short-term reaction by-product. Minimize contact and contamination of personal clothing and skin. Avoid vapor or aerosol inhalation. Wash hands thoroughly after handling.

#### Storage:

Store at 15 to 30°C (59 to 86°F). Keep container tightly closed in a dry and well-ventilated place. 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:

Provide adequate mechanical ventilation to keep airborne concentrations low. Facilities storing or using this preparation should be equipped with an eyewash fountain.

#### Personal Protective Equipment (PPE):

<b>Respiratory</b>	A respiratory protection program that meets U.S. Federal OSHA 29 CFR 1910.134 and ANSI Z99.2, Canadian CSA Standard Z94.4-93, European Standard CR 529, or other applicable regulatory standards must be followed whenever exposure limits may be exceeded (if applicable), engineering controls are not feasible, or if insufficient ventilation or workplace conditions warrant respirator use.
<b>Eye/Face</b>	Wear appropriate protective chemical safety goggles.
<b>Skin</b>	Wear lab coat or other protective garments. Wear impervious shoe covers for spill clean-up. Remove contaminated clothing promptly.
<b>Gloves</b>	Wear chemical resistant protective gloves.
<b>General</b>	Follow company-specific safety procedures.

## 9. PHYSICAL AND CHEMICAL PROPERTIES

<b>Appearance:</b>	Clear, pink liquid	<b>pH:</b>	9 (approximate)
<b>Odor:</b>	Not available	<b>Solubility:</b>	Water-soluble
<b>Specific Gravity:</b>	1.08 (approximate)	<b>Vapor Pressure:</b>	Not available
<b>Boiling Point:</b>	Not available	<b>Partition Coefficient (n-octanol/water):</b>	Not available
<b>Melting Point:</b>	Not applicable	<b>Vapor Density:</b>	Not available
<b>Freezing Point:</b>	Not available		
<b>Chemical Family:</b>	Alkaline solution		



## MATERIAL SAFETY DATA SHEET

### OSOM® Ultra Strep A Extraction Reagent A

**Flammability/Explosivity Limits in Air, Lower:** Not available  
**Flammability/Explosivity Limits in Air, Upper:** Not available  
**Auto-Ignition Temperature:** Not available  
**Flash Point:** Not available

#### 10. STABILITY AND REACTIVITY

**Chemical Stability:**

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

**Conditions to Avoid:**

Solution is oxidized by air. Avoid high temperatures.

**Incompatible Materials:**

Avoid amines, ammonium salts, cyanides and reducing agents. Heat and acids will result in release of nitrous gas. Under certain conditions, nitrite compounds may react with secondary and tertiary amines to form nitrosamines, which are known carcinogens in animals.

**Hazardous Decomposition Products:**

Thermal decomposition may lead to release of irritating gases and vapors.

**Possibility of Hazardous Reactions:**

Hazardous polymerization will not occur.

#### 11. TOXICOLOGICAL INFORMATION

**Acute Effects:**

Toxic by ingestion. Harmful by inhalation and in contact with skin. May cause severe eye irritation. Sodium nitrite exposure may result in a drop in blood pressure, headache, vertigo, palpitations, visual disturbances, methemoglobinemia, dyspnea and respiratory depression.

**Toxicology Data - Selected LD50s and LC50s**

Sodium nitrite	7632-00-0	Inhalation LC50 Rat: 5500 µg/m <sup>3</sup> /4H; Oral LD50 Rat: 88 mg/kg
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**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



# MATERIAL SAFETY DATA SHEET

## OSOM® Ultra Strep A Extraction Reagent A

### Ecotoxicity:

#### Ecotoxicity - Freshwater Fish Species Data

Sodium nitrite	7632-00-0	96 Hr LC50 Oncorhynchus mykiss: 0.19 mg/L [flow-through] (juvenile)
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### Persistence 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 nitrite	7632-00-0	Toxic; Ignitable; Reactive
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## 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

Packing Group: PG III

Packaging Instruction: Y915

Special Provisions: A44 (excepted quantities)

U.S. Department of Transportation (DOT)

Consumer Commodity, ORM-D

## 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 nitrite	7632-00-0	Present
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#### U.S. - CERCLA/SARA - Hazardous Substances and their Reportable Quantities

Sodium nitrite	7632-00-0	100 lb final RQ; 45.4 kg final RQ
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#### U.S. - CERCLA/SARA - Section 313 - Emission Reporting

Sodium nitrite	7632-00-0	1.0 % de minimis concentration
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### US State Regulations:

#### U.S. - California - 8 CCR Section 339 - Director's List of Hazardous Substances

Sodium nitrite	7632-00-0	Present
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# MATERIAL SAFETY DATA SHEET

## OSOM® Ultra Strep A Extraction Reagent A

### 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 - Ingredient Disclosure List

Sodium nitrite 7632-00-0 1 %

#### EU - Dangerous Substances Directive (67/548/EEC) - Annex I - Classification

Sodium nitrite 7632-00-0 O;R8 T;R25 N;R50

#### EU - Dangerous Substances Directive (67/548/EEC) - Annex I - Concentration Limits

Sodium nitrite 7632-00-0 25%≤C: T,N; R25-50 5%≤C<25%: T; R25 1%≤C<5%: Xn; R22

#### EU - Dangerous Substances Directive (67/548/EEC) - Annex I - Safety Phrases

Sodium nitrite 7632-00-0 S:1/2-45-61

#### Germany - Water Classification (VwVwS) - Annex 2 - Water Hazard Classes

Sodium nitrite 7632-00-0 ID Number 161, hazard class 2 - hazard to waters

#### Inventory - Australia - Inventory of Chemical Substances (AICS)

Sodium nitrite 7632-00-0 Present

#### Inventory - Canada - Domestic Substances List (DSL)

Sodium nitrite 7632-00-0 Present

#### Inventory - China

Sodium nitrite 7632-00-0 Present

#### Inventory - European Union - European Inventory of Existing Commercial Chemical Substances (EINECS)

Sodium nitrite 7632-00-0 231-555-9

#### Inventory - Japan Existing and New Chemical Substances (ENCS)

Sodium nitrite 7632-00-0 1-483

#### Inventory - Korea - Existing and Evaluated Chemical Substances

Sodium nitrite 7632-00-0 KE-31546

#### Canadian Hazardous Products:

WHMIS Status Exempt

#### European Communities Dangerous Substances/Preparations:

EC Hazard Class T - Toxic

#### Symbols



#### Risk Phrases

R25 Toxic if swallowed.

#### Safety Phrases

S24/25 Avoid contact with skin and eyes.

S26 In case of contact with eyes, rinse immediately with plenty of water and seek medical advice.

S36/39 Wear suitable protective clothing 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:

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® Ultra Strep A Extraction Reagent A

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**MSDS Origination Date:** January 13, 2005

**Version #:** 6

**Revision Date:** November 13, 2008

**Disclaimer:**

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**MATERIAL SAFETY DATA SHEET**  
**OSOM® Ultra Strep A Extraction Reagent B**

**1. PRODUCT AND COMPANY IDENTIFICATION**

**Product Name:** OSOM® Ultra Strep A Extraction Reagent B

**Synonym(s):** Ultra Strep A Extraction Reagent B

**Product Use:** Component of OSOM® Ultra Strep A Test kit (catalog # 149). For use in the qualitative detection of Group A Streptococcal antigen. For In Vitro Diagnostic Use Only.

**Description:** Aqueous, acidic solution.

**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

**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. Irritating to the eyes. May be irritating to skin and respiratory system. Avoid contact with eyes and skin. Do not ingest or inhale. Preparation appearance: clear, colorless liquid.

**Routes of Exposure:**

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

**Potential Health Effects:**

- Inhalation** Inhalation may be irritating to the nasal passages and throat.
- Eye** Eye exposure will cause immediate irritation, redness and pain.
- Skin** Prolonged skin contact may cause skin irritation with discomfort and rash.
- Ingestion** If large amounts are ingested, symptoms may include digestive irritation and discomfort.
- Chronic Effects** Prolonged or repeated skin contact may cause chronic irritation.
- Target Organs** Eyes and skin.

**Regulatory Status:**

This preparation is classified as hazardous under U.S. OSHA 29 CFR 1910.1200; E.C. Directive 1999/45/EC; Canadian R.S. 1985, c. H-3; U.K. CHIP 2002 No. 1689; and/or U.N. GHS ST/SG/AC 10/30.

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:**

None expected.

**3. COMPOSITION / INFORMATION ON INGREDIENTS**

<b>Ingredient Name</b>	<b>CAS #</b>	<b>EC #</b>	<b>% (wt/wt)</b>
Water	7732-18-5	231-791-2	98 - 99
<b>EC R-Phrases:</b> None	<b>EC Hazard Class:</b> None		



**MATERIAL SAFETY DATA SHEET**  
**OSOM® Ultra Strep A Extraction Reagent B**

Ingredient Name	CAS #	EC #	% (wt/wt)
Acetic acid EC R-Phrases: R10, R35	64-19-7	200-580-7	1 - 2
	EC Hazard Class: C, F		

**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 immediate medical attention.

**Skin Contact:**

In case of contact, flush skin with 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:**

When heated to decomposition, may produce carbon dioxide (CO<sub>2</sub>) and carbon monoxide (CO).

**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. Ensure adequate ventilation. Wear Personal Protective Equipment (PPE) as indicated in Section 8. Wash hands thoroughly after handling.

**Environmental Precautions:**

No special environmental precautions required.

**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.



## MATERIAL SAFETY DATA SHEET

### OSOM® Ultra Strep A Extraction Reagent B

#### 7. HANDLING AND STORAGE

##### Handling:

Follow good laboratory hygiene practices. See Section 8, Engineering Controls. Mixing Strep A Extraction Reagents A and B yields nitrous acid, which may immediately decompose into toxic nitrous gas, a short-term reaction by-product. Minimize contact and contamination of personal clothing and skin. Avoid vapor or aerosol inhalation. Wash hands thoroughly after handling.

##### Storage:

Store at 15 to 30°C (59 to 86°F). Keep container tightly closed. Do not store with incompatible substances; see Section 10.

#### 8. EXPOSURE CONTROLS / PERSONAL PROTECTION

##### Exposure Guidelines:

###### ACGIH - Threshold Limits Values - Short Term Exposure Limits (TLV-STEL)

Acetic acid 64-19-7 15 ppm STEL

###### ACGIH - Threshold Limits Values - Time Weighted Averages (TLV-TWA)

Acetic acid 64-19-7 10 ppm TWA

###### Australia - Occupational Exposure Standards - STELs

Acetic acid 64-19-7 15 ppm STEL; 37 mg/m<sup>3</sup> STEL

###### Australia - Occupational Exposure Standards - TWAs

Acetic acid 64-19-7 10 ppm TWA; 25 mg/m<sup>3</sup> TWA

###### Canada - Quebec - Occupational Exposure Limits - STEVs

Acetic acid 64-19-7 15 ppm STEV; 37 mg/m<sup>3</sup> STEV

###### Canada - Quebec - Occupational Exposure Limits - TWAEVs

Acetic acid 64-19-7 10 ppm TWAEV; 25 mg/m<sup>3</sup> TWAEV

###### China - Occupational Exposure Limits - Permissible Concentration-Short Term (PC-STEL)

Acetic acid 64-19-7 20 mg/m<sup>3</sup> STEL

###### China - Occupational Exposure Limits - Permissible Concentration-Time Weighted Average (PC-TWA)

Acetic acid 64-19-7 10 mg/m<sup>3</sup> TWA

###### EU - Occupational Exposure Directive (2006/15/EC) Indicative Occupational Exposure Limit Values (IOELV) - TWAs

Acetic acid 64-19-7 10 ppm TWA; 25 mg/m<sup>3</sup> TWA

###### Israel - Occupational Exposure Limits - STELs

Acetic acid 64-19-7 15 ppm STEL

###### Israel - Occupational Exposure Limits - TWAs

Acetic acid 64-19-7 10 ppm TWA

###### Japan - Recommended Exposure Limits - TWAs

Acetic acid 64-19-7 10 ppm OEL; 25 mg/m<sup>3</sup> OEL

###### Korea - Occupational Exposure Limits - STELs

Acetic acid 64-19-7 15 ppm STEL; 37 mg/m<sup>3</sup> STEL

###### Korea - Occupational Exposure Limits - TWAs

Acetic acid 64-19-7 10 ppm TWA; 25 mg/m<sup>3</sup> TWA

###### U.S. - OSHA - Final PELs - Time Weighted Averages (TWAs)

Acetic acid 64-19-7 10 ppm TWA; 25 mg/m<sup>3</sup> TWA

##### Engineering Controls:

Provide adequate ventilation by means of mechanical exhaust, to keep airborne concentrations low. Facilities storing or using this preparation should be equipped with an eyewash fountain.

##### Personal Protective Equipment (PPE):

###### Respiratory

A respiratory protection program that meets U.S. Federal OSHA 29 CFR 1910.134 and ANSI Z99.2, Canadian CSA Standard Z94.4-93, European Standard CR 529, or other applicable regulatory standards must be followed whenever exposure limits may be exceeded (if applicable), engineering controls are not feasible, or if insufficient ventilation or workplace conditions warrant respirator use. In such cases an air purifying respirator equipped with an organic vapor/acid gas cartridge is recommended.



## MATERIAL SAFETY DATA SHEET

### OSOM® Ultra Strep A Extraction Reagent B

#### Personal Protective Equipment (PPE):

<b>Eye/Face</b>	Wear appropriate protective chemical safety goggles.
<b>Skin</b>	Wear lab coat or other protective garments. Remove contaminated clothing promptly.
<b>Gloves</b>	Wear chemical resistant protective gloves.
<b>General</b>	Follow company-specific safety procedures.

### 9. PHYSICAL AND CHEMICAL PROPERTIES

<b>Appearance:</b>	Clear, colorless liquid	<b>pH:</b>	2.6 (approximate)
<b>Odor:</b>	Sour, pungent odor like vinegar	<b>Solubility:</b>	Water-soluble
<b>Boiling Point:</b>	Not available	<b>Density:</b>	Not applicable
<b>Melting Point:</b>	Not applicable	<b>Vapor Pressure:</b>	Not available
<b>Freezing Point:</b>	Not available	<b>Partition Coefficient (n-octanol/water):</b>	Not available
		<b>Vapor Density:</b>	Not available

**Chemical Family:** Acidic solution

**Flammability/Explosivity Limits in Air, Lower:** Not available

**Flammability/Explosivity Limits in Air, Upper:** Not available

**Auto-ignition Temperature:** Not available

**Flash Point:** Not available

### 10. STABILITY AND REACTIVITY

#### Chemical Stability:

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

#### Conditions to Avoid:

None known.

#### Incompatible Materials:

Avoid strong oxidizing agents, most common metals (except aluminum), strong bases and amines.

#### Hazardous Decomposition Products:

Thermal decomposition may lead to release of irritating gases and vapors.

#### Possibility of Hazardous Reactions:

Hazardous polymerization will not occur.

### 11. TOXICOLOGICAL INFORMATION

#### Acute Effects:

##### Toxicology Data - Selected LD50s and LC50s

Acetic acid	64-19-7	Inhalation LC50 Rat: 11.4 mg/L/1H; Oral LD50 Rat:3310 mg/kg; Dermal LD50 Rabbit:1060 mg/kg
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#### Local Effects:

Causes eye irritation and may cause skin and respiratory tract irritation.



## MATERIAL SAFETY DATA SHEET

### OSOM® Ultra Strep A Extraction Reagent B

**Chronic Effects:**

Prolonged or repeated skin contact may cause dermatitis.

**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**

Acetic acid	64-19-7	96 Hr LC50 Pimephales promelas: 88 mg/L [static]; 96 Hr LC50 Lepomis macrochirus: 75 mg/L
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**Ecotoxicity - Microtox Data**

Acetic acid	64-19-7	5 min EC50 Photobacterium phosphoreum: 8.8 mg/L; 15 min EC50 Photobacterium phosphoreum: 8.8 mg/L; 25 min EC50 Photobacterium phosphoreum: 8.8 mg/L
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**Ecotoxicity - Water Flea Data**

Acetic acid	64-19-7	24 Hr EC50 Daphnia magna: 95 mg/L
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**Persistence 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**

Acetic acid	64-19-7	Toxic; Corrosive; Ignitable
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## 14. TRANSPORT INFORMATION



**MATERIAL SAFETY DATA SHEET**  
**OSOM® Ultra Strep A Extraction Reagent B**

**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  
Packing Group: PG III  
Packaging Instruction: Y915  
Special Provisions: A44 (excepted quantities)

U.S. Department of Transportation (DOT)  
Consumer Commodity, ORM-D

**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)**

Acetic acid	64-19-7	Present
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**U.S. - CERCLA/SARA - Hazardous Substances and their Reportable Quantities**

Acetic acid	64-19-7	5000 lb final RQ; 2270 kg final RQ
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**US State Regulations:**

**U.S. - California - 8 CCR Section 339 - Director's List of Hazardous Substances**

Acetic acid	64-19-7	Present (exempt in solutions of less than 10% or when present in food or beverages)
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# MATERIAL SAFETY DATA SHEET

## OSOM® Ultra Strep A Extraction Reagent B

### 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**

Acetic acid 64-19-7 B3, E (including 56%, 80%, 84%, 92%); E (30%, 36%); D2B (3%)

#### **Canada - WHMIS - Ingredient Disclosure List**

Acetic acid 64-19-7 1 %

#### **EU - Dangerous Substances Directive (67/548/EEC) - Annex I - Classification**

Acetic acid 64-19-7 R10 C;R35

#### **EU - Dangerous Substances Directive (67/548/EEC) - Annex I - Concentration Limits**

Acetic acid 64-19-7 90%≤C: C; R35 25%≤C<90%: C; R34 10%≤C<25%: Xi; R36/38

#### **EU - Dangerous Substances Directive (67/548/EEC) - Annex I - Safety Phrases**

Acetic acid 64-19-7 S:1/2-23-26-45

#### **Germany - Water Classification (VwVwS) - Annex 2 - Water Hazard Classes**

Acetic acid 64-19-7 ID Number 93, hazard class 1 - low hazard to waters

#### **Inventory - Australia - Inventory of Chemical Substances (AICS)**

Acetic acid 64-19-7 Present

#### **Inventory - Canada - Domestic Substances List (DSL)**

Acetic acid 64-19-7 Present

#### **Inventory - Canada - Non-Domestic Substances List (NDSL)**

Acetic acid 64-19-7 Present

#### **Inventory - China**

Acetic acid 64-19-7 Present

#### **Inventory - European Union - European Inventory of Existing Commercial Chemical Substances (EINECS)**

Acetic acid 64-19-7 200-580-7

#### **Inventory - Japan Existing and New Chemical Substances (ENCS)**

Acetic acid 64-19-7 2-688

#### **Inventory - Korea - Existing and Evaluated Chemical Substances**

Acetic acid 64-19-7 KE-00013

#### **Canadian Hazardous Products:**

WHMIS Status Exempt

#### **European Communities Dangerous Substances/Preparations:**

EC Hazard Class Exempt

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).



**MATERIAL SAFETY DATA SHEET**  
**OSOM® Ultra Strep A Extraction Reagent B**

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**MSDS Origination Date:** January 13, 2005

**Version #:** 5

**Revision Date:** November 13, 2008

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**MATERIAL SAFETY DATA SHEET**  
**OSOM® Strep A Positive Control**

**1. PRODUCT AND COMPANY IDENTIFICATION**

**Product Name:** OSOM® Strep A Positive Control

**Synonym(s):** Strep A Positive Control; Ultra Strep A Positive Control

**Product Use:** Component of OSOM® Strep A Test kit (catalog # 141, 141E & 141E-20) and OSOM® Ultra Strep A Test kit (catalog # 147 & 149). For external quality control testing. For In Vitro Diagnostic Use Only.

**Description:** Aqueous solution containing heat-inactivated bacteria and preservative.

**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:**

CAUTION! The chemical, physical and toxicological properties of this preparation have not been thoroughly characterized. Avoid contact with eyes and skin. Do not ingest or inhale. Harmful by ingestion. Preparation appearance: clear, colorless liquid.

**Routes of Exposure:**

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

**Potential Health Effects:**

- |                        |  |
|------------------------|--|
| <b>Inhalation</b>      | Aerosol inhalation may cause coughing and sore throat.   |
| <b>Eye</b>             | Eye exposure may cause irritation, redness and watering.   |
| <b>Skin</b>            | Skin contact may cause irritation, dryness and redness. Sodium azide may be absorbed through the skin and result in systemic effects.  |
| <b>Ingestion</b>       | Ingestion of sodium azide may cause nausea, diarrhea, vomiting, headache, slight lowering of blood pressure, abdominal pain, and a general feeling of apprehension and unwellness. |
| <b>Chronic Effects</b> | No data available.   |
| <b>Target Organs</b>   | Sodium azide: Cardiovascular and central nervous system.   |



## MATERIAL SAFETY DATA SHEET

### OSOM® Strep A Positive Control

**Regulatory Status:**

This preparation is classified as hazardous under U.S. OSHA 29 CFR 1910.1200; E.C. Directive 1999/45/EC; Canadian R.S. 1985, c. H-3; U.K. CHIP 2002 No. 1689; and/or U.N. GHS ST/SG/AC 10/30.

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:**

Unknown.

### 3. COMPOSITION / INFORMATION ON INGREDIENTS

Ingredient Name	CAS #	EC #	% (wt/wt)
Water	7732-18-5	231-791-2	93 - 96
<b>EC R-Phrases:</b> None	<b>EC Hazard Class:</b> None		
Non-viable Group A Streptococci	Not Assigned	Not Assigned	1 - 5
<b>EC R-Phrases:</b> None	<b>EC Hazard Class:</b> None		
Sodium azide	26628-22-8	247-852-1	0.1
<b>EC R-Phrases:</b> R28, R32, R50, R53	<b>EC Hazard Class:</b> 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:**

When heated to decomposition, may produce hydrazoic acid fumes.



## MATERIAL SAFETY DATA SHEET

### OSOM® Strep A Positive Control

#### 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 15 to 30°C (59 to 86°F). Keep container tightly closed. Do not store with incompatible substances; see Section 10.

## 8. EXPOSURE CONTROLS / PERSONAL PROTECTION

#### Exposure Guidelines:

##### ACGIH - Threshold Limits Values - Ceilings (TLV-C)

Sodium azide 26628-22-8 0.29 mg/m<sup>3</sup> Ceiling (as NaN<sub>3</sub>); 0.11 ppm Ceiling (vapor, as hydrazoic acid)

##### Canada - Quebec - Occupational Exposure Limits - Ceilings

Sodium azide 26628-22-8 0.11 ppm Ceiling; 0.3 mg/m<sup>3</sup> Ceiling

##### EU - Occupational Exposure Directive (2006/15/EC) Indicative Occupational Exposure Limit Values (IOELV) - Skin Notations

Sodium azide 26628-22-8 possibility of significant uptake through the skin

##### EU - Occupational Exposure Directive (2006/15/EC) Indicative Occupational Exposure Limit Values (IOELV) - STELS

Sodium azide 26628-22-8 0.3 mg/m<sup>3</sup> STEL

##### EU - Occupational Exposure Directive (2006/15/EC) Indicative Occupational Exposure Limit Values (IOELV) - TWAs

Sodium azide 26628-22-8 0.1 mg/m<sup>3</sup> TWA

##### Israel - Occupational Exposure Limits - Ceilings

Sodium azide 26628-22-8 0.29 mg/m<sup>3</sup> Ceiling (as NaN<sub>3</sub>); 0.11 ppm Ceiling (vapor, as Hydrazoic acid)

##### Korea - Occupational Exposure Limits - Ceilings

Sodium azide 26628-22-8 0.1 ppm Ceiling; 0.3 mg/m<sup>3</sup> Ceiling

#### 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):

- |                    |  |
|--------------------|--|
| <b>Respiratory</b> | A respirator is not required under normal conditions of use.                       |
| <b>Eye/Face</b>    | Wear appropriate protective chemical safety glasses.                               |
| <b>Skin</b>        | Wear lab coat or other protective garments. Remove contaminated clothing promptly. |
| <b>Gloves</b>      | Wear chemical resistant protective gloves.   |



## MATERIAL SAFETY DATA SHEET

### OSOM® Strep A Positive Control

#### Personal Protective Equipment (PPE):

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

### 9. PHYSICAL AND CHEMICAL PROPERTIES

<b>Appearance:</b>	Clear, colorless liquid	<b>pH:</b>	7.2 (approximate)
<b>Odor:</b>	Not available	<b>Solubility:</b>	Water-soluble
<b>Boiling Point:</b>	Not available	<b>Vapor Pressure:</b>	Not available
<b>Melting Point:</b>	Not applicable	<b>Partition Coefficient (n-octanol/water):</b>	Not available
<b>Freezing Point:</b>	Not available	<b>Vapor Density:</b>	Not available
<b>Flammability/Explosivity Limits in Air, Lower:</b>	Not available		
<b>Flammability/Explosivity Limits in Air, Upper:</b>	Not available		
<b>Auto-Ignition Temperature:</b>	Not available		
<b>Flash Point:</b>	Not available		

### 10. STABILITY AND REACTIVITY

#### Chemical Stability:

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

#### Conditions to Avoid:

Avoid prolonged exposure to direct sunlight.

#### Incompatible Materials:

Avoid strong oxidizing agents, acids, 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 azide 26628-22-8 Oral LD50 Rat: 27 mg/kg; Dermal LD50 Rabbit: 20 mg/kg

#### Local Effects:

No data available.

#### Chronic Effects:

No data available.

#### Carcinogenicity:

##### ACGIH - Threshold Limits Values - Carcinogens

Sodium azide 26628-22-8 A4 - Not Classifiable as a Human Carcinogen

##### Canada - Manitoba - Occupational Exposure Limits - Carcinogens

Sodium azide 26628-22-8 A4 - Not Classifiable as a Human Carcinogen

#### Mutagenicity:

No data available.



## MATERIAL SAFETY DATA SHEET

### OSOM® Strep A Positive Control

**Teratogenicity:**

No data available.

**Reproductive Effects:**

No data available.

**Sensitization:**

No data available.

## 12. ECOLOGICAL INFORMATION

**Ecotoxicity:****Ecotoxicity - Freshwater Fish Species Data**

Sodium azide	26628-22-8	96 Hr LC50 Oncorhynchus mykiss: 0.8 mg/L; 96 Hr LC50 Lepomis macrochirus: 0.7 mg/L; 96 Hr LC50 Pimephales promelas: 5.46 mg/L [flow-through]
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**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.

**Waste Classification:****U.S. - California - 22 CCR - Presumed Hazardous Wastes**

Sodium azide	26628-22-8	Ignitable; Reactive
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**U.S. - RCRA (Resource Conservation & Recovery Act) - P Series Wastes - Acutely Toxic Wastes**

Sodium azide	26628-22-8	waste number P105
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## 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

Packing Group: PG III

Packaging Instruction: Y915

Special Provisions: A44 (excepted quantities)

U.S. Department of Transportation (DOT)

Consumer Commodity, ORM-D



# MATERIAL SAFETY DATA SHEET

## OSOM® Strep A Positive Control

### 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 azide 26628-22-8 Present

#### **U.S. - CERCLA/SARA - Hazardous Substances and their Reportable Quantities**

Sodium azide 26628-22-8 1000 lb final RQ; 454 kg final RQ

#### **U.S. - CERCLA/SARA - Section 302 Extremely Hazardous Substances EPCRA RQs**

Sodium azide 26628-22-8 1000 lb EPCRA RQ

#### **U.S. - CERCLA/SARA - Section 302 Extremely Hazardous Substances TPQs**

Sodium azide 26628-22-8 500 lb TPQ (This material is a reactive solid. The TPQ does not default to 10000 pounds for non-powder, non-molten, non-solvent form)

#### **U.S. - CERCLA/SARA - Section 313 - Emission Reporting**

Sodium azide 26628-22-8 1.0 % de minimis concentration

#### US State Regulations:

#### **U.S. - California - 8 CCR Section 339 - Director's List of Hazardous Substances**

Sodium azide 26628-22-8 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 azide 26628-22-8 D1A

#### **Canada - WHMIS - Ingredient Disclosure List**

Sodium azide 26628-22-8 1 %

#### **EU - Dangerous Substances Directive (67/548/EEC) - Annex I - Classification**

Sodium azide 26628-22-8 T+;R28 R32 N;R50-53

#### **EU - Dangerous Substances Directive (67/548/EEC) - Annex I - Safety Phrases**

Sodium azide 26628-22-8 S:1/2-28-45-60-61

#### **Germany - Water Classification (VwVwS) - Annex 2 - Water Hazard Classes**

Sodium azide 26628-22-8 ID Number 636, hazard class 2 - hazard to waters

#### **Inventory - Australia - Inventory of Chemical Substances (AICS)**

Sodium azide 26628-22-8 Present

#### **Inventory - Canada - Domestic Substances List (DSL)**

Sodium azide 26628-22-8 Present

#### **Inventory - China**

Sodium azide 26628-22-8 Present

#### **Inventory - European Union - European Inventory of Existing Commercial Chemical Substances (EINECS)**

Sodium azide 26628-22-8 247-852-1

#### **Inventory - Japan Existing and New Chemical Substances (ENCS)**

Sodium azide 26628-22-8 1-482

#### **Inventory - Korea - Existing and Evaluated Chemical Substances**

Sodium azide 26628-22-8 KE-31357

#### **Canadian Hazardous Products:**

WHMIS Status Exempt



## MATERIAL SAFETY DATA SHEET

### OSOM® Strep A Positive Control

#### European Communities Dangerous Substances/Preparations:

**EC Hazard Class** Xn - Harmful

**Symbols**



**Risk Phrases**

R22 Harmful if swallowed.  
R32 Contact with acids liberates very toxic gas.

**Safety Phrases**

S35 This material and its container must be disposed of in a safe way.  
S45 In case of accident or if you feel unwell, seek medical advice immediately (show the label where possible).

### 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:** January 07, 2005

**Version #:** 6

**Revision Date:** November 13, 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.



# MATERIAL SAFETY DATA SHEET

## OSOM® Strep A Negative Control

### 1. PRODUCT AND COMPANY IDENTIFICATION

**Product Name:** OSOM® Strep A Negative Control

**Synonym(s):** Strep A Negative Control; Ultra Strep A Negative Control

**Product Use:** Component of OSOM® Strep A Test kit (catalog # 141, 141E & 141E-20) and OSOM® Ultra Strep A Test kit (catalog # 147 & 149). For external quality control testing. For In Vitro Diagnostic Use Only.

**Description:** Aqueous solution containing heat-inactivated bacteria and preservative.

**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:**

CAUTION! The chemical, physical and toxicological properties of this preparation have not been thoroughly characterized. Avoid contact with eyes and skin. Do not ingest or inhale. Harmful by ingestion. Preparation appearance: clear, colorless liquid.

**Routes of Exposure:**

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

**Potential Health Effects:**

- |                        |  |
|------------------------|--|
| <b>Inhalation</b>      | Aerosol inhalation may cause coughing and sore throat.   |
| <b>Eye</b>             | Eye exposure may cause irritation, redness and watering.   |
| <b>Skin</b>            | Skin contact may cause irritation, dryness and redness. Sodium azide may be absorbed through the skin and result in systemic effects.  |
| <b>Ingestion</b>       | Ingestion of sodium azide may cause nausea, diarrhea, vomiting, headache, slight lowering of blood pressure, abdominal pain, and a general feeling of apprehension and unwellness. |
| <b>Chronic Effects</b> | No data available.   |
| <b>Target Organs</b>   | Sodium azide: Cardiovascular and central nervous system.   |



## MATERIAL SAFETY DATA SHEET

### OSOM® Strep A Negative Control

#### Regulatory Status:

This preparation is classified as hazardous under U.S. OSHA 29 CFR 1910.1200; E.C. Directive 1999/45/EC; Canadian R.S. 1985, c. H-3; U.K. CHIP 2002 No. 1689; and/or U.N. GHS ST/SG/AC 10/30.

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:

Unknown.

### 3. COMPOSITION / INFORMATION ON INGREDIENTS

Ingredient Name	CAS #	EC #	% (wt/wt)
Water	7732-18-5	231-791-2	93 - 96
EC R-Phrases: None	EC Hazard Class: None		
Non-viable Group C Streptococci	Not Assigned	Not Assigned	1 - 5
EC R-Phrases: None	EC Hazard Class: None		
Sodium azide	26628-22-8	247-852-1	0.1
EC R-Phrases: R28, R32, R50, R53	EC Hazard Class: 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:

When heated to decomposition, may produce hydrazoic acid fumes.



## MATERIAL SAFETY DATA SHEET

### OSOM® Strep A Negative Control

#### 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 15 to 30°C (59 to 86°F). Keep container tightly closed. Do not store with incompatible substances; see Section 10.

## 8. EXPOSURE CONTROLS / PERSONAL PROTECTION

#### Exposure Guidelines:

##### ACGIH - Threshold Limits Values - Ceilings (TLV-C)

Sodium azide 26628-22-8 0.29 mg/m<sup>3</sup> Ceiling (as NaN<sub>3</sub>); 0.11 ppm Ceiling (vapor, as hydrazoic acid)

##### Canada - Quebec - Occupational Exposure Limits - Ceilings

Sodium azide 26628-22-8 0.11 ppm Ceiling; 0.3 mg/m<sup>3</sup> Ceiling

##### EU - Occupational Exposure Directive (2006/15/EC) Indicative Occupational Exposure Limit Values (IOELV) - Skin Notations

Sodium azide 26628-22-8 possibility of significant uptake through the skin

##### EU - Occupational Exposure Directive (2006/15/EC) Indicative Occupational Exposure Limit Values (IOELV) - STELs

Sodium azide 26628-22-8 0.3 mg/m<sup>3</sup> STEL

##### EU - Occupational Exposure Directive (2006/15/EC) Indicative Occupational Exposure Limit Values (IOELV) - TWAs

Sodium azide 26628-22-8 0.1 mg/m<sup>3</sup> TWA

##### Israel - Occupational Exposure Limits - Ceilings

Sodium azide 26628-22-8 0.29 mg/m<sup>3</sup> Ceiling (as NaN<sub>3</sub>); 0.11 ppm Ceiling (vapor, as Hydrazoic acid)

##### Korea - Occupational Exposure Limits - Ceilings

Sodium azide 26628-22-8 0.1 ppm Ceiling; 0.3 mg/m<sup>3</sup> Ceiling

#### 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):

- |                    |  |
|--------------------|--|
| <b>Respiratory</b> | A respirator is not required under normal conditions of use.                       |
| <b>Eye/Face</b>    | Wear appropriate protective chemical safety glasses.                               |
| <b>Skin</b>        | Wear lab coat or other protective garments. Remove contaminated clothing promptly. |
| <b>Gloves</b>      | Wear chemical resistant protective gloves.   |



## MATERIAL SAFETY DATA SHEET

### OSOM® Strep A Negative Control

#### Personal Protective Equipment (PPE):

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

### 9. PHYSICAL AND CHEMICAL PROPERTIES

<b>Appearance:</b>	Clear, colorless liquid	<b>pH:</b>	7.2 (approximate)
<b>Odor:</b>	Not available	<b>Solubility:</b>	Water-soluble
<b>Boiling Point:</b>	Not available	<b>Vapor Pressure:</b>	Not available
<b>Melting Point:</b>	Not applicable	<b>Partition Coefficient (n-octanol/water):</b>	Not available
<b>Freezing Point:</b>	Not available	<b>Vapor Density:</b>	Not available
<b>Flammability/Explosivity Limits in Air, Lower:</b>	Not available		
<b>Flammability/Explosivity Limits in Air, Upper:</b>	Not available		
<b>Auto-Ignition Temperature:</b>	Not available		
<b>Flash Point:</b>	Not available		

### 10. STABILITY AND REACTIVITY

#### Chemical Stability:

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

#### Conditions to Avoid:

Avoid prolonged exposure to direct sunlight.

#### Incompatible Materials:

Avoid strong oxidizing agents, acids, 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 azide 26628-22-8 Oral LD50 Rat: 27 mg/kg; Dermal LD50 Rabbit: 20 mg/kg

#### Local Effects:

No data available.

#### Chronic Effects:

No data available.

#### Carcinogenicity:

##### ACGIH - Threshold Limits Values - Carcinogens

Sodium azide 26628-22-8 A4 - Not Classifiable as a Human Carcinogen

##### Canada - Manitoba - Occupational Exposure Limits - Carcinogens

Sodium azide 26628-22-8 A4 - Not Classifiable as a Human Carcinogen

#### Mutagenicity:

No data available.



## MATERIAL SAFETY DATA SHEET

### OSOM® Strep A Negative Control

**Teratogenicity:**

No data available.

**Reproductive Effects:**

No data available.

**Sensitization:**

No data available.

## 12. ECOLOGICAL INFORMATION

**Ecotoxicity:****Ecotoxicity - Freshwater Fish Species Data**

Sodium azide	26628-22-8	96 Hr LC50 <i>Oncorhynchus mykiss</i> : 0.8 mg/L; 96 Hr LC50 <i>Lepomis macrochirus</i> : 0.7 mg/L; 96 Hr LC50 <i>Pimephales promelas</i> : 5.46 mg/L [flow-through]
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**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.

**Waste Classification:****U.S. - California - 22 CCR - Presumed Hazardous Wastes**

Sodium azide	26628-22-8	Ignitable; Reactive
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**U.S. - RCRA (Resource Conservation & Recovery Act) - P Series Wastes - Acutely Toxic Wastes**

Sodium azide	26628-22-8	waste number P105
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## 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

Packing Group: PG III

Packaging Instruction: Y915

Special Provisions: A44 (excepted quantities)

U.S. Department of Transportation (DOT)

Consumer Commodity, ORM-D



**MATERIAL SAFETY DATA SHEET**  
**OSOM® Strep A Negative Control**

**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 azide 26628-22-8 Present

**U.S. - CERCLA/SARA - Hazardous Substances and their Reportable Quantities**

Sodium azide 26628-22-8 1000 lb final RQ; 454 kg final RQ

**U.S. - CERCLA/SARA - Section 302 Extremely Hazardous Substances EPCRA RQs**

Sodium azide 26628-22-8 1000 lb EPCRA RQ

**U.S. - CERCLA/SARA - Section 302 Extremely Hazardous Substances TPQs**

Sodium azide 26628-22-8 500 lb TPQ (This material is a reactive solid. The TPQ does not default to 10000 pounds for non-powder, non-molten, non-solvent form)

**U.S. - CERCLA/SARA - Section 313 - Emission Reporting**

Sodium azide 26628-22-8 1.0 % de minimis concentration

**US State Regulations:**

**U.S. - California - 8 CCR Section 339 - Director's List of Hazardous Substances**

Sodium azide 26628-22-8 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 azide 26628-22-8 D1A

**Canada - WHMIS - Ingredient Disclosure List**

Sodium azide 26628-22-8 1 %

**EU - Dangerous Substances Directive (67/548/EEC) - Annex I - Classification**

Sodium azide 26628-22-8 T+;R28 R32 N;R50-53

**EU - Dangerous Substances Directive (67/548/EEC) - Annex I - Safety Phrases**

Sodium azide 26628-22-8 S:1/2-28-45-60-61

**Germany - Water Classification (VwVwS) - Annex 2 - Water Hazard Classes**

Sodium azide 26628-22-8 ID Number 636, hazard class 2 - hazard to waters

**Inventory - Australia - Inventory of Chemical Substances (AICS)**

Sodium azide 26628-22-8 Present

**Inventory - Canada - Domestic Substances List (DSL)**

Sodium azide 26628-22-8 Present

**Inventory - China**

Sodium azide 26628-22-8 Present

**Inventory - European Union - European Inventory of Existing Commercial Chemical Substances (EINECS)**

Sodium azide 26628-22-8 247-852-1

**Inventory - Japan Existing and New Chemical Substances (ENCS)**

Sodium azide 26628-22-8 1-482

**Inventory - Korea - Existing and Evaluated Chemical Substances**

Sodium azide 26628-22-8 KE-31357

**Canadian Hazardous Products:**

WHMIS Status Exempt



## MATERIAL SAFETY DATA SHEET

### OSOM® Strep A Negative Control

#### European Communities Dangerous Substances/Preparations:

**EC Hazard Class** Xn - Harmful

**Symbols**



**Risk Phrases**

R22 Harmful if swallowed.  
R32 Contact with acids liberates very toxic gas.

**Safety Phrases**

S35 This material and its container must be disposed of in a safe way.  
S45 In case of accident or if you feel unwell, seek medical advice immediately (show the label where possible).

### 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:** January 07, 2005

**Version #:** 6

**Revision Date:** November 13, 2008

**Disclaimer:**

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## **Regulatory Information & Accrediting Agencies**

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### **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

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**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.colaprof.org](http://www.colaprof.org).

## List of Approved Accrediting Organizations under CLIA - *continued*

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**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.

Information obtained from, [www.aabb.org](http://www.aabb.org).

**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).

Information obtained from, [www.aoa-net.org](http://www.aoa-net.org).

**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](http://www.ashi-hla.org)

## Proficiency Testing

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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

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### **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*

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### **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

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