

CLIA Training Packet



OSOM[®] Influenza A & B Test CLIA Moderate

**Genzyme Diagnostics
Point of Care Diagnostic Products**

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Genzyme Diagnostics CLIA Packet

Welcome to the Genzyme OSOM[®] Influenza A & B Test Moderate Testing Handbook. This packet has been put together as an aid in meeting many of the regulations surrounding waived testing. The Genzyme OSOM[®] influenza A & B Test kit has a CLIA complexity of Moderate.

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

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OSOM[®] is a registered trademark of Genzyme Corporation.
BVBLUE[®] is registered trademark of Gryphus Diagnostics, LLC.

Some information you may find useful:

CLIA Complexity: Moderate

CPT Code: Influenza A – 87804
Influenza B – 87804-59

Note: In order to be eligible for reimbursement for both Influenza A & B, the requisition must list all 3 alternatives; Influenza A, Influenza B, & Influenza A + Influenza B.

Kit Storage: Store test sticks and extraction buffer tightly capped at room temperature (15°- 30°C / 59°- 86°F). Recap the desiccated container immediately after removing a test stick.

Specimen: Only nasal swabs can be used with this test. Use of nasal washes or aspirates has not been validated.
Use only the swabs supplied in the OSOM influenza A&B Test kit. Swabs from other suppliers have not been validated.

Specimen Storage: Test the swab as soon as possible after collecting the specimen. If swabs cannot be processed immediately, specimens may be held at room temperature for no longer than 8 hours. Swabs may also be stored at 2°- 8°C (36°- 46°F) for up to 24 hours. Extracted samples may be held at room temperature or refrigerated (2°- 8°C/36°- 46°F) for up to 24 hours.
To transport patient samples place swab in a clean, dry container such as a plastic or glass tube.
If a culture result is desired, a separate swab must be collected for the culture.

Quality Control: The OSOM Influenza A&B Test provides two types of controls: procedural internal controls to aid in determining test validity, and two external positive and negative controls for influenza A and influenza B. The influenza A control swab acts as a negative control for the influenza B antigen and conversely, the influenza B control swab serves as a negative control for influenza A antigen.

The appearance of the control line in the results window is an internal positive procedural control and the clearing of the background in the results area may be documented as an internal procedural control.

Use the Controls to help ensure that the test sticks are functioning properly and to demonstrate proper performance by the test operator.

External controls are intended to monitor substantial reagent failure. The positive controls will not challenge the assay at the cutoff.

Quality Control requirements should be established in accordance with local, state and federal regulators or accreditation requirements. Minimally, Genzyme Diagnostics recommends that positive and negative external controls be run with each new lot, shipment received and with each new operator. Additional controls may be purchased separately (OSOM Influenza A&B Control Kit #191).

Procedural Tips: Specimens and Extraction Buffer vial should be at Room Temperature.

Read the results at 10 minutes (some positives may be seen earlier).

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

Expected Results: Influenza viruses can cause epidemics which typically occur during the winter months and can also cause pandemics, during which rates of illness and death from influenza-related complications can increase dramatically worldwide. Influenza viruses cause disease among all age groups. Rates of infection are highest among children, but rates of serious illness and death are highest among persons aged > 65 years and persons of any age who have medical conditions that place them at increased risk for complications from influenza.

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

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

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I. TEST NAME

OSOM[®] Influenza A & B Test

CLIA Complexity: Moderate

II. INTENDED USE

The OSOM Influenza A&B Test is an in vitro diagnostic immunochromatographic assay intended for the qualitative detection of influenza A and influenza B viral nucleoprotein antigens from nasal swab specimens in symptomatic patients. It is intended to aid in the rapid differential diagnosis of influenza A and/or B viral infections. This test is not intended for the detection of influenza C viruses. A negative test is presumptive and it is recommended these results be confirmed by cell culture. Negative results do not preclude influenza virus infection and should not be used as the sole basis for treatment or other management decisions.¹

III. SUMMARY AND EXPLANATION OF TEST

Along with the common cold, influenza is one of the most common acute respiratory infections, producing symptoms such as headache, chills, dry cough, body aches and fever. It affects 10%-20% of the United States population annually, resulting in more than 110,000 hospitalizations and 10,000 to 40,000 deaths.²

The influenza A virus is typically more prevalent and is associated with the most serious influenza epidemics, while influenza B infections usually present more mild symptoms. Diagnosis is difficult because the initial symptoms can be similar to those caused by other infectious agents. Considering that the influenza virus is highly contagious, accurate diagnosis and prompt treatment of patients can have a positive effect on public health. Accurate diagnosis and the ability to distinguish between A or B antigens can also help reduce the inappropriate use of antibiotics and gives the physician the opportunity to prescribe an appropriate antiviral therapy. Initiation of antiviral therapy within 48 hours of symptom onset is recommended for more rapid reduction of symptoms and to reduce viral shedding.³ The OSOM influenza A&B Test can provide rapid detection of influenza A and/or B viral antigens from symptomatic patients.

IV. PRINCIPLES OF TEST

The OSOM Influenza A&B Test consists of a test stick that separately detects influenza A and B. The test procedure requires the solubilization of the nucleoproteins from a swab by mixing the swab in Extraction Buffer. The test stick is then placed in the sample mixture, which then migrates along the membrane surface. If influenza A and/or B viral antigens are present in the sample, it will form a complex with mouse monoclonal IgG antibodies to influenza A and/or B nucleoproteins conjugated to colloidal gold. The complex will then be bound by another mouse anti-influenza A and/or B antibody coated on the nitrocellulose membrane. A pink to purple control line must appear in the control region of the stick for results to be valid. The appearance of a second and possibly a third light pink to purple line will appear in the test line region indicating an A, B or A and B positive result.

V. KIT CONTENTS AND STORAGE

25 Test Sticks

25 Test tubes

25 Foam Swabs

1 Extraction Buffer vial

- 12 mL (20 mM phosphate buffered salt solution (pH 7.6) , 0.25 % protein stabilizer, 0.6% detergent and 0.09% sodium azide as a preservative)

1 Extraction Buffer dropper top

1 Influenza A Positive Control Swab (packaged with a desiccant tablet)

- Formalin inactivated influenza A/Kitakushu/159/93 containing 0.05% sodium azide. Inactivity confirmed by inability of virus to infect cell culture.
- Result is representative of a mid-level positive

1 Influenza B Positive Control Swab (packaged with a desiccant tablet)

- Formalin inactivated influenza B/LEE/40 containing 0.05% sodium azide. Inactivity confirmed by inability of virus to infect cell culture.
- Result is representative of a mid-level positive

1 Directional Insert

1 Procedure/Result Interpretation Guide

1 Workstation

Note: Two extra test sticks have been included in the kit for external QC testing. In addition, extra components (swabs, tubes) have been provided for your convenience.

STORAGE CONDITIONS

- Store test sticks and extraction buffer tightly capped at room temperature (15°- 30°C/59°- 86°F).
- Do not freeze any of the test kit components.
- Do not use test sticks and reagents after expiration date.
- Recap the desiccated container immediately after removing a test stick.
- Test sticks that have been outside of the desiccated container for more than 1 hour should be discarded.

At this facility, kits are stored: _____.

VI. MATERIALS REQUIRED BUT NOT PROVIDED

A timer or a watch.

VII. WARNINGS AND PRECAUTIONS

- For in vitro diagnostic use only.
- Follow your clinical and/or laboratory safety guidelines in the collection, handling, storage, and disposal of patient specimens, and all items exposed to patient specimens.⁴
- Swabs, test tubes, and test sticks are for single use only.

- The Extraction Buffer contains a solution with a preservative (0.09 % sodium azide). If solution comes in contact with the skin or eyes, flush with ample volumes of water.
- Solutions that contain sodium azide may react explosively with lead or copper plumbing. Use large quantities of water to flush discarded solutions down a sink.
- Do not interchange or mix components from different kit lots.
- If infection with a novel influenza A virus is suspected based on current clinical and epidemiological screening criteria recommended by public health authorities, specimens should be collected with appropriate infection control precautions for novel virulent influenza viruses and sent to state or local health departments for testing. Viral culture should not be attempted in these cases unless a BSL 3+ facility is available to receive and culture specimens.¹

VII. PATIENT PREPARATION & SPECIMEN COLLECTION

This facility's procedure for patient preparation is: _____

This facility's procedure for sample labeling is: _____

Specimen Collection and Handling:

- Only nasal swabs can be used with this test. Use of nasal washes or aspirates has not been validated.
- Insert the swab into the nostril that appears to have the most secretion. Using a gentle rotation, push the swab until resistance is met at the level of the turbinates (at least one inch into the nostril). Rotate the swab a few times against the nasal wall.
- Use only the swabs supplied in the OSOM influenza A&B Test kit. Swabs from other suppliers have not been validated. Do not use swabs that have cotton, rayon or polyester tips or wooden shafts.
- Test the swab as soon as possible after collecting the specimen. If swabs cannot be processed immediately, specimens may be held at room temperature for no longer than 8 hours. Swabs may also be stored at 2°- 8°C (36°- 46°F) for up to 24 hours. Extracted samples may be held at room temperature or refrigerated (2°- 8°C/36°- 46°F) for up to 24 hours.
- To transport patient samples place swab in a clean, dry container such as a plastic or glass tube.
- If a culture result is desired, a separate swab must be collected for the culture.
- The test performance depends on the quality of the sample obtained as well as the handling and transport of the sample. Negative results can occur from inadequate specimen collection and/or handling. Training in specimen collection is recommended because of the importance of specimen quality.

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

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

IX. QUALITY CONTROL & ASSURANCE

The OSOM Influenza A&B Test provides two types of controls: procedural internal controls to aid in determining test validity, and two external positive and negative controls for influenza A and influenza B. The influenza A control swab acts as a negative control for the influenza B antigen and conversely, the influenza B control swab serves as a negative control for influenza A antigen.

Internal Procedural Controls

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

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

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

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

2. The clearing of the background in the results area may be documented as an internal procedural control. It also serves as an additional capillary flow control. At the read time, the background should appear white to light pink and not interfere with the reading of the test. If the background color does not clear and interferes with the test result, the test is invalid. Call Genzyme Diagnostics Technical Service at (800) 332-1042 if you experience a problem.

External Quality Control Testing

The OSOM Influenza A&B Test kit includes one Influenza A Positive Control Swab and one Influenza B Positive Control Swab, each of which contains inactivated virus, for external quality control testing. The Influenza A control swab acts as a negative control for the influenza B antigen and conversely, the Influenza B control swab serves as a negative control for influenza A antigen.

Use the Controls to help ensure that the test sticks are functioning properly and to demonstrate proper performance by the test operator

- The presence of a light pink to purple line at the "A" test line position and at the "Control" line position when the Influenza A positive control swab is tested, indicates that the influenza antigen binding property of the test stick is functional.
- The presence of a light pink to purple line at the "B" test line position and at the "Control" line position when the Influenza B positive control swab is tested, indicates that the influenza antigen binding property of the test stick is functional.

External controls are intended to monitor substantial reagent failure. The positive controls will not challenge the assay at the cutoff.

Quality Control requirements should be established in accordance with local, state and federal regulators or accreditation requirements. Minimally, Genzyme Diagnostics recommends that positive and negative external controls be run with each new lot, shipment received and with each new operator. Additional controls may be purchased separately (OSOM Influenza A&B Control Kit #191).

QC Testing Procedures

The Positive Control Swabs are impregnated with sufficient influenza A or B antigen to produce a visible positive test result. To perform a positive or negative control test, complete the steps in the Test Procedure section treating the control swab in the same manner as a specimen swab. The influenza A control swab acts as a negative control for the influenza B antigen and conversely, the influenza B control swab serves as a negative control for influenza A antigen.

QC Testing Frequency and Documentation

For this facility, External QC is run: _____

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

X. TEST PROCEDURE

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

STEP 1: ADD EXTRACTION BUFFER

Using the supplied dropper top, add 0.3 mL of Extraction Buffer to each test tube. Fill the dropper to the line indicated on the barrel of the dropper top and expel entire contents into tube. **Note: Add Extraction Buffer to the tube before putting in the specimen swab to prevent contaminating the Extraction Buffer vial.**

STEP 2: MIX SWAB IN BUFFER

Put the specimen swab into the tube. Vigorously mix the solution by rotating the swab forcefully against the side of the tube at least ten times (while submerged). Best results are obtained when the specimen is vigorously mixed in the solution.

STEP 3: SQUEEZE LIQUID FROM SWAB

Squeeze out as much liquid as possible from the swab by pinching the side of the flexible test tube as the swab is removed. Discard the swab in a suitable biohazardous waste container.

STEP 4: ADD TEST STICK

Remove a Test Stick from the canister. Recap the canister immediately. Place the test stick (arrows pointing downward) into the tube with the extraction buffer solution.

Set a timer for 10 minutes.

STEP 5: READ RESULTS

At 10 minutes remove the test stick from the tube and read the results (some positive results may be seen earlier).

For help in reading the test stick or for correct line placement refer to the Result Interpretation Guide in the directional insert.

Discard used test tubes and Test Sticks in suitable biohazardous waste container.

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

XI. INTERPRETATION OF RESULTS

The appearance of a Control Line, with or without a Test Line, indicates a valid result. A pink-to-purple line that appears uneven in color shading is still considered a valid line. In cases of moderate or high positive specimens, some color behind the Test Line may be seen. As long as the Test Line and the Control Line are visible, the results are valid. For help in reading the test stick or for correct line placement refer to the Results Interpretation Guide in the directional insert.

Influenza A Positive

A pink-to-purple Test Line at the "A" test line position and a pink-to-purple Control Line is a positive result for the detection of influenza A antigen. Note that the pink-to-purple lines can be any shade of that color and can be lighter or darker than the line in the package insert picture.

Influenza B Positive

A pink-to-purple Test Line at the "B" test line position and a pink-to-purple Control Line is a positive result for the detection of influenza B antigen. Note that the pink-to-purple lines can be any shade of that color and can be lighter or darker than the line in the package insert picture.

Negative

A pink-to-purple Control Line but no Test Line is a presumptive negative result. A negative result means that no influenza antigen was detected, or that the level of the antigen in the sample was below the detection limit of the assay.

Invalid

If no pink-to-purple Control Line appears or background color makes reading the pink-to-purple Control Line impossible, the result is invalid. If this occurs, repeat the test on a new Test Stick or contact Genzyme Diagnostics' Technical Service.

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

XII. RESULT REPORTING

- Report negative test results as influenza A (or B) virus antigen not detected. Infection due to influenza cannot be ruled out since the antigen may be present in the specimen below the detection limit of the test. Negative tests are presumptive and should be confirmed by culture.
- Report positive test results as positive for influenza A (or B) virus antigen. This result does not rule out co-infections with other pathogens or identify any specific influenza A virus subtype.
- If result is considered invalid, repeat the test using a new sample and a new test dipstick.

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

XIII. LIMITATIONS

- The OSOM Influenza A&B Test is for the qualitative detection of influenza A and B viral antigens. The test performance depends on antigen load and may not correlate with cell culture performed on the same specimen. Negative test results are not intended to rule out other non-influenza viral infections.
- Sensitivity can differ with various strains of influenza due to difference in antigen expression. Specimens might contain new, non-identified strains of influenza that express varying amounts of antigen.
- This test detects both viable and non-viable influenza A and B, and may yield a positive result in the absence of living organisms.
- The test performance depends on the quality of the sample obtained as well as the handling and transport of the sample. Negative results can occur from inadequate specimen collection and/or handling.
- As with all diagnostic assays, the results obtained with this test kit yield data that must be used only as an adjunct to other information available to the physician.
- Use of nasal wash or aspirate has not been validated.
- *Staphylococcus aureus* in specimens at concentrations greater than 9×10^8 cfu/mL may interfere with the test results. Bacterial levels in sinonasal infections have been reported at levels that are much less than those that affect the assay; typically ranging between 10^5 and 10^7 cfu/mL.⁵
- High levels of blood on specimen swabs might cause an intense red background on the test strip that could interfere with the test interpretation. Avoid samples that have been heavily contaminated with whole blood.
- It is well-recognized that testing done with children will appear more sensitive because children shed virus more abundantly and longer than adults.⁶

- Positive and negative predictive values of these diagnostic assays are highly dependent on prevalence or current level of influenza activity.⁶ During peak influenza activity in a season, positive predictive values are higher, with false positives less likely; and negative predictive values are lower, with false negatives more likely. Conversely, during low influenza activity (e.g., off-season or beginning of a season), negative predictive values are higher and positive predictive values lower, with false positive test results more likely.
- Additional testing is required to differentiate any specific influenza A subtypes or strains, in consultation with state or local public health departments.¹
- Individuals who received nasally administered influenza vaccine may have positive test results for up to three days after vaccination.¹
- Monoclonal antibodies may fail to detect with less sensitivity, influenza A viruses that have undergone minor amino acid changes in the target epitope region.¹

XIV. EXPECTED RESULTS

Influenza viruses can cause epidemics which typically occur during the winter months and can also cause pandemics, during which rates of illness and death from influenza-related complications can increase dramatically worldwide. Influenza viruses cause disease among all age groups. Rates of infection are highest among children, but rates of serious illness and death are highest among persons aged > 65 years and persons of any age who have medical conditions that place them at increased risk for complications from influenza.

XV. CROSS REACTIVITY

The OSOM Influenza A&B Test was evaluated with 44 bacterial and viral isolates. Cross-reactivity testing was performed with materials obtained from ATCC. Bacterial isolates were tested at a concentration of approximately $>10^8$ cfu/mL. Very high levels of *Staphylococcus aureus* ($>9 \times 10^8$ cfu/mL) produced a positive result for influenza A. All other bacteria listed gave negative responses. Viral isolates were tested at approximately 1.4×10^5 - 2.3×10^8 TCID₅₀/test.

All viruses listed produced negative responses.

Bacterial Panel:

<i>Acinetobacter calcoaceticus</i>	<i>Legionella pneumophila</i>	<i>Staphylococcus aureus</i>
<i>Bordetella pertussis</i>	<i>Moraxella catarrhalis</i>	<i>Staphylococcus epidermidis</i>
<i>Candida albicans</i>	<i>Mycobacterium avium</i>	<i>Streptococcus Group A</i>
<i>Corynebacterium diphtheriae</i>	<i>Mycobacterium tuberculosis</i>	<i>Streptococcus Group B</i>
<i>Enterococcus faecalis</i>	<i>Neisseria meningitidis</i>	<i>Streptococcus mutans</i>
<i>Enterococcus gallinarum</i>	<i>Proteus mirabilis</i>	<i>Streptococcus pneumoniae</i>
<i>Escherichia coli</i>	<i>Proteus vulgaris</i>	<i>Torulopsis glabrata</i>
<i>Haemophilus influenza</i>	<i>Pseudomonas aeruginosa</i>	
<i>Klebsiella pneumoniae</i>	<i>Serratia marcescens</i>	

Viral Panel:

<i>Adenovirus Type 1</i>	<i>Coxsackievirus B5</i>	<i>Parainfluenza Type 2</i>
<i>Adenovirus Type 2</i>	<i>Echovirus 6</i>	<i>Parainfluenza Type 3</i>
<i>Adenovirus Type 3</i>	<i>Echovirus 11 (Gregory)</i>	<i>Parainfluenza Type 4B</i>
<i>Adenovirus Type 6</i>	<i>Echovirus 30</i>	<i>Rhinovirus 3</i>
<i>Coxsackievirus B2</i>	<i>Measles</i>	<i>Rhinovirus 4</i>
<i>Coxsackievirus B3</i>	<i>Mumps (Enders strain)</i>	<i>Rhinovirus 7</i>
<i>Coxsackievirus B4</i>	<i>Parainfluenza Type 1</i>	<i>RSV (Long strain)</i>

XVI. INTERFERING SUBSTANCES

The following potential interferents were tested and were found to have no affect on the performance of the OSOM Influenza A&B Test.

Potential Interferent	Concentration
Acetyl Salicylic Acid	20 mg/mL
Acetamidophenol	10 mg/mL
Chlorpheniramine maleate	5 mg/mL
Dextromethorphan HBr	20 mg/mL
Diphenhydramine HCl	5 mg/mL
Ephedrine HCl	20 mg/mL
Guiacol Glyceryl Ether	20 mg/mL
Oxymetazoline HCl	10 mg/mL
Phenylephrine HCl	100 mg/mL
Phenylpropanolamine	20 mg/mL
Whole Blood	2%
<i>OTC Throat Drops</i>	
Throat Drop (Halls)	25%
Throat Drop (Zinc)	25%
Throat Drop (Ricola)	25%
<i>OTC Nasal Sprays</i>	
Nasal Spray (Zicam)	10%
Nasal Spray (Afrin)	10%
Nasal Spray (Vicks Sinex)	10%

Note: A very high hemoglobin concentration could interfere with the interpretation of the test result.

XVII. PERFORMANCE CHARACTERISTICS & POL STUDIES

Refer to directional insert – OSOM[®] Influenza A&B Test

XVIII. REFERENCES

Refer to directional insert – OSOM[®] Influenza A&B Test

XIX. ASSISTANCE

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



OSOM® Influenza A&B Patient Test Log

Hospital/Clinic Name: _____

Kit Lot#: _____ Exp. Date: _____

Received Date: _____ Date in Use: _____

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

TEST RESULTS: Negative = a pink to purple Control line only Positive = a pink to purple A or B Test line and a pink to purple Control line

	Date	Operator	Patient Name/ ID	Test Result (Neg/Pos A/ Pos B)	INTERNAL QUALITY CONTROL		Comments/Actions
					Pink to purple Control Line Visible? Y/N	Clear Background? Y/N	
					IF "NO" ANSWERED ABOVE, TEST IS INVALID- REPEAT WITH NEW SAMPLE		
1			Positive A /Negative B Control Lot: Exp. Date:	A: B:			
2			Positive B /Negative A Control Lot: Exp. Date:	A: B:			
3							
4							
5							
6							
7							
8							
9							
10							
11							



OSOM® Influenza A&B Patient Test Log (page 2)

	Date	Operator	Patient Name/ ID	Test Result (Neg/Pos A/ Pos B)	INTERNAL QUALITY CONTROL		Comments/Actions
					Pink to purple Control Line Visible? Y/N	Clear Background? Y/N	
					IF "NO" ANSWERED ABOVE, TEST IS INVALID- REPEAT WITH NEW SAMPLE		
12							
13							
14							
15							
16							
17							
18							
19							
20							
21							
22							
23							
24							
25							

CLIA Waived.com™

Certificate



Training Certification

CLIA Waived.comTM

Name

has been successfully trained on the following Genzyme products:

- | | | | |
|--|---|---|--|
| <input type="checkbox"/> OSOM [®] Strep A | <input type="checkbox"/> OSOM [®] Ultra Strep A | <input type="checkbox"/> OSOM [®] Mono | <input type="checkbox"/> OSOM [®] hCG Combo |
| <input type="checkbox"/> OSOM [®] hCG Urine | <input type="checkbox"/> OSOM [®] Card Pregnancy | <input type="checkbox"/> OSOM [®] Influenza A&B | |
| <input type="checkbox"/> OSOM [®] BV ^{BLUE} [®] | <input type="checkbox"/> OSOM [®] Trichomonas | <input type="checkbox"/> OSOM [®] ImmunoDip [®] Urinary Albumin | |

Trainer/ Title

Date

OSOM[®] Influenza A&B Test - Operator Competency Exam

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

Operator Name (printed): _____ **Employee Number:** _____

Unit, Clinic, or Department: _____ **Training:** _____
(Initial, Annual, Re-Training)

Practical Training In-service:

- Procedural review, including control requirements
- Demonstration of the test procedure
- Successful performance of the OSOM[®] Influenza A&B Test procedure (i.e. External Controls)
- Test interpretation and results

I have read and understood the complete OSOM[®] Influenza A&B Test procedure, and have been trained in the test procedure.

Operator Signature: _____ **Date:** _____

Competency Exam:

The following exam is administered as proof of competency for personnel performing the OSOM[®] Influenza A&B Test using patient samples and external controls. Please circle your response to each question.

- The OSOM[®] Influenza A&B Test is for the detection of influenza antigen from which sample type(s)?**
 - Throat swabs only
 - Nasopharyngeal washings
 - Nasal swabs only
- The OSOM[®] Influenza A&B Test will detect only live Influenza virus.**
 - true
 - false
- The first step in running the test is to add ____ of Extraction Buffer to the supplied test tube.**
 - 0.3 mL (the fill line on the dropper barrel)
 - 1-2 drops
- Negative results from the OSOM[®] Influenza A&B test stick must be read _____ .**
 - at one minute
 - at ten minutes
 - at any point after the appearance of the Control line

5. Interpret the following results using guide:



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

#1



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

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

#2



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

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

#3



- A. Positive A
- B. Positive B
- C. Negative
- D. 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)

**** ANSWER KEY - FOR PROGRAM ADMINISTRATOR ONLY! ****

OSOM[®] Influenza A&B Test - Operator Competency Exam Key

Competency Exam Answers:

1. The OSOM[®] Influenza A&B Test is for the detection of influenza antigen from which sample type(s)?
C. Nasal swabs only
2. The OSOM[®] Influenza A&B Test will detect only live Influenza virus.
B. false
3. The first step in running the test is to add ____ of Extraction Buffer to the supplied test tube.
A. 0.3 mL (the fill line on the dropper barrel)
4. Negative results from the OSOM[®] Influenza A&B test stick must be read _____.
B. at ten minutes
5. Interpret the following results:

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

#1



A. Positive A

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

#2



B. Positive B

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

#3



C. Negative



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50 Gibson Drive
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Kent ME19 4AF
UK

Phone: +44 (0) 1732 220022

MATERIAL SAFETY DATA SHEETS

Catalog Number:	Kit Name:
190, 190E	OSOM[®] Influenza A&B Test

Item Number:	Component Name:
2077	OSOM[®] Influenza A&B Test Extraction Buffer

The Influenza A Positive Control Swab is an "article" and does not require an MSDS.
The Influenza B Positive Control Swab is an "article" and does not require an MSDS.



MATERIAL SAFETY DATA SHEET
OSOM® Influenza A&B Test Extraction Buffer

1. PRODUCT AND COMPANY IDENTIFICATION

Product Name: OSOM® Influenza A&B Test Extraction Buffer

Synonym(s): Extraction Buffer

Product Use: Component of OSOM® Influenza A&B Test kit (catalog # 190, 190E). For use in the qualitative detection of influenza A and B viral antigens. For In Vitro Diagnostic Use Only.

Description: Aqueous solution containing salts, detergent, albumin protein and bactericide.

Corporate Headquarters

Genzyme Corporation

500 Kendall Street
Cambridge, MA 02142
USA

Phone: 617-252-7500

Manufacturer/Distributor

Genzyme Diagnostics

6659 Top Gun Street
San Diego, CA 92121
USA

Phone: 858-452-3198

Distributor

Genzyme Diagnostics

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

Phone: 44 (0) 1732 220022

Emergency Telephone Numbers

Genzyme (U.S.): 617-562-4555

CHEMTREC (U.S.): 800-424-9300

CHEMTREC (Outside U.S.): 703-527-3887

2. HAZARDS IDENTIFICATION

Precautionary Statements:

The chemical, physical and toxicological properties of this preparation have not been thoroughly characterized. May be irritating to eyes and skin. Avoid contact with eyes and skin. Do not ingest or inhale. The bovine serum albumin (BSA) in this product is of US origin and meets the current standards for reduction of TSE (Transmissible Spongiform Encephalopathy) risk. Preparation appearance: clear, colorless liquid.

Routes of Exposure:

Occupational exposure routes may include eye and skin contact.

Potential Health Effects:

Inhalation	Aerosol inhalation may cause coughing and sore throat.
Eye	Eye exposure may cause irritation, redness and watering.
Skin	Skin contact may cause irritation, dryness and redness.
Ingestion	No data available.
Chronic Effects	No data available.
Target Organs	Unknown.

Regulatory Status:

This preparation is not 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.



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Potential Environmental Effects:

Unknown.

3. COMPOSITION / INFORMATION ON INGREDIENTS

Ingredient Name	CAS #	EC #	% (wt/wt)
Water	7732-18-5	231-791-2	95 - 96
EC R-Phrases: None	EC Hazard Class: None		
L-Aspartic acid, monosodium salt	3792-50-5	223-264-0	2 - 3
EC R-Phrases: None	EC Hazard Class: None		
Trade Secret Ingredient	Trade Secret	Trade Secret	< 1
EC R-Phrases: None	EC Hazard Class: None		
Sodium chloride	7647-14-5	231-598-3	< 1
EC R-Phrases: None	EC Hazard Class: None		
Sodium phosphate dibasic, anhydrous	7558-79-4	231-448-7	< 1
EC R-Phrases: None	EC Hazard Class: None		
Bovine serum albumin	9048-46-8	232-936-2	< 1
EC R-Phrases: None	EC Hazard Class: None		
Ethylene glycol	107-21-1	203-473-3	< 1
EC R-Phrases: R22	EC Hazard Class: Xn		
Sodium azide	26628-22-8	247-852-1	< 0.1
EC R-Phrases: R28, R32, R50, R53	EC Hazard Class: T+, N		
Sodium phosphate monobasic dihydrate	13472-35-0	231-449-2	< 0.1
EC R-Phrases: None	EC Hazard Class: None		
Methylchloroisothiazolinone	26172-55-4	247-500-7	< 0.01
EC R-Phrases: R23/24/25, R34, R43, R50/53	EC Hazard Class: C, T, N		
Modified alkyl carboxylate	Not Assigned	Not Assigned	< 0.01
EC R-Phrases: None	EC Hazard Class: None		
Methylisothiazolinone	2682-20-4	220-239-6	< 0.01
EC R-Phrases: R23/24/25, R34, R43, R50/53	EC Hazard Class: C, 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.



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5. FIRE FIGHTING MEASURES

Flammable Properties:

Dilute aqueous solution not considered a fire hazard.

Suitable Extinguishing Media:

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

Unsuitable Extinguishing Media:

Unknown.

Specific Hazards Arising from the Chemical:

None expected.

Standard Protective Equipment and Precautions for Firefighters:

Firefighters should wear NIOSH-approved or equivalent Self-Contained Breathing Apparatus and full protective gear.

6. ACCIDENTAL RELEASE MEASURES

Personal Precautions:

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

Environmental Precautions:

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

Methods and Materials for Containment and Clean-Up:

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

7. HANDLING AND STORAGE

Handling:

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

Storage:

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

8. EXPOSURE CONTROLS / PERSONAL PROTECTION

Exposure Guidelines:

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

Engineering Controls:

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

Personal Protective Equipment (PPE):

Respiratory A respirator is not required under normal conditions of use.

Eye/Face Wear appropriate protective safety eye glasses or goggles.



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Personal Protective Equipment (PPE):

Skin	Wear lab coat or other protective garments. Remove contaminated clothing promptly.
Gloves	Wear chemical resistant protective gloves.
General	Follow company-specific safety procedures.

9. PHYSICAL AND CHEMICAL PROPERTIES

Appearance:	Clear, colorless liquid	pH:	7.6 (approx.)
Odor:	Not available	Solubility:	Water-soluble
Boiling Point:	Not available	Vapor Pressure:	Not available
Melting Point:	Not applicable	Partition Coefficient (n-octanol/water):	Not available
Freezing Point:	Not available	Vapor Density:	Not available
Flammability/Explosivity Limits in Air, Lower:	Not available		
Flammability/Explosivity Limits in Air, Upper:	Not available		
Auto-Ignition Temperature:	Not applicable		
Flash Point:	Not available		

10. STABILITY AND REACTIVITY

Chemical Stability:

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

Conditions to Avoid:

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

Incompatible Materials:

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

Hazardous Decomposition Products:

None expected under normal conditions of use.

Possibility of Hazardous Reactions:

Hazardous polymerization will not occur.

11. TOXICOLOGICAL INFORMATION

Acute Effects:

No data available.

Local Effects:

No data available.

Chronic Effects:

No data available.

Carcinogenicity:

No data available.

Mutagenicity:

No data available.



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Teratogenicity:

No data available.

Reproductive Effects:

No data available.

Sensitization:

No data available.

12. ECOLOGICAL INFORMATION

Ecotoxicity:

No data available.

Persistence and Degradability:

No data available.

Bioaccumulative Potential:

No data available.

Mobility in Environmental Media:

No data available.

13. DISPOSAL CONSIDERATIONS

Methods of Disposal:

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

14. TRANSPORT INFORMATION

Basic Shipping Description:

Not classified as dangerous goods. Not regulated per IATA and DOT regulations.

15. REGULATORY INFORMATION

US Federal Regulations:

This preparation is a component of an FDA-regulated in vitro diagnostic device.

Inventory - United States - Section 8(b) Inventory (TSCA)

L-Aspartic acid, monosodium salt	3792-50-5	Present
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International Regulations:

If approved for European Communities use, this product is regulated under the In Vitro Diagnostic Medical Devices Directive (98/79/EC).

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

L-Aspartic acid, monosodium salt	3792-50-5	Present
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Inventory - European Union - European Inventory of Existing Commercial Chemical Substances (EINECS)

L-Aspartic acid, monosodium salt	3792-50-5	223-264-0
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Inventory - Japan Existing and New Chemical Substances (ENCS)

L-Aspartic acid, monosodium salt	3792-50-5	2-1308
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Canadian Hazardous Products:

WHMIS Status Exempt

European Communities Dangerous Substances/Preparations:

EC Hazard Class None

Risk Phrases None

Safety Phrases None

16. OTHER INFORMATION

Further Information:

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

MSDS Origination Date: July 24, 2006

Version #: 4

Revision Date: November 12, 2008

Disclaimer:

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Regulatory Information & Accrediting Agencies

Regulatory

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

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

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

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

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

Accreditation

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

A list of CLIA approved accreditation organization follows.

List of Approved Accrediting Organizations under CLIA

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

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

Information obtained from www.jcaho.org.

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

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

Information obtained from, www.cap.org.

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

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

Information obtained from, www.colaprof.org.

List of Approved Accrediting Organizations under CLIA - *continued*

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.

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.

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

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

Information obtained from, www.ashi-hla.org

Proficiency Testing

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

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

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

At this time, sites performing only waived testing are not required to perform proficiency testing to comply with CLIA regulations. However, some states and most accreditation agencies are encouraging or requiring such testing. Proficiency testing for all tests performed at your site provides documentation of accuracy in the event of an inspection, and helps to ensure quality test results.

CLIA Approved Proficiency Testing Programs - 2008

American Association of Bioanalysts (AAB)

Proficiency Testing Service
205 West Levee Street
Brownsville, Texas 78520-5596
(800)234-5315

American Academy of Family Physicians (AAFP)

11400 Tomahawk Creek Parkway
Leawood, Kansas 66211-7911
(800)274-7911

Accutest

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

American Proficiency Institute (API)

1159 Business Park Drive
Traverse City, Michigan 49686
(800)333-0958

California Thoracic Society (CTS)

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

The College of American Pathologists (CAP) – Surveys & EXCEL

325 Waukegan Road
Northfield, Illinois 60093-2750
(847)832-7000

Idaho Bureau of Laboratories

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

Medical Laboratory Evaluation (MLE)

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

New Jersey Department of Health and Senior Services

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

Ohio Department of Health

1571 Perry Street
P.O.Box 2568
Columbus, Ohio 43216-2568
(614)466-2278

CLIA Approved Proficiency Testing Programs - *continued*

Commonwealth of Pennsylvania

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

Puerto Rico Department of Health

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

Wisconsin State Laboratory of Hygiene

465 Henry Mall
Madison, Wisconsin 53706-1578
(800)462-5261

New York State Department of Health

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

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