

**Warde**  
Medical Laboratory

# Bulletins

*Test Updates and New Test Bulletins*

September 1, 2009

Enclosed are Test Information pages with changes/additions to our test listing. The changes are as follows:

## **NEW LISTING**

### **HERPES SIMPLEX VIRUS 1 & 2 PCR**

**Effective: September 21, 2009**

30-91740 **New Listing**

*Specimen Required:*

Specimen source required.

Swab specimens (genital, dermal, vesicle, ocular, oral, nasal, throat, rectal) in viral transport medium.

Swabs in Cultiures must be transferred to viral transport within 24 hours of collection.

Biopsy/tissue specimens in saline or viral transport medium (Snap frozen -20°C).

Bronchoalveolar lavage/wash in sterile leak-proof container 1.0 mL (0.5 mL minimum)

CSF and body fluids undiluted in sterile leak-proof container. 1.0 mL (0.5 mL minimum)

Nasal aspirates in vacuum trap. 1.0 mL (0.5 mL minimum)

Nasal washes in leak proof sterile container 1.0 mL (0.5 mL minimum)

Blood in EDTA (lavender top) tube, 2.0 mL (1.0 mL minimum).

EDTA plasma (lavender top), 1.0 mL (0.5 mL minimum)

Bone Marrow in EDTA, 1.0 mL (0.5 mL minimum)

*Alternate Specimen:*

The Laboratory Director or Supervisor must approve testing of specimens other than those listed above.

*Rejection Criteria:*

Rectal swabs preserved in formalin, SAF, or PVA.

Specimens in Amplicor, EIA, Gen-Probe, or ProbeTec transport media.

Specimens in bacteriological blood culture media.

Dry swabs, calcium alginate swabs, and swabs in gel transports Cultiures older than 24 hours.

Specimens received in non-sterile or leaking containers.

*Stability:*

Room Temperature (18-25°C): 3 days; Refrigerated (2-8°C): 2 weeks;

Frozen (-20°C): 2 weeks; Frozen (-70°C): 3 months

*Methodology:*

Herpes Simplex Virus (HSV) detection is performed by a real-time PCR amplification and detection procedure. The HSV type 1 assay detects a genetic sequence at the glycoprotein G-J junction while the HSV-2 assay targets a portion of the glycoprotein G gene. The analytical sensitivity of this assay is 50 copies/mL. A negative result does not rule out infection.

*Reference Range:*

Negative

*Performed:*

Monday-Saturday

*Turnaround Time:*

1-2 days

*Test Code:*

HSVTPCR

*CPT-4 Code(s):*

87529 x 2

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## INFLUENZA A, B, AND SWINE PANEL

Effective: September 21, 2009

30-70700      **New Listing**

<i>Specimen Required:</i>	Specimen source required. NP and throat swabs in viral transport medium. Swabs in culettes must be transferred to viral transport within 24 hours of collection. Bronchoalveolar lavage/wash in sterile leak-proof container 1.0 mL (0.5 mL minimum). Sputum undiluted in sterile leak-proof container. 1.0 mL (0.5 mL minimum). Nasal aspirates in vacuum trap. 1.0 mL (0.5 mL minimum). Nasal washes in leak proof sterile container 1.0 mL (0.5 mL minimum). Cell culture medium in sterile leak proof container.
<i>Alternate Specimen:</i>	The Laboratory Director or Supervisor must approve testing of specimens other than those listed above.
<i>Rejection Criteria:</i>	Specimens in Amplicor, EIA, Gen-Probe, or ProbeTec transport media Specimens in bacteriological blood culture media Dry swabs, calcium alginate swabs, and swabs in gel transports Culturette specimens older than 24 hours Specimens received in non-sterile or leaking containers
<i>Stability:</i>	Room Temperature (18-25°C): 3 days; Refrigerated (2-8°C): 2 weeks; Frozen (-20°C): 2 weeks; Frozen (-70°C): 3 months
<i>Methodology:</i>	The procedure detects and identifies all influenza A subtypes, influenza B, and Swine influenza viruses. Virus detection is performed by reverse transcription of influenza A and influenza B RNA sequences and real-time PCR amplification and detection. The influenza A assay detects the presence of a conserved region of the matrix gene; the influenza B assay detects a conserved region of the NS1 protein gene; and the Swine influenza assay detects the presence of the swine influenza hemagglutinin gene. A negative result does not rule out influenza infection.
<i>Reference Range:</i>	Influenza A:      Negative Influenza B:      Negative Swine Influenza: Negative
<i>Performed:</i>	Sunday-Thursday midnights Saturday, days
<i>Turnaround Time:</i>	1-2 days
<i>Test Code:</i>	FLUABSW
<i>CPT-4 Code(s):</i>	87798 x 3

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## INFLUENZA A. NOVEL (SWINE-ORIGIN) H1N1 PCR

**Effective: September 21, 2009**

30-70610

**New Listing**

*Specimen Required:*

Specimen source required.

NP and throat swabs in viral transport medium

Swabs in culturettes must be transferred to viral transport within 24 hours of collection

Bronchoalveolar lavage/wash in sterile leak-proof container 1.0 mL (0.5 mL minimum)

Sputum undiluted in sterile leak-proof container. 1.0 mL (0.5 mL minimum)

Nasal aspirates in vacuum trap. 1.0 mL (0.5 mL minimum)

Nasal washes in leak proof sterile container 1.0 mL (0.5 mL minimum)

Cell culture medium in sterile leak proof container

*Alternate Specimen:*

The Laboratory Director or Supervisor must approve testing of specimens other than those listed above.

*Rejection Criteria:*

Specimens in Amplicor, EIA, Gen-Probe, or ProbeTec transport media

Specimens in bacteriological blood culture media

Dry swabs, calcium alginate swabs, and swabs in gel transports

Culturette specimens older than 24 hours

Specimens received in non-sterile or leaking containers

*Stability:*

Room Temperature (18-25°C): 3 days; Refrigerated (2-8°C): 2 weeks;

Frozen (-20°C): 2 weeks; Frozen (-70°C): 3 months

*Methodology:*

This procedure utilizes reverse transcription and real-time PCR detection of a 100 bp portion of the Novel H1N1 (Swine Origin) influenza hemagglutinin gene. This procedure will not detect endemic strains of influenza A or influenza B. A negative result does not rule out influenza infection.

*Reference Range:*

Swine Influenza: Negative

*Performed:*

Sunday-Thursday midnights

Saturday, days

*Turnaround Time:*

1-2 days

*Test Code:*

FLUSW

*CPT-4 Code(s):*

87798

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## TEST UPDATES

### AMYLASE ISOENZYMES

**Effective: September 22, 2009**

37-05320

**Test Update: Reference Range**

*Reference Range:*

Total Amylase: 20-120 U/L

**Pancreatic Amylase: 13-53 U/L**

Salivary Amylase: <48 U/L

Macroamylase: Not Detected

*Test Code:*

AISP

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**PROCAINAMIDE**

**Effective: September 9, 2009**

37-17350      **Test Update: Reference Range**

*Reference Range:*

Therapeutic:

Procainamide: 4-10 µg/mL

N-Acetyl-procainamide: 6-20 µg/mL

**Procainamide & NAPA: 10-30 µg/mL**

*Test Code:*

PROC

**TEST INACTIVATION**

**HERPES SIMPLEX VIRUS PCR**

30-16050      HSVPCR

Inactivation 09/21/09

Replaced by: 30-91740    HSVTPCR

**HERPES SIMPLEX VIRUS TYPING BY PCR**

30-91800      HSVT

Inactivation 09/21/09

Replaced by: 30-91740    HSVTPCR

## New Test Update - Novel (Swine-Origin) H1N1 Influenza Testing

On September 21, 2009, Warde Medical Laboratory will offer testing for the 2009 Novel H1N1 influenza virus. This test has been validated in cooperation with the Michigan Department of Community Health. Two test options will be available.

### **Influenza A, (Swine-origin) H1N1**

Mnemonic: FLUSW

Test No: 30-70610

This PCR test should be used for specimens that are positive for influenza A virus by culture, indirect fluorescent antibody methods, universal (non-differentiating) PCR methods, or rapid tests. The influenza A, (Swine-origin) H1N1 test only detects the presence of the novel swine-origin influenza virus and a negative result does not rule out the presence of seasonal influenza types.

### **Influenza A, B, and Swine Panel**

Mnemonic: FLUABSW

Test No: 30-70700

This PCR panel will test for the presence of influenza A, influenza B, and swine-origin influenza A. The influenza A test in this panel will detect the presence of all influenza types but cannot differentiate swine-origin influenza from seasonal influenza types. Therefore, a swine-origin influenza virus will be positive for influenza A and the swine-origin influenza virus. Seasonal influenza A viruses will be positive for influenza A only (Table 1).

**Table 1. Interpretation guide for the Influenza A, B, and Swine Panel.**

<b>Flu A:</b>	<b>Negative</b>	<b>Positive</b>	<b>Positive</b>	<b>Negative</b>	<b>Negative</b>
<b>Flu B:</b>	<b>Negative</b>	<b>Negative</b>	<b>Negative</b>	<b>Positive</b>	<b>Negative</b>
<b>Swine:</b>	<b>Negative</b>	<b>Negative</b>	<b>Positive</b>	<b>Negative</b>	<b>Positive</b>
<b>Interp.</b>	<b>Influenza not detected</b>	<b>Seasonal Influenza Virus</b>	<b>Swine-origin Influenza Virus</b>	<b>Influenza B Virus</b>	<b>Indeterminate Result</b>

While differentiating novel H1N1 influenza from seasonal influenza is not necessary in all cases, testing is indicated when antiviral therapies are contemplated (Table 2). Pre-approval is not necessary for swine influenza testing.

Antiviral Drug	Swine-Origin H1N1	Seasonal A/H1N1	Seasonal A/H3N2
Zanamivir	Sensitive	Sensitive	Sensitive
Oseteltamivir	Sensitive	<b>Resistant</b>	Sensitive
Amantadine/ Rimantadine	<b>Resistant</b>	Sensitive*	<b>Resistant</b>

\*0.5% of isolates are resistant

Please contact Dr. Wiedbrauk [734-214-0300] if you have any questions.