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TEST CHANGE ALERT #355

December 21, 2009

Summary Of Changes

TestCode(s)	Test Description
AMSH	MELANOCYTE STIM HORMONE, ALPHA (Specimen Requirements)
BCRAB	BCR-ABL GENE REARRANGEMENT (Reference Range)
CDTPCR	C. DIFFICILE BY PCR (CPT Code)
CECS	CULTURE STOOL E COLI 0157 SCREEN (Delete)
CECST	CULTURE, ECOLI 0157 WITH SHIGA TOXIN (REFLEX) (New)
CRE.A (CREAF)	CREATININE (AMNIO) (Method)
CSTLYR	CULTURE,STOOL WITH YERSINIA (REFLEXIVE) (Delete)
CSTLYS	CULTURE, STOOL WITH YERSINIA & SHIGA TOXIN (REFLEX) (New)
ENTPCR	ENTEROVIRUS DETECTION BY RT-PCR (Delete)
ESTF	ESTROGENS, FRACTIONATED (Specimen Requirements)
EVPCR	ENTEROVIRUS DETECTION BY RT-PCR (New)
HGQT	MERCURY, SERUM/PLASMA (Description, Method, Specimen Requirements)
HPVDG	HUMAN PAPILOMAVIRUS DNA PROBE HR (Other Acceptable Specimens)
I2MAFD (I2MAF)	INTERLEUKIN 2 RECEPTOR SOLUBLE MAFD (Change in Flexilab Ordercode Only)
I6MAFD (I6MAF)	INTERLEUKIN 6 BY MAFD (Change in Flexi Ordercode Only)
INSULA	INSULIN ANTIBODIES, SERUM (New)
JCPCR	JC VIRUS PCR, CSF (Description Only)
LDH (LD)	LD (TOTAL) (Specimen Requirements)
NAR (NARDIL)	NARDIL (Specimen Requirements)
NIACIN VITAMIN B3 NIACIN (NICOTINIC ACID)	(Reference Range correction for the website)
PROTO (PROTOF)	PROTOPORPHYRIN FREE ERYTHROCYTE (Specimen Requirements)
RAPFLU	INFLUENZA AG, A/B, RAPID (PSC ONLY) (CPT Code)
RDS	RDS RISK PANEL (Method)
REF.SMPCR (SMPCR)	SPINAL MUSCULAR ATROPHY DIAGNOSTIC STUDY (Description Only)
RESPCR	FLU A, FLU B AND RSV BY PCR (New)
TAC	TACROLIMUS BY LC-MS/MS (Reference Range)



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The following tables reflect revisions only; other existing data remain unchanged.

AMSH

AMSH

MELANOCYTE STIM HORMONE, ALPHA
(Specimen Requirements)

order code

flexilab code

Effective	Immediately
Specimen Requirements	<i>3 mL frozen serum or plasma (red top tube). Separate serum from cells ASAP & put in separate plastic tube & freeze. Store & transport frozen.</i> This is a critical frozen sample. Separate samples must be submitted when multiple tests are ordered. Patient should not be on any steroid, ACTH or hypertension medication, if possible, for at least 18 hours prior to specimen collection.
Comments	<i>1) Min Amt: 1 mL. 2) Other acceptable specimens: frozen EDTA plasma (lavender top tube). 3) Unacceptable conditions: specimens not received frozen. 4) ARUP# 98819.</i>

BCRAB

BCRAB

BCR-ABL GENE REARRANGEMENT (Reference Range)

order code

flexilab code

Effective	Immediately		
Reference Ranges	Source BCRABL Translocation		<p>Not detected</p> <p>A bcr/abl t(9;22) translocation was not detected.</p> <p>Major fusion transcript(p210 fusion gene product): Not detected.</p> <p><i>Minor fusion transcript(p190 fusion gene product): Not detected</i></p> <p>The bcr/abl fusion gene transcript is found in GT 99% of patients with chronic myelogenous leukemia (CML) & 25-40% of adult patients with ALL. A negative result does not absolutely rule out the presence of the fusion transcript in this patient's sample.</p> <p>This test is performed by real-time quantitative reverse transcription PCR using fluorescence detection. Analytical specificity: detects the 3 major fusion transcripts, b3a2, b2A2, E1A2. Limit of detection and limit of quantification p210: 0.0005% & 0.005%. Limit of detection and limit of quantification for p190: 0.01% and 0.1%.</p> <p>Direct comparison of results generated in different laboratories</p>

			<p>is not recommended due to variation between assay configurations. Direct comparison of sequential results generated from the same sample type will provide the most meaningful information.</p> <p>Test results should always be considered complementary to morphologic and other relevant data; therefore, should not be independently used to make a diagnosis of malignancy.</p> <p>This test was developed and its performance characteristics determined by Providence Sacred Heart Medical Center & Children's Hospital. It has not been cleared or approved by the FDA. The FDA has determined that such clearance or approval is not necessary. This test is used for clinical purposes. It should not be regarded as investigational or for research.</p> <p>This laboratory is certified under the Clinical Laboratory Improvement Amendments of 1988 (CLIA) as qualified to perform high complexity clinical testing.</p>	
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CDTPCR

order code

CDTPCR

flexilab code

C. DIFFICILE BY PCR (CPT Code)

Effective	01/01/2010
CPT4	<i>87493</i>

CECS

order code

CECS

flexilab code

CULTURE STOOL E COLI 0157 SCREEN (Delete)

Effective	01/19/2010
Delete	<i>This test is being discontinued. Use the ordercode CECST to order this test.</i>

CECST

order code

CECST

flexilab code

CULTURE, ECOLI 0157 WITH SHIGA TOXIN (REFLEX) (New)

Effective	01/19/2010
Method	<i>Culture & immunochromatographic</i>
CPT4	<i>87081, 87015, 87899 x 2</i>
Specimen Requirements	<i>GT 1 mL feces. Collect stool sample in a clean, leakproof plastic container. If transportation time to the laboratory will exceed 2 hours from time of collection, specimen should be refrigerated or placed in enteric</i>

	<i>transport medium (Modified Cary-Blair). This test may reflex to additional tests depending upon the results of this test. Additional fees will be added.</i>		
Comments	<i>1) Min Amt: 1 mL. 2) Unacceptable conditions: cultures are not recommended for inpatients that have been hospitalized for 3 or more days. 3) Stability: RT-2 hours, Refrigerated-1 day. 4) PSHMC-Microbiology Department.</i>		
Reference Ranges	<i>Culture, Ecoli O157 with Shiga Toxin Report Culture, Ecoli O157 with Shiga Toxin Status</i>		

CRE.A
order code

CREAF
flexilab code

CREATININE (AMNIO) (Method)

Effective	01/19/2010
Method	<i>Enzymatic (IDMS Traceable)</i>

CSTLYR

CSTLYR

CULTURE,STOOL WITH YERSINIA (REFLEXIVE)
(Delete)

order code

flexilab code

Effective	01/19/2010
Delete	<i>This test is being discontinued. Use the ordercode CSTLYS to order this test.</i>

CSTLYS

CSTLYS

CULTURE, STOOL WITH YERSINIA & SHIGA
TOXIN (REFLEX) (New)

order code

flexilab code

Effective	01/19/2010
Method	<i>Culture & Immunochromatographic</i>
CPT4	<i>87045, 87046 x 3, 87015, 87899 x 2</i>
Specimen Requirements	<i>GT 1 mL feces. Collect stool in a clean, leakproof plastic container. If transportation time to the laboratory will exceed 2 hours from time of collection, specimen should be refrigerated or placed in enteric transport medium (Modified Cary-Blair). If Vibrio, Aeromonas, or Plesiomonas are suspected, please note on request form. This test may reflex to additional tests depending upon the results of this test. Additional fees will be added.</i>
Comments	<i>1) Min Amt: 1 mL. 2) Unacceptable conditions: cultures are not recommended for inpatients that have been hospitalized for 3 or more days. 3) Stability: RT-2 hours, Refrigerated-1 day. 4) PSHMC-Microbiology Department.</i>
Reference Ranges	<i>Culture, Stool with Yersinia & Shiga Toxin</i>

<i>Result Culture, Stool with Yersinia & Shiga Toxin Status</i>			
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ENTPCR
order code

ENTPCR
flexilab code

ENTEROVIRUS DETECTION BY RT-PCR (Delete)

Effective	01/19/2010
Delete	<i>This test is being discontinued. Use the ordercode EVPCR to order this test.</i>

ESTF
order code

ESTF
flexilab code

ESTROGENS, FRACTIONATED (Specimen Requirements)

Effective	Immediately
Specimen Requirements	2 mL frozen serum (red top tube). Separate serum from cells and put in separate plastic tube and freeze. Store and transport frozen. <i>The estradiol is a critical frozen specimen. Separate samples must be submitted when ordering multiple tests.</i>

EVPCR
order code

EVPCR
flexilab code

ENTEROVIRUS DETECTION BY RT-PCR (New)

Effective	01/19/2010		
Method	<i>Real-Time PCR</i>		
CPT4	<i>87498</i>		
Specimen Requirements	<i>1 mL frozen CSF, Stool (sterile container) or EDTA plasma (lavender top tube). NP swabs (flocked preferred) or rectal swabs in M4 viral transport media. Separate plasma from the cells and put in sterile plastic tube. Store and transport all specimens frozen. Indicate source. Ship 650.</i>		
Comments	<i>1) Min Amt: 0.3 mL. 2) Other acceptable specimens: Rectal or NP or NP/Throat swab(s) in M4RT or UTM transport media. 3) Unacceptable conditions: nonfrozen samples, samples exposed to repeated freeze/thaw cycles, non-sterile or leaking containers, heparinized samples and hemolyzed samples. 4) Stability: RT-LT 1 hour, Refrigerated-1 day, Frozen(-20C)-3 months, Frozen(-70)-indefinitely.</i>		
Compliance(ASRA) PAML/SHMC	<i>Analyte Specific Reagents (ASR) are used in many laboratory tests necessary for standard medical care and generally do not require U.S. Food and Drug Administration (FDA) approval or clearance. This test was developed and its performance characteristics determined by PAML/PSHMC Division of Laboratory Medicine. It has not been approved or cleared by the U.S. Food and Drug Administration. This test should not be regarded as investigational or for research use.</i>		
Reference Ranges	<i>Source Enterovirus Detection by RT-PCR</i>		<i>Not detected A result of Not Detected does not rule out the presence of PCR inhibitors in the patient specimen or Enterovirus nucleic acid in concentrations below the level of detection of the assay. Comment Analyte Specific Reagents (ASR) are</i>

			<p><i>used in many laboratory tests necessary for standard medical care and generally do not require U.S. Food & Drug Administration (FDA) approval or clearance. This test was developed and its performance characteristics determined by PAML/ PSHMC Division of Laboratory Medicine. It has not been approved or cleared by the U.S. Food and Drug Administration. This test should not be regarded as investigational or for research use. This test performed pursuant to an agreement with Roche Molecular Systems.</i></p>
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HGQT

HGQT

MERCURY, SERUM/PLASMA (Description, Method, Specimen Requirements)

order code

flexilab code

Effective	03/01/2010
Method	<i>ICP/MS</i>
Specimen Requirements	<i>1 mL plasma (metal free EDTA royal blue top tube). Collect specimens at end of shift at end of work week. Separate plasma from cells & put in separate plastic tube. Store and transport refrigerated.</i>
Comments	<i>1) Min Amt: 0.4 mL. 2) Other acceptable specimens: serum (plain trace metal free blue top tube - no additive). 3) Unacceptable conditions: SST or PST tubes. 4) Stability: RT-2 weeks, Refrigerated-2 weeks, Frozen-2 weeks. 4) NMS# 2670SP.</i>

HPVDG

HPVDG

HUMAN PAPILLOMAVIRUS DNA PROBE HR (Other Acceptable Specimens)

order code

flexilab code

Effective	01/19/2010
Comments	<i>1) Min Amt: ThinPrep Pap Test-4 mL after Pap test; SurePath Pap Test-2 mL after Pap test. 2) Other acceptable samples: Cervical brushes collected in a Digene Cervical Sample for HPV testing, cervical biopsies between 2-5 mm stored in specimen transport medium @ -20C. 3) Unacceptable conditions: samples in EIA transport media, wooden swabs and male samples, ThinPrep samples that have been frozen.</i>

I2MAFD

I2MAF

INTERLEUKIN 2 RECEPTOR SOLUBLE MAFD (Change in Flexilab Ordercode Only)

order code

flexilab code

Effective	Immediately
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I6MAFD

order code

I6MAF

flexilab code

INTERLEUKIN 6 BY MAFD (Change in Flexi
Ordercode Only)

Effective	Immediately
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INSULA

order code

INSULA

flexilab code

INSULIN ANTIBODIES, SERUM (New)

Effective	01/19/2010		
Method	<i>RIA</i>		
CPT4	<i>86337</i>		
Specimen Requirements	<i>1 mL serum (red top tube). Separate serum from cells and put in separate plastic tube. Store and transport refrigerated.</i>		
Comments	<i>1) Stability: RT-3 days, Refrigerated-2 days. 2) MAYO# 8666.</i>		
Other	<i>This test was developed and its performance characteristics determined by Laboratory Medicine and Pathology, Mayo Clinic. This test has not been cleared or approved by the U.S. Food and Drug Administration.</i>		
Reference Ranges	<i>Insulin Abs, Serum</i>		<i>0.00-0.02 nmol/L This test was developed and its performance characteristics determined by Laboratory Medicine & Pathology, Mayo Clinic. This test has not been cleared or approved by the U.S. Food & Drug Administration</i>

JCPCR

order code

JCPCR

flexilab code

JC VIRUS PCR, CSF (Description Only)

Effective	Immediately
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LDH

order code

LD

flexilab code

LD (TOTAL) (Specimen Requirements)

Effective	Immediately
Specimen Requirements	<i>2 mL serum (red top tube). Separate serum from cells ASAP and put in separate plastic tube. Store and transport refrigerated or at room temperature.</i>
Comments	<i>1) Min Amt: 0.2 mL. 2) Other acceptable specimens: EDTA or lithium heparin plasma (lavender or green top tube). 3) Unacceptable conditions: hemolysis or sodium fluoride-potassium oxalate plasma (grey top tube). 4) Stability: RT-3 days, Ref-3 days. Frozen samples show decreased activity of isoenzymes LD4 and LD5 and thus a total LD activity that is decreased.</i>

NAR
order code

NARDIL
flexilab code

NARDIL (Specimen Requirements)

Effective	Immediately
Specimen Requirements	<i>5 mL frozen serum (red top tube). Separate serum from cells ASAP and put in separate plastic tube and freeze. Store and transport frozen. Protect from light.</i>
Comments	<i>1) Min Amt: 2 mL. 2) Other acceptable specimens: frozen plasma. 3) Unacceptable conditions: not received light protected, at room temperature or refrigerated. 4) Stability: RT-unacceptable, Refrigerated-unacceptable, Frozen-1 week. 5) NMS# 3550SP.</i>

NIACIN

NIACIN

VITAMIN B3 NIACIN (NICOTINIC ACID) (Reference Range correction for the website)

order code

flexilab code

Effective	Immediately			
Reference Ranges	Niacin		<p>After oral administration, peak plasma concentrations are achieved in 30-60 minutes. The plasma half-life after administration of 1000 mg nicotinic acid is around 1 hour. Following extended release niacin therapy, the following plasma levels of niacin have been <i>measured: a 1000 mg nighttime dose</i> results in a peak concentration of 0.6 mcg/mL, 1500 mg nighttime dose results in a peak concentration of 4.9 mcg/mL, and 2000 mg nighttime dose results in a peak concentration of 15.5 mcg/mL. Another study (Pfuhl et al, 2005) has reported that the administration of a 1000 mg extended release tablet, resulted in concentrations of niacin of less than 0.05 mcg/mL.</p>	mcg/mL

PROTO

PROTOF

PROTOPORPHYRIN FREE ERYTHROCYTE (Specimen Requirements)

order code

flexilab code

Effective	01/11/2010
Specimen Requirements	<i>5 mL sodium heparinized whole blood (green top tube). Place tube directly into wet ice. Send entire heparinized whole blood specimen refrigerated. Specimen cannot be frozen, it must arrive at Mayo within 48 hours of collection. Do not separate or wash cells from the sample.</i>
Comments	<i>1) Draw specimen after patient has been fasting 12-14 hours. The patient should be off medications for at least a week if possible otherwise forward a list of medications with the specimen. Patient should abstain from alcohol for 24 hours. 2) No deviation from protocol is acceptable. 3) Stability: Refrigerated-it must arrive at Mayo within 48 hours of collection. 3) MAYO# 8739.</i>

RAPFLU**RAPFLU**

INFLUENZA AG, A/B, RAPID (PSC ONLY) (CPT Code)

order code

flexilab code

Effective	Immediately
CPT4	<i>87804</i>

RDS**RDS**

RDS RISK PANEL (Method)

order code

flexilab code

Effective	01/19/2010
Method	<i>TLC, Enzymatic (IDMS Traceable)</i>

REF.SMAPCR**SMAPCR**

SPINAL MUSCULAR ATROPHY DIAGNOSTIC STUDY (Description Only)

order code

flexilab code

Effective	Immediately
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RESPCR**RESPCR**

FLU A, FLU B AND RSV BY PCR (New)

order code

flexilab code

Effective	01/19/2010		
Method	<i>Real-Time PCR</i>		
CPT4	<i>87798 x 3</i>		
Specimen Requirements	<i>Nasopharyngeal (NP) swab (flocked preferred) in viral transport media (M4- RT). Store and transport refrigerated. Ship 650.</i>		
Comments	<i>1) Other acceptable specimens: Polyester, rayon or nylon tipped swabs or flocked swabs in M4, M4RT, M5, M6, Copan or BD Universal Transport Media. 2) Stability: RT-unacceptable, Refrigerated-3 days, Frozen(-20C)-unaccept- able, Frozen(-70C)-indefinitely.</i>		
Reference Ranges	<i>Influenza A</i>		<i>Not detected</i>
	<i>Influenza B</i>		<i>Not detected</i>
	<i>Respiratory Syncytial Virus</i>		<i>Not detected</i>
	<i>Comment</i>		<i>A result of Not Detected does not rule out the possibility of influenza or RSV infection and should not be used as the sole basis for treatment or management decisions.</i>

Effective	Immediately			
Reference				
Ranges	<i>FK506</i>		<p><i>5.0-20.0</i></p> <p>Therapeutic range is based on a whole blood specimen drawn 12 hours post dose or prior to next dose (the trough). Some other factors influencing therapeutic range, dose administered, and result interpretation include time since transplantation, the organ transplanted, co-administration of other immunosuppressants, interaction with other drugs which may increase or decrease the tacrolimus concentration, and the preferences of the transplant centers and clinicians.</p> <p>This test was developed and its performance characteristics determined by PAML/PSHMC Division of Laboratory Medicine. The U.S. Food and Drug Administration (FDA) has not approved or cleared this test. However, FDA approval or clearance is currently not required for clinical use of this test. The results are not intended to be used as the sole means for clinical diagnosis or patient management decisions. PAML/PSHMC is authorized under Clinical Laboratory Improvement Amendments (CLIA) to perform high-complexity testing.</p>	<i>ng/mL</i>

[PAML Web Test Directory](#)