Revision Message!
Please note: 8/13/2013 communication revision for test code S52593- Acyclovir, Serum/Plasma, CPT code change.
Please note: 8/13/2013 communication revision for test code S52595- Flucytosine, test name and CPT code change.
Please note: 8/27/2013 communication revision for test code 90574- FLT3 ITD and TKD Mutation collection instruction and always message.

TEST CHANGES
Please Note: Not all test codes assigned to each assay are listed in the table of contents.
Please refer to the complete listing on the page numbers indicated.

Test Code	Former Test Code	Test Name	Effective Date	Page #
91747		Peanut, Total with Reflex to Peanut Component Panel	8/5/2013	1
90574	S52494	**FLT3 ITD and TKD Mutation**	9/3/2013	2

REDIRECTS
Please Note: Not all test codes assigned to each assay are listed in the table of contents.
Please refer to the complete listing on the page numbers indicated.

Test Code	Former Test Code	Test Name	Effective Date	Page #
S52593	S52555	**Acyclovir, Serum/Plasma (0158SP)**	8/12/2013	3
S52594	S48658	**Cycloserine, Level (CSH)**	8/12/2013	3
S52595	S49887,14675	**Flucytosine, Serum/Plasma (2085SP)**	8/12/2013	4
S52596	S48648, S52241	**Pyrazinamide, Level (PZAH)**	8/12/2013	5
S52597	S51395	**Rifampin, Level (RIFH)**	8/12/2013	6
S52598	S51478	**Streptomycin, Level (SMH)**	8/12/2013	7

DISCONTINUED TESTS
Please Note: Not all test codes assigned to each assay are listed in the table of contents.
Please refer to the complete listing on the page numbers indicated.

Test Code	Test Name	Effective Date	Page #
	Discontinued Tests	8/12/2013	8

Due to the background information related to these changes, we are unable to use our normal method of communication. These changes listed in this document are effective in less than 30 days. Please note the individual effective dates below, as some of these changes require IMMEDIATE ACTION.

Test Changes

The following test changes will be effective on the dates indicated below. **Please note that only the information that is changing appears in this update.** *Former test names and test codes have been italicized.*

Peanut, Total with Reflex to Peanut Component Panel	
Effective Date	**8/5/2013**
Test Code	91747
Performing Site	Quest Diagnostics Nichols Institute, Chantilly

CPU Mappings	<table><tr><th>Result Code</th><th>Result Name</th><th>Unit of Measure</th></tr><tr><td>91747</td><td>Peanut (F13) IgE</td><td>kU/L</td></tr><tr><td colspan="3">This is a reflex. Please build the unit code below separately. Orderable Reflex: 91681-Peanut Component Panel</td></tr></table>
Additional Information	If Peanut (f13) IgE is 0.35 kU/L or above, then Peanut Component Panel will be added at an additional charge (CPT code: 86003 (x5)).

FLT3 ITD and TKD Mutation	
Revision Message!	**Please note: Collection instruction was updated to revise the verbiage and the always message was updated to replace the medical director effective 8/27/13.**
Effective Date	**9/3/2013**
Former Test Name	*FLT3 (ITD) and D835 Variant Detection by PCR*
Former Test Code	*S52494*
Test Code	**90574**
Instructions	Include patient's date of birth and specimen source on test request form and specimen container. Fixed cells, FFPE and tissue are unacceptable. Submit PB and BM samples within 7 days of collection. Primary samples received after 7 days of collection will be run with a disclaimer, but if the sample is QNS, the lab will charge for testing. Primary samples that are older than 14 days will not be tested. Cell Pellets in cell culture media or buffered solutions without fixatives. **Isolated DNA samples: Using a different extraction method may impact the assay performance. Due to increased rate of failures associated with DNA samples, a failure result when DNA sample is received will be charged.**
Always Message	**Polymerase chain reaction (PCR) amplification for the detection of the FLT3 ITD and FLT3 TKD mutations was performed on DNA isolated from the patient sample. Fluorescently labeled primers amplified the sequences of interest. The TKD PCR product was cut with the EcoRV restriction enzyme. The ITD and the digested TKD products were run on the ABI 3500xl genetic analyzer and their sizes were determined. The ITD wild type produces a fragment that is approximately 327 +/-1 bp, while the presence of an insertion produces a fragment that is approximately >=330 bp. This assay has an analytical sensitivity of 5 mutation containing cells in 100 total cells. This assay does not detect ITD mutations greater than approximately 420 bp in size.** **This test was performed under the direction of Veena Singh, MD, FCAP, FACMG.** **The Laboratory for Personalized Molecular Medicine(TM) is CLIA certified and CAP accredited to perform high complexity testing.** **This test was developed and its performance characteristics determined by the Laboratory for Personalized Molecular Medicine™. It has not been cleared or approved by the U.S. Food and Drug Administration. However, such approval is not required for clinical implementation, and test results have been shown to be clinically useful.** **References:** **FLT3-ITD: S P Whitman et al., 2010 Blood 116: 3622-3626** **FLT3-TKD: U Bacher et al., 2008 Blood 111: 2527-2537** *FLT3 Mutation Testing is performed pursuant to patents licensed from Takara Bio of Otsu, Japan.
CPU Mappings	<table><tr><th>Result Code</th><th>Type</th><th>Result Name</th></tr><tr><td>86008014</td><td>Prompt-Result</td><td>Date of Birth</td></tr><tr><td>86010039</td><td>Prompt-Result</td><td>Specimen Type</td></tr><tr><td>86007922</td><td></td><td>FLT3 ITD</td></tr></table>

	86007923		**FLT3 TKD Mutation**
	86007925		**Interpretation**

Additional Information	Please note the Comment analyte has been removed.

Redirects

Acyclovir, Serum/Plasma (0158SP)	
Revision Message!	**Please note: CPT code was updated to 80299 effective 8/13/2013.**
Effective Date	**8/12/2013**
Former Test Name	*Acyclovir, HPLC*
Former Test Code	*S52555*
Test Code	**S52593**
CPT Codes	**80299**
Specimen Requirements	**Preferred:** **1 mL (0.21 mL minimum) serum collected in a red-top tube (no gel)** **Acceptable:** **Plasma collected in an EDTA (lavender-top) or sodium fluoride (gray-top) tube, sodium oxalate (gray-top) tube**
Reject Criteria	**Serum separator tube; polymer gel separation tube**
Instructions	**Promptly centrifuge and separate serum or plasma into a plastic screw cap vial.**
Transport Temperature	**Room temperature**
Specimen Stability	**Room temperature, Refrigerated and Frozen: 30 days**
Set-up/Analytic Time	**Set up: Thurs; Report available: 3 days**
Reference Range	**Usual therapeutic range (vs. genital herpes) during chronic oral daily divided dosages of 1200 to 2400 mg:** **Peak: 0.40 - 2.0 mcg/mL plasma** **Trough: 0.14 - 1.2 mcg/mL plasma**
Methodology	**High Performance Liquid Chromatography/Tandem Mass Spectrometry (HPLC/MS/MS)**
Performing Site	**This test previously performed at Focus Diagnostics, Inc. will now be performed at NMS Labs.**

CPU Mappings

Result Code	Result Name	Unit of Measure
113813	**Acyclovir**	**mcg/mL**

Cycloserine, Level (CSH)	
Message	*** This test is not available for New York patient testing***
Effective Date	**8/12/2013**
Former Test Name	*Cycloserine, HPLC*
Former Test Code	*S48658*

Test Code	**S52594**
Specimen Requirements	**Preferred:** 2 mL **(0.5 mL minimum)** serum collected in a red-top (no gel) tube **Acceptable:** **Plasma collected in an EDTA (lavender-top) tube, sodium heparin (green-top) tube**
Reject Criteria	**Gross hemolysis, serum separator tube**
Instructions	**Separate serum (or plasma) from cells immediately by centrifuge and aliquot into a labeled polypropylene or similar plastic tube. Use a separate tube for each test ordered. Allow room for expansion of sample. Freeze at -70° C if possible, but at minimum 20° C.**
Transport Temperature	**Frozen**
Specimen Stability	**Room temperature: 6 hours** **Refrigerated: 24 hours** **Frozen: 30 days**
Set-up/Analytic Time	**Set up: Mon-Fri; Report available: 2-7 days**
Always Message	**This test report is for cycloserine.** **Cycloserine (cycloSERINE) may be confused with cyclosporine (cycloSPORINE). These two drugs sound alike and look alike.** **The target range for mycobacterial infections is 20 to 35 mcg/mL 2 hours after oral dose. Samples drawn later than two hours after the dose may display concentrations below the stated range.** **Concentrations greater than 35 mcg/mL may be associated with CNS effects such as lethargy, confusion, depression and other effects. If the concentration is 35 to 45 mcg/mL, reduce the total daily dose by 250 mg. If the concentration is greater than 45 mcg/mL, discontinue the drug for 24 to 48 hours before resuming a lower dose.** **Cycloserine is renally cleared. Decreased renal function may cause elevated cycloserine concentrations. Such patients generally do not require twice daily dosing. Consider once daily doses, and monitor the patient carefully for CNS effects.** **Co-administration of pyridoxine (vitamin B6) 50 mg daily may reduce the potential for CNS effects.** **Concentrations greater than 50% above the ranges may be associated with CNS side effects. Decrease the dose by 100 mg for daily dose or by 300 mg for twice-weekly dose.** **Consider monitoring liver function tests periodically. Isoniazid concentrations may be elevated in patients with hepatic dysfunction.** **If the time of the dose and the blood draw were not accurately recorded, accurate interpretation of the concentration is not possible.**
Methodology	**Gas Chromatography/Mass Spectrometry (GC/MS)**
Performing Site	**This test previously performed at Focus Diagnostics, Inc. will now be performed at National Jewish Health.**
CPU Mappings	

Result Code	Type	Result Name	Unit of Measure
113814	Prompt-Result	Time/Date, Last Dose	
113815	Prompt-Result	Dose	
113816		Cycloserine	mcg/mL

Flucytosine, Serum/Plasma (2085SP)	
Revision Message!	**Please note: Test Name and CPT code was updated effective 8/13/2013.**

Effective Date	**8/12/2013**
Former Test Name	*5-Fluorocytosine, HPLC*
Former Test Code	*S49887,14675*
Test Code	**S52595**
CPT Codes	**80299**
Specimen Requirements	**Preferred:** **1 mL (0.21 mL minimum) serum collected in a** red-top tube (no gel) **Acceptable:** **Plasma collected in an EDTA (lavender-top) or EDTA (pink-top) tube**
Reject Criteria	**Serum separator tube; polymer gel separation tube**
Instructions	**Promptly centrifuge and separate serum or plasma into a plastic screw cap vial using approved guidelines.**
Transport Temperature	**Room temperature**
Specimen Stability	**Room temperature, Refrigerated and Frozen: 30 days**
Set-up/Analytic Time	**Set up: Mon-Sun; Report available: 7 days**
Reference Range	**Target therapeutic range: 25 to 100 mcg/mL.** **Normal adults given a 2 g oral dose had peak serum concentrations of 30 - 40 mcg/mL within 2 hours.**
Methodology	**High Performance Liquid Chromatography/Tandem Mass Spectrometry (HPLC/MS/MS)**
Assay Category	Laboratory Developed Test
Performing Site	**This test previously performed at Focus Diagnostics, Inc. will now be performed at NMS Labs**
CPU Mappings	**Result Code** / **Result Name** / **Unit of Measure** **113817** / **Flucytosine** / **mcg/mL**

Pyrazinamide, Level (PZAH)	
Message	***This test is not available for New York patient testing***
Effective Date	**8/12/2013**
Former Test Name	*Pyrazinamide, HPLC*
Former Test Code	*S48648, S52241*
Test Code	**S52596**
Specimen Requirements	**Preferred:** 2 mL **(0.5 mL minimum)** serum collected in a red-top tube (no gel) **Acceptable:** **Plasma collected in an EDTA (lavender-top) tube, sodium heparin (green-top) tube**
Reject Criteria	**Gel barrier/Serum Separator tubes; Gross hemolysis**
Instructions	**Separate serum (or plasma) from cells immediately by centrifuge and aliquot into a labeled polypropylene or similar plastic tube. Use a separate tube for each test ordered. Allow room for expansion of sample. Freeze at -70° C if possible, but at minimum -20° C.** **Include drug dose amount, frequency, method, and date and time of last dose prior to draw. Ship samples via overnight delivery on >3lbs of dry ice.**

Transport Temperature	Frozen
Specimen Stability	**Room temperature and Refrigerated: 24 hours** **Frozen: 30 days**
Set-up/Analytic Time	**Set up: Mon-Fri; Report available: 2-7 days**
Always Message	**The target range for mycobacterial infections is 20 to 60 mcg/mL 2 hours post oral dose.** **Concentration appears to be proportional to dose. Higher, twice weekly does (50mg/kg) appear to produce proportionally higher pyrazinamide concentrations (60 to 90 mcg/mL). Samples drawn later than 2 hours after the dose will often display concentrations below the state range.** **Pyrazinamide does not have clear concentration-related toxicity, and most patients tolerate concentrations above the state ranges without difficulty.** **Hepatic dysfunction may produce elevated pyrazinamide concentrations. Pyrazinamide concentrations greater than 50% above the range may warrant a dose reduction of 5 to 10 mg/kg for daily doses, or a dose reduction of 10 to 20 mg/kg for twice weekly doses.** **If the time of the dose and the blood draw were not accurately recorded, accurate interpretation of the concentration is not possible.**
Methodology	**Gastric Chromatography/Mass Spectrometry (GC/MS)**
Performing Site	**This test previously performed at Focus Diagnostics, Inc. will now be performed at National Jewish Health.**
CPU Mappings	

Result Code	Type	Result Name	Unit of Measure
113818	Prompt-Result	Time/Date, Last Dose	
113819	Prompt-Result	Dose	
113820		Pyrazinamide	mcg/mL

Rifampin, Level (RIFH)	
Message	*** This test is not available for New York patient testing***
Effective Date	**8/12/2013**
Former Test Name	*Rifampin, HPLC*
Former Test Code	*S51395*
Test Code	**S52597**
Specimen Requirements	**Preferred:** 2 mL **(minimum 0.5 mL)** serum collected in a red-top (no gel) tube **Acceptable:** P**lasma collected in an EDTA (lavender-top) tube, sodium heparin (green-top) tube**
Reject Criteria	**Gross hemolysis, serum separator tube**
Instructions	**Separate serum (or plasma) from cells immediately by centrifuge and aliquot into a labeled polypropylene or similar plastic tube. Use a separate tube for each test ordered. Allow room for expansion of sample. Freeze at -70°C if possible, but at minimum -20° C.**
Transport Temperature	**Frozen**
Specimen Stability	**Room temperature: 6 hours** **Refrigerated: 24 hours** **Frozen: 30 days**

Set-up/Analytic Time	**Set up: Mon-Fri; Report available: 2-7 days**
Always Message	**The target range for mycobacterial infections is 8 to 24 mcg/mL 2 hours after oral dose or 2 hours after the end of intravenous infusion. Samples drawn later than 2 hours after the dose will often display concentrations below the stated range.** **Rifampin generally should be given as a single daily dose. If the patient is receiving 2 small daily doses, consider combining the doses and rechecking the concentration.** **Rifampin absorption may be reduced by food. Take on an empty stomach if possible.** **Rifampin does not have clear concentration related toxicity and most patients tolerate concentration above the stated range without difficulty.** **Hepatic dysfunction may produce elevated rifampin concentrations. Rifampin concentrations greater than 50% above the range may warrant a dose reduction of 150 to 300 mg.** **If the time of the dose and the blood draw were not accurately recorded, accurate interpretation of the concentration is not possible.**
Methodology	High Performance Liquid Chromatography (HPLC)
Performing Site	**This test previously performed at Focus Diagnostics, Inc. will now be performed at National Jewish Health.**
CPU Mappings	

Result Code	Type	Result Name	Unit of Measure
113821	**Prompt-Result**	**Time/Date, Last Dose**	
113822	**Prompt-Result**	**Dose**	
113823		**Rifampin Level**	**mcg/mL**

Streptomycin, Level (SMH)	
Message	*** This test is not approved for New York patient testing***
Effective Date	**8/12/2013**
Former Test Name	*Streptomycin, HPLC*
Former Test Code	*S51478*
Test Code	**S52598**
Specimen Requirements	**Preferred:** 2 mL **(minimum 0.5 mL)** serum collected in a red-top (no gel) **Acceptable:** **Plasma collected in an EDTA (lavender-top) tube, sodium heparin (green-top) tube**
Reject Criteria	**Gross hemolysis, serum separator tube**
Instructions	**Separate serum (or plasma) from each cells immediately by centrifuge and aliquot into a labeled polypropylene or similar plastic tube. Use a separate tube for each test ordered. Allow room for expansion of sample. Freeze at -70° C if possible, but at minimum-20° C.**
Transport Temperature	**Frozen**
Specimen Stability	**Room temperature and Refrigerated: 24 hours** **Frozen: 30 days**
Set-up/Analytic Time	**Set up: Mon-Fri; Report available: 2-7 days**
Always Message	**The target range for conventional treatment of mycobacterial infections is 35 to 45 mcg/mL approximately 1 hour after intramuscular injection or 1 hour after the end of intravenous infusion.**

	The target range for high dose, 3 times weekly treatment of mycobacterial infections is 65 to 80 mcg/mL approximately 1 hour after intramuscular injection or 1 hour after the end of intravenous infusion. **To allow for drug distribution, samples are drawn 2 hours after IV infusion or IM injection. These samples will often display concentrations below the state ranges. The patient's maximum concentration can be back calculated from 2 measured concentrations using linear regression. The patient's elimination rate constant can be also calculated.** **In patients with normal renal function, conventional doses of 12 to 15 mg/kg are often used daily or 5 times weekly; high dose therapy of 22 to 25 mg/kg should be used 2 to 3 times weekly.** **Streptomycin is renally cleared. Renal dysfunction may result in elevated streptomycin concentrations and this drug should be used cautiously in these patients. Carefully monitor audiogram and bun, creatinine, magnesium, potassium, and calcium concentrations at least once monthly.** **Samples drawn hours after the usual peak will be lower than the ranges listed above.** **If the time of the dose and the blood draw were not accurately recorded, accurate interpretation of the concentration is not possible.**
Methodology	High Performance Liquid Chromatography (HPLC)
Performing Site	**This test previously performed at Focus Diagnostics, Inc. will now be performed at National Jewish Health.**
CPU Mappings	

Result Code	Type	Result Name	Unit of Measure
113824	**Prompt-Result**	**Time/Date, Last Dose**	
113825	**Prompt-Result**	**Dose**	
113826		**Streptomycin Level**	**mcg/mL**

Discontinued Tests

Discontinued Tests	
Effective Date	**8/12/2013**
Performing Site	Focus Diagnostics, Inc.
Additional Information	These tests will be discontinued, there are no recommended alternatives.
Tests Affected	

Test Codes:	Name:
S49158	Ampicillin Level, BA
S52485	Anidulafungin, HPLC
S48636	Antifungal Serum Level, Amphotericin B, HPLC
S52397	Antimicrobial Level, Linezolid Level, HPLC
S49511	Azithromycin Level, BA
S50640	Aztreonam Level, BA
S51326	Capreomycin, HPLC
S44305	Cefazolin Level, BA
S50643	Cefotaxime Level, BA
S43930	Ceftazidime Level, BA

S51111	Ceftriaxone Level, BA
S50528	Cefuroxime Level, BA
S44840	Cephalexin Level, BA
S48777	Ciprofloxacin Level, BA
S52381	Clarithromycin Level, BA
S47940	Clindamycin Level, BA
S49530	Erythromycin Level, BA
S46770	Imipenem Level, BA
S43095	Kanamycin Level, BA
90946	Ketoconazole, HPLC
S51479	Levofloxacin Level, BA
S48370	Minocycline Level, BA
S43125	Nafcillin Level, BA
S50088	Neomycin Level, BA
S51007	Oxacillin Level, BA
S49265	Penicillin Level, BA
S50744	Piperacillin Level, BA
S52332	Rifabutin, HPLC
S51436	Sulfamethoxazole, HPLC
S48664	Tetracycline Level, BA