

April 25, 2008

Dear Colleague:

Specialty Laboratories is pleased to announce several significant enhancements to the HIV-1 RNA Quantitative PCR assays currently offered. The new technology utilizes real-time PCR for the determination of HIV-1 viral load. This platform offers an improved lower limit of detection (48 copies/mL), while extending the upper limit to 10,000,000 copies/mL (from 750,000). This extended level of detection provides several additional benefits to the client:

- Reflex to an alternate ultrasensitive assay is no longer required.
- Elevated HIV-1 viral loads greater than 750,000 copies/mL no longer require repeat testing on dilution.
- Improved result turnaround for both elevated samples and previously-reflexed panels.
- Simplification of the ordering process, with several panels being consolidated into three.

Vitamin D-1,25 testing is being converted to the more sensitive LCMSMS methodology and will be sent to the Nichols Institute temporarily, as of June 9, 2008, while *Specialty Laboratories* completes the validation study. It is expected that the validation study will be completed by the end of the year. *Specialty* clients should continue to send all of their reference testing work to *Specialty Laboratories*. No significant impact on the turnaround time for Vitamin D-1,25 is anticipated during this validation period.

We thank you for choosing *Specialty* and look forward to your continued support.

For additional information, please visit our Web site at www.specialtylabs.com or contact Client Relations at 800-421-4449.

Respectfully Yours,



Christopher Lockhart, M.D.
Laboratory Director

New Tests:

1821R Human Papillomavirus High Risk DetectR™ Anal/Rectal (Available May 6, 2008)

<u>Component</u>	<u>Method</u>	<u>Reference Range/Units</u>
HPV High Risk DetectR™	HC	Not detected

Specimen/Stability	Swab Digene Transport Medium 1.0 (1.0) mL; Ambient 14 days, Refrigerated 21 days, Frozen 3 months
Alternate Specimen	ThinPrep Vial 8.0 (4.0) mL; Ambient 21 days, Refrigerated 21 days SurePath Vial 4.0 (2.0) mL; Ambient 28 days, Refrigerated 6 months
Collection	Anal and rectal swab specimens should be collected using the Digene Specimen Collection Kit and transported in the Digene Specimen Transport Medium. Specimens collected in at least 4 mL of ThinPrep or SurePath vials may be held up to 2 weeks prior to shipping.
Schedule	Tuesday-Sunday
Report	Same day
CPT Code	87621
Clinical Utility	The majority of anal cancers are squamous cell carcinomas (<i>in situ</i> and epidermoid), which are usually associated with HPV.

1822R Human Papillomavirus High & Low Risk DetectR™ Anal/Rectal (Available May 6, 2008)

<u>Component</u>	<u>Method</u>	<u>Reference Range/Units</u>
HPV High & Low Risk DetectR™	HC	Not detected

Specimen/Stability	Swab Digene Transport Medium 1.0 (1.0) mL; Ambient 14 days, Refrigerated 21 days, Frozen 3 months
Alternate Specimen	ThinPrep Vial 8.0 (4.0) mL; Ambient 21 days, Refrigerated 21 days SurePath Vial 4.0 (2.0) mL; Ambient 28 days, Refrigerated 6 months
Collection	Anal and rectal swab specimens should be collected using the Digene Specimen Collection Kit and transported in the Digene Specimen Transport Medium. Specimens collected in at least 4 mL of ThinPrep or SurePath vials may be held up to 2 weeks prior to shipping.
Schedule	Tuesday-Sunday
Report	Same day
CPT Code	87621x2
Clinical Utility	The majority of anal cancers are squamous cell carcinomas (<i>in situ</i> and epidermoid), which are usually associated with HPV.

4096U Phenobarbital Urine (Available May 6, 2008)

<u>Component</u>	<u>Method</u>	<u>Reference Range/Units</u>
Phenobarbital	LC-MS-MS	By report Limit of Quantitation = 2.0 ng/mL

Specimen/Stability	Urine 4.0 (2.0) mL; Ambient 30 days, Refrigerated 30 days, Frozen 30 days
Collection	Do not use any preservatives or additives.
Schedule	Tuesday, Thursday, Saturday
Report	Same day
CPT Code	80184
Clinical Utility	Confirmation of screen-positive results.
Note	This test is not approved for the testing of patient samples from New York State. This will replace the panel currently being referred to a send out laboratory – S51183

Test Changes:

5720 **Microsporidia Spore Stain**

Effective	Immediately
Specimen/Stability	Stool SAF; Ambient 14 days, Refrigerated 14 days
Alternate Specimens	Stool Formalin; Ambient 14 days, Refrigerated 14 days Sterile Container/Tube; Ambient 24 hours, Refrigerated 3 days
Collection Instructions	Note: Stool PVA and unpreserved stools are not acceptable specimens 1. Fresh stool should be preserved in formalin or SAF immediately. 2. Acceptable specimens: Body fluids (urine, CSF, sputum, bronchial lavage). Unacceptable specimens: Unpreserved and PVA preserved stools. 3. Sterile container is to be used for body fluids only. 4. Ship to Specialty at ambient temperature within 24 hours of collection.

2363 **Ova & Parasite: Coccidia Evaluation**

Effective	Immediately
Specimen/Stability	Stool SAF; Ambient 14 days, Refrigerated 14 days
Alternate Specimens	Stool Formalin; Ambient 14 days, Refrigerated 14 days Sputum (Induced); Ambient 14 days, Refrigerated 14 days
Collection Instructions	Note: Stool PVA and unpreserved stools are not acceptable specimens It is recommended to submit three specimens collected on three separate days.

5653 **AFB Suscept: Other *Mycobacterium* spp. By Agar Proportion**

Effective	Immediately
CPT Code	87190x9

7485A **HIV-1 RNA Quant by Roche Ultrasensitive**

Effective	May 5
Name	HIV-1 RNA Quantitative, Real Time PCR
Ref Range	HIV-1 RNA Quant <48 copies/mL HIV-1 RNA (log 10) <1.68
Methodology	RT-PCR
Specimen/Stability	Plasma EDTA; Ambient 24 hours, Refrigerated 5 days, Frozen 35 days
Alternate Specimens	Plasma ACD; Frozen 2 months Plasma PPT; Ambient 2 days, Refrigerated 3 days
Collection Instructions	If plasma is physically separated from PPT, it is considered EDTA plasma and MUST be shipped as indicated below. Plasma EDTA: Plasma must be separated within 4 hours of collection to ensure accuracy. Refrigerated or frozen plasma collected in and separated from either K3 EDTA or PPT tubes is STRONGLY RECOMMENDED for maximum analytical sensitivity (See NOTE below referring to freezing of PPT tubes). Split separated plasma into 2 vials. Ship within 24 hours of collection by overnight courier. Samples may be shipped ambient if arrival in testing department is guaranteed within 24 hours of collection; however, refrigeration or freezing is preferred.
Note	Quantitates HIV-1 virus RNA down to 48 copies/mL to monitor viral load in established HIV-1 infected individuals (specimens with viral loads greater than 10,000,000 copies/mL will be reported out as >10,000,000 copies/mL).
Also affected	7485ASR

Test Changes: (Cont'd)

7482A	HIV-1 RNA Ultrasensitive by Roche w/Reflex GenotypR™ PLUS	
Effective	May 5	
Name	HIV-1 RNA Quantitative, Real Time PCR w/Reflex GenotypR™ PLUS	
Ref Range	HIV-1 RNA Quant	<48 copies/mL
	HIV-1 RNA (log 10)	<1.68
Methodology	RT-PCR	
Specimen/Stability	Plasma EDTA; Frozen 35 days	
Alternate Specimens	Plasma ACD; Frozen 2 months	
	Plasma PPT; Ambient 2 days, Refrigerated 3 days	
Collection Instructions	If plasma is physically separated from PPT, it is considered EDTA plasma and MUST be shipped as indicated below. Plasma EDTA: Plasma must be separated within 4 hours of collection to ensure accuracy. Refrigerated or frozen plasma collected in and separated from either K3 EDTA or PPT tubes is STRONGLY RECOMMENDED for maximum analytical sensitivity (See NOTE below referring to freezing of PPT tubes). Split separated plasma into 2 vials. Ship within 24 hours of collection by overnight courier. Samples may be shipped ambient if arrival in testing department is guaranteed within 24 hours of collection; however, refrigeration or freezing is preferred.	
Note	Quantitates HIV-1 virus RNA down to 48 copies/mL to monitor viral load in established HIV-1 infected individuals (specimens with viral loads greater than 10,000,000 copies/mL will be reported out as >10,000,000 copies/mL). If viral load quantitation is greater than or equal to 1000 copies/mL, a reflex to GenotypR™ PLUS will be performed for an additional fee. Add on CPT codes 87901. Add up to 10 days to the turnaround time.	
1615	Complement C1q	
Effective	May 5	
Ref Range	7 – 48 mg/dL	
3133	Cyclic Citrullinated Peptide (CCP) IgG Abs	
Effective	May 27	
Ref Range	Less than 20 units	Negative
	20 - 39 Units	Weak Positive
	40 - 59 Units	Moderate Positive
	Greater than or equal 60 Units	Strong Positive
Methodology	EIA	
Specimen/Stability	Serum 1.0 (0.5) mL; Ambient 7 days, Refrigerated 14 days, Frozen 2 months	
Also affected	1013, 1014	
7440SW	<i>Chlamydia trach</i>/<i>N. gonorrhoeae</i> rRNA PLUS [TMA] w/Rfx Confirm	
Effective	May 5	
Ref Range	Not detected	
	Results will be reported as: Not detected	
	Screen detected, reflexed to confirmation	
Note	Screen detected results will automatically reflex to confirmatory testing for an additional fee (CPT codes 87491 and/or 87591)	

Test Changes: (Cont'd)

9898 HTLV-I/II Abs

Effective	May 20
Ref Range	Nonreactive
Also affected	9899

1580 Protein Electrophoresis (PEP)

Effective	May 20	
Ref Range	Albumin	2.37 – 4.57 g/dL
	Alpha-1	0.24 – 0.58 g/dL
	Alpha-2	0.54 – 1.13 g/dL
	Beta	0.52 – 0.98 g/dL
	Gamma	0.55 – 1.57 g/dL
	A/G Ratio	0.75 – 1.86
Also affected	1580G, 1583, 1583G, 1584	

7480 HIV-1 GenotypR™ PLUS (Rev Trans & Prot Inhib)

Effective	May 20	
Component	Darunavir + Ritonavir (DRV/r)	ADD
	Delavirdine (DLV)	REMOVE
	Saquinavir (SQV)	REMOVE
	Ritonavir (RTV)	REMOVE
Also affected	7480NY, Reflex of 7482 & 7482A	

Discontinued Tests:

Effective Immediately:

4911 Alpha-Fetoprotein-L3% (%ALP-L3)
Replaced by: No replacement

Effective May 5, 2008:

7482SR HIV-1 RNA UltraQuant® [bDNA] w/SR w/Reflex GenotypR™ PLUS
Replaced by: 7482 (without serial reporting) HIV-1 RNA UltraQuant® [bDNA] W/Reflex GenotypR™ PLUS (RTI+PI)

7482ASR HIV-1 RNA Ultrasensitive by Roche w/Reflex GenotypR™ PLUS SR
Replaced by: 7482A (without serial reporting) HIV-1 RNA Quantitation [REAL TIME PCR] w/Reflex GenotypR™ PLUS

7482FPNY HIV-1 RNA Quant by Roche w/Reflex GenotypR™ PLUS [NY]
Replaced by: 7482A - HIV-1 RNA Quantitation [REAL TIME PCR] w/Reflex GenotypR™ PLUS

7484A HIV-1 RNA Quant by Roche w/Reflex GenotypR™ PLUS
Replaced by: 7482A - HIV-1 RNA Quantitation [REAL TIME PCR] w/Reflex GenotypR™ PLUS

9874A HIV-1 RNA Quant [Roche Amplicor] w/Reflex Ultrasensitive
Replaced by: 7485A - HIV-1 RNA Quantitation [REAL TIME PCR]

9874ASR HIV-1 RNA Quant by Roche w/SR w/Reflex Ultrasensitive
Replaced by: 7485ASR - HIV-1 RNA Quantitation [REAL TIME PCR] w/Serial Report

9874AFN HIV-1 RNA Quant by Roche w/Reflex Ultrasensitive New York
Replaced by: 7485A - HIV-1 RNA Quantitation [REAL TIME PCR]

9874AFNS HIV-1 RNA Quant by Roche w/SR w/Reflex Ultrasensitive NY
Replaced by: 7485ASR - HIV-1 RNA Quantitation [REAL TIME PCR] w/Serial Report

9884A HIV-1 RNA Quantitation [Roche Amplicor]
Replaced by: 7485A - HIV-1 RNA Quantitation [REAL TIME PCR]

9884ASR HIV-1 RNA Quant by Roche Amplicor w/Serial Reporting
Replaced by: 7485ASR - HIV-1 RNA Quantitation [REAL TIME PCR] w/Serial Report

9884FPNY HIV-1 RNA Quant by Roche New York Prognostic (FPNY)
Replaced by: 7485A - HIV-1 RNA Quantitation [REAL TIME PCR]

9884FPNS HIV-1 RNA Quant by Roche New York Prognostic (FPNY) w/SR
Replaced by: 7485ASR - HIV-1 RNA Quantitation [REAL TIME PCR] w/Serial Report

Discontinued Tests: (cont'd)

Effective May 27, 2008:

- 3129U Cortisol, Free 24Hr Urine UltraQuant®**
Replaced by: S51655 – Cortisol, Free, 24-Hour Urine LC/MS/MS (11280X)
- 3129UR Cortisol, Free Urine Random**
Replaced by: S51655 - Cortisol, Free, 24-Hour Urine LC/MS/MS (11280X)
- 3286W Hydroxytryptamine, 5- (Serotonin) Whole Blood**
Replaced by: S51656 – Serotonin, Blood (818X)
- 3503 Vitamin K1**
Replaced by: S51649 – Vitamin K (36585X)
- 3508 Vitamin C**
Replaced by: S51650 – Vitamin C (929X)
- 4126 Ethosuximide**
Replaced by: S51651 – Ethosuximide (Zarontin) (214X)
- 4159U 5-Aminolevulinic Acid 24Hr Urine**
Replaced by: S51659 – Delta Aminolevulinic Acid, 24-hr Urine (3970N)
- 4159UR 5-Aminolevulinic Acid Random Urine**
Replaced by: S51660 – Delta Aminolevulinic Acid, Random Urine (43554N)
- 4169U Porphobilinogen 24Hr Urine**
Replaced by: S51657 – Porphobilinogen, Quant, 24-hr Urine (7294N)
- 4169UR Porphobilinogen Urine Random**
Replaced by: S51658 – Porphobilinogen, Quant, Random Urine (84889N)
- 4180U Porphyrins, Fractionated w/ Porphobilinogen 24Hr Urine**
Replaced by: 4812U – Porphyrins, Fractionated 24Hr Urine AND S51657 – Porphobilinogen, Quant, 24-hr Urine (7294N)
- 4921 Flecainide [HPLC]**
Replaced by: S51652 – Flecainide (5309X)
- 4927 Zonisamide (Zonegran)**
Replaced by: S51653 – Zonisamide (37852N)
- 4935 Haloperidol**
Replaced by: S51654 – Haloperidol (564X)
- IHC222 IHC Human Placental Lactogen (HPL)**
Replaced by: No replacement
- IHC223 IHC Cyclin E**
Replaced by: No replacement

Discontinued Tests: (cont'd)

- IHC224 IHC Calponin B**
Replaced by: No replacement
- IHC228 IHC A1-Antichymotrypsin (A1-ACT)**
Replaced by: No replacement
- IHC231 IHC HMB-45 (AP-Red)**
Replaced by: No replacement
- IHC232 IHC HAM56**
Replaced by: No replacement
- IHC233 IHC A1-Antitrypsin (A1-AT)**
Replaced by: No replacement
- IHC234 IHC Melan-A (AP-Red)**
Replaced by: No replacement

Effective June 9, 2008:

- 3520 Vitamin D, 1, 25-Dihydroxy**
Replaced by: S51661 Vitamin D, 1, 25-Dihydroxy, LC/MS/MS (4861)
- 3523 Vitamin D, 1, 25-Dihydroxy & 25-Hydroxy**
Replaced by: 3521 – Vitamin D, 25-Hydroxy and S51661 - Vitamin D, 1, 25-Dihydroxy, LC/MS/MS (4861)