Test Name	Test Code	Effective Date
HIV-1 Genotyping Assay and Profile Addition	**TN88-5**	**7/8/2024**

We are pleased to launch TN88-5, a new FDA-approved HIV-1 genotyping assay. This will now be part of the HIV-1, RNA, Ultra Quant PCR Reflex to Genotype profile (test code M392-9). The testing algorithm will be based on the results of the viral load run at BioReference.

This assay is a next generation sequencing (NGS)-based test intended for use in detecting HIV-1 genomic mutations in the protease (PI), reverse transcriptase (NRTI and NNRTI) and integrase regions of the pool gene as an aid in monitoring and treating HIV-1 infection. This test is used in adjunct to the therapeutic management of patients diagnosed with HIV-1 Group M subtypes A-K infection, with various viral loads, in EDTA plasma specimens.

Profile code M392 HIV-1, RNA, Ultra Quant PCR Reflex To Genotype

- When viral load for HIV-1 RNA Ultra Quant PCR is >/= 1000 copies /mL test code TN88 HIV-1 Genotype (NRTI, NNRTI, PI, Integrase Inhibitors) will be added
- When viral load for HIV-1, RNA, Ultra Quant PCR is >500 but <1000 copies/mL test code TQ70 will be added HIV-1 Genotype (NRTI, NNRTI, PI, Integrase Inhibitors)
- When viral load for HIV-1, RNA, Ultra Quant PCR is </=500 copies /mL test code J001 GENOSURE ARCHIVE (NRTI, NNRTI, PI, Integrase Inhibitors) will be added

Note: TQ70 and J001 will no longer be orderable as stand-alone tests. They will only be performed based on the reflex criteria.

Results should be used in conjunction with other available laboratory and clinical information and are not intended for use as an aid in the diagnosis of infection with HIV, to confirm the presence of HIV infection, or for screening donors of blood, plasma or human cells, tissues and cellular and tissue-based products.

	Previous Test Information	New Test Information
Primary Container	EDTA lavender top *	EDTA lavender top
Minimum Volume	1.0 ml	2.0 ml
Turn Around Time*	13 days	12 days
Transportation Temp	2-8 degrees C	2-8 degrees C
Stability	Ambient 6 hours, after separation from cells ambient 24 hours, 2-8 degrees C for 5 days, frozen 4 months	Ambient 2 hours, after separation from cells 2-8 degrees C for 7 days, frozen for 1 month, avoid freeze thaw cycles
Methodology	Real-time PCR	Next generation sequencing (NGS)
Reference Range	Not Detected	Susceptible
Collection Instructions	Centrifuge lavender top at high speed for 15 minutes. Transfer plasma to plastic transfer tube. Label with date/time collected, EDTA PLASMA and patient's name.	Gently invert lavender top 8-10 times. Store tubes in upright position for up to 2 hours prior to centrifugation. Centrifuge at 1900 x g for 10 minutes at 2-8 degrees C. Transfer plasma to plastic transfer tube and label with date/time collected, EDTA PLASMA and patient's name.
Profile Components	Protease, reverse transcriptase (NRTI and NNRTI), and integrase regions	Protease, reverse transcriptase (NRTI and NNRTI), and integrase regions
CPT Code(s)**	87900, 87901	0219U
Clinical Utility (If applicable)	Management of HIV-1 infection. Identifies drug resistance to HIV-1 protease, reverse transcriptase, and Integrase genes.	Management of HIV-1 infection. Identifies drug resistance to HIV-1 protease, reverse transcriptase and integrase regions of POL gene.

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Test Name	Test Code	Effective Date
Lactose Tolerance Test	**1178-3**	**Immediately**

Effective immediately, we will discontinue collection for test code 1178-3, Lactose Tolerance test, in our Patient Service Centers and In-Office phlebotomy sites. We will continue to provide testing and the lactate solution supply to the few client/physician offices that do perform these collections. Our Directory of Service will be updated to reflect the following messaging:

Note: The test collection cannot be performed at a patient service center due to the required preparation of the lactate solution and potential GI impact for the patient. We do provide the lactate solution for physician administration and collection.

Test Name	Test Code	Effective Date
Vasoactive Intestinal Polypeptide (VIP), Plasma	**0338-4**	**Immediately**

Due to an update in testing platform, test code 0338, Vasoactive Intestinal Polypeptide (VIP), Plasma have been updated for all locations. Please refer to the table below for details including the updated transportation temp and specimen stability.

	Previous Test Information	New Test Information
Primary Container	ALQE - Aliquot Plasma-EDTA-Lavender Top	ALQE - Aliquot Plasma-EDTA-Lavender Top – with Traysol
Minimum Volume	1.1mL	2mL
Turn Around Time*	14 days	11 days
Transportation Temp	**Strict Frozen**	**Refrigerate**
Stability	**90 days Frozen**	**14 days Frozen**
Methodology	Radioimmunoassay	Radioimmunoassay
Reference Range	<78 pg/mL	0.0–58.8 pg/mL
Collection Instructions	ALQE: Centrifuge lavender-top at high speed for 15 minutes. Transfer plasma into plastic transfer tube. Label with date/time collected, EDTA PLASMA and patient's name.	**Patient must not have received radioactive substances 24 hours prior to test**. Using a chilled 6-mL lavender-top (EDTA) tube taken from the kit, collect a whole blood specimen. Mix the specimen several times by inverting the EDTA collection tube. After removing the cap from the EDTA draw tube, take one of the sterile, Beral pipettes (from under the gray foam), and add 0.25 mL Trasylol® to the EDTA tube. Recap the EDTA tube and invert several times to mix well. Centrifuge the EDTA tube to separate the plasma from the cells, and immediately transfer the plasma into one of the brown screw-cap transfer tubes provided in the kit. There should be a "Trasylol® Added" label affixed to the brown transfer tubes. Cap and freeze the labeled transfer tube containing the EDTA plasma with Trasylol® added.
CPT Code(s)**	84586	84586
Clinical Utility (If applicable)	Detection of vasoactive polypeptide producing tumors in patients with chronic diarrheal diseases.	This test is used to measure the level of vasoactive intestinal polypeptide (VIP) in plasma.

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Test Name	Test Code	Effective Date
H. Pylori Urea Breath Test Pediatric	**J292-4**	**Immediately**

Test code J292-4, H. Pylori Urea Breath Test Pediatric will be retired. Adult and pediatric patients for H. Pylori Urea Breath testing will be available under one test code 6236-4, H. Pylori Urea Breath Test.

Test Name	Test Code	Effective Date
C4a Level	**A127-3**	**Immediately**

Test code A127-3, C4a Level will be retired. Suggested alternate test code is TQ93-9, Complement C4a. Please refer to the table below for details including the updated transportation temp and specimen stability.

	Previous Test Information	New Test Information
Primary Container	ALQE - Aliquot Plasma-EDTA-Lavender Top	ALQE - Aliquot Plasma-EDTA-Lavender Top
Minimum Volume	0.2mL	1 mL
Turn Around Time*	38 Days	6-9 Days
Transportation Temp	**Strict Frozen**	**Refrigerate**
Stability	**365 days frozen**	**8 days Refrigerate, 90 days frozen**
Methodology	Radioimmunoassay	Radioimmunoassay (RIA)
Reference Range	0-2830 ng/mL	0.0–58.8 pg/mL
Collection Instructions	Centrifuge lavender-top at high speed for 15 minutes. Transfer plasma into plastic transfer tube. Label with date/time collected, EDTA PLASMA and patient's name.__	Collect EDTA whole blood sample into a chilled lavender-top tube. Immediately add Futhan preservative as directed in the Futhan collection kit. Recap lavender tube and invert several times to mix well. Centrifuge the whole blood specimen to separate the plasma. Transfer the plasma into the plastic screw-cap tube that is included in the collection kit. The specimen must be submitted in this transfer tube, which is labeled with the words "Futhan Added." separate specimen must be submitted for testing.
CPT Code(s)**	86160	86160

Test Name	Test Code	Effective Date
Creatine, Serum	**0875-5**	**Immediately**

Due to quality control measures, test code 0875-5, Creatine, Serum will be updated to a strict frozen specimen.

	Previous Test Information	New Test Information
Transportation Temp	**Refrigerate**	**Frozen**
Collection Instructions		Centrifuge and transfer serum specimen to a clean, plastic screw-cap vial. Freeze and ship frozen.

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Test Name	Test Code	Effective Date
Borrelia Burgdorferi (Lyme) Antibodies, Immunoblot	**B662-8**	**Immediately**

Test B662-8, Borrelia Burgdorferi (Lyme) Antibodies, Immunoblot, will no longer be offered. The recommended alternate is test 4033-7, Lyme Antibody West-Blot IgG/IgM.

	Previous Test Information	New Test Information
Test Name	Borrelia Burgdorferi (Lyme) Antibodies, Immunoblot	Lyme Antibody West-Blot IgG/IgM
Test Code	B662	4033
Methodology	Immunoblot	Western Blot
Turn Around Time	**6 days**	**2 days**
Sample Type	Serum from SST or Red Top tube	Serum from SST or Red Top tube
Sample Volume	1.0 ml	2.0 mL
Sample Stability	Room Temperature: 7 days Refrigerated: 14 days Frozen: 30 days	Room Temperature: N/A Refrigerated: 7 days Frozen: N/A
Transport Temperature	Refrigerate	Refrigerate
Reference Ranges	Negative	Negative
CPTs	86617x2	86617x2

Test Name	Test Code	Effective Date
Ashkenazi Jewish DNA panel 8 (Non-NY) **Ashkenazi Jewish DNA 8 (NY)** **Ashkenazi Jewish 10** **Ashkenazi Jewish 11** **Ashkenazi Jewish 17** **Ashkenazi Jewish 18**	**A282-6** **P223-1** **A660-3** **P658-8** **A661-1** **P659-6**	**Immediately**

In order to simplify our Ashkenazi Jewish (AJ) carrier screening options, the 6 test codes listed above will be retired. These panels screened for 8, 10, 11, 17, or 18 conditions common in the AJ population. We will continue to offer 3 different AJ carrier screening panel options for patients desiring AJ carrier screening:

- J293-2 Ashkenazi Jewish Expanded Profile- screens for 47 genes
- Q161-2 Ashkenazi Jewish Carrier Screen 25- screens for 25 genes
- 3267-2 Ashkenazi Jewish Carrier Screen 9- screens for 9 genes

Please call customer service and ask to speak to a prenatal genetic counselor if you would like additional information about any of these test options.

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Test Name	Test Code	Effective Date
Prader Willi/Angelman Syndrome **Uniparental Disomy** **Amniotic Fluid Cystic Fibrosis** **Beta Globin Known Mutation, Fetal** **Beta Globin Sequencing, Fetal**	**B795-6** **B848-9** **B219-7** **B218-9** **B217-1**	**Immediately**

The send out test codes listed above will be retired. Fetal known mutation testing continues to be available for most genes/variants using test code B118. Please call customer service to speak to a prenatal genetic counselor if other specialized testing not included on our test menu is needed on a CVS or amniotic fluid sample.

Test Name	Test Code	Effective Date
RhD Gene (RHD) Copy Number **RhE/e (RHCE) Antigen Genotyping** **RhC/c (RHCE) Antigen Genotyping** **Kell K/k (KEL) Antigen Genotyping**	**J117-3** **J017-5** **TH77-1** **B926-7**	**Immediately**

Due to changes at the sendout lab, the 4 antigen genotyping tests listed above are now only available on blood samples (lavender top- EDTA or yellow top- ACD) and will no longer be available for chronic villus (CVS) or amniotic fluid samples.

RhD is now the only fetal antigen genotyping available through BioReference and can be ordered using test code TQ76 (RhD Gene (RHD) Copy Number, Fetal).

Questions? Please contact your Account Executive or Customer Service directly.

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