Test Name	Test Code	Effective Date
HIV-1, RNA, Ultra-PCR, Viral load	**1010-8**	4/29/2025

The following changes have been implemented to the reporting of HIV Viral Load:

- Previously reported < 20 Not Detected will now be reported as Not Detected.
- Previously reported < 20 Detected was not reported as abnormal and in Red and will now be reported as <20 Detected as Abnormal in RED.

In addition, the following comments have been added to the laboratory report:

- < 20 Detected copies/ml in HIV positive patients on anti-retroviral therapy is consistent with adequate viral suppression. This result should be taken in context with patient's history and clinical status.
- < 20 Detected copies/ml in patients on PrEP or PEP could be consistent with newly acquired infections, follow up testing is recommended. In patients on PrEP or PeP who are tested early after HIV acquisition, the Elecsys Ag/Ab can be negative but there can be a minimal amount of HIV virus present. Most instances however will be associated with a high viral load.[1]

Reference:

1. Zucker J, Carnevale C, Rai AJ, Gordon P, Sobieszczyk ME. Positive or Not, That Is the Question: HIV Testing for Individuals on Pre-exposure Prophylaxis. J Acquir Immune Defic Syndr. 2018 Jun 1;78(2):e11-e13. doi: 10.1097/QAI.0000000000001665. PMID: 29481487; PMCID: PMC5953799.

HIV Geenius Reagent Issue

Due to a nationwide shortage of HIV Geenius reagent, the following changes in testing will be implemented until the Geenius reagent is back in stock:

1. The Elecsys HIV Duo HIV Antigen/Antibody test will be run as a screening test.
2. A Negative HIV Duo will be reported as negative for HIV.
3. A positive Elecsys Duo will be reflexed to the Aptima HIV-1 Qualitative assay.
    a. If the Aptima HIV-1 Qualitative assay is positive, the result will be reported as HIV-1 positive.
        i. The HIV-1 Geenius will be released as Test Not Performed (TNP).

The Centers for Disease Control and Prevention (CDC), New Jersey Department of Health (NJDOH), and New York State Department of Health (NYDOH) are aware of the HIV-1 Geenius reagent shortage.

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Test Name	Test Code	Effective Date
New Respiratory Panels***	**Various (see below)**	**5/6/2025**

BioReference is now offering new Respiratory Panels from nasopharyngeal swabs. The new offerings will allow a more targeted approach to detecting respiratory viruses. The new respiratory panels are:

- M465-3: Adenovirus (ADV), Human Metapneumovirus (hMPV), and Rhinovirus
- M466-1: Parainfluenza NAAT
- M468-7: Flu A, Flu B, and RSV NAAT
- M469-5: Flu A, Flu B

The new respiratory panels will be in addition to our existing targeted panels of :

- M123-8 – COVID, Flu A, Flu B
- M322-6 - COVID, Flu A, Flu B, and RSV

	M465, M466, M468, and M469 Test Information
Primary Container	Swab-Viral Culturette
Turn Around Time*	3 days
Transportation Temp	Refrigerate 2-8°C
Stability	4 days Refrigerate 2-8°C
Methodology	RT-PCR
Reference Range	Not Detected
Collection Instructions	SV: Collect sample, place in holder, label with patient name. Not to be used for bacterial transport
CPT Code(s)**	87631 (for test codes M465, M466, M468) 87502 (for test code M469)

Test Name	Test Code	Effective Date
COVID-19 AB Qual/Quant (Retired) COVID-19 Antibody (Retired) COVID-19 AB Qual/Quant w/ Reflex to TH99 (Retired)	**M160-0** **TH99-5** **M162-6**	**5/21/2025**

Test codes M160, TH99, and M162 will be retired effective 5/21/2025. The recommended alternative test is test code M217-8 SARS-CoV-2 Trimerics IgG.

Test Name	Test Code	Effective Date
TRaB (TSH Receptor Binding Antibody) (Retired) Thyrotropin Receptor Antibody, Serum (Retired) Thyroid Stimulating Immunoglobulin (Retired)	**1044-7** **B877-2** **J510-9**	**5/19/2025**

Test codes 1044, B877, and J510 will be retired effective 5/19/2025. The recommended alternative test is

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TR39 Anti-Thyroid Stimulating Hormone Receptor (see below).

Test Name	Test Code	Effective Date
Anti-Thyroid Stimulating Hormone Receptor	**TR39-0**	**5/19/2025**

	Test Information
Primary Container	SST
Minimum Volume	1.0mL
Turn Around Time*	1 day
Transportation Temp	Refrigerate
Stability	6 days Refrigerated
Methodology	Electrochemiluminescence Immunoassay
Reference Range	<1.76 IU/L
Collection Instructions	SST: Fill tube, invert gently 5 times, label with patient name, let stand for a minimum of 30 minutes, maximum of 1 hr., spin for 10-15 minutes
CPT Code(s)**	84235
Clinical Utility	The anti-TSH receptor determination is used in the assessment of patients suspected of Graves' Disease

Test Name	Test Code	Effective Date
Toxoplasma Avidity G/M, ELISA (Retired)	**B376-5**	**6/2/2025**

Test code B376-5 for Toxoplasma Avidity will no longer be offered effective 6/2/2025. For clients requesting Toxoplasma Avidity, the new test code will be M419-0 Toxoplasma IgG with Reflex Avidity. The Avidity test will only be available as a reflex option.

	Previous Test Information	New Test Information
Primary Container	SST - SST Tube	SST-SST tube
Minimum Volume	0.5 ml	1.0 mL
Turn Around Time*	10 days	1 day; add 7 days if reflexed
Transportation Temp	Refrigerate	Refrigerate
Stability	14 days Refrigerated, 1 year Frozen	7 days Refrigerated
Methodology	Enzyme Linked Immunoabsorbance	Chemiluminescence
Reference Range	Negative 0.0-1.6 Equivocal 1.7-1.9 Positive >=2.0	Negative
Collection Instructions	SST: Fill tube, invert gently 5 times, label with patient name, let stand for a minimum of 30 minutes, maximum of 1 hr., spin for 10-15 minutes	SST: Fill tube, invert gently 5 times, label with patient name, let stand for a minimum of 30 minutes, maximum of 1 hr., spin for 10-15 minutes
Profile Components	Toxoplasma IgG Toxoplasma IgM When IgG antibodies are positive, Avidity will be performed	Toxoplasma IgG When IgG antibodies are positive, Avidity will be performed

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CPT Code(s)**	86777x1, 86778x1	86777x1 (If applicable, an additional 86777x1 for reflex)

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

**TAT is based upon receipt of the specimen at the laboratory.*
***CPT codes provided are based on AMA guidelines and are for informational purposes only. CPT coding is the sole responsibility of the billing party. Please direct any questions regarding coding to the payer being billed.*
****Healthcare providers should only order panels if each test in the panel is medically necessary.*

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