BioReference LABORATORIES | genpath

OPKO Health Companies

Client Update

FEBRUARY 2020

Test Name	Test Code	Effective Date
BioKit (SureVue) HSV2	**L625 and B528**	**Immediately**

Due to quality control issues with the current lot of reagent, **BioKit (SureVue)** testing to confirm or diagnose serologic evidence of HSV2 infection will be suspended until further notice. For any questions please contact Customer Service and request to speak to Dr. Jeff Gilbert, Medical Director: STIs

Anti-platelet Antibody Direct and Indirect assays **5702 and 5703** **January 6, 2020**

As of January 6, 2020, Anti-platelet antibody-Direct (code 5702) and Anti-platelet antibody-Indirect (code 5703) have been discontinued. The reagent manufacturer for the Anti-platelet antibody Direct and Indirect assay kit has discontinued the manufacturing of the kits and there are no other FDA cleared kits currently available.

The recommended alternative for Anti-platelet antibody-Direct (code 5702) is Platelet antibody Direct Flow cytometry (code 3675). The recommended alternative for Anti-platelet antibody-Indirect (code 5703) is Platelet antibody identification test (code 5776). This test additionally screens for antibodies to HLA class I and the platelet glycoproteins IV antigens and to polymorphic epitopes on the platelet glycoproteins IIb/IIIa, Ib/IX and Ia/IIa.

Please note: You may have seen it was indicated in the January Client Update that these tests would automatically convert to the suggested alternate tests. ***However the alternate tests will not be performed automatically and clients will need to request alternate testing separately***. Please contact your Account Executive or Customer Service with any questions.

REMINDER - 4Kscore Test **J148, J264 and K135** **Immediately**

The final Local Coverage Determination (LCD) from the Medicare MAC for the 4Kscore® Test, Novitas, is now effective. Please be reminded that the LCD includes defined coverage criteria from Medicare, including required documentation of Shared Decision Making prior to ordering the 4Kscore Test. Full text of the final LCD can be found at http://bit.ly/4KscoreLCD.

The 4Kscore Test requisition form was modified to support the updated coverage criteria and is now the only requisition form that can be used to place an order for the 4Kscore Test. If documentation is **INCOMPLETE**, results may be delayed. In cases where complete documentation is not received by the lab following communication with your office, the test may be cancelled after a holding period.

Summary of Changes:

1. BOTH provider and patient signatures, legible names, and dates attesting to Shared Decision Making are required when ordering the 4Kscore Test, and must be sent to the laboratory.
2. ALL questions in the Prostate Cancer Risk Evaluation section of the requisition form MUST BE COMPLETED.
3. A COPY of the completed test requisition with Shared Decision Making should be retained in the patient's medical record.

Your Account Executive can provide you with additional details and information as needed. If you have any further questions, please call our 4Kscore Customer Service team at **833-4KSCORE (833-457-2673)** or visit our website at https://www.4kscore.com/.

REMINDER - Cryoglobulins **N/A** **February 15, 2020**

Cryoglobulins are serum immunoglobulins that precipitate at temperatures below 37°C (body temperature) and dissolve upon rewarming. They are heterogeneous in composition; most are mixed antigen-antibody complexes, and behave differently in vivo and in vitro. It is well recognized that the blood from patients suspected of having a cryoglobulin should be collected in preheated tubes, must be allowed to clot at 37°C for at least one hour, and need to centrifuged at 37°C to avoid false negative results. Since these strict pre-analytic collection conditions cannot be verified or met, BioReference will no longer offer this test, to prevent false negative results. Patients with suspected cryoglobulins should be sent to specialized laboratories which can provide these strict collection criteria.

REMINDER - General Thrombophilia Panel **6800** **February 1, 2020**

The **General thrombophilia panel** has been modified by updating the test for Anti-thrombin activity - Xa based (test code-5723) with Anti-thrombin activity- thrombin based (test code 5714). Anti-thrombin activity - Xa based activity is still available upon request.

481 Edward H Ross Drive | Elmwood Park NJ 07407 | tel 800 229 5227 | fax 201 791 1941 | www.bioreference.com

BioReference LABORATORIES | genpath

OPKO Health Companies

Client Update

FEBRUARY 2020

Test Name	Test Code	Effective Date
REMINDER - SPEP, UPEP, Immunofixation	**0085, 0404, 0413, 1644**	**February 1, 2020**

Protein electrophoresis is a method of separating proteins based on their net charge, size, and shape. There are six fractions of proteins: Albumin, Alpha-1, Alpha-2, Beta-1, Beta-2, and Gamma. Serum protein electrophoresis (SPEP or SPE) testing is chiefly done as a screening test for the detection of monoclonal proteins as seen in monoclonal gammopathies, and distinguishing a monoclonal protein band from polyclonal gammopathies and other inflammatory states. Evaluation of abnormal protein electropherograms (of either serum proteins, urine proteins, and immunofixation) requires significant training and clinical correlation, and are conducted by one of our board-certified pathologists.

BioReference will be including a charge for pathologist interpretation for the following test codes as of 2/1/2020.

Test Name	Test Code	CPT Code**
Serum protein electrophoresis	0085	84165-26
Urine protein electrophoresis	0404	84166-26
Immunotyping (immunofixation), serum	0413	86334-26
Immunotyping, urine	1644	86335-26

REMINDER - Comprehensive Respiratory Panel **L740** **Immediately**

Please be reminded that **The Comprehensive Respiratory Panel** is now available for testing. The panel provides comprehensive testing for upper respiratory infections, and simultaneously detects 17 viral and 4 bacterial infectious agents that present with similar flu-like symptoms.

	New Test Information
Primary Container	Viral Swab - Media Male And Flu Naso (Item # 510).
Turn Around Time*	2 Days
Transportation Temp	Refrigerate
Stability	3 Days
Methodology	Polymerase Chain Reaction
Collection Instructions	Nasopharyngeal Swab (NPS) collected according to standard technique and immediately placed in 1-3 mL of Viral transport media.
Profile Components	**Viral:** Adenovirus, Coronavirus HKU1, Coronavirus NL63, Coronavirus 229E, Coronavirus OC43, Human Metapneumovirus, Human Rhinovirus/Enterovirus, Influenza A, Influenza A/H1, Influenza A/H3, Influenza A/H1-2009, Influenza B, Parainfluenza Virus 1, Parainfluenza Virus 2, Parainfluenza Virus 3, Parainfluenza Virus 4, Respiratory Syncytial Virus. **Bacterial:** Bordetella parapertussis, Bordetella pertussis, Chlamydia pneumonia, Mycoplasma pneumoniae
CPT Code(s)**	87486x1, 87581x1, 87633x1, 87798x1
Clinical Utility	Assess for various viral and bacterial infectious agents associated with symptomatic upper respiratory infections.

NOTE: When ordering tests, providers should only order tests that are medically necessary for the diagnosis or treatment of a patient, generally not for screening. Only a few screening tests are covered by most government and third party payers for certain conditions at specific intervals.

NOTES:

Client updates are also available to be received via email instead of fax. To subscribe to receive client updates via email, please visit http://bioreferencelabs.bioreference.com/go-green

* 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.

481 Edward H Ross Drive | Elmwood Park NJ 07407 | tel 800 229 5227 | fax 201 791 1941 | www.bioreference.com