BioReference LABORATORIES | genpath

OPKO Health Companies

# Client Update

## JANUARY 2020

| Test Name | Test Code | Effective Date |
|---|---|---|
| **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).**

| | | |
|---|---|---|
| **Aetna Better Health** | **N/A** | **Immediately** |

BioReference and GeneDx are now contracted with Aetna Better Health in multiple states across the country, providing nearly 3 million members with access to the comprehensive test menus of BioReference and GeneDx. **Coverage applies to the following states:** CA, KS, TX, LA, FL, IL, OH, KY, WV, VA, MD, NJ, PA

Aetna Better Health is Aetna's Medicaid product and is recognized as an industry leader in coordinating care and allowing for lower out of pocket costs to save money. BioReference and GeneDx, working with Aetna Better Health, can provide innovative programs and services that promote members' strengths and goals.

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

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. As of January 6, 2020, **Anti-platelet antibody-Direct (code 5702)** and **Indirect platelet antibody testing (code 5703)** have been discontinued. However, the laboratory will automatically update any request for **Anti-platelet antibody-Direct (code 5702)** to **Platelet antibody Direct Flow cytometry (code 3675)** which will be sent to a licensed and accredited referral laboratory. Any request for **Anti-platelet antibody-Indirect (code 5703)** will be updated to **Platelet antibody identification testing (code 5776),** which 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. Due to these updates, there will be a change in list price and self-pay price.

| | | |
|---|---|---|
| **Bacterial Meningitis Antigen Panel, CSF** | **3567** | **January 13, 2020** |

Due to changes at our referral lab, **Bacterial Meningitis Antigen Panel, CSF** has been discontinued with no alternate testing provided.

| | | |
|---|---|---|
| **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.


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| Test Name | Test Code | Effective Date |
|---|---|---|
| **Directory of Service** | **N/A** | **January 20, 2020** |

We are pleased to announce the Directory of Service 2020-2021 edition is now available to order. This directory takes a deep dive into the operations of the lab and the test codes offered. Clients that wish to obtain the paperback version may do so by including a request in standard supply orders using order #924. Pease contact your dedicated account representative or our Customer Service Department with questions or to place an order.

**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.

**Herpesvirus 8 (HHV-8) DNA, Quantitative RT-PCR (Non-NY)** **3419** **Immediately**

Due to changes at our referral lab, **Herpesvirus 8 (HHV-8) DNA, Quantitative RT-PCR (Non-NY)** is no longer available for New York patients.

**Lyme (Borrelia), DNA,PCR, Urine** **1719** **Immediately**

Due to changes at our referral lab, **Lyme (Borrelia), DNA, PCR, Urine** has been discontinued with no alternate testing provided.

**Pancreastatin** **A664** **Immediately**

Due to changes at our referral lab, test information has been updated for **Pancreastatin.**

| | Previous Test Information | New Test Information |
|---|---|---|
| Primary Container | 1mL serum collected in GI tube | 1mL serum (special tube is not required) |
| Methodology | RIA | ELISA |

**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 |

**TRAb (TSH Receptor Binding Antibody)** **1044** **Immediately**

Due to changes at our referral lab, test information has been updated for **TRAb (TSH Receptor Binding Antibody)**.

| | Previous Test Information | New Test Information |
|---|---|---|
| Methodology | Radio Receptor Assay | Enzyme Linked Immunosorbent Assay |
| Reference Range | < or = 16% Inhibition | < or = 2.00 IU/L |
| CPT Code(s)** | 83519 | 83520 |


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| Test Name | Test Code | Effective Date |
|---|---|---|
| **REGIONAL UPDATE - Rubeola/Measles IgG** | **T007 and 0567** | **See Below** |

Due to updates made by the manufacturer, reference ranges for **Rubeola/Measles IgG** have been updated when performed at our Elmwood Park, NJ (Effective November 26, 2019) and Melbourne, FL (Effective January 6, 2020) laboratory locations.

| | Previous Test Information | | New Test Information | |
|---|---|---|---|---|
| Reference Range | **Range (AU/mL)** | **Interpretation** | **Range (AU/mL)** | **Interpretation** |
| | <25.0 | Negative Non-Immune | <13.5 | Negative Non-Immune |
| | 25.0-29.9 | Equivocal Retest | 13.5-16.4 | Equivocal Retest |
| | > or=30.0 | Positive Immune | > or=16.5 | Positive Immune |

**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.<br>**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.


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