Client Update

BioReference LABORATORIES | genpath
OPKO Health Companies

February 2022

Test Name	Test Code	Effective Date
HER2 Immunohistochemistry	**Multiple**	**February 7,2022**

Temporary Breast Cancer HER2 Biomarker Change: Due to unavailability of **HER2 IHC (Immunohistochemistry)** reagents for the next several weeks, all HER2 IHC test orders will be converted to **HER2 FISH (Fluorescence in-situ Hybridization).**

The 4Kscore® Test **J148, J149** **Immediately**

The 4Kscore® Test is now approved by the U.S. Food and Drug Administration (FDA). This test is approved for use in men age 45 and older who have not had a prior prostate biopsy or are biopsy negative and have an age-specific abnormal total PSA and/or abnormal digital rectal exam (DRE). The 4Kscore Test provides a numerical value to assess the presence of aggressive prostate cancer before a decision is made to perform a prostate biopsy.

The 4Kscore Test is currently available at BioReference Laboratories, an OPKO Health Company, through its specialty oncology and urology division, GenPath.

The 4Kscore Test is an in vitro serum or plasma test that combines four immunoassays (Roche Elecsys total PSA (prostate specific antigen), Roche Elecsys free PSA, intact PSA and human kallikrein 2) into a single numerical score that also incorporates a patient's age, previous biopsy status and digital rectal exam results. The 4Kscore Test is indicated for use with other patient information as an aid in the decision for prostate biopsy in men 45 years of age and older who have an abnormal age-specific total PSA and/or abnormal DRE. The 4Kscore Test is intended to aid in detection of aggressive prostate cancer (Gleason score ≥7/Gleason Grade Group ≥2) for whom a biopsy would be recommended by a urologist, based on current standards of care before consideration of the 4Kscore Test. A 4Kscore <5.0 is associated with decreased likelihood of a Gleason score ≥7 on biopsy.

The intended use population are:

- Men 45-54 years old and total PSA ≥2 ng/mL and/or abnormal DRE
- Men 55-75 years old and total PSA ≥3 ng/mL and/or abnormal DRE
- Men ≥76 years old and total PSA ≥4 ng/mL and/or abnormal DRE

Prostate biopsy is required for the diagnosis of cancer. The test is not recommended more than once every 6 months. The test is intended for professional use only. For more information about the 4Kscore Test, please visit www.4Kscore.com.

Gonadrotopin Releasing Hormone (NON-NY) **0719** **Immediately**

Due to changes at our reference laboratory, test information for **Gonadrotopin Releasing Hormone (NON-NY)** has been updated. Please refer to the table below for changes.

	Previous Test Information	New Test Information
Primary Container	Serum	Plasma (Lavender); alternate: serum
Minimum Volume	1mL	0.7mL
Stability	Refrigerated: 7 days	Room temp: unacceptable Refrigerated: unacceptable Frozen: 90 days
CPT Code(s)*	83520	83727

REMINDER - Scarlet Health® for COVID-19 Test Collections **N/A** **Immediately**

If your patient is isolating due to exposure or having trouble finding a place to have their COVID-19 swab collected, **Scarlet®** phlebotomists make it easy by going directly to your patient to collect their specimen, at-home.

If your practice is set up with Scarlet, simply add the Scarlet test code to the BioReference order. Alternately, you may give your patient a copy of their test order and they can schedule the Scarlet collection themselves at scarlethealth.com. Please contact your dedicated account representative or email hello@scarlethealth.com to learn more.

**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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