BioReference LABORATORIES | genpath

OPKO Health Companies

Client Update

APRIL 2020

Test Name	Test Code	Effective Date
4Kscore® Test – Medicare Denial Letter Sent to Patients	**J148, J264 and K135**	**Immediately**

We are currently in the process of submitting and appealing Medicare claims for the 4Kscore® Test from 2019, during the non-coverage period.

- Your patient may receive a standard letter from Medicare indicating that the test was not covered.
- This is not related to our current Medicare coverage policy, effective from December 30, 2019, which does provide coverage to men who meet the defined criteria.
- It will also not result in any responsibility for your patient for these tests from last year, since we did not require an ABN for the 4Kscore® Test during the non-coverage period, to allow for continued care as we worked with Medicare to gain the current coverage policy.

Please click here for an example of the letter your patient may have received. bit.ly/4KMedicareAppeal

The 4kscore® Test is currently available at BioReference Laboratories, an OPKO Health Company, through its specialty oncology and urology division, GenPath. If you have any further questions, please call our dedicated 4Kscore® Customer Service team at 833-4KSCORE (833-457-2673) or visit our website at www.4kscore.com.

Aspergillus Precipitins ID, CSF	**3942**	**Immediately**

Due to changes at our reference laboratory, testing for **Aspergillus Precipitins ID, CSF** was discontinued with no alternate testing provided.

GenArray™ Molecular Karyotyping	**5306**	**April 1**

Effective April 1, 2020, **GenArray™ Molecular Karyotyping by array comparative genomic hybridization** (array CGH, test code 5306) will be discontinued. This test, which can detect unbalanced gains and losses of genomic DNA in hematologic neoplasia, has been used as in the past as a supplement to conventional cytogenetic karyotypic analysis. The advent and growth of NGS (Next Generation Sequencing) testing has generally supplanted the utility of array CGH, typically provides more actionable information, and is included in the NCCN guidelines.

Oncology Requisitions - Archival Retrieval Date Field	**N/A**	**May 11**

Oncology requisitions have been updated to include a new field, entitled "**Archive Retrieval Date**," which is located at the top of the requisition forms. This field should be filled out when paraffin-embedded tissue blocks that are used for solid tumor testing that have been taken from storage. The Archive Retrieval Date is the date the block was pulled from storage. Please provide this date, if applicable, in the space provided. It is needed for billing purposes. Also, please include a copy of the surgical pathology report with the completed requisition.

PD-L1 22C3 for Keytruda® for Esophageal Squamous Cell Carcinoma by IHC	**TH62 (Global Only)**	**March 5**

GenPath Oncology is pleased to now offer **PD-L1 223 IHC clone for Esophageal Squamous Cell Carcinoma** (ESCC).

- PD-L1 clone 22C3 is FDA-approved as companion diagnostics in ESCC. It is intended for use in the detection of PD-L1 protein in FFPE tissues, and aids in identifying patients eligible for treatment with the immunotherapy drug, Keytruda.
- PD-L1 protein expression in ESCC is determined by using the Combined Positive Score (CPS), which is the number of PD-L1 staining cells (tumor cells, lymphocytes, macrophages) divided by the total number of viable tumor cells, multiplied by 100. The specimen should be considered to have PD-L1 expression if CPS>=10.
- Keytruda (pembrolizumab) is indicated for the treatment of patients with recurrent locally advanced or metastatic squamous cell carcinoma of the esophagus whose tumors express PD-L1 [Combined Positive Score (CPS) ≥10] as determined by an FDA-approved test, with disease progression after one or more prior lines of systemic therapy.

- Please see Test Information on Next Page -

BioReference LABORATORIES | genpath

OPKO Health Companies

Client Update

APRIL 2020

Test Name	Test Code	Effective Date

- PD-L1 22C3 for Keytruda® for Esophageal Squamous Cell Carcinoma by IHC Continued-

	New Test Information
Specimen Requirements	BLK – Formalin-fixed, Paraffin-embedded Tissue
Turn Around Time*	2 days
Transportation Temperature	Ship with cold pack during warm weather
Methodology	Immunohistochemistry
Collection Instructions	BLK: This comes in block form from client with surgical number imprint
CPT Code(s)**	88360x1
List Price	$475

PD-L1 22C3 for Keytruda® for Head and Neck Squamous Cell Carcinoma by IHC **TH63 (Global Only)** **March 5**

GenPath Oncology is pleased to now offer **PD-L1 223 IHC clone for Head and Neck Squamous Cell Carcinoma** (HNSCC).

- PD-L1 IHC 22C3 pharmDx is the only companion diagnostics approved by FDA that aids in identifying patients with HNSCC who may benefit from the immunotherapy drug, Keytruda.
- PD-L1 protein expression in HNSCC is determined by using the Combined Positive Score (CPS) which is the number of PD-L1 staining cells (tumor cells, lymphocytes, macrophages) divided by the total number of viable tumor cells, multiplied by 100. The specimen should be considered to have PD-L1 expression if CPS>=1.
- Keytruda is indicated for HNSCC:
  - In combination with platinum and FU for the first-line treatment of patients with metastatic or with unresectable, recurrent HNSCC.
  - As a single agent for the first-line treatment of patients with metastatic or with unresectable, recurrent HNSCC whose tumors express PD-L1 [Combined Positive Score (CPS) ≥1] as determined by an FDA-approved test.
  - As a single agent for the treatment of patients with recurrent or metastatic HNSCC with disease progression on or after platinum containing chemotherapy.

	New Test Information
Specimen Requirements	BLK – Formalin-fixed, Paraffin-embedded Tissue
Turn Around Time*	2 days
Transportation Temperature	Ship with cold pack during warm weather
Methodology	Immunohistochemistry
Collection Instructions	BLK: This comes in block form from client with surgical number imprint
CPT Code(s)**	88360x1
List Price	$475

REGIONAL UPDATE - INR **1112** **March 19**

Due to reagent changes, the reference range for Normal Non-Medicated Patients for **INR** has been updated when performed at our **Melbourne, FL** laboratory location.

	Previous Test Information	New Test Information
Reference Range	0.81-1.16	0.81-1.17

NOTES:

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

BioReference LABORATORIES | genpath

OPKO Health Companies

Client Update

APRIL 2020

Test Name	Test Code	Effective Date

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