Client Update

BioReference® | GenPath®

Test Name	Test Code	Effective Date
PD-L1 (SP142) TECENTRIQ® for NSCLC	**TQ19-4**	**Immediately**

BioReference®/GenPath® is pleased to offer PD-L1 SP142, an FDA-approved PD-L1 assay that can predict the therapy response of non-small cell cancer patients to TECENTRIQ®. PD-L1 expression in ≥ 50% tumor cells or ≥ 10% immune cells determined by PD-L1 (SP142) assay in non-small cell lung cancer (NSCLC) patients may be associated with enhanced overall survival from TECENTRIQ.

- TECENTRIQ, as a single agent, is indicated as adjuvant treatment following resection and platinum-based chemotherapy for adult patients with stage II-IIIA non-small cell lung cancer (NSCLC) whose tumors have PD-L1 expression on ≥1% of tumor cells, as determined by an FDA-approved test.
- TECENTRIQ, as a single agent, is indicated for the first-line treatment of adult patients with metastatic non-small cell lung cancer (NSCLC) whose tumors have high PD-L1 expression (PD-L1–stained ≥50% of tumor cells [TC ≥50%] or PD-L1–stained tumor-infiltrating immune cells [IC] covering ≥10% of the tumor area [IC ≥10%]), as determined by an FDA-approved test, with no EGFR or ALK genomic tumor aberrations.

Please visit the Roche Tissue Diagnostics website or refer to TECENTRIQ prescribing information for further information.

	New Test Information
Primary Container	BLK – non-decalcified formalin-fixed paraffin-embedded tissue
Turn Around Time*	3-4 days
Transportation Temp	Ambient/Room Temperature. Include ice pack in warmer weather
Methodology	Immunohistochemistry
Collection Instructions	BLK: This comes in block form from client with surgical number imprint
Profile Components	N/A
CPT Code(s)**	88360x1
Clinical Utility (If applicable)	FDA approved to predict non-small cell carcinoma (NSCLC), patient response to TECENTRIQ

Test Name	Test Code	Effective Date
Vitamin B12 Binding Capacity	**0906**	**Immediately**

Due to reagent unavailability, Vitamin B12 Binding Capacity (test code 0906), has been discontinued at Quest with no alternate.

Test Name	Test Code	Effective Date
Partial Thromboplastin Time (PTT)	**0139-6**	**Immediately**

Due to an update in testing platform, the reference ranges for PTT **(test code 0139-6)** for the **Houston** laboratory have been updated. Please refer to the table below for details.

	Previous Test Information	New Test Information
Reference Range	23.2 to 29.6	24.5 to 32.9

**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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Test Name	Test Code	Effective Date
Advanced Lipid Panel, Cardio IQ	**TN57-0**	**Immediately**

Due to an update in testing platform, the volume requirements for Advanced Lipid Panel **(test code TN57-0)** have been updated. Please refer to the table below for details.

	Previous Test Information	New Test Information
Minimum Volume	2mL	4mL
Collection Instructions		Submit separate SST when ordering multiple tests

Test Name	Test Code	Effective Date

Non-BioReference Requisition/Incomplete BioReference Requisition/Handwritten Test Order
Processing of your test order may be delayed if BioReference receives a test order on a non-BioReference test requisition form, an incomplete BioReference test requisition form or a handwritten test order.

Just a reminder that it is BioReference policy for any handwritten test order received for a **"CBC",** BioReference shall perform a **"CBC w/DIFF, Platelet Ct."** BioReference Test Requisitions include both test codes **0053-9 CBC w/DIFF, Platelet Ct. and 0034-9 CBC w/o DIFF (Hemogram)/Platelet Ct.** In addition, both test codes (0053-9 and 0034-9) are also available in InsightDx for your ease of ordering.

Provision of Equipment and Supplies
In accordance with applicable law, BioReference policy prohibits the provision of Equipment or Supplies to Healthcare Providers (HCPs) which may have an independent value to the HCP or which could be used for multiple purposes by the HCP as that may be viewed as an inducement under the Stark Law, Anti-Kickback Statute and comparable state fraud and abuse laws. Exceptionally, and absent a specific state law prohibition, BioReference may make available certain Equipment and Supplies to HCPs as long as there are Legitimate Operational and Quality Needs and that any Equipment or Supplies so provided are integral to and used by the HCP exclusively for ordering testing performed by BioReference. BioReference will distribute supplies to clients as needed and based upon client utilization of testing performed by BioReference.

Test Name	Test Code	Effective Date
Strep Group B (Amplified Probe) / Group B Strep (Non NY)	**0202-2 / J966-3**	

Test Code 0202, Strep Group B is for testing antepartum patients for colonization and should be collected using an E-swab.
Test Code J966, Group B Strep is a RT-PCR aerobic vaginitis panel that includes Group B Strep (GBS). It is not currently approved for use in pregnancy. Further, ordering this test code will not allow subculture for antibiotic susceptibility testing in patients with a PCN allergy

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

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