CLINICAL PATHOLOGY LABORATORIES
A Sonic Healthcare Company

Test Discontinuation: Cancer Antigen 27.29 (Order Code 4825)

Offering our clients state-of-the-art testing is part of CPL's ongoing commitment to excellence.

Effective June 18, 2018, Clinical Pathology Laboratories (CPL) will no longer offer in-house testing for Cancer Antigen 27.29 (CA 27.29) due to manufacturer reagent unavailability. Cancer Antigen (CA 15-3), order code 4827, testing is routinely performed in-house and may be considered an appropriate alternative.

Both CA 27.29 and CA 15-3 are mucin antibodies which detect soluble forms of MUC-1, a transmembrane mucin which can become overexpressed in epithelial cancer cells. Analytic antibodies for CA 27.29 partially overlap the binding sites used for CA 15-3 testing, yielding clinically similar results. According to Centers for Medicare and Medicaid Services (CMS) policy, CA 27.29 is equivalent to CA 15-3 in its usage in management of patients with breast cancer. Serial tumor marker testing must be used in conjunction with other clinical methods for monitoring breast cancer. If medically necessary for monitoring, ***clinicians should consistently use either CA 15-3 or CA 27.29, not both***. ***CPL will offer rebaselining for initial transition from CA 27.29 to CA 15-3 from June 18, 2018 to August 31, 2018***.

Please contact your Account Executive should you have any questions regarding rebaselining and testing details.

Order Code/Test Name:	**4827 Cancer Antigen 15-3**
Test Method:	Electrochemiluminesence Immunoassay (ECLIA)
Specimen Requirements:	2 mL serum. Allow SST to clot in an upright position for at least 30 minutes, then centrifuge sample within 2 hours of collection. Refrigerate. *Note: Do not collect samples from patients receiving therapy with high biotin doses (>5 mg/day) until at least 8 hours following the last biotin administration.*
Transport Temperature:	Refrigerated
Stability (collection to initiation of testing):	Ambient: (15 - 25 °C) 2 days Refrigerated: (2 - 8 °C) 5 days Frozen: (≤ -20 °C) 3 months
Performed:	Monday through Friday PM Shift
Analytic Time:	1 day
Reference Range:	≤25 U/mL
CPT Code:	86300 (LOINC code: 6875-9) *Limited Coverage Test for Medicare.* *Advance Beneficiary Notice of Non-Coverage (ABN) required if diagnosis not covered.*

References:
Centers for Medicare and Medicaid Services. National Coverage Determination (NCD) for Tumor Antigen by Immunoassay CA15-3/CA 27.29 (190.29). 11/25/2002.
Graham, Lindsey J., et al. "Current Approaches and Challenges in Monitoring Treatment Responses in Breast Cancer." Journal of Cancer, vol. 5, no. 1, 2014, pp. 58–68., doi:10.7150/jca.7047.
Handy, Beverly. "The Clinical Utility of Tumor Markers." Laboratory Medicine, vol. 40, no. 2, 2009, pp. 99–103., doi:10.1309/lmtrkskyw4gi6sbj.

Thank you for supporting Clinical Pathology Laboratories