A Sonic Healthcare Company

## Change in Instrumentation: Beta-2-Microglobulin

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

Effective February 10, 2020, Clinical Pathology Laboratories will implement the Roche COBAS c502 immunoturbidometric assay for Beta-2-Microglobulin (B2M) to replace the Siemens Immulite 2000 method. In validation studies and literature review, the new assay demonstrates up to a 20% positive bias relative to the prior assay. As a result and in accordance with the package insert, CPL will:

Adjust reference intervals to those given in the chart below:

Testing Platform	Age	Reference Range
Siemens Immulite	All	< 2.6 mg/L
Roche c502	< 60 Years	0.8 - 2.5 mg/L
	≥ 60 Years	≤ 3.0 mg/L

We will retain B2M specimens for 30 days from implementation until March 10th and offer to reestablish baselines until April 10th 2020 at clinician request. Tested specimens will be archived frozen, and will be available to compare Roche Cobas results to the prior method (Siemens Immulite) at no additional charge. After March 10<sup>th</sup> 2020, specimens will be retained refrigerated for 7 days.

## Background:

B2M is a small protein identical to the light chain of the class I major histocompatibility complex (MHC) antigens (HLA, A, B, C). This is expressed on the membrane of nearly all cells with lymphocytes acting as the major source of serum B2M. This is continuously released into the blood but rapidly filtered through the renal glomeruli. B2M concentrations are increased in chronic inflammation, liver disease, renal dysfunction, some acute viral infections, and B-cell lymphoma/leukemias as well as multiple myeloma. In myeloma, B2M acts as a tumor marker and significant prognostic factor. Various assay methods are available for B2M including radioimmunoassays (RIA), enzyme immunoassays (EIA), and nephelometry. The Roche B2M assay is a latex enhanced immunoturbidometric method.

## Additional Test Information:

Specimen Requirements:	0.5 mL serum from SST	
Transport Temperature:	Refrigerated	
Stability (collection to initiation of testing):	3 days Room Temperature; 7 days Refrigerated; 6 months Frozen	
Performed:	Monday through Friday	
Analytic Time:	1 day	
Specimen Retention:	30 days through 3/10/2020, then 7 days	
CPT Codes:	82232	

Please contact your Account Representative should you have any questions regarding re-baselining and testing details.