



### Client Communication

## Change in testing: Interleukin-6

Effective April 25, 2022:

Clinical Pathology Laboratories is pleased to announce that Interleukin-6 (IL-6) analysis will now be performed in-house using the Roche Elecsys Immunoassay. The Roche assay is approved for Emergency Use Authorization by the US FDA.

The Roche Elecsys IL-6 electrochemiluminescent immunoassay (eCLIA) is an in vitro diagnostic test for the quantitative determination of Interleukin-6 (IL-6) in human serum. The assay is used to assist in identifying severe inflammatory response in patients with confirmed COVID-19 illness to aid in determining the risk of intubation with mechanical ventilation, in conjunction with clinical findings and the results of other laboratory testing. Additionally, IL-6 assessment may be informative of a systemic inflammatory response to conditions such as infection, sepsis, lupus or rheumatoid arthritis or to evaluate diabetes, stroke, cardiovascular disease, autoimmunity and cancer.

Name	Test Code
Interleukin-6	5329

### Changes in reporting:

Assay	Test Code	Previous Reference Range	New Reference Range
Interleukin-6	5329	≤ 2.0 pg/mL	≤ 7.0 pg/mL

Using a clinical cutoff of IL-6 >35.0 pg/mL for PCR-confirmed, hospitalized COVID-19 positive patients, performance specifications for mechanical intubation are given below:

- Sensitivity: 84%
- Specificity: 63%
- Pos. predictive value (PPV): 59%
- Neg. predictive value (NPV): 86%

Assay	Test Code	Previous Clinical Reporting Range	New Clinical Reporting Range
Interleukin-6	5329	N/A	1.5-50,000.0 pg/mL

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<b>Order Unit Codes and Test Names:</b>	5329 - <a href="#">Interleukin-6</a>
<b>Specimen Requirements</b>	<i>1 ML SERUM. ALLOW SST TO CLOT IN AN UPRIGHT POSITION FOR AT LEAST 30 MINUTES, THEN CENTRIFUGE SAMPLE WITHIN 2 HOURS OF COLLECTION. TRANSFER SERUM TO A PLASTIC TRANSPORT TUBE. CLEARLY LABEL AS SERUM. FREEZE. CRITICAL FROZEN (CFZ). WHEN MULTIPLE TESTS ARE ORDERED, SUBMIT SEPARATE TUBE FOR THIS TEST.</i>
<b>Transport Temperature:</b>	Critical Frozen
<b>Stability (collection to initiation of testing):</b>	Ambient, 15-25°C: 6 Hrs Refrigerated, 2-8°C: 2 Days Frozen, (-15)- (-25)°C: 24 Months
<b>Performed:</b>	Monday through Friday / AM Shift
<b>Analytic Time:</b>	1 day
<b>CPT Code:</b>	83529