

**May 4th, 2020**

WestPac Labs (WPL) is now offering antibody/serology testing for SARS-CoV-2, the causative agent of COVID-19 clinical illness. The antibody/serology testing is used to assess prior exposure and sero-prevalence of a specific population, and not diagnostic and should not be used to solely establish active disease. For diagnosing new and active infections, WestPac offers SARS-CoV-2 RT-PCR/NAAT testing as previously communicated.

WestPac will be performing the following two serology assays at its Santa Fe Springs facility.

Both tests are authorized by FDA under Manufacturer’s Emergency Use Authorization (EUA).

The Abbott Architect chemiluminescent microparticle immunoassay (CMIA) is currently available and is designed to detect IgG antibodies against the nucleocapsid protein of SARS-CoV-2 in serum.

The Roche Elecsys Anti-SARS-CoV-2 IgM/IgA/IgG combo assay will be available on or around the 11th of May and is designed to detect the presence of IgM, IgA or IgG in a sandwich method against a SARS-CoV-2-specific recombinant antigen using electrochemiluminescence immunoassay (ECLIA) method. A single result will be reported on whether one or more of the subclasses is detected.

		<b>Abbott IgG</b>	<b>Roche IgM, IgA, IgG Combo (expected go live May 11, 2020)</b>
Target		Nucleocapsid antigen	Nucleocapsid antigen
Sensitivity	Day 0-6	33.3%*	<b>65.5%**</b>
(Time from onset of symptom* or positive PCR**)	Day 7-13	91.8%*	88.1%**
	Day 14+	100%*	100%**
Specificity		99.63%	<b>99.81%</b>
Cross-reactivity with Common cold and Coronavirus panels		No data	<b>0% cross-reactivity</b>

Antibodies to SARS-CoV-2 are generally detectable in blood several days after initial infection and in 100% of patients by day 14 post symptom onset. At this time, it is unknown for how long antibodies persist following infection and if the presence of antibodies confers protective immunity. Patients may have detectable virus present for several weeks following seroconversion.

Negative results do not preclude acute SARS-CoV-2 infection. If acute infection is suspected direct testing by NAAT (RT-PCR or TMA) for SARS-CoV-2 is necessary.



**WESTPAC LABS**

A Sonic Healthcare Company

### Test Information:

Test Code	Test Name	Testing Available
787	SARS-CoV-2 IgG	Monday, May 4, 2020
794	SARS-CoV-2 Combined IgA, IgM, IgG	Monday, May 11, 2020

### Specimen Requirements and Handling:

#### Preferred Sample Type:

2 mL serum from SST - Allow SST to clot in an upright position for at least 30 minutes, then centrifuge sample within 2 hours of collection.

#### Special Instructions:

For phlebotomy service to a recently symptomatic patient, please have patient present at least 3 days beyond end of symptoms, at least 10 days from symptom onset for phlebotomy.

**Please instruct all patients ordered for COVID-19 antibody to wear a facemask for phlebotomy.**

**Transport Temperature:** Refrigerated

**Specimen Stability:** 2 Days Room Temperature; 7 Days Refrigerated; 1 Month Frozen

**Rejection Criteria:** 2 freeze/thaw cycles, heat inactivated specimens, pooled specimens, grossly hemolyzed specimens, obvious microbial contamination specimens.

### Testing Schedule:

- Testing is performed Daily
- Expected TAT is 1-2 days.

**CPT Codes:** 86769