



CLINICAL PATHOLOGY LABORATORIES

A Sonic Healthcare Clinical Laboratory

Information for Providers

High-Affinity Total COVID-19 Antibody

Effective 4/6/2021, CPL will perform all antibody testing for the Nucleocapsid antigen of SARS-CoV-2 (the causative agent of COVID-19) using the Roche Elecsys Anti-SARS-CoV-2 chemiluminescent immunoassay (unit code 7304). This is a sandwich immunoassay format designed to select for high-affinity total anti-COVID-19 antibody (IgG, IgA and IgM). **The IgG-only COVID-19 Nucleocapsid antigen immunoassay will be discontinued (unit code 7301).**

The Elecsys SARS-CoV-2 Nucleocapsid total antibody assay is intended for use as an aid in identifying individuals with an adaptive immune response to SARS-CoV-2, indicating recent or prior infection. As previously, this test should not be used to diagnose acute SARS-CoV-2 infection for which PCR testing is available. The assay can detect seropositivity in 60.2% of patients within the first week after PCR confirmation and sensitivity rises to 99.5% by day 14. Specificity is among the highest of immunoassays at 99.8%, and there is no cross-reactivity with ordinary endemic common-cold coronavirus species (HKU1, NL63, OC43, etc). For testing performed beyond 100 days, the Elecsys total-antibody assay remains persistently positive, whereas the IgG-only antibody assays show decreased sensitivity for prior COVID-19 infection.

UNIT CODE	7301 - TO BE DISCONTINUED	7304
REPORTING TITLE	SARS-CoV-2 IgG Ab, N protein	SARS-CoV-2 Total Ab, N protein
SPECIMEN REQUIREMENTS	2 ML SERUM. ALLOW SST TO CLOT IN AN UPRIGHT POSITION FOR ATLEAST 30 MINUTES, THEN CENTRIFUGE SAMPLE WITHIN 2 HOURS OF COLLECTION. REFRIGERATE. CLINICAL DATA IS REQUESTED FOR EPIDEMIOLOGY AND PUBLIC HEALTH PURPOSES. SEE EXAMPLE REQUISTION/HISTORY SHEET LINK BELOW: COVID-19 Requisition: http://www.cpllabs.com/COVID19_Req COVID-19 History Form: http://www.cpllabs.com/COVID19_History_Form For more information, see URL: www.cpllabs.com/COVID-19-IgG-Serology7301	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. CLINICAL DATA IS REQUESTED FOR EPIDEMIOLOGY AND PUBLIC HEALTH PURPOSES. SEE EXAMPLE REQUISTION/HISTORY SHEET LINK BELOW: COVID-19 Requisition: http://www.cpllabs.com/COVID19_Req COVID-19 History Form: http://www.cpllabs.com/COVID19_History_Form For more information, see URL: http://www.cpllabs.com/COVID-19-Total-Antibody Para mas informacion en espanol, consulte la URL: https://www.cpllabs.com/covid-19-total-antibody-spanish/
TRANSPORT TEMPERATURE	REFRIGERATED	REFRIGERATED

Information for Providers

UNIT CODE	7301 - TO BE DISCONTINUED	7304
REPORTING TITLE	SARS-CoV-2 IgG Ab, N protein	SARS-CoV-2 Total Ab, N protein
MINIMUM SPECIMEN VOLUME	1 ML SERUM OR EDTA PLASMA	1 ML SERUM
METHODOLOGY	CHEMILUMINESCENT MICROPARTICLE IMMUNOASSAY (CMIA)	ELECTROCHEMILUMINESCENCE IMMUNOASSAY (ECLIA)
REF. RANGE AND UNITS OF MEASURE	< 1.4 = NEGATIVE >= 1.4 = POSITIVE	COI < 1.0 NEGATIVE COI >= 1.0 POSITIVE
STABILITY	2 DAYS ROOM TEMPERATURE 7 DAYS REFRIGERATED 1 MONTH FROZEN	3 DAYS ROOM TEMPERATURE 7 DAYS REFRIGERATED 28 DAYS FROZEN
CPT CODE	86769	86769

Ref:

Mohanraj D et al. Comparative assessment of SARS-CoV-2 serology in healthcare workers with Abbott Architect, Roche Elecsys and The Binding site ELISA immunoassays. medRxiv 2021.03.19.21253518; doi: <https://doi.org/10.1101/2021.03.19.21253518>