Jan. 25, 2021

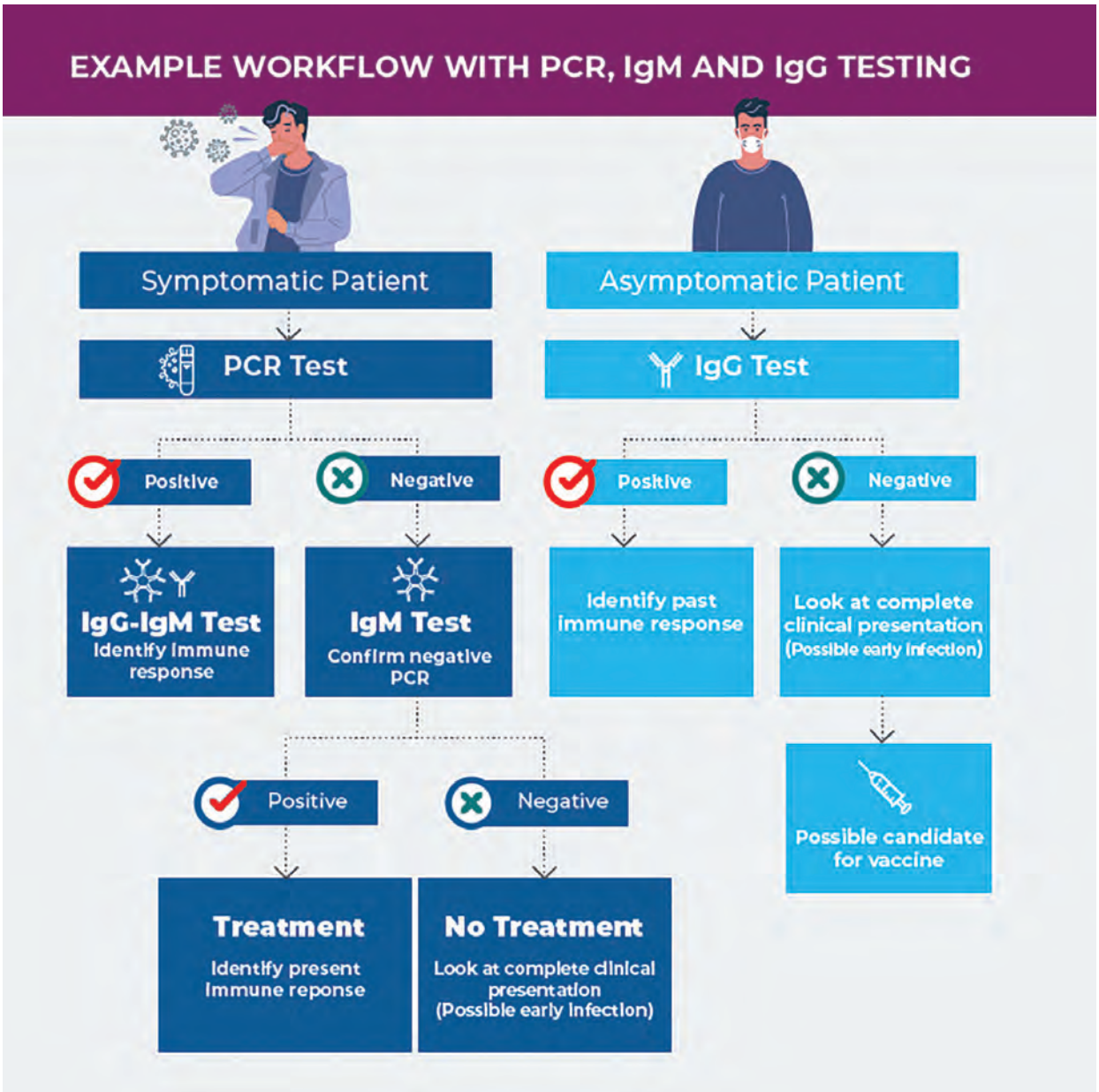
NEW TEST CODES FOR COVID-19 SEROLOGY TESTING

HNL Lab Medicine now offers three new test codes for SARS-CoV-2 Serology Testing:

1. **SARS CoV-2 IgG (CVABG)**
2. **SARS CoV-2 IgM (CVABM)**
3. **SARS CoV-2 Antibody Profile (CVABP)**

The SARS-CoV-2 IgM assay and SARS-CoV-2 IgG assay work to provide a clearer picture about whether an individual has potentially developed a longer-term immune response (IgG) or may complement diagnostic testing to aid in interpreting results and/or responding to results of a false or repeatedly negative test when clinical presentation may be pointing to COVID-19 due to a more recent infection (IgM).[1]

The SARS CoV-2 IgM assay and the SARS CoV-2 IgG assay can potentially aid in correctly identifying those who might have a longer lasting immune response, which may help access candidates for vaccines.[2]



SARS CoV-2 IgG (CVABG) *This will replace HNL test code: CVAB*	
EFFECTIVE DATE:	**1/26/21**
ALTERNATE NAME:	COVID-19 IgG Antibody
METHODOLOGY:	Two-step enzyme immunoassay
TESTING SCHEDULE:	Seven days a week
REPORT AVAILABILITY:	Seven days a week
SPECIMEN REQUIREMENTS:	Minimum Volume: • 1 mL Container: • SST or EDTA
REFERENCE RANGE:	Reporting will be **Non-Reactive, Equivocal or Reactive**. This is an update from the previous platform, which resulted as Negative or Positive.
CLINICAL UTILITY:	Testing for the presence of IgG antibodies to SARS CoV-2 can help to inform clinical management of patients with current, or recent COVID-19.

SARS CoV-2 IgM (CVABM)	
EFFECTIVE DATE:	**1/26/21**
ALTERNATE NAME:	COVID-19 IgM Antibody
METHODOLOGY:	Two-step immunocapture immunoassay
TESTING SCHEDULE:	Seven days a week
REPORT AVAILABILITY:	Seven days a week
SPECIMEN REQUIREMENTS:	Minimum Volume: • 1 mL Container: • SST or EDTA
REFERENCE RANGE:	Reporting will be **Non-Reactive, or Reactive**.
CLINICAL UTILITY:	Testing for the presence of IgM antibodies to SARS CoV-2 can help to inform clinical management of patients with current, or recent COVID-19.

SARS CoV-2 Antibody Profile (CVABP)	
EFFECTIVE DATE:	**1/26/21**
METHODOLOGY:	Two-step enzyme immunoassay and two-step immunocapture immunoassay, respectively.
TESTING SCHEDULE:	Seven days a week
REPORT AVAILABILITY:	Seven days a week
SPECIMEN REQUIREMENTS:	Minimum Volume: • 2 mL Container: • SST or EDTA
REFERENCE RANGE:	Reporting will be Non-Reactive, Equivocal or Reactive for IgG, and Non-Reactive or Reactive for IgM.
CLINICAL UTILITY:	Testing for the presence of IgG/IgM antibodies to SARS CoV-2 can help to inform clinical management of patients with current, or recent COVID-19.

For questions, please call **877-402-4221**.

For technical questions related to this test, please ask for **Technical Support** between the hours of **8 a.m. and 4:30 p.m.** For general inquiries, Customer Care is available to assist at any time.

References
[1,2] Information provided by Beckman Coulter, Inc.

HNL Lab Medicine®

Clinical Sensitivity and Specificity
SARS CoV-2 IgG Antibody
Beckman Coulter DxI800 Platform

CLINICAL SENSITIVITY

The clinical sensitivity of the Access SARS-CoV-2 IgG assay was evaluated in 192 individual patients in a study of 247 serum and plasma samples from symptomatic individuals diagnosed with SARS-CoV-2 by PCR methods from France and the United States. The results are presented in the following table, classified by days between the positive PCR test and the blood sample draw. The evaluation was determined by the Wilson Score method. Two samples with results in the gray zone (from 0.8 to less than 1.0) were excluded from clinical sensitivity calculation.

Days between positive PCR & Sample Collection	**Total Samples**	Number Non-reactive	Number Reactive	Number Equivocal	**Clinical Sensitivity (95% CI)**
0 – 6	47	14	33	0	70.2% (56.0 – 81.3%)
7 – 14	88	4	84	0	95.5% (88.9 – 98.2%)
>14	112	1	109	2	99.1% (95.0 – 99.8%)
>18	58	0	58	0	100% (93.8 – 100%)

CLINICAL SPECIFICITY

The clinical specificity of the Access SARS-CoV-2 IgG assay was evaluated in a study of 1,400 samples collected prior to December 2019* in France and the United States. This total includes 1,000 samples from blood donors in France and 200 samples each from routine clinical laboratory diagnostic samples in France and the United States. Based on this evaluation, the overall clinical specificity of the Access SARS-CoV-2 IgG assay is 99.8% (1395/1398), with a 95% confidence interval of 99.4% – 99.9% determined by the Wilson Score method. Two samples with results in the gray zone (≥ 0.8 to < 1.0) were excluded from clinical specificity calculation.

Population	**Total Samples**	Number Non-reactive	Number Reactive	Number Equivocal	**Clinical Sensitivity (95% CI)**
Blood Donors (France)	1,000	997	2	1	99.8% (99.3 – 99.9%)
Diagnostic Samples (France)	200	199	1	0	99.5% (97.2 – 99.9%)
Diagnostic Samples (United States)	200	199	0	1	100% (98.1 – 100%)
Total	**1,400**	**1,395**	**3**	**2**	**99.8% (99.4 – 99.9%)**

** It has been shown that over 90% of the adult population have antibodies to all four common circulating coronavirus.*

HNL Lab Medicine®

Clinical Sensitivity and Specificity
SARS CoV-2 IgM Antibody
Beckman Coulter DxI800 Platform

POSITIVE AGREEMENT

The positive percent agreement (PPA) of the Access SARS-CoV-2 IgM assay was evaluated in 173 individual serum and plasma samples from symptomatic subjects diagnosed with SARS-CoV-2 by PCR methods from France and the United States. The results are presented in the following table, classified by days between symptomon onset and the blood sample draw. The 95% confidence interval was determined by the Wilson Score method.

Days Post Symptom Onset	Total Samples	Number Non-reactive	Number Reactive	PPA (95% CI)
0 – 7	22	10	12	54 – 5% (34.7 – 73.1%)
8 – 14	36	3	33	91.7% (78.2 – 97.1%)
15 – 30	115	2	113	98.3% (93.9 – 99.5%)

The positive percent agreement of the Access SARS-CoV-2 IgM assay for all serum and plasma samples tested was 91.3% (158/173; 95% CI 86.2 – 94.7%).

NEGATIVE AGREEMENT

The negative percent agreement (NPA) of the Access SARS-CoV-2IgM assay was evaluated in a study of 1,400 samples collected prior to December 2019* in France and the United States. This total includes 1,000 samples from blood donors in France and 200 samples each from routine clinical laboratory diagnostic samples in France and the United States. Based on this evaluation, the overall negative percent agreement of the Access SARS-CoV-2 IgM assay is 99.9% (1,398/1,400), with a 95% confidence interval of 99.5 - 100.0% determined by the Wilson Score method.

Population	Total Samples	Number Non-reactive	Number Reactive	NPA (95% CI)
Blood Donors (France)	1,000	999	1	99.9% (99.4 – 100.0%)
Diagnostic Samples (France)	200	199	1	99.5% (97.2 – 99.9%)
Diagnostic Samples (United States)	200	200	0	100.0% (98.1 – 100.0%)
Total	1,400	1,398	2	99.9% (99.5 – 100.0%)

** It has been shown that over 90% of the adult population have antibodies to all four common circulating coronavirus.*