

## Laboratory Request for Information

We are interested in evaluating the following tests for clinical use in our practice:

**Serology Testing**

- Sensitivity \_\_\_\_\_
- Specificity \_\_\_\_\_
- Coefficient of Variation \_\_\_\_\_

**Viral RNA Testing**

- Sensitivity \_\_\_\_\_
- Specificity \_\_\_\_\_
- Coefficient of Variation \_\_\_\_\_

**Please provide information on the *clinical validation* with each test:**

- Where are you obtaining the kits or reagents to do your testing?
- What are the control samples? Are you using clinical samples as opposed to 'spiked' (i.e., artificial) samples?
- Are you using confirmed SARS-CoV-2 positive samples, and if so, how and when was this confirmed?
- If an antibody test, when was the sample collected in relation to a positive viral RNA test?
- What are the demographics of the clinical test population?
- Did the positive test population have symptoms in addition to a positive PCR test?
- Were pre-pandemic samples used in the negative test group?
- Did the assay evaluate samples that had exposure to other respiratory viruses such as influenza and RSV, as well as other coronaviruses, to determine cross reactivity and specificity?
- How many samples were used in the validation?
- Are you doing progressive validation studies after the test is released?

Thank you for your prompt attention to this matter.