COVID-19 Lateral Flow Serology Recommendations

On March 16, 2020, the FDA issued their Policy for Diagnostic Tests for Coronavirus Disease-2019 during the Public Health Emergency. Section IV.D. of this guidance, entitled "Commercial Manufacturer Development and Distribution and Laboratory Development and Use of Serology Tests Without an EUA," permitted development and distribution of COVID-19 serology tests without FDA review. Since that moment, FDA has been notified of over 70 test kits under Section IV.D, and the list is maintained on FDA's FAQ page.

We have received numerous requests for help with implementing COVID-19 lateral flow serology kits, which are often from unconventional suppliers and have sparse or vague performance data. Many organizations recognize the risks of using tests that have not been reviewed by the FDA, but have expressed that "something is better than nothing" in critical times such as this. Babson and its Scientific Advisory Board have assembled five recommendations to support those who implement lateral flow serology test kits:

1. Collect Serum or Plasma Samples to Optimize Sample Quality

Many of the available kits are labeled for use with serum, plasma, or whole blood. To minimize the number of variables in this uncertain time, Babson recommends running serum as the cleanest sample type, with plasma (lithium heparin or EDTA) as a second choice. Extra contaminants from whole blood may have an unknown effect on test methods. Use an FDA-cleared serum separator tube or plasma separator tube according to the manufacturer's instructions.

2. Collect Large-Volume Venous Samples

Many of the available lateral flow test kits are labeled for use with either capillary blood from a fingerstick or venous blood from venipuncture. During this early research-intensive stage, Babson recommends using venous blood, because a large sample can be collected. Collect a large (e.g. 6mL or even 10mL) venous sample so that the remnant sample can be banked for research and future testing.

3. Retest All Samples Multiple Times as Technology Evolves

Aliquot remnant patient samples into multiple cryovials and store them at -70C. As lateral flow test kits achieve EUAs and as high-sensitivity automated serology tests with expanded claims and quantification capabilities become available, retesting samples provides the ability to evaluate the relative performance of different test methods as well as the opportunity to go back and correct previous test results.

4. Validate Tests in a High-Complexity CLIA Laboratory

Despite being available under FDA's Section IV.D, these tests do not have a CLIA categorization, and thus are considered high-complexity testing unless designated otherwise by FDA review to be performed as moderate or waived complexity. In addition to being the law, it's

also a good idea to run in a high-complexity laboratory, because these labs have the oversight and infrastructure to verify test performance and to run the tests safely. Given that most testing will be done on individuals with known or suspected COVID-19 exposure, universal precautions must be observed.

5. Precision Pipette into Lateral Flow Kits

There is a lack of available evidence on the impact of variable sample quantity on the performance of the test kits. With the aim of reducing as many sources of imprecision as possible, Babson recommends using a precision pipette with a disposable tip to dispense sample into the testing device. Using a precision pipette provides an additional opportunity to visually inspect the sample for quality problems such as residual fibrin.