



COVID-19 FDA Emergency Use Authorization Investor FAQ's:

1) Why does the Fluidigm website and every Fluidigm PR contain the disclaimer: "Fluidigm products are provided for Research Use Only. Not for use in diagnostic procedures."?

All Fluidigm Product are for Research Use Only. Not for use in diagnostic procedures. When FDA Emergency Use Authorization is granted, we will remove the disclaimer from documents that relate to the authorized products and continue to use it for RUO products.

2) When will you get FDA approval?

The Advanta Dx SARS-CoV-2 RT-PCR Assay is the subject of an EUA filing with the FDA. The FDA may require additional data, validation and/or testing, and may not ultimately provide authorization.

3) In the event FDA EUA is granted for the saliva test, who will be conducting the tests and who's equipment will be utilized?

The Advanta™ Dx SARS-CoV-2 RT-PCR Assay is intended for use by high-complexity labs certified under the Clinical Laboratory Improvement Amendments of 1988 (CLIA) in the United States utilizing the authorized Fluidigm System (Instruments, reagents, IFC's and software)

4) Is it a diagnostic test?

Yes, the test detects the SARS-CoV-2 virus. The Advanta Dx SARS-CoV-2 RT-PCR Assay is a real-time RT-PCR test intended for the qualitative detection of RNA from the SARS-CoV-2 in saliva specimens from individuals suspected of COVID-19 by their healthcare provider.

5) Will other companies be able to use the test to diagnose?

Testing is limited to Laboratories - certified under CLIA, to perform high complexity tests, or by similarly qualified non-U.S. laboratories.

6) The FDA website lists the submission under (not FDA authorized) Commercial Manufacturers that have notified the FDA that they have validated and intend to distribute diagnostic test kits as set forth in Section IV.C: Is there a discrepancy between the disclaimer and the FDA listing?

As per FDA Guidance, the FDA does not object to initializing commercial distribution upon completion of the validation and submission within 15 days. We have notified the FDA of our Intent to begin commercial distribution.

7) Why don't you press release more often?

Press releases require approvals from customers and take time. We do not press release all information on our business, although we may decide to post information on our social media feeds.

Forward-Looking Statements

The Advanta Dx SARS-CoV-2 RT-PCR Assay has been validated by Fluidigm, but the FDA's review of this validation is pending.