



**As of September 29, 2020**

**COVID-19 FDA Emergency Use Authorization Investor FAQs:**

- 1) Has anything changed since the FDA authorized the test? Is the test currently being commercialized?**

Nothing has changed. Yes, the test is being commercialized.

- 2) Could you comment on the number of COVID-19 tests enabled to date in Q3 2020?**

We have not provided a Q3 2020 update. On our most recent quarterly earnings call (held on August 6, 2020), we stated that we had enabled more than 100,000 tests in Q2 and that, in the month of July, shipments of our COVID-19 associated reagents and IFCs exceeded the number we sold in Q2.

- 3) How many labs in the United States are currently providing COVID-19 tests using Fluidigm instruments? (E.g., Immunogenomics)**

We have not provided specific numbers. On the August 6, 2020 earnings call, we reported that 5 customers had filed for Emergency Use Authorization with the FDA in Q2. These were for COVID-19 tests that such customers had developed as Laboratory Developed Tests for their own lab(s), using Fluidigm's products.

- 4) Are any facilities outside of the United States providing COVID-19 tests with Fluidigm instruments? Could you provide some insights on the numbers?**

Yes, there are facilities outside of the U.S. We haven't provided numbers, but some details are reflected in social media posts from our Fluidigm social media accounts.

- 5) I saw the 8-K filing that posted on September 29 regarding the NIH RADx funding. Is the \$22 million on top of the \$37 million you have previously announced?**

No. The 8-K announced that On September 28, 2020, the Company executed a definitive contract with the NIH as an amendment to the letter contract to expand production capacity and throughput capabilities for COVID-19 testing with Fluidigm microfluidics technology. The total contract value is up to approximately \$34 million upon achievement of milestones. On September 8, we issued a press release that Fluidigm has achieved the initial milestone under its letter contract with the NIH, providing initial payment of approximately \$11 million.



**6) Why did the total funding amount change between your August press release and the 8-K filing issued on September 29?**

The National Institutes of Health process for the RADx grants is to enter into a letter contract first and then complete the process of executing a definitive contract. Funding of “up to \$37 million” was specified in the letter contract with RADx. The \$34 million in the 8-K reflects the actual funding after refinements to the project plan.

**7) What are the details of the milestones in the contract?**

The detailed milestones are not public, but the intent of the project is to expand production capacity and throughput capabilities for COVID-19 testing with Fluidigm microfluidics technology.

**8) What is Fluidigm’s progress on its barcoding technology; will it require additional EUA(s) from the FDA?**

We have not provided an update on development progress other than as reported on our August 6, 2020 earnings call. We would expect to file an EUA application with the FDA with respect to any diagnostic assay developed using that technology.

**9) Can barcoding technology be used for population surveillance? Do you require authorization from the FDA?**

Yes, when it is available. Surveillance uses does not require authorization from the FDA.

**10) Is Fluidigm pursuing a full FDA clearance for the use of the Advanta Dx SARS-CoV-2 RT-PCR Assay?**

We have received Emergency Use Authorization for the assay. We can sell the diagnostic assay with an EUA in the U.S. and, depending on local regulations, there may also be opportunities for sales outside of the U.S.

Longer-term, we may consider an in vitro diagnostic FDA clearance of an assay with our platform, but that would be part of a longer-term diagnostic strategy.

**11) Does the EUA you received apply to both symptomatic and asymptomatic patients?**

The use of Advanta Dx SARS-CoV-2 RT-PCR Assay is intended for the qualitative detection of nucleic acid from the SARS-CoV-2 in saliva specimens collected without preservatives in a



sterile container from individuals suspected of COVID-19 by their healthcare provider. This is described in the instructions for use posted on our [company website](#).

## 12) What is the price per test or kit?

We negotiate pricing with our customers. We discussed a \$17-22 range on our August 6, 2020 earnings call. This pricing is in a comparable range with other PCR-based test providers.

## 13) Must a specimen be sent to a lab or can a doctor's office get results the same day using your instruments?

As explained in the FDA letter for our Emergency Use Authorization, testing is limited to laboratories certified under CLIA that meet requirements to perform high complexity tests. This assay is not for use in a doctor's office.

## 14) What is the FDA Reference Panel Comparative Data? What does it mean?

The FDA reported the results of the Reference Panel for several assays. As stated by the FDA:

“While the FDA SARS-CoV-2 Reference Panel helps determine the comparative performance among authorized tests, the panel is not a replacement for the analytical and clinical validation recommendations the FDA has provided in the [EUA templates](#). For example, the panel only includes one strain of SARS-CoV-2 and one cross-reactant, MERS-CoV. Recent mutations reported for SARS-CoV-2 (e.g., D614G), which may impact molecular testing, are not included”.

The LOD for our test is 6.25 GE/uL (6,250 per ml) as was determined by our analytical validation study and reported in the Instructions For Use for Advanta Dx SARS-CoV-2 RT-PCR Assay. The clinical data we submitted to the FDA shows that our test is able to detect viral loads in line with authorized nasopharyngeal tests. Additionally, our clinical testing also included ~20% low positive samples, which demonstrates that our assay is able to detect the virus with 100 percent agreement to the comparator nasopharyngeal assays even for samples that are near the limit of detection of nasopharyngeal assays.

In summary, we continue to be highly confident in our saliva-based test as authorized by the FDA which demonstrated 100% clinical agreement with nasopharyngeal/swab-based tests. Limit of Detection is one piece of information about a test, but it is also important to consider clinical performance data.

## 15) 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.

**16) I am seeing many social media posts, including tweets and videos, discussing Fluidigm products. Are these being issued by the company?**

In addition to our press releases (available at <http://investors.fluidigm.com/press-releases>) and SEC filings ([www.sec.gov](http://www.sec.gov)), we use our website ([fluidigm.com](http://fluidigm.com)), investor site ([investors.fluidigm.com](http://investors.fluidigm.com)), corporate Twitter account ([@fluidigm](https://twitter.com/fluidigm)), Facebook page ([facebook.com/Fluidigm](https://facebook.com/Fluidigm)), and LinkedIn page ([linkedin.com/company/fluidigm-corporation](https://linkedin.com/company/fluidigm-corporation)) as channels of distribution of information about our products, our planned financial and other announcements, our attendance at upcoming investor and industry conferences, and other matters. You should not rely on any Fluidigm-related content that originates from a different website or social media account, as such content may not have been authorized by Fluidigm. Many social media accounts include discussion of Fluidigm's products and prospects due to increased focus on Fluidigm's microfluidics products, based in part on Fluidigm's diagnostic assay. Some of these posts may include statements that are contrary to Fluidigm's instructions for use or make claims that Fluidigm has not made or endorsed regarding the assay. The only Fluidigm-approved source of information about the assay and its authorized use is posted on our [company website](#) as noted above.

Information about our products and business may be deemed material information, and, based on SEC rules, we cannot comment individually to investors or others on material non-public information. Therefore, you should monitor our website and our social media accounts and follow our press releases, SEC filings, public conference calls, and webcasts to obtain the most recent information about Fluidigm and its products and business.

**Forward-Looking Statements**

These FAQs contains forward-looking statements within the meaning of the Private Securities Litigation Reform Act of 1995, including, among others, statements concerning the Advanta Dx SARS-CoV-2 RT-PCR Assay, including with respect to FDA authorization and clearance plans and strategies, expansion of COVID-19 testing, and customer demand for and commercialization of the assay and other Fluidigm products and technology. Forward-looking statements are subject to numerous risks and uncertainties that could cause actual results to differ materially from currently anticipated results, including but not limited to risks relating to the potential adverse effects of the coronavirus pandemic on our business and operating results; uncertainties in contractual relationships; our ability and/or the ability of the research institutions utilizing our products and technology to obtain and maintain Emergency Use Authorization from the FDA and any other requisite approvals to use our products and technology for diagnostic testing purposes; potential changes in priorities or requirements for Emergency Use Authorizations; potential limitations of any Emergency Use Authorization; potential changes in the priorities of government agencies; challenges inherent in developing, manufacturing, launching, marketing, and selling new products; risks relating to company research and development and



distribution plans and capabilities; interruptions or delays in the supply of components or materials for, or manufacturing of, Fluidigm products; potential product performance and quality issues; intellectual property risks; and competition. Information on these and additional risks and uncertainties and other information affecting Fluidigm business and operating results is contained in Fluidigm's Annual Report on Form 10-K for the year ended December 31, 2019, and in our other filings with the Securities and Exchange Commission. These forward-looking statements speak only as of the date of these FAQs. Fluidigm disclaims any obligation to update these forward-looking statements except as may be required by law.