

**EUA Summary Report for Condition of Authorization (Item Q)
Harvard University Clinical Laboratory
Quaeris SARS-CoV-2 Assay (EUA210157)**

This summary report is submitted by Harvard University Clinical Laboratory (HUCL) to satisfy Item Q in the Conditions of Authorization for EUA210157 for the Quaeris SARS-CoV-2 Assay. The summary report provides data for the timeframe from May 21, 2021 (the date of initial EUA authorization) through July 8, 2021.

Request from FDA:

You must submit to FDA a summary report within 30 calendar days of authorization summarizing the results of any testing performed using specimens collected with COVID-19 Self-Swab Collection Kit for Harvard University Clinical Laboratory (HUCL), for use with your product during that timeframe, including how many kits were activated via the online portal, purchased from an authorized distributor for home collection, or collected at a community-based site or distribution center, how many specimens were received, how many specimens had to be rejected during accession and the main reasons for rejection, and the positivity rate for specimens collected with the authorized self-collection kit.

Summary Report:

From May 21, 2021, through July 8, 2021:

- 90,000 sample collection kits were distributed to patients;
- 83,853 sample collection kits were activated via the Color online portal; and
- 83,853 samples were received by HUCL for testing.

The following table includes details about the test results and reasons for rejection of samples received by HUCL during the relevant timeframe (5/21/2021 – 7/8/2021):

Result: Not Detected (Negative for SARS-CoV-2)	83,393
Result: Detected (Positive for SARS-CoV-2)	6
Result: Inconclusive	315
Rejected for Testing	138
<i>Broken or Uncapped Tube/Specimen unsatisfactory</i>	<i>34</i>
<i>Laboratory Accident*</i>	<i>102</i>
<i>Transport Delay</i>	<i>2</i>
Received but not Resulted (pending testing)	1
Total:	83,853

*Instrument malfunction or operator error necessitating recollection of sample.

The positivity rate for specimens collected with the authorized self-collection kit is 0.007%.