

## **TaqPath COVID-19 Fast PCR Combo Kit 2.0, EUA, originally issued on July 30, 2021.**

Link: [TaqPath COVID-19 Fast PCR Combo Kit 2.0 - Instructions for Use \(fda.gov\)](https://www.fda.gov/medical-devices/covid-19-tests/taqpath-covid-19-fast-pcr-combo-kit-2-0-eua)

For the *TaqPath COVID-19 Fast PCR Combo Kit 2.0*, determine the following, and please explain any jargon or abbreviations used in your answers:

- What kind of human sample type are they testing with this kit?
  - Human saliva from individuals suspected of having COVID-19
- What genes are this test using to test for SARS-CoV-2?
  - SARS-CoV-2 ORF1a
  - SARS-CoV-2 N gene
  - SARS-CoV-2 ORF1b
  - RNase P (human sample collection control)
- What were the positive cycle threshold (Ct) cut-off values for detecting SARS-CoV-2 genes?

Sample or Control	Target	C <sub>t</sub> cutoff
Positive Control	Viral targets	Valid Ct values are ≤37

- How would you determine if you had a positive COVID-19 test?

ORF1a	N gene	ORF1b	RNase P	Call	Assessment
POS	POS	POS	POS or NEG	Presence	REPORT - SARS-CoV-2 Detected
POS	POS	NEG	POS or NEG	Presence	REPORT - SARS-CoV-2 Detected
POS	NEG	POS	POS or NEG	Presence	REPORT - SARS-CoV-2 Detected
NEG	POS	POS	POS or NEG	Presence	REPORT - SARS-CoV-2 Detected

- What was the limit of detection indicated in this fact sheet for individual specimens using the QuantStudio 7 Flex?
  - 750 GCE/mL
    - GCE = genomic copy equivalents = amount of DNA in 1 copy of a genome.
- At the limit of detection using a QuantStudio 7 Flex, what was the average cycle threshold for each SARS-CoV-2 gene?
  - ORF1a: 32.96
  - N gene: 33.81
  - ORF1b: 34.23
- What is the positive percent agreement for this test when Real-time PCR was performed on the QuantStudio 7 Flex Real-time PCR instrument?
  - 97.1%

## **covidSHIELD, EUA, originally issued on Feb. 24, 2021**

Link: [covidSHIELD - EUA Summary \(fda.gov\)](https://www.fda.gov/medical-products/medical-products-approvals-and-regulatory-actions/emergency-use-authorization/eua-covid-19-test-covidshield)

For the *covidSHIELD*, determine the following:

- What kind of human sample type are they testing with this kit?
  - Human saliva from individuals with or without symptoms of COVID-19
- What genes are this test using to test for SARS-CoV-2?
  - ORF1ab (replicase)
  - N-gene (nucleocapsid)
  - S-gene (spike)
  - MS2 (internal control)
- What are the positive(Ct) cut-off values for the detection of SARS-CoV-2 genes?

ORF1ab	N-gene	S-gene	
Ct < 39	Ct < 39	Ct < 39	

- How would you determine if you had a positive COVID-19 test?
  - Samples are determined positive if any 2 - 3 genes yield Ct < 39
- What was the limit of detection indicated in this fact sheet for individual specimens using the QuantStudio 7 Flex?
  - 1000 copies/mL
- At the limit of detection using a QuantStudio 7 Flex and a Gilson robotic pipetting, what was the average Ct for each SARS-CoV-2 gene tested?

ORF1ab	N-gene	S-gene
33.2	32.8	33.4

- What is the positive percent agreement for this test when Real-time PCR was performed on the QuantStudio 7 Flex Real-time PCR instrument?
  - 95.8%