Clinical Performance of GenomeCoV19 Detection Kit (G628.v2)

Please note that the GenomeCoV19 Detection Kit has been validated in accordance with the FDA's Emergency Use Authorization guidance, however, the FDA's independent review of this validation is still currently pending.

Clinical Performance (Contrived Samples)

A contrived clinical study was conducted to evaluate the clinical performance of the GenomeCoV19 Detection Kit. A total of 30 negative and 30 contrived positive samples were tested. Positive samples were prepared by spiking ATCC-VR1986D SARS-CoV-2 reference genome RNA into human RNA at 1X, 10X, and 100X LoD. Samples were tested in a randomized and blinded fashion on the Bio-Rad CFX96 qPCR instrument. The positive and negative percent agreements between the GenomeCoV19 Detection Kit and the expected results are shown below.

Table 1: Contrived clinical samples performance testing of the GenomeCoV19 Detection Kit

SARS-CoV-2 concentration	Number of Samples	Detection Rate		Agreement (95% CIs)
1X LoD	24	24/24	100%	100% (86.2%-100%)
10X LoD	3	3/3	100%	100% (43.9%-100%)
100X LoD	3	3/3	100%	100% (43.9%-100%)
Negative	30	30/30	100%	100% (88.6%-100%)

Performance of the GenomeCoV19 Detection Kit against the expected results is:

Positive Percent Agreement	30/30 = 100% (95% CI: 88.6% - 100%)
Negative Percent Agreement	30/30 = 100% (95% CI: 88.6% - 100%)

Clinical Performance (Remnant Samples)

A further clinical study was conducted to evaluate the performance of the GenomeCoV19 Detection Kit with remnant clinical samples collected from patients. A SARS-CoV-2 panel containing nasopharyngeal, and oropharyngeal swab samples was purchased from a supplier for use in this study. Contained in this panel were a total of 30 COVID-19 positive and 30 COVID-19 negative remnant clinical specimens verified using an FDA EUA-approved COVID-19 detection kit.

Comprehensive details for each remnant clinical sample were provided by the supplier with the panel, including the COVID-19 testing status and individual Ct values for each sample. These samples were randomized and blinded prior to testing with the GenomeCoV19 Detection Kit on a Bio-Rad CFX96 qPCR machine. The positive and negative percent agreements between results from the GenomeCoV19 Detection Kit and the results provided by the supplier are presented below.

Table 2: Remnant clinical samples performance testing of the GenomeCoV19 Detection Kit

SARS-CoV-2 Status	Number of Samples	Detection Rate		Agreement (95% CIs)
Positive	30	30/30	100%	100% (88.6% - 100%)
Negative	30	30/30	100%	100% (88.6% - 100%)

Performance of the GenomeCoV19 Detection Kit against the expected results is:

Positive Percent Agreement 30/30 = 100% (95% CI: 88.6% - 100%)
Negative Percent Agreement 30/30 = 100% (95% CI: 88.6% - 100%)