Product Highlight

FTD SARS-CoV-2 Assay:* Analytical Sensitivity Study

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Background

- Molecular diagnostics and, in particular, RT-PCR technology, is the method of choice for clinical detection of SARS-CoV-2 RNA in nasopharyngeal swabs.
- The window of detection depends on the sensitivity of the PCR assay.
- It is critical to use highly sensitive assays in order to detect active infections and reduce the likelihood of false-negative results.

Study design

- Simulated respiratory matrix (SRM) was spiked with SARS-CoV-2 heat-inactivated quantified culture (US-WA1/2020) quantified in TCID50/mL.
- A panel of serially diluted SARS-CoV-2 artificial samples was created and tested with the FTD SARS-CoV-2 Assay.
- Probit regression analysis was performed with this dataset to calculate the limit of detection (LoD).
- The LoD was confirmed by testing 23 individual artificial samples (SRM spiked with culture) using three different lots of reagents (primer/probe mix).
- A conversion factor was calculated using a second inactivated culture from the same isolate US-WA1/2020 but quantified in cop/mL.

Results

- The LoD of 0.0023 TCID50/mL (0.0015–0.003 95% confidence interval) (Figure 1) was confirmed with a detection rate of 97.1%[1] (Table 1).

Table 1.

PPmix Lot	LoD TCID50/mL (95% CI)	Total Tested	Total Detected	Detection Rate (%)	Mean Ct Value	SD
1	0.0023 (0.0015–0.003)	23	22	95.7	37.4	0.8
2		23	22	95.7	38.0	0.9
3		23	23	100.0	37.4	0.9

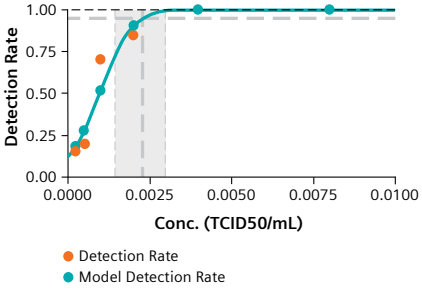
This study demonstrates the excellent analytical sensitivity of the FTD SARS-CoV-2 Assay. In addition, the FTD SARS-CoV-2 Assay was ranked by the U.S. FDA as one of the top 5 most sensitive assays on the market when using the U.S. FDA SARS-CoV-2 Reference Panel and the VERSANT® kPCR Molecular System for extraction.[2] A highly sensitive assay is essential for the early and accurate diagnosis of COVID-19 and for minimizing the risk of false negative results.

**CE-IVD labeled for diagnostic use in the EU. This test has not been FDA-cleared or approved. This test has been authorized by FDA under an EUA for use by authorized laboratories. This test has been authorized only for the detection of nucleic acid from SARS-CoV-2, not for any other viruses or pathogens. This test is only authorized for the duration of the declaration that circumstances exist justifying the authorization of emergency use of in vitro diagnostics for detection and/or diagnosis of COVID-19 under Section 564(b)(1) of the Act, 21. U.S.C. § 360bbb- 3(b)(1), unless the authorization is terminated or revoked sooner.*

FTD SARS-CoV-2 Assay*

- Targets highly conserved regions within ORF1ab and N gene.
- Robust dual-target design for high sensitivity.
- Dual-target design reduces potential for inconclusive results and the need for repeat testing.
- The same setup protocol and thermal-cycling profile as other FTD respiratory assays enables batch testing in single run.

Figure 1. Probit analysis



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Product availability may vary from country to country and is subject to varying regulatory requirements. Please contact your local representative for availability.

References:

1. Menard, et al. Analytical and clinical performance characteristics of the FTD SARS-CoV-2 Assay. ECCVID 2020. CE-IVD instruction for use. 11416283_en Rev. B, 2020-12.
2. FDA reference panel, https://www.fda.gov/medical-devices/coronavirus-covid-19-and-medical-devices/sars-cov-2-reference-panel-comparative-data.

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