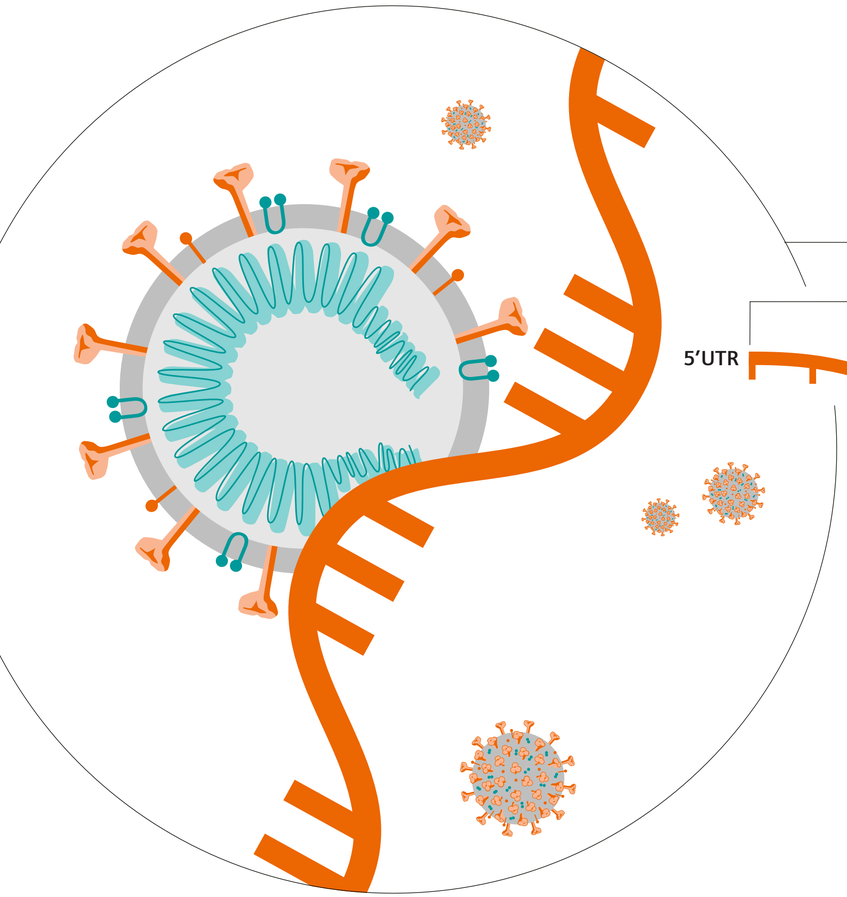
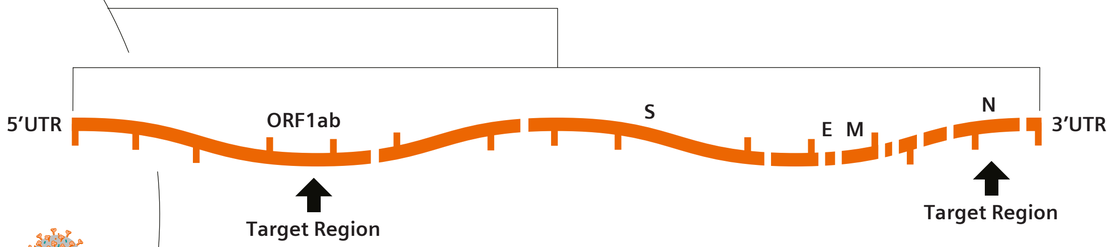
Dual-Targeting for Accurate SARS-CoV-2 Detection

Targeting highly conserved regions on the SARS-CoV-2 genome is essential for accurate detection.



The FTD SARS-CoV-2 Assay* uses real-time PCR to detect viral RNA from respiratory samples. The assay has a dual-target design that probes two highly conserved regions on the SARS-CoV-2 genome. **This feature increases confidence in your laboratory results.**

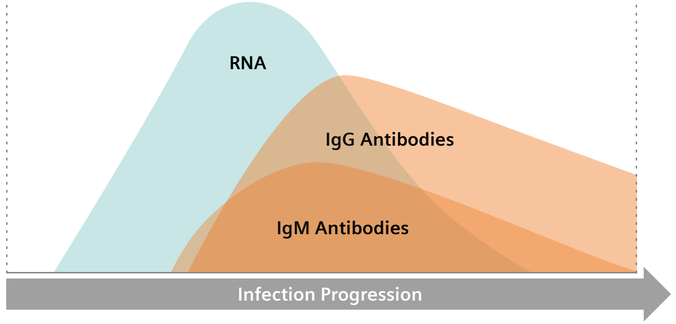


- Targets regions that show low rate of polymorphisms
- Limits potential for inconclusive results
- Less repeat testing

Inclusivity *in silico* study†			
Assay	**Databases**	**Complete Genomes Tested/ Complete Genomes Detected**	**Detection Rate (%)**
N gene	GenBank + GISAID	64253/64253	100
ORF1ab		65051/65051	

High Sensitivity Detection

Viral RNA can be detected before there is an immune response and antibodies are detectable. Having a highly sensitive assay increases the window of detection of active infection.‡



Why is sensitivity and specificity important? Confidence.

A highly sensitive test should eliminate **nearly all false negative results.**

A highly specific test should eliminate **nearly all false positive results.**

100% Sensitivity[1] + **100% Specificity[2]** = **Confidence**

**CE-marked for IVD 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.*

†Analytical and Clinical Performance Characteristics of the FTD SARS-CoV-2 Assay, Menard et al, ECCVID 2020

‡Cheng et al. Ann Intern Med. doi:10.7326/M20-1301

1. EUA Positive percent agreement of 100% (95% CI = 91.97–100)
2. EUA Negative percent agreement of 100% (95% CI = 88.65–100)

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