**Not for use in US**

**Abbott ID NOWTM COVID-19 – an established NAAT method for the detection of SARS-CoV-2**

SARS-CoV-2 "NAAT tests" (nucleic acid amplification technology - NAAT) refer to molecular nucleic acid amplification tests used to detect the presence of SARS-CoV-2 ribonucleic acids (RNA).

Various nucleic acid amplification techniques are used for direct detection of coronavirus SARS-CoV-2, such as reverse transcriptase-polymerase chain reaction (RT-PCR), loop-mediated isothermal amplification (LAMP), transcription-mediated amplification (TMA), and nicking endonuclease amplification reaction (NEAR). To date, the viral target genes of NAAT technologies for the detection of SARS-CoV-2 include the N, E, S, and RdRp genes[[1]](#footnote-1). By amplifying the nucleic acid, NAAT methods can detect very low levels of SARS-CoV-2 RNA in a clinical sample, making these assays extremely sensitive and reliable for the detection of COVID-19.1,2,3

**Abbott ID NOW**TM **COVID-19 Technology**

ID NOWTM COVID-19 is an automated nucleic acid assay based on a Nicking Enzyme Amplification Reaction (NEAR) that uses isothermal NAAT for the qualitative molecular detection of SARS-CoV-2 viral nucleic acids.4 Templates[[2]](#footnote-2) developed specifically for SARS-CoV-2 RNA amplify a unique region of the RdRp segment. Fluorescently marked molecular beacons specifically identify each of the amplified RNA targets.5

Currently, none of the emerging SARS-CoV-2 variants effect the specific region of the RdRp segment that is amplified and detected using the ID NOWTM COVID-19 assay. Therefore performance has not been affected.6 In addition, Abbott regularly reviews the sequence databases for potential mutations to ensure assay performance.

**Abbott ID NOW**TM **– NAAT used worldwide**

According to the test regulations of the German Federal Ministry of Health (dated March 8, 2021), procedures according to PCR, POC[[3]](#footnote-3) -PCR or other methods under the umbrella of nucleic acid amplification techniques are listed as “nucleic acid detection of the coronavirus SARS-CoV-2”, which therefore includes the ID NOWTM technology.7

Furthermore, the Abbott ID NOWTM COVID-19 test is listed in the European Commission's "COVID-19 In Vitro Diagnostic Devices and Test Methods Database" and, as a NAAT test, is one of the methods that will soon be recognized by all European countries according to the European Commission's proposal for a digital green certificate.3,8

The U.S. CDC[[4]](#footnote-4) cites NEAR technology, as utilized by the Abbott ID NOWTM System as an example of a NAAT. The ID NOW™ POC instrument for COVID-19 diagnostics can be used wherever a rapid response is needed and of top priority.2,9

**Abbott ID NOW**TM **provides equivalent performance to NAAT gold standard (RT-PCR)**

In April 2021, a study by the Robert Koch Institute (RKI) concluded that the ID NOWTM system with the COVID-19 assay is a reliable and faster method to standard PCR for detecting SARS-CoV-2: "*The ID NOW system has an analytical sensitivity close to that of real-time PCR systems*."6

Using 179 randomly selected SARS-CoV-2 positive samples, 56 of the positive samples showed a Ct value[[5]](#footnote-5) of <24.7 in the RKI RT-PCR[[6]](#footnote-6). The Ct value of 24.7 in the applied reference method corresponds to an identified genomic load of >106 copies per mL. Based on study data, the RKI classifies patients as potentially infectious if the genomic load is >106 copies per mL. Thus, while off-label VTM samples were used in this study, the ID NOWTM was able to detect 100% of potentially infectious individuals. Moreover, an additional 92 PCR-negative samples for SARS-CoV-2, including samples containing various respiratory viruses[[7]](#footnote-7), were correctly tested as negative for Covid-19 using the ID NOWTM platform. This resulted in an overall specificity of 100% for the ID NOWTM system.6

Due to the increasing awareness of asymptomatic, pre-symptomatic or pauci-symptomatic transmission, it is becoming increasingly important to reduce the time between testing and results.10 Therefore, the ID NOWTM system offers advantages in settings where a rapid and reliable result is needed.6,11-13 Numerous studies and users confirm that the ID NOWTM System is intuitive and easy to use, and specifically provides an optimal solution for use in a variety of point-of-care testing settings.11,12,13 The authors of the RKI study also confirmed that the ID NOWTM COVID-19 test can produce reliable results in under 13 minutes, thus providing the ID NOWTM platform with a significant time advantage over classical RT-PCR.6 In addition, the ID NOWTM system was confirmed to reliably detect the B.1.1.7 (UK), B.1.351 (SA) and Brazilian TY7-503 variants of the SARS-CoV-2 virus.6 In addition to the RKI study, other international studies have shown that the ID NOWTM COVID-19 test is a rapid and reliable complement to the PCR gold standard. The performance data are summarized in the following table.

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| **Study type** | **Study country** | **Sample number** | **Positive agreement (Sensitivity)** | **Negative agreement (Specificity)** |
| Multi-centre study12\*\* | France | 200 | 94.7%\* | 100% |
| Point of Care Setting (ER)13 | France | 395 | 98%\* | 97.5% |
| Performance14 | USA | 993 | 100%\* | 99.5% |
| Performance11\*\* | France | 48 | 100%\* | 100% |
| Performance15 | USA | 184 | 92% | 100% |
| Method Verification16 | USA | 48 | 98% | 100% |
| National Survey 17 | Canada | 16 | 100% | 100% |

**\***Data included only for Ct values lesser than or equal to 35. **\*\***These studies included off-label testing.

*“Summing up, the ID NOW*TM *COVID-19 test is a useful piece in the puzzle of diagnostic tools that are applied to identify SARS-CoV-2 infections.”* 6 (extracted from RKI Study)

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1. Nucleocapsid, Envelope, Surface, RNA-dependent RNA polymerase [↑](#footnote-ref-1)
2. Similar to primers which are used in PCR technology [↑](#footnote-ref-2)
3. Point of Care [↑](#footnote-ref-3)
4. Centers for Disease Control and Prevention [↑](#footnote-ref-4)
5. Cycle threshold [↑](#footnote-ref-5)
6. This study was not performed according to manufactures instructions5 [↑](#footnote-ref-6)
7. Influenza Viruses A/H1N1 (2009), B/vic, B/yam, H3N2, RSV, HMPV, AdV, HRV, PIV-1, PIV-2, PIV-3, PIV-4, HKU1, HCoV-229E, -OC43 oder -NL63 (Ct-values between 18-27). [↑](#footnote-ref-7)