CLIA Waiver by Application Approval Determination

Decision Memorandum

A. Document Number

CW220006

B. Parent Document Number

K221925

C. CLIA Waiver Type:

Dual 510(k) and CLIA Waiver by Application (Dual Submission)

D. Applicant

Abbott Diagnostics Scarborough, Inc.

E. Proprietary and Established Names

ID NOW COVID-19 2.0
ID NOW Instrument

F. Measurand (analyte)

RdRp gene of SARS-CoV-2 RNA.

G. Sample Type(s)

Direct nasal and nasopharyngeal swabs.

H. Type of Test

ID NOW COVID-19 2.0 is a rapid, instrument-based isothermal test for the qualitative detection of viral RNA from SARS-CoV-2 in direct nasal or nasopharyngeal swabs.

I. Test System Description

1. Overview

ID NOW COVID-19 2.0 is a rapid, instrument-based isothermal test for the qualitative detection of viral RNA from SARS-CoV-2 in direct nasal or nasopharyngeal swabs. ID NOW COVID-19 2.0 System utilizes isothermal nucleic acid amplification technology and is comprised of:

- Sample Receiver – single use, disposable containing the elution buffer
- Test Base – single use, disposable comprising two sealed reaction tubes, each containing a lyophilized pellet
- Transfer Cartridge – single use, disposable for transfer of the eluted sample to the Test Base
- Patient Swabs – sterile anterior nasal swabs (foam) for anterior nasal swab collection and for use as a Negative Control
- Positive Control Swab – single use, to ensure that test reagents are working properly and that the test is correctly performed, and
- ID NOW Instrument

The reaction tubes in the Test Base contain lyophilized reagents required for amplification of the target nucleic acid and an internal control. ID NOW COVID-19 2.0 utilizes a pair of templates (similar to primers) for the specific amplification of RNA from SARS-CoV-2 and a fluorescently labeled molecular beacon designed to specifically identify the amplified nucleic acid targets. ID NOW COVID-19 2.0 is performed within the confinement of the Test Base, and no other part of the ID NOW Instrument has contact with the sample during the amplification process.

To perform the assay, the Sample Receiver and Test Base are inserted into the ID NOW Instrument. The sample is added to the Sample Receiver and transferred via the Transfer Cartridge to the Test Base, resuspending the lyophilized pellets contained within the Test Base and initiating viral lysis and target amplification. Heating, mixing and detection by fluorescence is provided by the instrument, with results automatically reported.

Results are displayed by the ID NOW Instrument and are also stored in an on-board archive and are assigned to a sample ID that has been entered into the ID NOW Instrument by the operator either manually or using barcode scanner. Data can be retrieved and downloaded by the operator at any time after testing. An external Universal Printer can be attached via USB to the ID NOW Instrument to print test results.

2. Test System Components

- Sample Receiver (24 pieces/kit)
- Test Base (24 pieces/kit)
- Transfer Cartridge (24 pieces/kit)
- Sterile Patient Swabs (24 swabs/kit) for anterior nasal swab collection and for use as Negative Control Swab
- Positive Control Swab (1 swab/kit)
- ID NOW Instrument
- Package Insert (1)
- Quick Reference Instructions (1)
- Nasopharyngeal Swabs (required but not provided)

If additional Positive or Negative Control Swabs are required, ID NOW COVID-19 2.0 Control Swab Kit can be purchased separately. ID NOW COVID-19 2.0 Control Swab Kit contains 12 Positive Control Swabs and 12 sterile swabs for use as negative controls.

J. Demonstrating "Simple"

ID NOW COVID-19 2.0 System was designed to be simple and easy to use by incorporating the following features:

- ID NOW COVID-19 2.0 test components are provided as a "self-contained" test (test kit with unitized reagents). The test kit contains all of the components required to perform the test, and is comprised of:
    - Sample Receiver – single use, disposable, containing the elution buffer
    - Test Base – single use, disposable, comprising two sealed reaction tubes, each containing a lyophilized pellet
    - Transfer Cartridge – single use, disposable, for transfer of the eluted sample to the Test Base, and
    - Sterile Patient Swabs for anterior nasal swab collection and for use as Negative Control Swab
    - Positive Control Swab
    - ID NOW Instrument –required to perform the test, a fully automated instrument, provided separately.

  To perform the assay, the Sample Receiver and Test Base are inserted into the ID NOW Instrument. All steps of the assay process are timed by the instrument; no timing by the test operator is required. When prompted by the instrument, the swab sample is added to the Sample Receiver and mixed by swirling motion for 10 seconds, then discarded. The Transfer Cartridge is pressed onto the Sample Receiver and the sample is then transferred via the Transfer Cartridge to the Test Base, resuspending the lyophilized pellet contained within the Test Base and initiating target amplification. No further operator intervention is required. The subsequent heating, mixing, and detection by fluorescence is performed by the instrument, with results automatically reported.

- The test uses direct unprocessed specimens. The sample used in the test system is a nasal or nasopharyngeal swab, tested directly. Following collection, the swab is inserted in the Sample Receiver containing the elution buffer. The swab is removed and discarded. When prompted by the instrument, the sample is transferred to the Test Base using the Transfer Cartridge. All remaining assay steps are performed by the ID NOW Instrument.

- The test system does not require any reagent manipulation as all reagents are contained within the test components.

- The test does not require any operator intervention during the analysis step. After the sample is added to the Sample Receiver and transferred via the Transfer Cartridge to the Test Base, all subsequent steps, such as heating, mixing and detection by fluorescence, are executed by the instrument.

- The operators of the test device do not require any technical or specialized training with respect to troubleshooting or interpretation of results. The results are displayed on the instrument screen as "Positive," "Negative," or "Invalid." Error messages are clearly displayed on the ID NOW Instrument screen, with additional information provided in the ID NOW Instrument User Manual.

- ID NOW Instrument requires no electronic or mechanical maintenance. ID NOW Instrument contains no serviceable parts and is to be returned to Abbott Diagnostics Scarborough, Inc. for repair.

- The Quick Reference Instructions (QRI) included in the test kit is written at no higher than a 7th grade reading level. The Quick Start Guide included with the ID NOW Instrument, is primarily a pictorial representation of initial unpacking and set-up instructions.

K. Demonstrating "Insignificant Risk of an Erroneous Result"- Failure Alerts and Fail-safe Mechanisms

1. Risk Analysis

   A comprehensive risk analysis of the ID NOW COVID-19 2.0 run on the ID NOW Instrument has been conducted in accordance with ISO 14971:2019. The sponsor utilized the Device Hazard Analysis and the Failure Mode Effects Analysis (FMEA) methods to assess the risks of failure that may occur during use or misuse of the device. The FMEA includes identification of potential failure modes and effect of the failure, potential causes, built in design controls and evaluation of severity, frequency of occurrence, and ability to detect the failure. The elements considered included operator errors (human factors), sample and device handling and storage, and environmental factors.

   Potential sources of errors that could adversely affect system performance were identified and mitigated first through system design and then through additional cautions in the labeling. The identified risks which could result in erroneous test results were evaluated in flex studies that stressed the functional limits of the test system (see below).

   The sponsor provided detailed software validation and verification documentation, including requirements related to assay performance when using the ID NOW Instrument. The instrument software was reviewed under the parent 510(k) submission (K221925). The ID NOW Instrument on which ID NOW COVID-19 2.0 is run, has previously been cleared under 510(k) K141520 (Alere i Influenza A & B).

2. Fail-Safe and Failure Alert Mechanisms

   ID NOW COVID-19 2.0 run on the ID NOW Instrument was designed to include numerous features and fail-safe mechanisms built into the system to prevent erroneous results.

   Design Features

a. Test components are packaged in sealed aluminum pouches to ensure product stability.

b. The Sample Receiver and Test Base components are color coded and shaped only to fit into the proper location on the instrument and only in the proper orientation.

c. The Test Base contains a quick response (QR) code with information such as test type, expiration date, and lot number. Image analysis by the instrument reads the QR code and generates an error message if an expired Test Base is used. Upon confirmation of the Test Base insertion, the user is instructed to insert the Sample Receiver.

d. ID NOW Instrument detects the insertion of the Sample Receiver into the Sample Receiver holder and automatically instructs the user to insert and mix the sample in the elution buffer and transfer the sample to the Test Base using the Transfer Cartridge.

e. The instrument uses image analysis to confirm the Transfer Cartridge is present and instructs the user to close the lid before testing can begin. The lid operates using a magnetic switch that detects lid closure and automatically begins the testing process when the lid is closed.

f. The instrument software implements temperature control of both the Test Base and the Sample Receiver holders (heater blocks). Each of the heater blocks is managed independently with high precision temperature monitoring and control. Over temperature protection is assured by the following mechanisms:

   - The heater subsystem incorporates a software independent, over temperature protection circuit hardware.

   - The heater subsystem incorporates a local over temperature non-resetting thermal fuse in direct contact with the heater block.

g. If power is lost during a test run, the test is cancelled, and a result is not reported.

h. Additional software controls are implemented to ensure control of the testing process, i.e., all parameters of the testing process are within specifications. The instrument performs a self-test upon initial startup and before each test is run. If the self-test fails, an error is displayed, and the user is not able to proceed with sample testing. A description of the specific errors/warnings generated is provided in the ID NOW Instrument user manual.

Built-in Procedural Control

ID NOW COVID-19 2.0 contains a built-in procedural control. The control tests for sample inhibition, amplification, and assay reagent function. The result of the procedural control is displayed on the screen and is automatically stored in the instrument memory with each test result. “Procedural Control Valid” displayed on the instrument screen