February 16, 2021

Roche Molecular Systems, Inc.
Kaitlyn Hameister
Senior Regulatory Affairs Specialist I
4300 Hacienda Drive
Pleasanton, California 94588-2722

Re: K210234
Trade/Device Name: cobas Influenza A/B & RSV Nucleic acid test for use on the cobas Liat System
Regulation Number: 21 CFR 866.3980
Regulation Name: Respiratory Viral Panel Multiplex Nucleic Acid Assay
Regulatory Class: Class II
Product Code: OCC, OOI, OZE
Dated: January 26, 2021
Received: January 28, 2021

Dear Kaitlyn Hameister:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. Although this letter refers to your product as a device, please be aware that some cleared products may instead be combination products. The 510(k) Premarket Notification Database located at https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpmn/pmn.cfm identifies combination product submissions. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part

801 and Part 809); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803) for devices or postmarketing safety reporting (21 CFR 4, Subpart B) for combination products (see https://www.fda.gov/combination-products/guidance-regulatory-information/postmarketing-safety-reporting-combination-products); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820) for devices or current good manufacturing practices (21 CFR 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to https://www.fda.gov/medical-devices/medical-device-safety/medical-device-reporting-mdr-how-report-medical-device-problems.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance) and CDRH Learn (https://www.fda.gov/training-and-continuing-education/cdrh-learn). Additionally, you may contact the Division of Industry and Consumer Education (DICE) to ask a question about a specific regulatory topic. See the DICE website (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/contact-us-division-industry-and-consumer-education-dice) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

Maria Ines Garcia, Ph.D.
Branch Chief
Division of Microbiology Devices
OHT7: Office of In Vitro Diagnostics
and Radiological Health
Office of Product Evaluation and Quality
Center for Devices and Radiological Health

Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: 06/30/2023
See PRA Statement below.

510(k) Number *(if known)*
K210234

Device Name
cobas® Influenza A/B & RSV nucleic acid test for use on the cobas® Liat® System

Indications for Use *(Describe)*
The cobas® Influenza A/B & RSV Nucleic acid test for use on the cobas® Liat® System (cobas® Influenza A/B & RSV) is an automated multiplex real-time RT-PCR assay for the rapid in vitro qualitative detection and discrimination of Influenza A virus, Influenza B virus and respiratory syncytial virus (RSV) RNA in nasopharyngeal swab specimens from patients with signs and symptoms of respiratory infection in conjunction with clinical and epidemiological risk factors. The test is intended for use as an aid in the differential diagnosis of Influenza A, Influenza B, and RSV in humans and is not intended to detect Influenza C.

Negative results do not preclude Influenza virus or RSV infection and should not be used as the sole basis for treatment or other patient management decisions. Conversely, positive results do not rule-out bacterial infection or co-infection with other viruses. The agent detected may not be the definite cause of disease.

Performance characteristics for Influenza A were established during the 2013-2014 and the 2014-2015 Influenza seasons when Influenza A/H3 and A/H1N1 pandemic were the predominant Influenza A viruses in circulation. When other Influenza A viruses are emerging, performance characteristics may vary.

If infection with a novel Influenza A virus is suspected based on current clinical and epidemiological screening criteria recommended by public health authorities, specimens should be collected with appropriate infection control precautions for novel virulent Influenza viruses and sent to state or local health department for testing. Viral culture should not be attempted in these cases unless a BSL 3+ facility is available to receive and culture specimens.

Type of Use *(Select one or both, as applicable)*

☒ Prescription Use (Part 21 CFR 801 Subpart D) ☐ Over-The-Counter Use (21 CFR 801 Subpart C)

CONTINUE ON A SEPARATE PAGE IF NEEDED.

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cobas® Influenza A/B & RSV Nucleic Acid Test for use on the cobas® Liat® System 510(k) Summary

This summary of 510(k) safety and effectiveness information is being submitted in accordance with the requirements of 21 CFR 807.92.

Submitter Name	Roche Molecular Systems, Inc.
Address	4300 Hacienda Drive Pleasanton, CA 94588-2722
Contact	Kaitlyn Hameister Phone: (925) 368-0589 FAX: (925) 225-0207 Email: kaitlyn.hameister@roche.com
Date Prepared	January 18, 2021
Proprietary Name	cobas® Influenza A/B & RSV Nucleic acid test for use on the cobas® Liat® System
Common Name	Influenza A, B, RSV Panel
Classification Name	Respiratory viral panel multiplex nucleic acid assay Real Time Nucleic Acid Amplification System
Product Codes	OCC, 21 CFR 866.3980 OOI, 21 CFR 862.2570
Predicate Devices	cobas® Influenza A/B & RSV Nucleic Acid Test for use on the cobas® Liat® System (K200065)
Establishment Registration	Roche Molecular Systems, Inc. Branchburg, NJ Establishment Number: 2243471 Roche Molecular Systems, Inc. Pleasanton, CA Establishment Number: 3004141078

1. DEVICE DESCRIPTION

The cobas® Influenza A/B & RSV Nucleic Acid Test for use on the cobas® Liat® System (cobas® Influenza A/B & RSV) is an automated *in vitro* diagnostic test for the qualitative detection of Influenza A, Influenza B, and RSV RNA in nasopharyngeal swab (NPS) specimens. The sample-to-result time is ~20 minutes.

The assay is performed on the cobas® Liat® Analyzer which automates and integrates sample purification, nucleic acid amplification, and detection of the target sequence in biological samples using real-time RT-PCR assays. The assay targets a well-conserved region of the matrix gene of Influenza A (Inf A target), the non-structure protein gene of Influenza B (Inf B target), and the matrix gene of RSV (RSV target). An Internal Process Control (IPC) is also included. The IPC is present to control for adequate processing of the target virus through all steps of the assay process and to monitor the presence of inhibitors in the RT-PCR reactions.

The cobas® Liat® System consists of an instrument and preloaded software for running tests and viewing the results. The system requires the use of a single-use disposable cobas® Influenza A/B & RSV assay tube that holds the nucleic acid purification and RT-PCR reagents, and hosts the sample preparation and RT-PCR processes.

The detection module monitors the reaction in real-time, while an on-board computer analyzes the collected data and outputs an interpreted result. The latter is displayed in the assay report on the integrated LCD touch screen of the cobas® Liat® Analyzer and in an electronic file. The report can be printed directly through a USB or network-connected printer. The results can also be exported to an external server, middleware or data management system, or to a Laboratory Information System (LIS).

1.1. Test Workflow

Nasopharyngeal swab can be collected following the user institution's standard procedures. For nasopharyngeal swab samples suspended in collection media, a user transfers the sample into cobas® Influenza A/B & RSV assay tube.

A user then scans the assay tube barcode to identify the test and scans the sample barcode to code the sample ID using the cobas® Liat® System. The assay tube is then inserted into the cobas® Liat® Analyzer (Figure 1). The analyzer performs all test steps and outputs interpreted results in approximately 20 minutes. A report of the interpreted results can be viewed in the View Results window, and printed directly through a USB connected printer.

Figure 1: Illustration of cobas® Liat® Analyzer Assay Testing Process

2. INTENDED USE

The cobas® Influenza A/B & RSV Nucleic acid test for use on the cobas® Liat® System (cobas® Influenza A/B & RSV) is an automated multiplex real-time RT-PCR assay for the rapid *in vitro* qualitative detection and discrimination of Influenza A virus, Influenza B virus and respiratory syncytial virus (RSV) RNA in nasopharyngeal swab specimens from patients with signs and symptoms of respiratory infection in conjunction with clinical and epidemiological risk factors. The test is intended for use as an aid in the differential diagnosis of Influenza A, Influenza B, and RSV in humans and is not intended to detect Influenza C.

Negative results do not preclude Influenza virus or RSV infection and should not be used as the sole basis for treatment or other patient management decisions. Conversely, positive results do not rule out bacterial infection or co-infection with other viruses. The agent detected may not be the definite cause of disease.

Performance characteristics for Influenza A were established during the 2013-2014 and the 2014-2015 influenza seasons when Influenza A/H3 and A/H1N1 pandemic were the predominant Influenza A viruses in circulation. When other Influenza A viruses are emerging, performance characteristics may vary.

If infection with a novel Influenza A virus is suspected based on current clinical and epidemiological screening criteria recommended by public health authorities, specimens should be collected with appropriate infection control precautions for novel virulent Influenza viruses and sent to state or local health department for testing. Viral culture should not be attempted in these cases unless a BSL3+ facility is available to receive and culture specimens.

3. TECHNOLOGICAL CHARACTERISTICS

The technological characteristics and intended use of cobas® Influenza A/B & RSV for use on the cobas® Liat® System, when used with cobas® Influenza A/B & RSV Assay Script v1.16 has not changed from the predicate device. Table 1 provides a comparison of the modified device to the predicate device, as cleared through K200065.

Table 1: Comparison of the cobas® Influenza A/B & RSV Assay with cobas® Influenza A/B & RSV Assay Script v1.16 to the Predicate Device

Item Name	Submitted Device: cobas® Influenza A/B & RSV w/ cobas® Influenza A/B & RSV Assay Script (FRTA*/* v1.16	Predicate Device: K200065 cobas® Influenza A/B & RSV w/ cobas® Influenza A/B & RSV Assay Script (FRTA) v1.15
Intended Use	Same	The cobas® Influenza A/B & RSV Nucleic acid test for use on the cobas® Liat® System (cobas® Influenza A/B & RSV) is an automated multiplex real-time RT-PCR assay for the rapid *in vitro* qualitative detection and discrimination of Influenza A virus, Influenza B virus and respiratory syncytial virus (RSV) RNA in nasopharyngeal swab specimens from patients with signs and symptoms of respiratory infection in conjunction with clinical and epidemiological risk factors. The test is intended for use as an aid in the differential diagnosis of Influenza A, Influenza B, and RSV in humans and is not intended to detect Influenza C. Negative results do not preclude Influenza virus or RSV infection and should not be used as the sole basis for treatment or other patient management decisions. Conversely, positive results do not rule out bacterial infection or co-infection with other viruses. The agent detected may not be the definite cause of disease. Performance characteristics for Influenza A were established during the 2013-2014 and the 2014-2015 influenza seasons when Influenza A/H3 and A/H1N1 pandemic were the predominant Influenza A viruses in circulation. When other Influenza A viruses are emerging, performance characteristics may vary. If infection with a novel Influenza A virus is suspected based on current clinical and epidemiological screening criteria recommended by public health authorities, specimens should be collected with appropriate infection control precautions for novel virulent Influenza viruses and sent to state or local health department for testing. Viral culture should not be attempted in these cases unless a BSL3+ facility is available to receive and culture specimens.
Regulation	Same	21 CFR 866.3980
Product Code	Same	OCC, OOI
Assay Target	Same	Influenza A, Influenza B, RSV
Sample Type	Same	Nasopharyngeal Swab
Internal Control	Same	Yes for sample preparation and RT-PCR performance using encapsulated RNA

Item Name	Submitted Device: cobas® Influenza A/B & RSV w/ cobas® Influenza A/B & RSV Assay Script (FRTA) v1.16	Predicate Device: K200065 cobas® Influenza A/B & RSV w/ cobas® Influenza A/B & RSV Assay Script (FRTA) v1.15
Influenza A Viral Target	Same	Well conserved region of the matrix gene
Influenza B Viral Target	Same	Well conserved region of the non-structural protein (NSP) gene
RSV Viral Target	Same	Well conserved region of the matrix (M) gene
Assay Instrument	Same	cobas® Liat® Analyzer
CORE Software	Same	cobas® Liat® Analyzer Core Software 3.3 (K200065)
Assay Script (FRTA)	1.16	1.15
Self-contained System	Same	Yes, Integrated PC, software, and touch-screen display
All Assay Reagents Contained in Disposable	Same	Yes, no manual reagent addition required
Sample Volume Detection	Same	Yes, automatically checks that input sample volume exceeds lower limit
Automated Assay	Same	Yes, sample preparation, amplification and result interpretation
Error Diagnostic System	Same	Yes, monitors and records system parameters for error recover or abort if unrecoverable
Extraction Method	Same	Silica-magnetic bead-based nucleic acid extraction
Assay Method	Same	RT-PCR for detecting the presence/absence of viral RNA in clinical specimens
Detection Technique	Same	Multiplex assay using different reporter dyes for each target
Result Interpretation	Same	Automated

Item Name	Submitted Device: cobas® Influenza A/B & RSV w/ cobas® Influenza A/B & RSV Assay Script (FRTA*/* v1.16	Predicate Device: K200065 cobas® Influenza A/B & RSV w/ cobas® Influenza A/B & RSV Assay Script (FRTA) v1.15
PCR Curve Pattern Recognition	Same	Yes, ensures abnormal PCR curves are called “Invalid” or “Indeterminate”
Assay Result	Same	Qualitative
User	CLIA Waived (CW150018)	CLIA Waived (CW1500018)
Test Availability	Same	Random access, on-demand test
Time-to-result	Same	~20 minutes
Limit of Detection	Same	10^{-3} – 10^{-1} TCID50/mL
Reactivity	Same	Reactive against 28 Flu A, 15 Flu B, and 7 RSV strains tested
Cross Reactivity	Same	35 microorganisms and human genomic DNA tested. No cross reactivity found.
Interfering Microorganisms	Same	35 microorganisms and human genomic DNA tested. No effect on detection found.
Interfering Substances	Same	10 substances tested. No effect on detection found.
Reproducibility	Same	≥99.8% total percent agreement

4. DESCRIPTION OF CHANGE

cobas® Influenza A/B & RSV Assay Script v1.16 incorporates the following changes:

- Algorithm parameter changed for Influenza A and Influenza B targets to tolerate early Cts previously interpreted as invalid results.
- Correction of defects (bug fixes).

5. DESIGN AND DEVELOPMENT ACTIVITY SUMMARY

Roche Molecular Diagnostics (RMD), Pleasanton, CA designed and developed the script software component of the cobas® Liat® System. RMD in Pleasanton coordinated the development and verification of cobas® Influenza A/B & RSV Assay Script v1.16 at the Product Requirements, Technical Requirements and Technical Requirement Specifications (Unit Specifications) level. These activities included risk management, requirements management, configuration management, verification testing, and regression analysis.

6. ASSAY PERFORMANCE

Performance of the cobas® Influenza A/B & RSV assay with cobas® Influenza A/B & RSV Assay Script v1.16 was assessed by testing multiple sample types on both the predicate configuration (cobas® Influenza A/B & RSV Assay Script v1.15) and the modified configuration (cobas® Influenza A/B & RSV Assay Script v1.16). These sample types included negative controls, positive controls, negative specimens, and positive specimens containing co-formulated Influenza A, Influenza B, and RSV target material at a concentration of 3X the Limit of Detection (LoD). For each configuration (cobas® Influenza A/B & RSV Assay Script v1.15 and v1.16), each sample type was run on nine (9) cobas® Liat ® analyzers, and the assay run results for each configuration were compared and assessed for equivalency, based on the result output (for negative controls, positive controls, and negative samples) and mean Ct value (for 3X LoD samples). The results of this testing determined that the overall cobas® Influenza A/B & RSV assay performance claims were not impacted by changes implemented in cobas® Influenza A/B & RSV Assay Script v1.16, when compared to the current commercially available version of the assay script v1.15.

7. CONCLUSION

Equivalent performance of the modified device and the current commercial device has been demonstrated, and analytical and clinical performance has not changed. The modified device is substantially equivalent to the predicate device, as cleared through K200065 and CLIA waived through CW150018.