February 10, 2020

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

Re: K200065
Trade/Device Name: cobas Influenza A/B Nucleic acid test for use on the cobas Liat System,
cobas Influenza A/B & RSV Nucleic acid test for use on the cobas Liat System,
cobas Strep A 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, OZE, PGX, OOI
Dated: January 13, 2020
Received: January 13, 2020

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,

Ribhi Shawar, Ph.D. (ABMM)
Chief, General Bacteriology and Antimicrobial
Susceptibility Branch
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: 06/30/2020
See PRA Statement below.

510(k) Number *(if known)*

K200065

Device Name

The **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 BSL3+ 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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Department of Health and Human Services
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DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: 06/30/2020
See PRA Statement below.

510(k) Number *(if known)*

K200065

Device Name

cobas® Influenza A/B nucleic acid test for use on the **cobas**® Liat® System

Indications for Use *(Describe)*

The **cobas**® Influenza A/B Nucleic acid test for use on the **cobas**® Liat® System (**cobas**® Influenza A/B) is an automated multiplex real-time RT-PCR assay for the rapid *in vitro* qualitative detection and discrimination of Influenza A virus and Influenza B virus 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 and Influenza B in humans and is not intended to detect Influenza C.

Negative results do not preclude Influenza virus 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 when Influenza A/H1 and A/H3 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.

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)

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DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: 06/30/2020
See PRA Statement below.

510(k) Number *(if known)*

K200065

Device Name

cobas® Strep A nucleic acid test for use on the **cobas**® Liat® System

Indications for Use *(Describe)*

The **cobas**® Strep A nucleic acid test for use on the **cobas**® Liat® System (**cobas**® Strep A) is a qualitative *in vitro* diagnostic test for the detection of *Streptococcus pyogenes* (Group A β-hemolytic *Streptococcus*, Strep A) in throat swab specimens from patients with signs and symptoms of pharyngitis.

The **cobas**® Strep A assay utilizes nucleic acid purification and polymerase chain reaction (PCR) technology to detect *Streptococcus pyogenes* by targeting a segment of the *Streptococcus pyogenes* genome.

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)

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cobas® Influenza A/B 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) 730-8813 FAX: (925) 225-0207 Email: kaitlyn.hameister@roche.com
Date Prepared	December 20, 2019
Proprietary Name	**cobas**® Influenza A/B Nucleic acid test for use on the **cobas**® Liat® System
Common Name	Influenza A, B, 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 Nucleic Acid Test for use on the **cobas**® Liat® System (K191729)
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 Nucleic Acid Test for use on the **cobas**® Liat® System is a rapid, automated *in vitro* diagnostic test for qualitative detection and differentiation of Influenza type A and type B viral RNA. The assay is performed on the **cobas**® Liat® System. The system automates and integrates sample purification, nucleic acid amplification, and detection of the

target sequence in biological samples using real-time RT-PCR assays. The **cobas**® Liat® Analyzer consists of an instrument and preloaded software for running tests and viewing the results. The **cobas**® Liat® System consists of the analyzer and a single-use disposable **cobas**® Influenza A/B assay tube that holds the sample purification and RT-PCR reagents and hosts the sample preparation and RT-PCR processes. Other than adding the sample to the **cobas**® Influenza A/B assay tube, no reagent preparation or additional steps are required. Because each **cobas**® Influenza A/B assay tube is self-contained, cross-contamination between samples is minimized. Turnaround time for a test is 20 minutes.

The **cobas**® Influenza A/B assay includes reagents for the detection and differentiation of Influenza A and B viral RNA in nasopharyngeal swab (NPS) specimens in universal transport media (UTM) from patients suspected of having Influenza. The assay targets a well-conserved region of the matrix gene of Influenza A viral RNA (Inf A target) and non-structural protein (NS) gene of Influenza B (Inf B target). An Internal Process Control (IPC) is also included. The IPC is present to control for adequate processing of the target viruses through all steps of the assay process and to monitor the presence of inhibitors in the RT-PCR reactions.

The **cobas**® Influenza A/B assay tube uses a flexible tube as a sample processing vessel. It contains all requisite PCR reagents pre-packed in assay tube segments separated by breakable seals. When a **cobas**® Influenza A/B assay tube containing a raw biological sample is inserted into the **cobas**® Liat® Analyzer, multiple sample processing actuators in the **cobas**® Liat Analyzer compress the **cobas**® Influenza A/B assay tube to selectively release the reagents, moving the sample from one segment to the next, and controlling reaction conditions. An embedded microprocessor controls and coordinates these actions to perform all required assay processes, including sample preparation, nucleic acid extraction, target concentration enrichment, inhibitor removal, nucleic acid elution, and real-time PCR. All assay steps are performed within the closed and self-contained **cobas**® Influenza A/B assay tube, minimizing cross-contamination between samples.

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 UTM, a user transfers the UTM sample into **cobas**® Influenza A/B 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. The analyzer performs all test steps and outputs interpreted results in 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 Nucleic acid test for use on the **cobas**® Liat® System (**cobas**® Influenza A/B) is an automated multiplex real-time RT-PCR assay for the rapid *in vitro* qualitative detection and discrimination of Influenza A virus and Influenza B virus 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 and Influenza B in humans and is not intended to detect Influenza C.

Negative results do not preclude Influenza virus 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 when Influenza A/H1 and A/H3 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 for use on the **cobas**® Liat® System, when used with **cobas**® Liat® Analyzer Software 3.3d are substantially equivalent to the legally marketed device, which was most recently cleared with **cobas**® Liat® Analyzer Software 3.2. Table 1 provides a comparison of the modified device to the predicate device, as cleared through K191729.

Table 1: Comparison of the cobas® Influenza A/B Assay with cobas® Liat® Analyzer Software 3.3 to the Predicate Device

Item Name	Submitted Device: cobas® Influenza A/B w/ cobas® Liat® System Software 3.3	Predicate Device: K191729 cobas® Influenza A/B w/ cobas® Liat® System Software 3.2
Intended Use	Same	The **cobas**® Influenza A/B Nucleic acid test for use on the **cobas**® Liat® System (**cobas**® Influenza A/B) is an automated multiplex real-time RT-PCR assay for the rapid *in vitro* qualitative detection and discrimination of Influenza A virus and Influenza B virus 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 and Influenza B in humans and is not intended to detect Influenza C. Negative results do not preclude Influenza virus 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 when Influenza A/H1 and A/H3 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
Regulation	Same	21 CFR 866.3980
Product Code	Same	OCC, OOI
Assay Target	Same	Influenza A, Influenza B

Item Name	Submitted Device: **cobas® Influenza A/B w/ cobas® Liat® System Software 3.3**	Predicate Device: K191729 **cobas® Influenza A/B w/ cobas® Liat® System Software 3.2**
Sample Type	Same	Nasopharyngeal Swab
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
Assay Instrument	Same	**cobas**® Liat® Analyzer (Rebranded from Liat™ Analyzer)
Software	**cobas**® Liat® Analyzer Core Software 3.3 FABA 1.36	**cobas**® Liat® Analyzer Core Software 3.2 (K191729) FABA 1.35
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
PCR Curve Pattern Recognition	Same	Yes, ensures abnormal PCR curves are called “Invalid” or “Indeterminate”

Item Name	Submitted Device: cobas® Influenza A/B w/ cobas® Liat® System Software 3.3	Predicate Device: K191729 cobas® Influenza A/B w/ cobas® Liat® System Software 3.2
Assay Result	Same	Qualitative
User	CLIA Waived (CW150003)	CLIA Waived (CW150003)
Test Availability	Same	Random access, on-demand test
Time-to-result	Same	~20 minutes

4. DESCRIPTION OF CHANGE: CORE SOFTWARE

cobas® Liat® Analyzer Software 3.3 incorporates the following changes:

- Operating System Migration to LINUX OS
- Positive Patient ID
- Translations (not applicable to US customers)
- Enhanced Data Encryption
- Thermal Printer Support
- Generic Calculation Engine (not applicable to cleared assays)
- Assay Masking
- Integration of Advanced Tools
- Correction of defects (bug fixes)

5. DESIGN AND DEVELOPMENT ACTIVITY SUMMARY

Roche Molecular Diagnostics (RMD), Pleasanton, CA designed and developed the core software component of the cobas® Liat® System. The cobas® Liat® Analyzer core software was designed and developed by Roche Molecular Diagnostics in Rotkreuz, Switzerland.

RMD in Pleasanton and Rotkreuz coordinated the development and verification of **cobas**® Liat® Analyzer Software 3.3 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 assay with **cobas**® Liat® Analyzer Software 3.3 was evaluated. The result of this evaluation determined that the overall **cobas**® Influenza A/B assay performance and claims were not impacted by changes implemented in **cobas**® Liat® Analyzer Software 3.3, when compared to the current commercially available core software version.

7. CONCLUSION

Equivalent performance of the modified device and the current commercial device has been demonstrated, and analytical or clinical performance has not changed. The modified device is substantially equivalent to the predicate device, as cleared through K191729 and CLIA waived through CW150003.

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) 730-8813 FAX: (925) 225-0207 Email: kaitlyn.hameister@roche.com
Date Prepared	December 20, 2019
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 (K153544)
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**® Liat® Influenza A/B & RSV Nucleic Acid Test for use on the **cobas**® Liat® System 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 Analyzer which automates and integrates sample purification, nucleic acid amplification, and detection of the target sequence in biological samples using realtime 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 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 Universal Transport Media (UTM), a user transfers the UTM 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. The analyzer performs all test steps and outputs interpreted results in 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**® Liat® Analyzer Software 3.3. Table 1 provides a comparison of the modified device to the predicate device, as originally cleared through K153544.

Table 1: Comparison of the cobas® Influenza A/B & RSV Assay with cobas® Liat® Analyzer Software 3.3 to the Predicate Device

Item Name	Submitted Device: cobas® Influenza A/B & RSV w/ cobas® Liat® Analyzer Software 3.3	Predicate Device: K153544 cobas® Influenza A/B & RSV w/ cobas® Liat® Analyzer Software 1.5.4
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
Influenza A Viral Target	Same	Well conserved region of the matrix gene

Item Name	Submitted Device: **cobas® Influenza A/B & RSV w/ cobas® Liat® Analyzer Software 3.3**	Predicate Device: K153544 **cobas® Influenza A/B & RSV w/ cobas® Liat® Analyzer Software 1.5.4**
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
Software	**cobas®** Liat® Analyzer Core Software 3.3 FRTA 1.15	**cobas®** Liat® Analyzer Core Software 1.5.4 (K153544) FRTA 1.13
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
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)

Item Name	Submitted Device: cobas® Influenza A/B & RSV w/ cobas® Liat® Analyzer Software 3.3	Predicate Device: K153544 cobas® Influenza A/B & RSV w/ cobas® Liat® Analyzer Software 1.5.4
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: CORE SOFTWARE

cobas® Liat® System Software 3.3 incorporates the following changes:

- Operating System Migration to LINUX OS
- Positive Patient ID
- Translations (not applicable to US customers)
- Enhanced Data Encryption
- Thermal Printer Support
- Generic Calculation Engine (not applicable to cleared assays)
- Assay Masking
- Integration of Advanced Tools
- Correction of defects (bug fixes)

5. DESIGN AND DEVELOPMENT ACTIVITY SUMMARY

Roche Molecular Diagnostics (RMD), Pleasanton, CA designed and developed the core software component of the **cobas**® Liat® System. The **cobas**® Liat® Analyzer core software was designed and developed by Roche Molecular Diagnostics in Rotkreuz, Switzerland.

RMD in Pleasanton and Rotkreuz coordinated the development and verification of **cobas**® Liat® Analyzer Software 3.3 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**® Liat® Analyzer Software 3.3 was evaluated. The result of this evaluation determined that the overall **cobas**® Influenza A/B & RSV assay performance and claims were not impacted by changes implemented in **cobas**® Liat® Analyzer Software 3.3, when compared to the current commercially available core software version

7. CONCLUSION

Equivalent performance of the modified device and the current commercial device has been demonstrated, and analytical or clinical performance has not changed. The modified device is substantially equivalent to the predicate device, as cleared through K153544 and CLIA waived through CW150018.

cobas® Strep A 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) 730-8813 FAX: (925) 225-0207 Email: kaitlyn.hameister@roche.com
Date Prepared	December 20, 2019
Proprietary Name	**cobas**® Strep A Nucleic acid test for use on the **cobas**® Liat® System
Common Name	Strep A Test
Classification Name	Group A Streptococcus Nucleic Acid Amplification Assay System Real Time Nucleic Acid Amplification System
Product Codes	OYZ, 21 CFR 866.3470 OOI, 21 CFR 862.2570
Predicate Devices	**cobas**® Strep A Nucleic Acid Test for use on the **cobas**® Liat® System (K141338)
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**® Strep Nucleic Acid Test for use on the **cobas**® Liat® System is a rapid, automated in vitro diagnostic test for the qualitative detection of Streptococcus pyogenes (Group A β-hemolytic Streptococcus, Strep A) DNA in throat swab specimens in Amies media.

The assay utilizes silica magnetic bead-based nucleic acid extraction, and TaqMan probe-based real-time PCR amplification and detection. The assay targets a well-conserved region of the spy1258 gene of Strep A. An Internal Process Control (IPC) is also included. The IC is present to control for adequate processing of the target bacteria and to monitor the presence of inhibitors in the sample preparation and PCR.

The **cobas**® Liat® System automates and integrates sample purification, nucleic acid amplification, and detection of the target sequence in biological samples. Other than adding the sample to the **cobas**® Strep A assay tube, no reagent preparation or additional steps are required.

The system consists of an instrument with integrated software for running tests and analyzing the results. The system requires the use of a single-use disposable **cobas**® Strep A assay tube that holds all the sample purification and PCR reagents and hosts the sample preparation and PCR processes.

During the testing process, multiple sample processing actuators of the **cobas**® Liat® System compress the assay tube to selectively release reagents from tube segments, move the sample from one segment to another, and control reaction conditions such as reaction volume, temperature, pressure, and incubation time. Precise control of all these parameters provides optimal conditions for assay reactions, allowing the nucleic acid test to achieve performance similar to or better than that of laboratory assays. An embedded microprocessor controls and coordinates these actions to perform all required assay processes, including sample preparation, nucleic acid extraction, target enrichment, inhibitor removal, nucleic acid elution, and real-time PCR.

All assay steps are performed within the closed and self-contained assay tube, minimizing cross-contamination between samples. The collected data is automatically analyzed and an interpreted result is output in the assay report on the integrated touch screen of the **cobas**® Liat® System. Turnaround time for this nucleic acid test is ~15 minutes.

1.1. Test Workflow

Throat swab can be collected following the user institution’s standard procedures. For throat swab samples suspended in Amies transport media, a user transfers the Amies sample into **cobas**® Strep 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. The analyzer performs all test steps and outputs interpreted results in ~15 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**® Strep A nucleic acid test for use on the **cobas**® Liat® System (**cobas**® Strep A) is a qualitative *in vitro* diagnostic test for the detection of *Streptococcus pyogenes* (Group A β-hemolytic *Streptococcus*, Strep A) in throat swab specimens from patients with signs and symptoms of pharyngitis.

The **cobas**® Strep A assay utilizes nucleic acid purification and polymerase chain reaction (PCR) technology to detect *Streptococcus pyogenes* by targeting a segment of the *Streptococcus pyogenes* genome.

The **cobas**® Strep A Nucleic acid test for use on the **cobas**® Liat® System is intended for professional use in a clinical laboratory setting or point-of care (POC) location.

3. TECHNOLOGICAL CHARACTERISTICS

The technological characteristics and intended use of **cobas**® Strep A for use on the **cobas**® Liat® System, when used with **cobas**® Liat® Analyzer Software 3.3, are substantially equivalent to the legally marketed device. Table 1 provides a comparison of the modified device to the predicate device, as originally cleared through K141338.

Table 1: Comparison of the cobas® Strep A for use with cobas® Liat® System Softare 3.3 with the Predicate Device (K141388)

Item Name	Submitted Device: **cobas® Strep A w/ cobas® Liat® Analyzer Software 3.3**	Predicate Device: K141338 **cobas® Strep A w/ cobas® Liat® Analyzer Software 1.5.1**
Intended Use	Same	The **cobas**® Strep A nucleic acid test for use on the **cobas**® Liat® System (**cobas**® Strep A) is a qualitative in vitro diagnostic test for the detection of Streptococcus pyogenes (Group A β-hemolytic Streptococcus, Strep A) in throat swab specimens from patients with signs and symptoms of pharyngitis. The **cobas**® Strep A assay utilizes nucleic acid purification and polymerase chain reaction (PCR) technology to detect Streptococcus pyogenes by targeting a segment of the Streptococcus pyogenes genome. The **cobas**® Strep A Nucleic acid test for use on the **cobas**® Liat® System is intended for professional use in a clinical laboratory setting or point- of - care (POC) location.
Regulation	Same	21 CFR 866.3470
Product Code	Same	OYZ, OOI
Assay Target	Same	Streptococcus A
Sample Type	Same	Throat Swab
Internal Control	Same	Yes
Strep Target	Same	Conserved sequence in transcription regulator gene of *S. pyrogenes*
Assay Instrument	Same	**cobas**® Liat® Analyzer (Rebranded from Liat™ Analyzer)
Software	**cobas**® Liat® Analyzer Core Software 3.3 SASA 1.28	**cobas**® Liat® Analyzer Core Software 1.5.1 (K141338) SASA 1.26
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

Item Name	Submitted Device: cobas® Strep A w/ cobas® Liat® Analyzer Software 3.3	Predicate Device: K141338 cobas® Strep A w/ cobas® Liat® Analyzer Software 1.5.1
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	PCR for detecting the presence / absence of bacterial DNA in clinical specimens
Detection Technique	Same	Duplex assay using different reporter dyes for target and control
Result Interpretation	Same	Automated - **cobas**® Liat® Analyzer (Rebranded from Liat™ Analyzer)
PCR Curve Pattern Recognition	Same	Yes, ensures abnormal PCR curves are called “Invalid” or “Indeterminate”
Assay Result	Same	Qualitative
User	CLIA Waived (CW140014)	Technologist in CLIA Moderate complexity labs
Time-to-result	Same	~15 minutes
Error Diagnostic System	Same	Yes, monitors and records system parameters for error recovery or assay abort if unrecoverable
Limit of Detection	Same	10^0 – 10^1 CFU per test
Reactivity	Same	Reactive against 9 Strep A strains tested
Cross Reactivity	Same	63 human pathogens tested, including 13 other Streptococcus species, 42 other bacteria, and 8 viruses. No cross reactivity found
Interfering Microorganisms	Same	63 human pathogens tested. No effect on detection

Item Name	Submitted Device: cobas® Strep A w/ cobas® Liat® Analyzer Software 3.3	Predicate Device: K141338 cobas® Strep A w/ cobas® Liat® Analyzer Software 1.5.1
Interfering Substances	Same	28 substances at medically and/or physiologically relevant concentrations at near LOD. No effect on detection
Sensitivity	Same	98.5% (95% CI: 95.6% – 99.5%)
Specificity	Same	94.2% (95% CI: 91.6 – 96.1%)

4. DESCRIPTION OF CHANGE: CORE SOFTWARE

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6. ASSAY PERFORMANCE

Performance of the **cobas**® Strep A assay with **cobas**® Liat® Analyzer Software 3.3 was evaluated. The result of this evaluation determined that the overall **cobas**® Strep A assay performance and claims were not impacted by changes implemented in **cobas**® Liat® Analyzer Software 3.3, when compared to the current commercially available core software version

7. CONCLUSION

Equivalent performance of the modified device and the current commercial device has been demonstrated, and analytical or clinical performance has not changed. The modified device is substantially equivalent to the predicate device, as cleared through K141338 and CLIA waived through CW140014.