Rx Only

cobas® SARS-CoV-2 & Influenza A/B

Qualitative assay for use on the cobas® 6800/8800 Systems

For use under the Emergency Use Authorization (EUA) only

cobas® SARS-CoV-2 & Influenza A/B	P/N: 09233474190
cobas® SARS-CoV-2 & Influenza A/B Control Kit	P/N: 09233482190
cobas® 6800/8800 Buffer Negative Control Kit	P/N: 07002238190

Table of contents

Summary and explanation of the test

Intended use under the FDA Emergency Use Authorization

cobas® SARS-CoV-2 & Influenza A/B assay for use on the **cobas**® 6800/8800 Systems (**cobas**® SARS-CoV-2 & Influenza A/B) is an automated multiplex real-time RT-PCR assay intended for simultaneous qualitative detection and differentiation of SARS-CoV-2, influenza A virus, and/or influenza B virus RNA in healthcare provider-collected nasal and nasopharyngeal swab specimens, and self-collected nasal swab specimens (collected in a healthcare setting with instruction by a healthcare provider) from individuals suspected of respiratory viral infection consistent with COVID-19 by their healthcare provider. **cobas**® SARS-CoV-2 & Influenza A/B is intended for use as an aid in the differential diagnosis of SARS-CoV-2, influenza A, and influenza B in humans and is not intended to detect influenza C. Testing is limited to laboratories certified under the Clinical Laboratory Improvement Amendments of 1988 (CLIA), 42 U.S.C. §263a, that meet requirements to perform moderate or high complexity tests.

RNA from SARS-CoV-2, influenza A, and influenza B is generally detectable in respiratory specimens during the acute phase of infection. Positive results are indicative of the presence of SARS-CoV-2, influenza A, and/or influenza B RNA; clinical correlation with patient history and other diagnostic information is necessary to determine patient infection status. 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. Testing facilities within the United States and its territories are required to report all SARS-CoV-2 results to the appropriate public health authorities.

Negative results do not preclude infection from SARS-CoV-2, influenza A, and/or influenza B and should not be used as the sole basis for treatment or other patient management decisions. Negative results must be combined with clinical observations, patient history, and epidemiological information.

cobas® SARS-CoV-2 & Influenza A/B is intended for use by qualified clinical laboratory personnel specifically instructed and trained in the techniques of real-time PCR and on the use of the **cobas**® 6800/8800 Systems. In the US, **cobas**® SARS-CoV-2 & Influenza A/B is only for use under the Food and Drug Administration's Emergency Use Authorization.

Explanation of the test

cobas® SARS-CoV-2 & Influenza A/B is a qualitative test for the use on the **cobas**® 6800 System and **cobas**® 8800 System for the detection of the 2019 novel coronavirus (SARS-CoV-2), influenza A, and influenza B RNA in both nasal and nasopharyngeal swab samples collected in Copan Universal Transport Medium System (UTM-RT®) or BD™ Universal Viral Transport System (UVT) and additionally for nasal swab samples collected in **cobas**® PCR Media or 0.9% physiological saline. The RNA Internal Control, used to monitor the entire sample preparation and PCR amplification process, is introduced into each specimen during sample processing. In addition, the test utilizes external controls (low titer positive control and a negative control).

Principles of the procedure

cobas® SARS-CoV-2 & Influenza A/B is based on fully automated sample preparation (nucleic acid extraction and purification) followed by PCR amplification and detection. The **cobas**® 6800/8800 Systems consist of the sample supply module, the transfer module, the processing module, and the analytic module. Automated data management is performed by the **cobas**® 6800/8800 software, which assigns results for all tests. Results can be reviewed directly on the system screen, and printed as a report.

Nucleic acid from patient samples and added internal control RNA (RNA IC) molecules are simultaneously extracted. Nucleic acid is released by addition of proteinase and lysis reagent to the sample. The released nucleic acid binds to the silica surface of the added magnetic glass particles. Unbound substances and impurities, such as denatured protein, cellular debris and potential PCR inhibitors, are removed with subsequent wash steps and purified nucleic acid is eluted from the magnetic glass particles with elution buffer at elevated temperature. External controls (positive and negative) are processed in the same way with each **cobas**® SARS-CoV-2 & Influenza A/B run.

Selective amplification of SARS-CoV-2 target nucleic acid from the sample is achieved by the use of target-specific forward and reverse primers for ORF1a/b non-structural region that is unique to SARS-CoV-2. Additionally, a conserved region in the structural protein envelope E-gene was chosen for pan-Sarbecovirus detection. The pan-Sarbecovirus detection set will also detect SARS-CoV-2 virus. For influenza A and influenza B viruses, selective amplification of target nucleic acid from the sample is achieved by the use of target-specific forward and reverse primers for the matrix proteins 1 and 2 (M1/M2) for influenza A and the nuclear export protein (NEP) / nonstructural protein 1(NS1) genes for influenza B, respectively. Selective amplification of RNA Internal Control is achieved by the use of non-competitive sequence specific forward and reverse primers which have no homology with the coronavirus or influenza genomes. Amplified target is detected by cleavage of fluorescently labeled oligonucleotide probe. A thermostable DNA polymerase enzyme is used for amplification.

The **cobas**® SARS-CoV-2 & Influenza A/B master mix contains detection probes which are specific for the coronavirus type SARS-CoV-2, members of the Sarbecovirus subgenus, influenza A virus, influenza B virus and the RNA Internal Control nucleic acid. The coronavirus, influenza A, influenza B and RNA Internal Control detection probes are each labeled with unique fluorescent dyes that act as a reporter. Each probe also has a second dye which acts as a quencher. When not bound to the target sequence, the fluorescent signals of the intact probes are suppressed by the quencher dye. During the PCR amplification step, hybridization of the probes to the specific single-stranded DNA template results in cleavage of the probe by the 5' to 3' exonuclease activity of the DNA polymerase resulting in separation of the reporter and quencher dyes and the generation of a fluorescent signal. With each PCR cycle, increasing amounts of cleaved probes are generated and the cumulative signal of the reporter dye increases concomitantly. Each reporter dye is measured at defined wavelengths, which enables simultaneous detection and discrimination of the amplified coronavirus targets, influenza targets and the RNA Internal Control. The master mix includes deoxyuridine triphosphate (dUTP), instead of deoxythimidine triphosphate (dTTP), which is incorporated into the newly synthesized DNA (amplicon). Any contaminating amplicons from previous PCR runs are destroyed by the AmpErase enzyme [uracil-N-glycosylase], which is included in the PCR mix, when heated in the first thermal cycling step. However, newly formed amplicons are not destroyed since the AmpErase enzyme is inactivated once exposed to temperatures above 55°C.

Reagents and materials

The materials provided for **cobas**® SARS-CoV-2 & Influenza A/B can be found in Table 1. Materials required, but not provided can be found in Table 2, Table 3, Table 4, Table 7, Table 8 and Table 9.

Refer to the **Reagents and materials** section and **Precautions and handling requirements** section for the hazard information for the product.

cobas® SARS-CoV-2 & Influenza A/B reagents and controls

All unopened reagents and controls shall be stored as recommended in Table 1 to Table 4.

Table 1 cobas® SARS-CoV-2 & Influenza A/B

(SCoV2-FluA/B)

Store at 2-8°C
384 test cassette (P/N 09233474190)

Kit components	Reagent ingredients	Quantity per kit 384 tests
Proteinase Solution (PASE)	Tris buffer, < 0.05% EDTA, calcium chloride, calcium acetate, 8% proteinase, glycerol EUH210: Safety data sheet available on request. EUH208: Contains Subtilisin. May produce an allergic reaction.	38 mL
RNA Internal Control (RNA IC)	Tris buffer, <0.05% EDTA, <0.001% non-target related armored RNA construct containing primer and probe specific sequence regions (non-infectious RNA in MS2 bacteriophage), <0.1% sodium azide	38 mL
Elution Buffer (EB)	Tris buffer, 0.2% methyl-4 hydroxybenzoate	38 mL
Master Mix Reagent 1 (MMX-R1)	Manganese acetate, potassium hydroxide, < 0.1% sodium azide	14.5 mL
SCoV2-FluA/B Master Mix Reagent 2 (SCoV2-FluA/B MMX-R2)	Tricine buffer, potassium acetate, < 18% dimethyl sulfoxide, glycerol, < 0.1% Tween 20, EDTA, < 0.12% dATP, dCTP, dGTP, dUTPs, < 0.01% upstream and downstream SARS-CoV-2, Sarbecovirus, influenza A and influenza B primers, < 0.01% Internal Control forward and reverse primers, < 0.01% fluorescent-labeled oligonucleotide probes specific for SARS-CoV-2, Sarbecovirus, influenza A, influenza B and the RNA Internal Control, < 0.01% oligonucleotide aptamer, < 0.1% Z05D DNA polymerase, < 0.10% AmpErase (uracil-N-glycosylase) enzyme (microbial), < 0.1% sodium azide	17.5 mL

Table 2 cobas® SARS-CoV-2 & Influenza A/B Control Kit

(SCoV2-FluA/B (+)C)

Store at 2–8°C

(P/N 09233482190)

Kit components	Reagent ingredients	Quantity per kit
SCoV2-FluA/B Positive Control (SCoV2-FluA/B (+)C)	Tris buffer, < 0.05% Sodium azide, < 0.005% EDTA, < 0.003% Poly rA, < 0.01% Non-infectious plasmid DNA (microbial) containing SARS-CoV-2 sequence, < 0.01% Non-infectious plasmid DNA (microbial) containing pan-Sarbecovirus sequence, < 0.01% Non-infectious plasmid DNA (microbial) containing influenza A sequence, < 0.01% Non-infectious plasmid DNA (microbial) containing influenza B sequence	16 mL (16 x 1 mL)

Table 3 cobas® Buffer Negative Control Kit

(BUF (-) C)

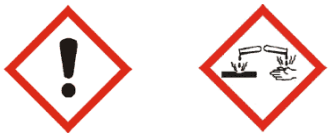
Store at 2-8°C

(P/N 07002238190)

Kit components	Reagent ingredients	Quantity per kit
cobas® Buffer Negative Control (BUF (-) C)	Tris buffer, < 0.1% sodium azide, EDTA, < 0.002% Poly rA RNA (synthetic)	16 mL (16 x 1mL)

cobas omni reagents for sample preparation

Table 4 **cobas omni** reagents for sample preparation*

Reagents	Reagent ingredients	Quantity per kit	Safety symbol and warning**
cobas omni MGP Reagent (MGP) Store at 2–8°C (P/N 06997546190)	Magnetic glass particles, Tris buffer, 0.1% methyl-4 hydroxybenzoate, < 0.1% sodium azide	480 tests	Not applicable
cobas omni Specimen Diluent (SPEC DIL) Store at 2–8°C (P/N 06997511190)	Tris buffer, 0.1% methyl-4 hydroxybenzoate, < 0.1% sodium azide	4 x 875 mL	Not applicable
cobas omni Lysis Reagent (LYS) Store at 2–8°C (P/N 06997538190)	43% (w/w) guanidine thiocyanate***, 5% (w/v) polydocanol***, 2% (w/v) dithiothreitol***, dihydro sodium citrate	4 x 875 mL	 **DANGER** H302 + H332: Harmful if swallowed or if inhaled. H314: Causes severe burns and eye damage. H412: Harmful to aquatic life with long lasting effects. EUH032: Contact with acids liberates very toxic gas. P261: Avoid breathing dust/fume/gas/mist/vapours/ spray. P273: Avoid release to the environment. P280: Wear protective gloves/ protective clothing/ eye protection/ face protection. P303 + P361 + P353: IF ON SKIN (or hair): Take off immediately all contaminated clothing. Rinse skin with water. P304 + P340 + P310: IF INHALED: Remove person to fresh air and keep comfortable for breathing. Immediately call a POISON CENTER/doctor. P305 + P351 + P338 + P310: IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing. Immediately call a POISON CENTER/ doctor. 593-84-0 Guanidinium thiocyanate 9002-92-0 Polidocanol 3483-12-3 (R*,R*)-1,4-dimercaptobutane-2,3-diol
cobas omni Wash Reagent (WASH) Store at 15–30°C (P/N 06997503190)	Sodium citrate dihydrate, 0.1% methyl-4 hydroxybenzoate	4.2 L	Not applicable

* These reagents are not included in the **cobas**® SARS-CoV-2 & Influenza A/B test kit. See listing of additional materials required (Table 7).

** Product safety labeling primarily follows EU GHS guidance

***Hazardous substance

Reagent storage and handling requirements

Reagents shall be stored and will be handled as specified in Table 5 and Table 6.

When reagents are not loaded on the **cobas**® 6800/8800 Systems, store them at the corresponding temperature specified in Table 5.

Table 5 Reagent storage (when reagent is not on the system)

Reagent	Storage temperature
cobas® SARS-CoV-2 & Influenza A/B - 384	2–8°C
cobas® SARS-CoV-2 & Influenza A/B Control Kit	2–8°C
cobas® Buffer Negative Control Kit	2–8°C
cobas omni Lysis Reagent	2–8°C
cobas omni MGP Reagent	2–8°C
cobas omni Specimen Diluent	2–8°C
cobas omni Wash Reagent	15–30°C

Reagents loaded onto the **cobas**® 6800/8800 Systems are stored at appropriate temperatures and their expiration is monitored by the system. The **cobas**® 6800/8800 Systems allow reagents to be used only if all of the conditions shown in Table 6 are met. The system automatically prevents use of expired reagents. Table 6 allows the user to understand the reagent handling conditions enforced by the **cobas**® 6800/8800 Systems.

Table 6 Reagent expiry conditions enforced by the **cobas**® 6800/8800 Systems

Reagent	Kit expiration date	Open-kit stability	Number of runs for which this kit can be used	On-board stability (cumulative time on board outside refrigerator)
cobas® SARS-CoV-2 & Influenza A/B - 384	Date not passed	90 days from first usage[a]	Max 40 runs[a]	Max 40 hours[a]
cobas® SARS-CoV-2 & Influenza A/B Control Kit	Date not passed	Not applicable[b]	Not applicable	Max 8 hours
cobas® Buffer Negative Control Kit	Date not passed	Not applicable[b]	Not applicable	Max 10 hours
cobas omni Lysis Reagent	Date not passed	30 days from loading[c]	Not applicable	Not applicable
cobas omni MGP Reagent	Date not passed	30 days from loading[c]	Not applicable	Not applicable
cobas omni Specimen Diluent	Date not passed	30 days from loading[c]	Not applicable	Not applicable
cobas omni Wash Reagent	Date not passed	30 days from loading[c]	Not applicable	Not applicable

[a]The performance has not been established for suggested use cycles and time, but is based on similar reagents used on the same system.

[b]Single use reagents

[c]Time is measured from the first time that reagent is loaded onto the **cobas**® 6800/8800 Systems.

Additional materials required

Table 7 Materials and consumables for use on **cobas**® 6800/8800 Systems

Material	P/N
cobas omni Processing Plate	05534917001
cobas omni Amplification Plate	05534941001
cobas omni Pipette Tips	05534925001
cobas omni Liquid Waste Container	07094388001
cobas omni Lysis Reagent	06997538190
cobas omni MGP Reagent	06997546190
cobas omni Specimen Diluent	06997511190
cobas omni Wash Reagent	06997503190
Solid Waste Bag and Solid Waste Container or Solid Waste Bag With Insert and Kit Drawer	07435967001 and 07094361001 or 08030073001 and 08387281001
cobas omni Secondary Tubes 13x75 (optional)	06438776001
cobas® PCR Media Tube Replacement Cap Kit	07958056190
cobas® PCR Media Disposable Tube Stand (Optional)	07958064190
MPA RACK 16 MM LIGHT GREEN 7001-7050*,**	03143449001
RD5 RACK – RD Standard rack 0001-0050 LR*,**	11902997001

* MPA 16mm and RD5 racks are required to use **cobas**® SARS-COV-2 & Influenza A/B only for samples collected in **cobas**® PCR Media tubes. Contact your local Roche representative for a detailed order list for sample racks, racks for clotted tips and rack trays accepted on the instruments.

MPA 16mm rack is the preferred rack for use with samples collected in **cobas® PCR Media tubes. If RD5 racks are used, make sure to fill in the sample tubes with not less than the recommended minimum sample input. The tubes sit higher in an RD5 rack because of the rubber gasket at the bottom of each tube position. Therefore, it is possible that when using RD5 racks, the system could accept tubes that are below the minimum sample input volume and cause pipetting errors later in the run.

Table 8 Alternative specimen collection kits used with **cobas**® SARS-CoV-2 & Influenza A/B

Collection Kit	P/N
cobas® PCR Media Uni Swab Sample Kit	07958030190
cobas® PCR Media Dual Swab Sample Kit	07958021190
cobas® PCR Media 100 tube kit	06466281190
cobas® Uni Swab 100 Kit	09205098190

Instrumentation and software required

The **cobas**® 6800/8800 software and **cobas**® SARS-CoV-2 & Influenza A/B analysis package must be installed on the instrument(s). The Instrument Gateway (IG) server will be provided with the system.

Table 9 Instrumentation

Equipment	P/N
cobas® 6800 System (Moveable Platform)	05524245001 and 06379672001
cobas® 6800 System (Fixed Platform)	05524245001 and 06379664001
cobas® 8800 System	05412722001
Sample Supply Module	06301037001
Instrument Gateway	06349595001

For additional information, please refer to the **cobas**® 6800/8800 Systems – User Assistance and/or User Guide.

Note: Contact your local Roche representative for a detailed order list for sample racks, racks for clotted tips and rack trays accepted on the instruments.

Precautions and handling requirements

Warnings and precautions

As with any test procedure, good laboratory practice is essential to the proper performance of this assay. Due to the high sensitivity of this test, care should be taken to keep reagents and amplification mixtures free of contamination.

- For in vitro diagnostic use under Food and Drug Administration's Emergency Use Authorization only.
- The **cobas**® SARS-COV-2 & Influenza A/B has not been FDA cleared or approved.
- The **cobas**® SARS-COV-2 & Influenza A/B has been authorized by FDA under an Emergency Use Authorization (EUA) for use by laboratories certified under the Clinical Laboratory Improvement Amendments (CLIA) of 1988, 42 U.S.C. §263a, that meet requirements to perform moderate or high complexity tests.
- The **cobas**® SARS-COV-2 & Influenza A/B has been authorized only for the detection of nucleic acid from SARS-CoV-2, influenza A virus, and influenza B virus, not for any other viruses or pathogens.
- The **cobas**® SARS-COV-2 & Influenza A/B 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 Federal Food, Drug, and Cosmetic Act, 21 U.S.C. § 360bbb-3(b)(1), unless the authorization is terminated or revoked sooner.
- Results (positive and negative) for influenza should be interpreted with caution. If an influenza result is inconsistent with clinical presentation and/or other clinical and epidemiological information, FDA-cleared Influenza NAATs are available for confirmation if clinically indicated.
- Laboratories within the United States and its territories are required to report all SARS-CoV-2 results to the appropriate public health authorities.
- All patient samples should be handled as if infectious, using good laboratory procedures as outlined in Biosafety in Microbiological and Biomedical Laboratories and in the CLSI Document M29-A4.[1,2] Only personnel proficient in handling infectious materials and the use of **cobas**® SARS-CoV-2 & Influenza A/B and **cobas**® 6800/8800 Systems should perform this procedure.
- All human-sourced materials should be considered potentially infectious and should be handled with universal precautions. If spillage occurs, immediately disinfect with a freshly prepared solution of 0.5% sodium hypochlorite in distilled or deionized water (dilute household bleach 1:10) or follow appropriate site procedures.
- The use of sterile disposable pipettes and nuclease-free pipette tips is recommended. Use only supplied or specified required consumables to ensure optimal test performance.
- Safety Data Sheets (SDS) are available on request from your local Roche representative.
- Closely follow procedures and guidelines provided to ensure that the test is performed correctly. Any deviation from the procedures and guidelines may affect optimal test performance.
- False positive results may occur if carryover of samples is not adequately controlled during sample handling and processing.

Reagent handling

- Handle all reagents, controls, and samples according to good laboratory practice in order to prevent carryover of samples or controls.
- Before use, visually inspect each reagent cassette, diluent, lysis reagent, and wash reagent to ensure that there are no signs of leakage. If there is any evidence of leakage, do not use that material for testing.
- **cobas omni** Lysis Reagent contains guanidine thiocyanate, a potentially hazardous chemical. Avoid contact of reagents with the skin, eyes, or mucous membranes. If contact does occur, immediately wash with generous amounts of water; otherwise, burns can occur.
- **cobas**® SARS-CoV-2 & Influenza A/B test kit, **cobas**® SARS-CoV-2 & Influenza A/B Control kit, **cobas**® Buffer Negative Control kit, **cobas omni** MGP Reagent, and **cobas omni** Specimen Diluent contain sodium azide as a preservative. Avoid contact of reagents with the skin, eyes, or mucous membranes. If contact does occur, immediately wash with generous amounts of water; otherwise, burns can occur. If these reagents are spilled, dilute with water before wiping dry.
- Do not allow **cobas omni** Lysis Reagent, which contains guanidine thiocyanate, to contact sodium hypochlorite (bleach) solution. This mixture can produce a highly toxic gas.
- Dispose of all materials that have come in contact with samples and reagents in accordance with country, state, and local regulations.

Good laboratory practice

- Do not pipette by mouth.
- Do not eat, drink, or smoke in designated work areas.
- Wear laboratory gloves, laboratory coats, and eye protection when handling samples and reagents. Gloves must be changed between handling samples and **cobas**® SARS-CoV-2 & Influenza A/B kits, **cobas**® SARS-CoV-2 & Influenza A/B Control kit, **cobas**® Buffer Negative Control kit and **cobas omni** reagents to prevent contamination. Avoid contaminating gloves when handling samples and controls.
- Wash hands thoroughly after handling samples and kit reagents, and after removing the gloves.
- Thoroughly clean and disinfect all laboratory work surfaces with a freshly prepared solution of 0.5% sodium hypochlorite in distilled or deionized water (dilute household bleach 1:10). Follow by wiping the surface with 70% ethanol.
- If spills occur on the **cobas**® 6800/8800 instrument, follow the instructions in the **cobas**® 6800/8800 Systems – User Assistance and/or User Guide to properly clean and decontaminate the surface of instrument(s).

Sample collection, transport, and storage

Note: Handle all samples and controls as if they are capable of transmitting infectious agents.

Sample collection

Table 10 summarizes what collection devices can be used with specific sample types.

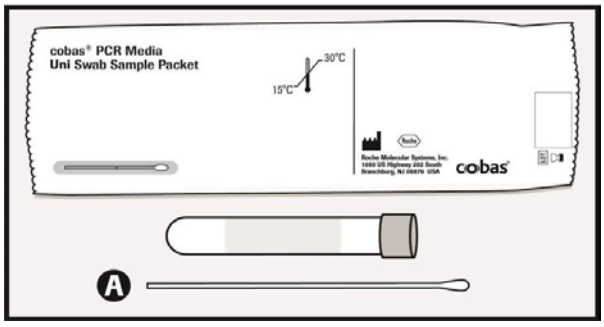
Table 10 Overview of collection devices and sample types

Collection Device	Nasopharyngeal	Nasal
Copan Universal Transport Media (UTM-RT®)	√	√
BD™ Universal Viral Transport (UVT)	√	√
0.9% Physiological Saline		√
cobas® PCR Media Uni Swab Sample Kit		√
cobas® PCR Media Dual Swab Sample Kit		√
cobas® PCR Media Kit (and 100 tube PCR Media Kit)		√

- Collect nasal and nasopharyngeal specimens according to standard collection technique using flocked or polyester-tipped swabs and immediately place in 3 mL of Copan Universal Transport Medium (UTM-RT®) or BD™ Universal Viral Transport (UVT) or equivalent.
- Collect nasal specimens according to standard collection technique using flocked or polyester-tipped swabs and immediately place into **cobas**® PCR Media tube from **cobas**® PCR Media Kit (P/N 06466281190).
- Collect nasal specimens using the **cobas**® PCR Media Uni Swab Sample Kit (P/N 07958030190) or **cobas**® PCR Media Dual Swab Sample Kit (P/N 07958021190) according to instructions below.
- Refer to the Instructions for Use of the Collection Devices for hazard information.

Nasal (anterior nares) swab specimen collection – healthcare worker or self-collected on site

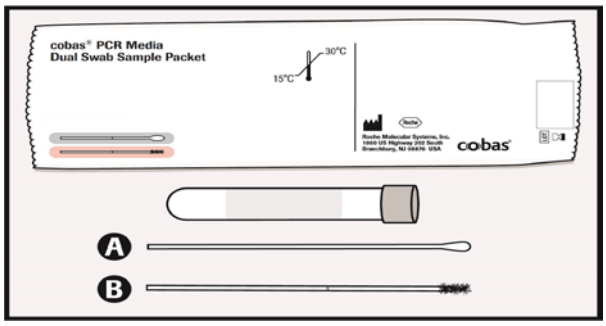
WARNING: DO NOT PRE-WET SWAB IN cobas® PCR MEDIA BEFORE COLLECTION!



The **cobas®** PCR Media Uni Swab Sample kit contains:

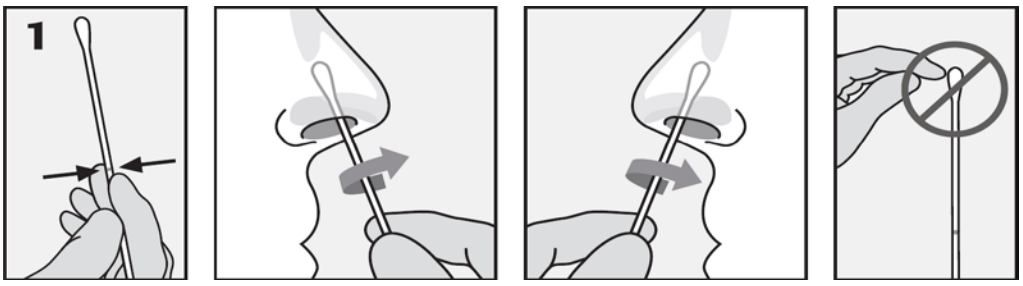
cobas® PCR Media Tube
Woven Swab: A

OR



The **cobas®** PCR Media Dual Swab Sample kit contains:

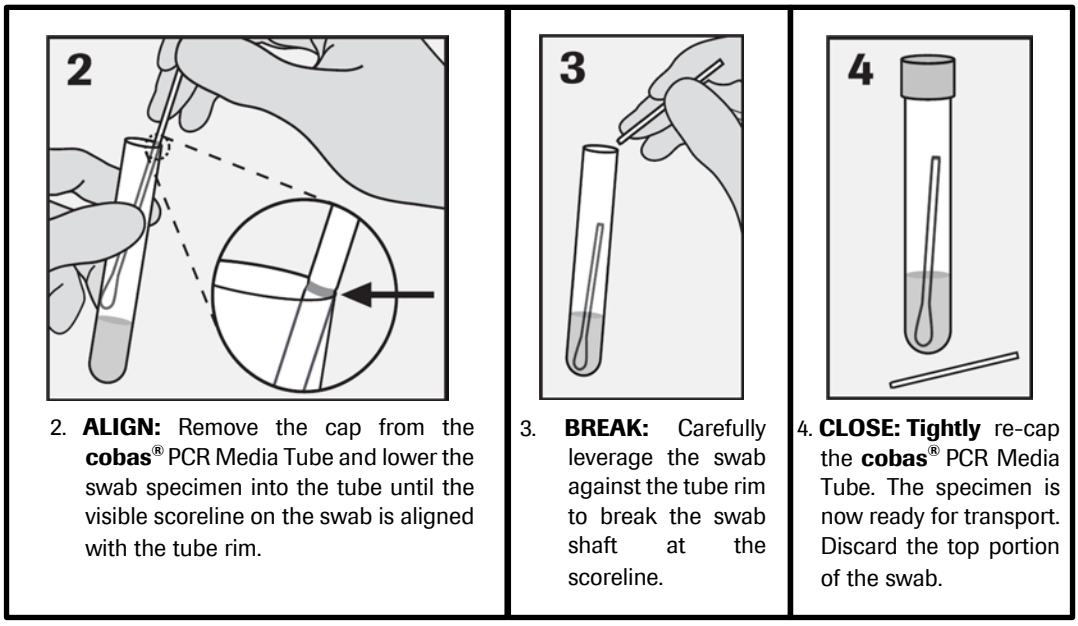
cobas® PCR Media Tube
Woven Swab: A
Flocked Swab: B



DO NOT PRE-WET SWAB IN cobas® PCR MEDIA BEFORE COLLECTION!

1. **COLLECT:** Hold the woven swab (Swab A) or the flocked swab (Swab B) with the scoreline above your hand. Insert the swab 1–2 cm into one of the anterior nares. Rotate the swab against the nasal mucosa for about 3 seconds and withdraw. Repeat with the other anterior nare using the same swab.

   Do not let the swab touch any surface before placing it into the collection tube.



2. **ALIGN:** Remove the cap from the **cobas**® PCR Media Tube and lower the swab specimen into the tube until the visible scoreline on the swab is aligned with the tube rim.

3. **BREAK:** Carefully leverage the swab against the tube rim to break the swab shaft at the scoreline.

4. **CLOSE: Tightly** re-cap the **cobas**® PCR Media Tube. The specimen is now ready for transport. Discard the top portion of the swab.

- Collect nasal specimens according to standard collection technique using flocked or polyester-tipped swabs and immediately place in 3 mL of 0.9% physiological saline.

Transport and storage

- Transportation of collected specimens must comply with all applicable regulations for the transport of etiologic agents.
- Samples collected in UTM-RT®,
  - After collection, specimens can be stored for up to 48 hours at 2-25°C followed by up to 3 days at 2-8°C.
- Samples collected in **cobas**® PCR Media,
  - After collection, specimens can be stored for up to 24 hours at 2-25°C followed by up to 3 days at 2-8°C.
- Samples collected in 0.9% physiological saline,
  - After collection, specimens can be stored for up to 48 hours at 2-25°C followed by up to 3 days at 2-8°C.
- If delivery and processing of samples exceeds specified time periods, specimens should be transported in dry ice and once in laboratory frozen at -70°C or colder.

Instructions for use

Procedural notes

- Do not use **cobas**® SARS-CoV-2 & Influenza A/B reagents, **cobas**® SARS-CoV-2 & Influenza A/B Control Kit, **cobas**® Buffer Negative Control Kit, or **cobas omni** reagents after their expiry dates.
- Do not reuse consumables. They are for one-time use only.
- Ensure that specimen barcode labels on sample tubes are visible through the openings on the side of the sample racks. Refer to the **cobas**® 6800/8800 Systems User Guide for proper barcode specifications and additional information on loading sample tubes.
- Refer to the **cobas**® 6800/8800 Systems – User Assistance and/or User Guide for proper maintenance of instruments.

Running cobas® SARS-CoV-2 & Influenza A/B

cobas® SARS-CoV-2 & Influenza A/B can be run with a minimum required sample volume of 0.6 mL in the **cobas omni** secondary tube for specimens collected in Copan Universal Transport Medium (UTM-RT®), BD™ Universal Viral Transport (UVT), **cobas**® PCR Media or 0.9% physiological saline. Specimens collected using **cobas**® PCR Media Uni Swab Sample Kit or **cobas**® PCR Media Dual Swab Sample Kit can be run in their primary collection tube with a minimum required sample volume of 1.0 mL.

Specimens collected in cobas® PCR Media, 0.9% physiological saline, UTM-RT® or UVT

Specimens collected in Copan Universal Transport Medium (UTM-RT®), BD™ Universal Viral Transport (UVT), **cobas**® PCR Media or 0.9% physiological saline must be transferred into a **cobas omni** Secondary tube prior to processing on the **cobas**® 6800/8800 Systems. Samples transferred to **cobas omni** Secondary tubes should be processed using the 'VTM' sample type selection in the user interface (UI) of the **cobas**® SARS-CoV-2 & Influenza A/B as described in Table 11.

Always use caution when transferring specimens from a primary collection tube to a secondary tube.

Use pipettes with aerosol-barrier or positive-displacement tips to handle specimens.

Always use a new pipette tip for each specimen.

Ensure samples are equilibrated to room temperature prior to transfer into a cobas omni Secondary Tube.

Follow the steps below to transfer patient sample from a primary collection tube into a **cobas omni** Secondary Tube:

- Unscrew the primary sample tube cap.
- Lift the cap and any attached swab to allow a pipette to be inserted into the sample tube.
- Transfer 0.6 mL into the prepared barcoded secondary tube.
- Transfer secondary tube to a rack. Close the primary sample tube cap.

Specimens collected using cobas® PCR Media Uni or Dual Swab Sample Kit

Samples collected using **cobas**® PCR Media Uni Swab Sample Kit or **cobas**® PCR Media Dual Swab Sample Kit must be uncapped and can be loaded directly onto racks for processing on the **cobas**® 6800/8800 Systems. Transfer into a secondary tube is not necessary. **cobas**® PCR Media tubes fit on to the MPA RACK 16 MM LIGHT GREEN 7001-7050 (P/N 03143449001) and can be processed with the swab remaining in the tube. Samples collected using **cobas**® PCR Media Uni Swab Sample Kit or **cobas**® PCR Media Dual Swab Sample Kits should be processed using the '**cobas**® PCR Media swab' sample type selection in the user interface (UI) of the **cobas**® SARS-CoV-2 & Influenza A/B as described in Table 11.

A properly collected swab specimen should have a single swab with the shaft broken at the scoreline. Swab shafts which are broken above the score line will appear longer than normal and may also be bent over to fit into the **cobas**® PCR Media tube. This may create an obstruction to the pipetting system which might cause the loss of sample, test results and/or mechanical damage to the instrument. In the event that a swab specimen has an improperly broken shaft, remove the swab prior to sample processing on the **cobas**® 6800/8800 Systems. Use caution when disposing of specimen swabs; avoid splashing or touching swabs to other surfaces during disposal to prevent contamination.

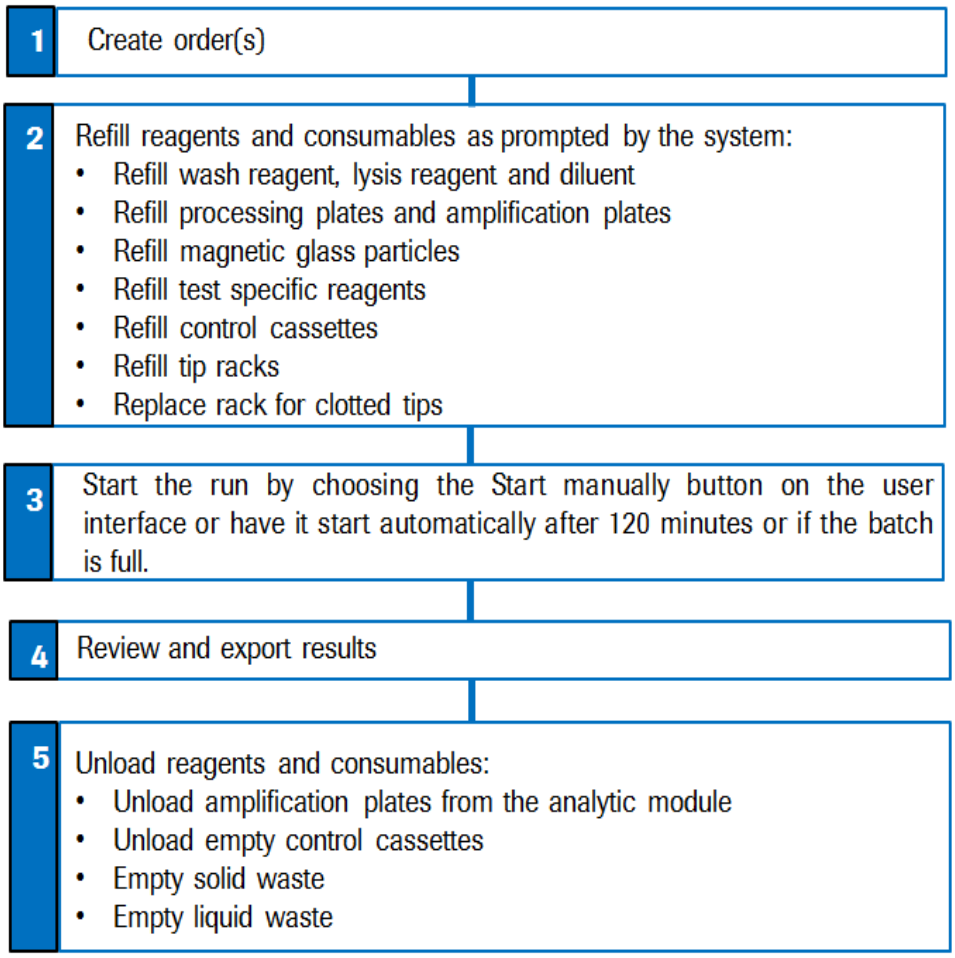
Incoming **cobas**® PCR Media primary swab specimen tubes with no swabs or with two swabs have not been collected according to the instructions in their respective collection kit IFU and should not be tested. If the sample containing two swabs in the **cobas**® PCR Media primary tubes must be tested, transfer 0.6 mL into the prepared barcoded secondary tube.

Occasionally, incoming swab specimens contain excessive mucus which may induce a pipetting error (e.g., clot or other obstruction) on the **cobas**® 6800/8800 Systems. Prior to retesting of specimens that exhibited clots during initial processing, remove and discard the swab, then re-cap and vortex these specimens for 30 seconds to disperse the excess mucus. Swab specimens can be processed twice on the **cobas**® 6800/8800 Systems while the swab is in the collection tube. If additional testing is required, or if the first test fails due to specimen pipetting error (e.g., clot or other obstruction), the swab must be removed and the remaining fluid must have a minimum volume of 1.0 mL. The test procedure is described in detail in the **cobas**® 6800/8800 Systems – User Assistance and/or User Guide. Figure 1 below summarizes the procedure.

Table 11 Sample type selection in the user interface of the **cobas**® SARS-CoV-2 & Influenza A/B

Collection kit/Matrix type	**Minimum volume (mL)** **Processing tube**	**Process as Sample Type**
Copan Universal Transport Medium BD™ Universal Viral Transport 0.9% physiological saline **cobas**® PCR Media Kit	0.6 mL **cobas omni** Secondary tube	**VTM**
cobas® PCR Media Uni or Dual Swab Sample Kit	1.0 mL Primary tube	**cobas**® **PCR Media swab**

Figure 1 **cobas**® SARS-CoV-2 & Influenza A/B procedure



Results

The **cobas**® 6800/8800 Systems automatically detects the SARS-CoV-2, influenza A and influenza B, for each individually processed sample and control, displaying individual target results for samples as well as test validity and overall results for controls.

Quality control and validity of results

- One **cobas**® Buffer Negative Control [(-) Ctrl] and one (SCoV2-FluA/B (+) C) are processed with each batch.
- In the **cobas**® 6800/8800 software and/or report, check for flags and their associated results to ensure the batch validity.
- All flags are described in the **cobas**® 6800/8800 Systems User Guide.
- The batch is valid if no flags appear for any controls. If the batch is invalid, repeat testing of the entire batch.

Validation of results is performed automatically by the **cobas**® 6800/8800 software based on negative and positive control performance.

Interpretation of results

cobas® SARS-CoV-2 & Influenza A/B for System Software v1.2

Display examples for **cobas**® SARS-CoV-2 & Influenza A/B for System Software v1.2 are shown in Figure 2.

Figure 2 Example of **cobas**® SARS-CoV-2 & Influenza A/B results display for System Software v1.2

Test	Sample ID	Valid*	Flags	Sample type	Overall result*	Target 1	Target 2	Target 3	Target 4
SCoV2-FluA/B 400 µL	Sample_01	Yes		VTM	**Negative**	FluA Negative	SCoV2 Negative	PanSarb Negative	FluB Negative
SCoV2-FluA/B 400 µL	Sample _02	No	Y40T	VTM	**Invalid**	Invalid	Invalid	Invalid	Invalid
SCoV2-FluA/B 400 µL	Sample _03	Yes		VTM	**Positive**	FluA Positive	SCoV2 Negative	PanSarb Negative	FluB Negative
SCoV2-FluA/B 400 µL	Sample _04	Yes		VTM	**Positive**	FluA Negative	SCoV2 Positive	PanSarb Positive	FluB Negative
SCoV2-FluA/B 400 µL	Sample _05	Yes		VTM	**Positive**	FluA Negative	SCoV2 Negative	PanSarb Negative	FluB Positive
SCoV2-FluA/B 400 µL	Sample _06	Yes		VTM	**Positive**	FluA Negative	SCoV2 Negative	PanSarb Positive	FluB Negative
SCoV2-FluA/B 400 µL	Sample _07	No	C01H2	VTM	**Invalid**	FluA Positive	Invalid	Invalid	Invalid
SCoV2-FluA/B 400 µL	Sample _08	No	C01H1	VTM	**Invalid**	Invalid	SCoV2 Positive	Invalid	FluB Positive
SCoV2-FluA/B	C161420284090428828404	Yes		(-) Ctrl	**Valid**	Valid	Valid	Valid	Valid
SCoV2-FluA/B	C161420284093009580264	Yes		SCoV2-FluA/B (+) C	**Valid**	Valid	Valid	Valid	Valid

* The "Valid" and "Overall Result" columns are not applicable to sample results for **cobas**® SARS-CoV-2 & Influenza A/B. Values reported in these columns are not applicable and do not impact the validity of results reported within individual Target Result columns. Refer to Table 12, **cobas**® SARS-CoV-2 & Influenza A/B results interpretation, for specific instructions on test results interpretation.

cobas® SARS-CoV-2 & Influenza A/B for System Software v1.3 or higher

Display examples for **cobas**® SARS-CoV-2 & Influenza A/B for System Software v1.3 or higher are shown in Figure 3.

Figure 3 Example of **cobas**® SARS-CoV-2 & Influenza A/B results display for System Software v1.3 or higher

Test	Sample ID	Valid*	Flags	Sample type	Overall result*	Target 1	Target 2	Target 3	Target 4
SCoV2-FluA/B 400 µL	Sample_01	NA		VTM	**NA**	FluA Negative	SCoV2 Negative	PanSarb Negative	FluB Negative
SCoV2-FluA/B 400 µL	Sample _02	NA	Y40T	VTM	**NA**	Invalid	Invalid	Invalid	Invalid
SCoV2-FluA/B 400 µL	Sample _03	NA		VTM	**NA**	FluA Positive	SCoV2 Negative	PanSarb Negative	FluB Negative
SCoV2-FluA/B 400 µL	Sample _04	NA		VTM	**NA**	FluA Negative	SCoV2 Positive	PanSarb Positive	FluB Negative
SCoV2-FluA/B 400 µL	Sample _05	NA		VTM	**NA**	FluA Negative	SCoV2 Negative	PanSarb Negative	FluB Positive
SCoV2-FluA/B 400 µL	Sample _06	NA		VTM	**NA**	FluA Negative	SCoV2 Negative	PanSarb Positive	FluB Negative
SCoV2-FluA/B 400 µL	Sample _07	NA	C01H2	VTM	**NA**	FluA Positive	Invalid	Invalid	Invalid
SCoV2-FluA/B 400 µL	Sample _08	NA	C01H1	VTM	**NA**	Invalid	SCoV2 Positive	Invalid	FluB Positive
SCoV2-FluA/B	C161420284090428828404	Yes		(-) Ctrl	**Valid**	Valid	Valid	Valid	Valid
SCoV2-FluA/B	C161420284093009580264	Yes		SCoV2-FluA/B (+) C	**Valid**	Valid	Valid	Valid	Valid

* The "Valid" and "Overall Result" columns are not applicable to sample results for **cobas**® SARS-CoV-2 & Influenza A/B. Values reported in these columns are not applicable and do not impact the validity of results reported within individual Target Result columns. Refer to Table 12, **cobas**® SARS-CoV-2 & Influenza A/B results interpretation, for specific instructions on test results interpretation.

Interpretation of results

The following result interpretation applies to both **cobas**® 6800/8800 software version 1.2 and **cobas**® 6800/8800 software version 1.3 and higher.

For a valid batch, check each individual sample for flags in the **cobas**® 6800/8800 software and/or report. The result interpretation should be as follows:

- A valid batch may include both valid and invalid sample results.
- **The "Valid" and "Overall Result" columns are not applicable to sample results for the cobas® SARS-CoV-2 & Influenza A/B. Values reported in these columns are not applicable and do not impact the validity of results reported within individual Target Result columns.**
- Invalid results for one or more target combinations are possible and are reported out specifically for each target. If any individual target result is invalid, the presence or absence of that individual target cannot be determined.
- Other initial valid target results can be interpreted as described in the table. Results and their corresponding interpretation for detecting SARS-CoV-2 & Influenza A/B are shown below (Table 12).

Table 12 cobas® SARS-CoV-2 & Influenza A/B results interpretation

Target 1 Influenza A*	Target 2 SARS-CoV-2	Target 3 Pan-Sarbecovirus	Target 4 Influenza B*	Interpretation
Negative	Negative	Negative	Negative	No target RNA Detected
Negative	Negative	Negative	Positive	Influenza B RNA Detected
Positive	Negative	Negative	Negative	Influenza A RNA Detected
Positive	Negative	Negative	Positive	Influenza A and Influenza B RNA Detected
Negative	Negative	Positive	Negative	Presumptive Positive for SARS-CoV-2 RNA. A negative SARS-CoV-2 result and a positive pan-Sarbecovirus results is suggestive of 1) a sample at concentrations near or below the limit of detection of the test, 2) a mutation in the SARS-CoV-2 target region in the oligo binding site, 3) infection with some other Sarbecovirus (e.g., SARS-CoV or some other Sarbecovirus previously unknown to infect humans), or 4) other factors. For samples with a Presumptive Positive result, additional confirmatory testing may be conducted, if it is necessary to differentiate between SARS-CoV-2 and SARS-CoV-1 or other Sarbecovirus currently unknown to infect humans, for epidemiological purposes or clinical management.
Negative	Negative	Positive	Positive	Presumptive Positive for SARS-CoV-2 RNA and Influenza B RNA Detected. A negative SARS-CoV-2 result and a positive pan-Sarbecovirus results is suggestive of 1) a sample at concentrations near or below the limit of detection of the test, 2) a mutation in the SARS-CoV-2 target region in the oligo binding site, 3) infection with some other Sarbecovirus (e.g., SARS-CoV or some other Sarbecovirus previously unknown to infect humans), or 4) other factors. For samples with a Presumptive Positive result, additional confirmatory testing may be conducted, if it is necessary to differentiate between SARS-CoV-2 and SARS-CoV-1 or other Sarbecovirus currently unknown to infect humans, for epidemiological purposes or clinical management.
Positive	Negative	Positive	Negative	Influenza A RNA Detected and Presumptive Positive for SARS-CoV-2 RNA. A negative SARS-CoV-2 result and a positive pan-Sarbecovirus results is suggestive of 1) a sample at concentrations near or below the limit of detection of the test, 2) a mutation in the SARS-CoV-2 target region in the oligo binding site, 3) infection with some other Sarbecovirus (e.g., SARS-CoV or some other Sarbecovirus previously unknown to infect humans), or 4) other factors. For samples with a Presumptive Positive result, additional confirmatory testing may be conducted, if it is necessary to differentiate between SARS-CoV-2 and SARS-CoV-1 or other Sarbecovirus currently unknown to infect humans, for epidemiological purposes or clinical management.
Positive	Negative	Positive	Positive	Influenza A RNA Detected, Presumptive Positive for SARS-CoV-2 RNA, and Influenza B RNA Detected. A negative SARS-CoV-2 result and a positive pan-Sarbecovirus results is suggestive of 1) a sample at concentrations near or below the limit of detection of the test, 2) a mutation in the SARS-CoV-2 target region in the oligo binding site, 3) infection with some other Sarbecovirus (e.g., SARS-CoV or some other Sarbecovirus previously unknown to infect humans), or 4) other factors. For samples with a Presumptive Positive result, additional confirmatory testing may be conducted, if it is necessary to differentiate between SARS-CoV-2 and SARS-CoV-1 or other Sarbecovirus currently unknown to infect humans, for epidemiological purposes or clinical management.

Target 1 Influenza A*	Target 2 SARS-CoV-2	Target 3 Pan-Sarbecovirus	Target 4 Influenza B*	Interpretation
Negative	Positive	Negative	Negative	SARS-CoV-2 RNA Detected. A positive SARS-CoV-2 result and a negative pan-Sarbecovirus results is suggestive of 1) a sample at concentrations near or below the limit of detection of the test, 2) a mutation in the pan-Sarbecovirus target region, or 3) other factors.
Negative	Positive	Negative	Positive	SARS-CoV-2 RNA and Influenza B RNA Detected. A positive SARS-CoV-2 result and a negative pan-Sarbecovirus results is suggestive of 1) a sample at concentrations near or below the limit of detection of the test, 2) a mutation in the pan-Sarbecovirus target region, or 3) other factors.
Positive	Positive	Negative	Negative	Influenza A RNA and SARS-CoV-2 RNA Detected. A positive SARS-CoV-2 result and a negative pan-Sarbecovirus results is suggestive of 1) a sample at concentrations near or below the limit of detection of the test, 2) a mutation in the pan-Sarbecovirus target region, or 3) other factors.
Positive	Positive	Negative	Positive	Influenza A RNA, SARS-CoV-2 RNA, and Influenza B RNA Detected. A positive SARS-CoV-2 result and a negative pan-Sarbecovirus results is suggestive of 1) a sample at concentrations near or below the limit of detection of the test, 2) a mutation in the pan-Sarbecovirus target region, or 3) other factors.
Negative	Positive	Positive	Negative	SARS-CoV-2 RNA Detected
Negative	Positive	Positive	Positive	SARS-CoV-2 RNA and Influenza B RNA Detected
Positive	Positive	Positive	Negative	Influenza A RNA and SARS-CoV-2 RNA Detected
Positive	Positive	Positive	Positive	Influenza A RNA, SARS-CoV-2 RNA, and Influenza B RNA Detected

If any individual target result is invalid, the presence or absence of that individual target cannot be determined. Other initial valid target results can be interpreted as described in the table.

* Results (positive and negative) for influenza should be interpreted with caution. If an influenza result is inconsistent with clinical presentation and/or other clinical and epidemiological information, FDA-cleared Influenza NAATs are available for confirmation if clinically indicated.

Procedural limitations

- **cobas**® SARS-CoV-2 & Influenza A/B has been evaluated only for use in combination with the **cobas**® SARS-CoV-2 & Influenza A/B Control Kit, **cobas**® Buffer Negative Control Kit, **cobas omni** MGP Reagent, **cobas omni** Lysis Reagent, **cobas omni** Specimen Diluent, and **cobas omni** Wash Reagent for use on the **cobas**® 6800/8800 Systems.
- Reliable results depend on proper sample collection, storage and handling procedures.
- This test is intended to be used for the detection of SARS-CoV-2, Influenza A, and Influenza B RNA in nasopharyngeal and nasal swab samples collected in a Copan Universal Transport Medium (UTM-RT®) or BD™ Universal Viral Transport System (UVT), and nasal swab samples collected in **cobas**® PCR Media and 0.9% physiological saline. Testing of other sample types with **cobas**® SARS-CoV-2 & Influenza A/B may result in inaccurate results.
- Detection of SARS-CoV-2 and Influenza A/B RNA may be affected by sample collection methods, patient factors (e.g., presence of symptoms), and/or stage of infection.
- As with any molecular test, mutations within the target regions of **cobas**® SARS-CoV-2 & Influenza A/B could affect primer and/or probe binding resulting in failure to detect the presence of virus.
- Due to inherent differences between technologies, it is recommended that, prior to switching from one technology to the next, users perform method correlation studies in their laboratory to qualify technology differences. One hundred percent agreement between the results should not be expected due to aforementioned differences between technologies. Users should follow their own specific policies/procedures.
- False negative or invalid results may occur due to interference. The Internal Control is included in **cobas**® SARS-CoV-2 & Influenza A/B to help identify the specimens containing substances that may interfere with nucleic acid isolation and PCR amplification.
- The addition of AmpErase enzyme into the **cobas**® SARS-CoV-2 & Influenza A/B Master Mix reagent enables selective amplification of target RNA; however, good laboratory practices and careful adherence to the procedures specified in this Instructions For Use document are necessary to avoid contamination of reagents.
- Results (positive and negative) for influenza should be interpreted with caution. If an influenza result is inconsistent with clinical presentation and/or other clinical and epidemiological information, FDA-cleared Influenza NAATs are available for confirmation if clinically indicated.
- The performance of this test was established based on the evaluation of a limited number of clinical specimens. The clinical performance has not been established in all circulating variants but is anticipated to be reflective of the prevalent variants in circulation at the time and location of the clinical evaluation. Performance at the time of testing may vary depending on the variants circulating, including newly emerging strains of SARS-CoV-2 and their prevalence, which change over time.

Conditions of Authorizations for Labs

The **cobas**® SARS-CoV-2 & Influenza A/B Letter of Authorization, along with the authorized Fact Sheet for Healthcare Providers, the authorized Fact Sheet for Patients, and authorized labeling are available on the FDA website: https://www.fda.gov/medical-devices/coronavirus-disease-2019-covid-19-emergency-useauthorizations-medical-devices/vitro-diagnostics-euas.
However, to assist clinical laboratories using the **cobas**® SARS-CoV-2 & Influenza A/B ("your product" in the conditions below), the relevant Conditions of Authorization are listed below:

A. Authorized laboratories using this product[1] will include with test result reports, all authorized Fact Sheets. Under exigent circumstances, other appropriate methods for disseminating these Fact Sheets may be used, which may include mass media.
B. Authorized laboratories using this product will use this product as outlined in the authorized labeling. Deviations from the authorized procedures, including the authorized instruments, authorized extraction methods, authorized clinical specimen types, authorized control materials, authorized other ancillary reagents and authorized materials required to use this product are not permitted.
C. Authorized laboratories that receive this product will notify the relevant public health authorities of their intent to run this product prior to initiating testing.
D. Authorized laboratories using this product will have a process in place for reporting test results to healthcare providers and relevant public health authorities, as appropriate.
E. Authorized laboratories will collect information on the performance of this product and report to DMD/OHT7-OIR/OPEQ/CDRH (via email: CDRH-EUA-Reporting@fda.hhs.gov) and Roche Diagnostics US Customer Technical Support (via telephone number 1-800-526-1247) any suspected occurrence of false positive or false negative results and significant deviations from the established performance characteristics of this product of which they become aware.
F. All laboratory personnel using this product must be appropriately trained in RT-PCR techniques, the specific processes and instruments used in the **cobas**® SARS-CoV-2 & Influenza A/B, and use appropriate laboratory and personal protective equipment when handling this kit, and use this product in accordance with the authorized labeling.
G. Roche Molecular Systems, authorized distributors, and authorized laboratories using this product will ensure that any records associated with this EUA are maintained until otherwise notified by FDA. Such records will be made available to FDA for inspection upon request.

[1] "This product" refers to the **cobas**® SARS-CoV-2 & Influenza A/B. The letter of authorization refers to, "Laboratories certified under the Clinical Laboratory Improvement Amendments of 1988 (CLIA), 42 U.S.C. §263a, that meet requirements to perform moderate or high complexity tests" as "authorized laboratories."

Non-clinical performance evaluation

Key performance characteristics

Analytical sensitivity (Limit of Detection)

The LoD study determines the lowest detectable concentration of SARS-CoV-2, influenza A, and influenza B at which greater or equal to 95% of all (true positive) replicates test positive.

To determine the LoD, six cultured viruses – two each of influenza A and influenza B strains as well as the live and the heat-inactivated form of SARS-CoV-2 isolate from a US patient – were serially diluted in simulated clinical matrix to build two co-formulated target panels and three target single-formulated panels with one strain per virus. Seven to eight concentration levels, with two-fold serial dilutions between the levels, were prepared on three days and tested with a total of 63 replicates per concentration across three reagent lots for co-formulated panels and with a total of 21 replicates per concentration using one reagent lot for single-formulated panels. Table 13 to Table 16 summarize the established LoD values.

Table 13 Summary of LoD for influenza A

Viral Strain	Kit lot	Panel	95% Probit [$TCID_{50}$/mL]	95% CI of Probit [$TCID_{50}$/mL]	Hit rate ≥95% [$TCID_{50}$/mL]	Mean Ct at ≥95% Hit rate
A/Kansas/14/2017 (H3N2) Cat No 0810586CF Lot 323540	Lot 1	single-formulated	**0.050**	0.034 – 0.098	**0.036**	38.2
	Lot 1	co-formulated	**0.12**	0.073 – 0.28	**0.071**	36.6
	Lot 2	co-formulated	**0.083**	0.054 – 0.17	**0.14**	36.7
	Lot 3	co-formulated	**0.062**	0.040 – 0.14	**0.071**	37.0
	Lot 1-3	co-formulated	**0.086**	0.065 – 0.12	**0.071**	37.5
A/Brisbane/02/2018 (H1N1) Cat No 0810585CF Lot 323771	Lot 1	co-formulated	**0.020**	0.013 – 0.048	**0.026**	37.4
	Lot 2	co-formulated	**0.020**	0.013 – 0.064	**0.026**	38.4
	Lot 3	co-formulated	**0.025**	0.016 – 0.059	**0.026**	38.1
	Lot 1-3	co-formulated	**0.022**	0.017 – 0.034	**0.026**	38.0

Table 14 Summary of LoD for influenza B

Viral Strain	Kit lot	Panel	95% Probit [$TCID_{50}$/mL]	95% CI of Probit [$TCID_{50}$/mL]	Hit rate ≥95% [$TCID_{50}$/mL]	Mean Ct at ≥95% Hit rate
B/Phuket/3073/2013 (Yamagata lineage) Cat No 0810515CF Lot 320436	Lot 1	single-formulated	**0.011**	0.0076 – 0.023	**0.017**	35.4
	Lot 1	co-formulated	**0.019**	0.012 – 0.044	**0.034**	35.1
	Lot 2	co-formulated	**0.016**	0.0095 – 0.050	**0.017**	35.4
	Lot 3	co-formulated	**0.019**	0.010 – 0.084	**0.017**	35.3
	Lot 1-3	co-formulated	**0.017**	0.012 – 0.026	**0.017**	35.3
B/Colorado/06/2017 (Victoria lineage) Cat No 0810573CF Lot 323459	Lot 1	co-formulated	**0.027**	0.017 – 0.065	**0.026**	34.9
	Lot 2	co-formulated	**0.032**	0.019 – 0.084	**0.053**	34.5
	Lot 3	co-formulated	**0.019**	0.012 – 0.050	**0.026**	35.0
	Lot 1-3	co-formulated	**0.026**	0.019 – 0.040	**0.026**	34.9

Table 15 Summary of LoD for SARS-CoV-2

Viral Strain	Kit lot	Panel	95% Probit [$TCID_{50}$/mL]	95% CI of Probit [$TCID_{50}$/mL]	Hit rate ≥95% [$TCID_{50}$/mL]	Mean Ct at ≥95% Hit rate
USA-WA1/2020 heat-inactivated Cat No 0810587CFHI Lot 324045	Lot 1	single-formulated	**0.068**	0.044 – 0.15	**0.058**	36.9
	Lot 1	co-formulated	**0.14**	0.086 – 0.35	**0.12**	36.3
	Lot 2	co-formulated	**0.13**	0.083 – 0.26	**0.12**	36.4
	Lot 3	co-formulated	**0.10**	0.065 – 0.25	**0.12**	35.9
	Lot 1-3	co-formulated	**0.13**	0.094 – 0.19	**0.12**	36.2
USA-WA1/2020 infectious culture Cat No NR-52281 Lot 70033175*	Lot 1	co-formulated	**0.0081**	0.0041 – 0.049	**0.0079**	36.2
	Lot 2	co-formulated	**0.0071**	0.0044 – 0.018	**0.0079**	36.2
	Lot 3	co-formulated	**0.0052**	0.0032 – 0.013	**0.0079**	35.9
	Lot 1-3	co-formulated	**0.0063**	0.0046 – 0.010	**0.0079**	36.1

* Based on the information provided in the Certificate of Analysis from the vendor, 1 $TCID_{50}$/mL is equal to 7,393 genome equivalents by ddPCR.

Table 16 Summary of LoD for pan-Sarbecovirus

Viral Strain	Kit lot	Panel	95% Probit [$TCID_{50}$/mL]	95% CI of Probit [$TCID_{50}$/mL]	Hit rate ≥95% [$TCID_{50}$/mL]	Mean Ct at ≥95% Hit rate
USA-WA1/2020 heat-inactivated Cat No 0810587CFHI Lot 324045	Lot 1	single-formulated	**0.14**	0.082 – 0.37	**0.12**	35.6
	Lot 1	co-formulated	**0.28**	0.17 – 0.67	**0.55**	34.5
	Lot 2	co-formulated	**0.23**	0.14 – 0.49	**0.23**	35.1
	Lot 3	co-formulated	**0.18**	0.11 – 0.37	**0.23**	34.8
	Lot 1-3	co-formulated	**0.23**	0.17 – 0.34	**0.55**	34.2
USA-WA1/2020 infectious culture Cat No NR-52281 Lot 70033175*	Lot 1	co-formulated	**0.0090**	0.0057 – 0.020	**0.016**	34.6
	Lot 2	co-formulated	**0.0076**	0.0049 – 0.016	**0.016**	34.7
	Lot 3	co-formulated	**0.0080**	0.0053 – 0.017	**0.0079**	35.3
	Lot 1-3	co-formulated	**0.0082**	0.0062 – 0.012	**0.016**	34.7

* Based on the information provided in the Certificate of Analysis from the vendor, 1 TCID50/mL is equal to 7,393 genome equivalents by ddPCR.

Inclusivity

The inclusivity of **cobas**® SARS-CoV-2 & Influenza A/B for the detection of influenza A, influenza B and SARS-CoV-2 was confirmed by testing ten influenza A, five influenza B and three SARS-CoV-2 strains. The lowest target analyte at which all four tested replicates were positive are reported in Table 17. Further, **cobas**® SARS-CoV-2 & Influenza A/B was shown to be inclusive for the CDC Human Influenza Virus Panel (2020) (Cat. Number VP2020, Lot Number 200330). The lowest concentration where at least one out of five replicates was positive is reported as the minimum reactive concentration in Table 18.

Table 17 Summary of inclusivity

Viral Target	Strain	Catalog Number	Lot Number	Lowest Concentration Detected
Influenza A	A/Canada/6294/09 (H1N1)	0810109CFJ	315868 (sublot: 527158)	0.002 $TCID_{50}$/mL
	A/California/07/09 (H1N1)	0810165CF	319956 (sublot: 533042)	0.026 $TCID_{50}$/mL
	A/Mexico/4108/09 (H1N1)	0810166CF	313217 (sublot: 514161)	0.0062 $TCID_{50}$/mL
	A/Texas/50/12 (H3N2)	0810238CF	318887 (sublot: 529536)	0.45 $TCID_{50}$/mL
	A/Singapore/63/04 (H1N1)	0810246CF	315905 (sublot: 525169)	0.0069 $TCID_{50}$/mL
	A/Perth/16/09 (H3N2)	0810251CF	313218 (sublot: 522582)	0.014 $TCID_{50}$/mL
	A/Wisconsin/67/05 (H3N2)	0810252CF	318888 (sublot: 531612)	0.041 $TCID_{50}$/mL
	A/Switzerland/9715293/13 (H3N2)	0810511CF	319398 (sublot: 526171)	0.0069 $TCID_{50}$/mL
	A/HongKong/4801/14 (H3N2)	0810526CF	317320 (sublot: 529140)	0.097 $TCID_{50}$/mL
	A/Michigan/45/15 (H1N1)	0810538CF	321053 (sublot: 533618)	0.013 $TCID_{50}$/mL
Influenza B	B/Brisbane/60/2008 (Victoria lineage)	0810254CF	313257 (sublot: 513438)	0.002 $TCID_{50}$/mL
	B/Utah/9/14 (Yamagata lineage)	0810516CF	317295 (sublot: 527062)	0.017 $TCID_{50}$/mL
	B/Alabama/2/17 (Victoria lineage)	0810572CF	322548	0.0064 $TCID_{50}$/mL
	B/Florida/78/2015 (Victoria Lineage)	VR-1931	70020870	0.076 $TCID_{50}$/mL
	B/Wisconsin/1/2010 (Yamagata Lineage)	VR-1883	70012127	0.070 $CEID_{50}$/mL
SARS-CoV-2	BetaCoV/France/IDF0372/2020	014V-03890	Not available	0.038 PFU/mL
	BetaCoV/Munich/BavPat1/2020	026V-03883	Not available	0.0036 PFU/mL
	2019-nCoV/Italy-INMI1	008V-03893	Not available	0.062 $TCID_{50}$/mL

Table 18 Summary of CDC Human Influenza Virus Panel (2020)

Virus	Strain	Minimum Reactive Concentration [EID_{50}/mL]
Influenza A	A/Perth/16/2009 (H3N2)	2.62E+00
	A/Hong Kong/2671/2019 (H3N2)	8.29E-02
	A/Christ Church/16/2010 (H1N1 pdm)	2.08E+01
	A/Guangdong-maonan/1536/2019 (H1N1 pdm)	6.00E-01
Influenza B	B/Michigan/09/2011	1.30E-02
	B/Washington/02/2019	2.08E+00
	B/Texas/81/2016	6.54E-02
	B/Phuket/3073/2013	2.08E+01

Precision (repeatability)

Within-laboratory precision was examined using a panel composed of co-spiked influenza A (A/Kansas/14/2017), influenza B (B/Phuket/3073/2013) and SARS-CoV-2 (USA-WA1/2020, heat-inactivated) cultures diluted in simulated clinical matrix in UTM-RT®. Sources of variability were examined with a panel consisting of three concentration levels, using three lots of **cobas**® SARS-CoV-2 & Influenza A/B reagents and two instruments over a time course of 15 days for a total of 30 runs. A description of the precision panel and the observed positivity rates are shown in Table 19. All negative panel members tested negative throughout the study. Analysis of standard deviation and percent coefficient of variation (CV) of the Ct values from tests performed on positive panel members (see Table 20) yielded overall CVpercentage ranging from 1.2% to 5.1% for influenza A, influenza B, and SARS-CoV-2.

Table 19 Summary of within laboratory precision

Target Concentration	N Tested	N Positive	Positivity Rate	95% Confidence Interval	
				Lower Limit	Upper Limit
Influenza A					
Negative	90	0	0%	0%	4.1%
Weak Positive ~ 0.3 x LoD (0.043 $TCID_{50}$/mL)	90	87	96.7%	90.7%	98.9%
Low Positive ~ 1 x LoD (0.14 $TCID_{50}$/mL)	90	90	100%	95.9%	100%
Moderate Positive ~ 3 x LoD (0.43 $TCID_{50}$/mL)	90	90	100%	95.9%	100%
Influenza B					
Negative	90	0	0%	0%	4.1%
Weak Positive ~ 0.3 x LoD (0.010 $TCID_{50}$/mL)	90	81	90.0%	82.1%	94.7%
Low Positive ~ 1 x LoD (0.034 $TCID_{50}$/mL)	90	90	100%	95.9%	100%
Moderate Positive ~ 3 x LoD (0.10 $TCID_{50}$/mL)	90	90	100%	95.9%	100%
SARS-CoV-2					
Negative	90	0	0%	0%	4.1%
Weak Positive ~ 0.3 x LoD (0.035 $TCID_{50}$/mL)	90	83	92.2%	84.8%	96.2%
Low Positive ~ 1 x LoD (0.12 $TCID_{50}$/mL)	90	87	96.7%	90.7%	98.9%
Moderate Positive ~ 3 x LoD (0.35 $TCID_{50}$/mL)	90	90	100%	95.9%	100%
pan-Sarbecovirus					
Negative	90	0	0%	0%	4.1%
Weak Positive ~ 0.06 x LoD (0.035 $TCID_{50}$/mL)	90	73	81.1%	71.8%	87.9%
Low Positive ~ 0.2 x LoD (0.12 $TCID_{50}$/mL)	90	87	96.7%	90.7%	98.9%
Moderate Positive ~ 0.6 x LoD (0.35 $TCID_{50}$/mL)	90	90	100%	95.9%	100%

Table 20 Overall mean, standard deviation, and percent coefficient of variation for Ct values by positive panel member

Target Concentration	Positivity Rate	Mean Ct	Between instrument		Between lot		Between day		Between run		Within run		Total	
			SD	CV%	SD	CV%	SD	CV%	SD	CV%	SD	CV%	SD	CV%
Influenza A														
Weak Positive ~ 0.3 x LoD (0.042 TCID50/mL)	96.7%	38.3	0.00	0.0	0.29	0.8	0.43	1.1	0.00	0.0	1.90	5.0	1.97	5.1
Low Positive ~ 1 x LoD (0.14 TCID50/mL)	100%	35.7	0.00	0.0	0.00	0.0	0.19	0.5	0.15	0.4	0.90	2.5	0.93	2.6
Moderate Positive ~ 3 x LoD (0.42 TCID50/mL)	100%	34.4	0.11	0.3	0.00	0.0	0.11	0.3	0.00	0.0	0.43	1.2	0.46	1.3
Influenza B														
Weak Positive ~ 0.3 x LoD (0.010 $TCID_{50}$/mL)	90.0%	35.6	0.11	0.3	0.00	0.0	0.236	0.6	0.09	0.3	0.62	1.7	0.67	1.9
Low Positive ~ 1 x LoD (0.034 $TCID_{50}$/mL)	100%	34.7	0.00	0.0	0.00	0.0	0.19	0.5	0.21	0.6	0.51	1.5	0.58	1.7
Moderate Positive ~ 3 x LoD (0.10 $TCID_{50}$/mL)	100%	33.8	0.07	0.2	0.00	0.0	0.17	0.5	0.00	0.0	0.82	2.4	0.84	2.5
SARS-CoV-2														
Weak Positive ~ 0.3 x LoD (0.035 $TCID_{50}$/mL)	92.2%	36.6	0.00	0.0	0.00	0.0	0.32	0.9	0.07	0.2	0.60	1.6	0.68	1.9
Low Positive ~ 1 x LoD (0.12 $TCID_{50}$/mL)	96.7%	35.7	0.06	0.2	0.07	0.2	0.00	0.0	0.05	0.1	0.40	1.1	0.42	1.2
Moderate Positive ~ 3 x LoD (0.35 $TCID_{50}$/mL)	100%	34.6	0.17	0.5	0.00	0.0	0.19	0.6	0.00	0.0	0.57	1.7	0.63	1.8
pan-Sarbecovirus														
Weak Positive ~ 0.06 x LoD (0.035 $TCID_{50}$/mL)	81.1%	35.8	0.00	0.0	0.00	0.0	0.16	0.4	0.11	0.3	0.63	1.8	0.66	1.82.0
Low Positive ~ 0.2 x LoD (0.12 $TCID_{50}$/mL)	96.7%	34.9	0.00	0.0	0.04	0.2	0.00	0.0	0.00	0.0	0.52	1.5	0.52	1.5
Moderate Positive ~ 0.6 x LoD (0.35 $TCID_{50}$/mL)	100%	33.9	0.13	0.4	0.00	0.0	0.10	0.3	0.00	0.0	0.54	1.6	0.57	1.7

Analytical specificity (cross-reactivity and microbial interference)

A panel of 41 viruses, bacteria, and fungi (including those commonly found in respiratory tract) were tested with **cobas**® SARS-CoV-2 & Influenza A/B to assess analytical specificity. The organisms listed in Table 21 were spiked at concentrations of 1 x 10^5 units/mL for viruses and 1 x 10^6 units/mL for other organisms, unless otherwise noted. Testing was performed with each potential interfering organism in the absence and presence of influenza A, influenza B, and SARS-CoV-2 target (spiked at ~3 x LoD – 0.42, 0.10 and 0.36 $TCID_{50}$/mL, respectively). None of the organisms interfered with the test performance by generating false positive results. Testing of SARS-CoV-1 generated an expected pan-Sarbecovirus positive result. Detection of influenza A, influenza B, and SARS-CoV-2 targets was not affected in the presence of the organisms tested. Potential cross-reactivity of influenza C, *Leptospira interrogans*, *Chlamydia psittaci*, *Bacillus anthracis* and *Coxiella burnetii* was evaluated in silico. Based on the in silico analyses, selected organisms are highly unlikely to interfere with the performance of **cobas**® SARS-CoV-2 & Influenza A/B.

Table 21 Microorganisms tested for analytical specificity/cross reactivity

Microorganism	**Concentration**
Adenovirus (AdV-1)	1.0E+05 $TCID_{50}$/mL
Bordetella pertussis	1.0E+06 CFU/mL
Candida albicans	1.0E+06 CFU/mL
Chlamydia pneumoniae	7.9E+04 $TCID_{50}$/mL
Corynebacterium diphtheriae	1.0E+06 CFU/mL
Cytomegalovirus	1.0E+05 IU/mL
Enterovirus (EV68)	1.0E+05 $TCID_{50}$/mL
Epstein Barr Virus	1.0E+05 cp/mL
Escherichia coli	1.0E+06 CFU/mL
Haemophilus influenzae	1.0E+06 CFU/mL
Human coronavirus 229E	1.0E+05 $TCID_{50}$/mL
Human coronavirus HKU1	1.0E+05 genome cp/mL
Human coronavirus NL63	2.5E+04 $TCID_{50}$/mL
Human coronavirus OC43	1.0E+05 $TCID_{50}$/mL
Human Metapneumovirus	1.0E+05 $TCID_{50}$/mL
Lactobacillus acidophilus	1.0E+06 CFU/mL
Legionella pneumophila	1.0E+06 CFU/mL
Legionella longbeachae	1.0E+06 CFU/mL
Measles virus	1.0E+05 $TCID_{50}$/mL
MERS-coronavirus	1.0E+05 cp/mL
Moraxella catarrhalis	1.0E+06 CFU/mL
Mumps Virus	1.0E+05 $TCID_{50}$/mL
Mycobacterium tuberculosis	1.0E+06 CFU/mL
Mycoplasma pneumoniae	1.0E+06 CCU/mL
Neisseria elongata	1.0E+06 CFU/mL
Neisseria meningitidis	1.0E+06 CFU/mL
Parainfluenza virus 1	1.0E+05 $TCID_{50}$/mL
Parainfluenza virus 2	1.0E+05 $TCID_{50}$/mL
Parainfluenza virus 3	1.0E+05 $TCID_{50}$/mL
Parainfluenza virus 4	1.0E+05 $TCID_{50}$/mL
Parechovirus	1.0E+05 $TCID_{50}$/mL
Pseudomonas aeruginosa	1.0E+06 CFU/mL
Pneumocystis jirovecii	5.0E+03 organisms/mL
Respiratory Syncytial Virus	1.0E+05 PFU/mL
Human Rhinovirus	1.0E+05 PFU/mL
SARS-coronavirus (SARS-CoV-1)	1.0E+05 PFU/mL
Staphylococcus aureus	1.0E+06 CFU/mL
Staphylococcus epidermidis	1.0E+06 CFU/mL
Streptococcus salivarius	1.0E+06 CFU/mL
Streptococcus pneumoniae	1.0E+06 CFU/mL
Streptococcus pyogenes	1.0E+06 CFU/mL

Co-infection (competitive interference)

To assess potential competitive interference between influenza A, influenza B, and SARS-CoV-2, samples were tested in replicates of 5 where low (approximately 3 x LoD) concentrations of any two targets were mixed with very high (1.0E+05 $TCID_{50}$/mL) concentrations of the third target,. None of the targets present at very high concentration interfered with the detection of low levels of the other two targets.

Collection media equivalence

Equivalence between different collection media (UTM-RT®, **cobas**® PCR Media, and saline) was evaluated using one strain each for influenza A (A/Kansas/14/2017 (H3N2)), influenza B (B/Phuket/3073/2013 (Yamagata lineage)) and SARS-CoV-2 (USA-WA1/2020, heat-inactivated culture). Virus cultures were co-formulated to a target concentration of approximately 2 x LoD into simulated clinical matrix formulated either in Universal Transport Media (UTM-RT®), **cobas**® PCR Media (CPM), or in 0.9% physiological saline. A total of 21 replicates were tested for each collection media type. All replicates tested were positive in all simulated matrices for influenza A and influenza B. For SARS-CoV-2, positivity rates were 100% for both UTM-RT® and CPM and 95.2% for saline.

FDA SARS-CoV-2 reference panel testing

The evaluation of sensitivity and MERS-CoV cross-reactivity was performed using reference material (concentrated stock T1 from FDA panel), blinded samples and a standard protocol provided by the FDA. The study included a range finding study and a confirmatory study for LoD. Blinded sample testing was used to establish specificity and to confirm the LoD. The results are summarized in Table 22.

Table 22 Summary of LoD confirmation result using the FDA SARS-CoV-2 reference panel

Reference Materials Provided by FDA	Specimen Type	Product LoD	Cross-Reactivity
SARS-CoV-2	Nasopharyngeal Clinical Sample	1.8 x10^3 NDU/mL	N/A
MERS-CoV		N/A	ND

NDU/mL = RNA NAAT detectable units/mL

N/A: Not applicable

ND: Not detected

Clinical performance evaluation

The performance of **cobas**® SARS-CoV-2 & Influenza A/B was evaluated at one external site using archived nasopharyngeal swab (NPS) samples from patients with signs and symptoms of a respiratory infection, collected in UTM-RT® or UVT. Clinical samples were collected by qualified personnel according to the package insert of the collection device.

The clinical evaluation study included a total of 349 NPS samples, 57 of which were longitudinal samples from COVID-19 patients. **cobas**® SARS-CoV-2 and **cobas**® Influenza A/B & RSV for use on the **cobas**® Liat® System were utilized as the comparator test for assessment of performance of the **cobas**® SARS-CoV-2 & Influenza A/B for SARS-CoV-2 and Influenza A/B, respectively, in the clinical evaluation. One of the 349 NPS samples did not have a valid comparator SARS-CoV-2 result and five of the 349 NPS samples did not have valid comparator influenza A/B results, therefore, were excluded from the performance calculations for SARS-CoV-2 and influenza A and influenza B, respectively.

As shown in Table 23, the **cobas**® SARS-CoV-2 & Influenza A/B demonstrated high percent agreement with the comparator tests for the detection of SARS-CoV-2, influenza A, and influenza B.

Table 23 Comparison of **cobas**® SARS-CoV-2 & Influenza A/B with **cobas**® SARS-CoV-2 and **cobas**® Influenza A/B & RSV for use on the **cobas**® **Liat**® System

Virus	Number of Samples	Test Results				Agreement Statistics		
		Concordant Positive (N)	Discordant Positive (N)	Concordant Negative (N)	Discordant Negative (N)	Agreement Parameter	Percent Agreement (%)	95% CI (LCL, UCL)*
SARS-CoV-2#	348	53	6	287	2	PPA	96.4%	(87.7%, 99.0%)
						NPA	98.0%	(95.6%, 99.1%)
Influenza A	344	60	1	283	0	PPA	100.0%	(94.0%, 100.0%)
						NPA	99.6%	(98.0%, 99.9%)
Influenza B	344	37	1	306	0	PPA	100.0%	(90.6%, 100.0%)
						NPA	99.7%	(98.2%, 99.9%)

PPA = Positive Percent Agreement

NPA = Negative Percent Agreement

CI = confidence interval; LCL = Lower confidence Limit; UCL = Upper confidence Limit

*Confidence interval is calculated using Wilson's Score method

A positive result is defined as detection of either of the two SARS-CoV-2 or pan-Sarbecovirus target of the assay

Discordant results between the **cobas**® SARS-CoV-2 & Influenza A/B assay and the comparator methods were observed for 10 samples. Of these, 8 were longitudinal samples with discordant results for SARS-CoV-2 that showed late Ct values (between 35-43), which are indicative of samples from recovery/convalescent patients with decreasing viral loads close to or below the limit of detection of both the **cobas**® SARS-CoV-2 & Influenza A/B and **cobas**® SARS-CoV-2 tests. **cobas**® SARS-CoV-2 & Influenza A/B detected an additional influenza A virus and an additional influenza B virus positive sample compared to **cobas**® Influenza A/B & RSV for use on the **cobas**® Liat® System. Post-PCR analysis of the amplicon from all discordant samples confirmed the presence of SARS-CoV-2 and influenza A but not influenza B.

cobas® SARS-CoV-2 & Influenza A/B was further evaluated in a prospective clinical study in comparison with an FDA cleared test with fresh NPS and nasal swab (NS) clinical samples. A total of 604 NPS and a total of 608 NS samples (304 self-collected and 304 health care worker collected) with valid results by the comparator method were evaluated. The NPA was 100% (95% Score CI of 99.4% to 100%) for influenza A for both NPS and NS samples. The NPA for influenza B was

100% (95% Score CI of 99.4% to 100%) for NPS samples and 99.8% (95% Score CI of 99.1% to 100%) for NS samples. The PPA for NPS samples was not calculable for influenza A and influenza B, as there were no positive samples by the comparator method. The PPA for NS samples for influenza A and influenza B was 0% (0/1) with a 95% Score CI of 0% to 94.9%, as there was one positive sample by the comparator method and negative on **cobas**® SARS-CoV-2 & Influenza A/B.

Discordant results between the **cobas**® SARS-CoV-2 & Influenza A/B assay and the comparator method were observed for 2 samples. One NS sample tested positive for influenza A and influenza B by the comparator method and was negative on **cobas**® SARS-CoV-2 & Influenza A/B. Sequencing analysis of the sample did not confirm the presence of influenza A or influenza B. One NS sample tested positive for influenza B on cobas® SARS-CoV-2 & Influenza A/B and was negative on the comparator method. Post-PCR analysis of the amplicon of this discordant NS sample did not confirm the presence of influenza B.

Additional information

Key test features

Sample type	Nasopharyngeal swab samples collected in the Copan UTM-RT® System or the BD™ UVT System Nasal swab samples collected in the Copan UTM-RT® System, the BD™ UVT System, the **cobas®** PCR Media, and 0.9% physiological saline
Minimum amount of sample required	0.6 mL or 1.0 mL*
Sample processing volume	0.4 mL
Test duration	Results are available within less than 3.5 hours after loading the sample on the system.

*Dead volume of 0.2 mL is identified for the **cobas omni** Secondary tubes. Dead volume of 0.6 mL is identified for the **cobas®** PCR Media primary tubes. Other tubes compatible with **cobas®** 6800/8800 Systems (consult User Assistance Guide) may have different dead volume and require more or less minimum volume.

Symbols

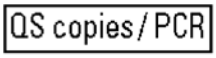
The following symbols are used in labeling for Roche PCR diagnostic products.

Table 24 Symbols used in labeling for Roche PCR diagnostics products

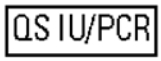
Age/DOB	Age or Date of Birth
SW	Ancillary Software
Assigned Range [copies/mL]	Assigned Range (copies/mL)
Assigned Range [IU/mL]	Assigned Range (IU/mL)
EC REP	Authorized representative in the European Community
BARCODE	Barcode Data Sheet
LOT	Batch code
	Biological risks
REF	Catalogue number
Collect Date	Collect date
	Consult instructions for use
Σ	Contains sufficient for <*n*> tests
CONTENT	Contents of kit
CONTROL	Control
	Date of manufacture
D	Distributed by
	Do not re-use
	Female
	For IVD performance evaluation only
GTIN	Global Trade Item Number
IVD	*In vitro* diagnostic medical device
LLR	Lower Limit of Assigned Range
	Male
	Manufacturer
CONTROL −	Negative control
NON STERILE	Non sterile
#	Patient number
?	Patient Name


Peel here

Positive control



QS copies per PCR reaction, use the QS copies per PCR reaction in calculation of the results.



QS IU per PCR reaction, use the QS International Units (IU) per PCR reaction in calculation of the results.

Serial number

Site

Standard Procedure

Sterilized using ethylene oxide


Store in the dark


Temperature limit

Test Definition File

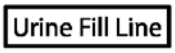

CE marking of conformity; this device is in conformity with the applicable requirements for CE marking of an *in vitro* diagnostic medical device


This way up

Unique Device Identification

Ultrasensitive Procedure

Upper Limit of Assigned Range



Urine Fill Line

US Only: Federal law restricts this device to sale by or on the order of a physician.


Use-by date


Device for near-patient testing


Device Not for Near Patient Testing


Device for self-testing


Device not for self-testing

Technical support

For technical support (assistance) please reach out to your local affiliate:
https://www.roche.com/about/business/roche_worldwide.htm

Manufacturer and distributors

Table 25 Manufacturer and distributors

Roche Molecular Systems, Inc.
1080 US Highway 202 South
Branchburg, NJ 08876 USA
www.roche.com

Made in USA

Distributed by	Roche Diagnostics GmbH Sandhofer Strasse 116 68305 Mannheim, Germany	Roche Diagnostics 9115 Hague Road Indianapolis, IN 46250-0457 USA (For Technical Assistance call the Roche Response Center toll-free: 1-800-526-1247)

Trademarks and patents

See http://www.roche-diagnostics.us/patents

Copyright

IVD

References

1. Center for Disease Control and Prevention. Biosafety in Microbiological and Biomedical Laboratories, 5th ed. U.S. Department of Health and Human Services, Public Health Service, Centers for Disease Control and Prevention, National Institutes of Health HHS Publication No. (CDC) 21-1112, revised December 2009.
2. Clinical and Laboratory Standards Institute (CLSI). Protection of laboratory workers from occupationally acquired infections. Approved Guideline-Fourth Edition. CLSI Document M29-A4:Wayne, PA;CLSI, 2014.

Document Revision

Document Revision Information	
Doc Rev. 1.0 09/2020	First Publishing
Doc Rev. 2.0 01/2021	Data for analytical sensitivity using FDA SARS-CoV-2 reference panel added to **Non-clinical performance evaluation** section. Corrected typographical errors. Added precautionary statement to **Precautions and handling requirements** and **Results** sections. Added note regarding results to **Table 12**. Added Made in USA statement. Please contact your local Roche Representative if you have any questions.
Doc Rev. 3.0 05/2021	Added text pointing to the sample collection kits' IFU for hazard information. "Refer to the Instructions for Use of the Collection Devices for hazard information. Please contact your local Roche Representative if you have any questions.
Doc Rev. 4.0 06/2021	Added clinical data for influenza A and influenza B to the **Clinical performance evaluation** section. Please contact your local Roche Representative if you have any questions.
Doc Rev. 5.0 09/2021	Added the following statement to the **Procedural limitations** section: The performance of this test was established based on the evaluation of a limited number of clinical specimens.

cobas® SARS-CoV-2 & Influenza A/B

KIT LOT

IVD

For USA: Emergency Use Authorization only

SW

cobas® SCoV2-FluA/B ASAP Version 10.1.0 or higher

cobas® 6800/8800 System Software
Version 1.2 or higher

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 simultaneous qualitative detection and differentiation of nucleic acids from SARS-CoV-2, influenza A virus, and influenza B virus, and 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.

USA

website: http://e-labdoc.roche.com
Product No.: 09233474190
09233679001-05 Doc Rev. 5.0

Please contact your local Roche representative at 1-800-526-1247 if you require a printed copy free of charge or need technical support to access the package insert.

CANADA

website: http://e-labdoc.roche.com
Method Sheet Catalog No.: 09233474190 Doc Rev. 1.0

Non-USA

website: http://e-labdoc.roche.com
Method Sheet Catalog No.: 09233474190 Doc Rev. 3.0

Please contact your local Roche representative if you require a printed copy free of charge or need technical support to access the package insert./ Bei Ihrer zuständigen Roche-Vertretung erhalten Sie einen kostenfreien Ausdruck oder technische Unterstützung für den Zugriff auf die Packungsbeilage./ Veuillez contacter votre représentant Roche local pour obtenir un exemplaire papier gratuit ou une assistance technique pour accéder à la notice./ Contattare il rappresentante Roche locale per ottenere gratuitamente una copia stampata o richiedere istruzioni per reperire il foglio illustrativo./ Póngase en contacto con su representante local de Roche si necesita una copia impresa gratuita o ayuda del servicio técnico para acceder al boletín técnico./ Se desejar uma cópia impressa gratuita ou necessitar de assistência técnica para aceder ao folheto informativo, entre em contacto com o representante local da Roche./ Kontakt den lokale Roche-repræsentant, hvis du ønsker en gratis skriftlig kopi eller har brug for teknisk support for at få adgang til indlægssedlen./ Kontakta din Roche-representant om du vill ha en pappersversion kostnadsfritt eller om du behöver teknisk support för att komma åt bipacksedeln.

Roche Molecular Systems, Inc.
1080 US Highway 202 South
Branchburg, NJ 08876 USA

09233687001-06