Rx Only

cobas® SARS-CoV-2 Qualitative

Nucleic acid test for use on the cobas® 5800/6800/8800 systems

For in vitro diagnostic use

cobas® SARS-CoV-2 Qualitative 192T	P/N: 09446109190
cobas® SARS-CoV-2 Qualitative 480T	P/N: 09448870190
cobas® SARS-CoV-2 Qualitative Control Kit	P/N: 09446117190
cobas® Buffer Negative Control Kit	P/N: 09051953190

Table of contents

Intended use 4

Summary and explanation of the test 4

Reagents and materials 6

cobas® SARS-CoV-2 Qualitative reagents and controls 6

cobas® **omni** reagents for sample preparation 8

Reagent storage requirements 9

Reagent handling requirements for the **cobas**® 5800 system and **cobas**® 6800/8800 systems 9

Additional materials required for the **cobas**® 5800/6800/8800 systems 10

Instrumentation and software required 11

Precautions and handling requirements 12

Warnings and precautions 12

Reagent handling 12

Good laboratory practice 13

Sample collection, transport, and storage 13

Sample collection – swab specimen types 13

Transport and storage – swab specimen types 14

Instructions for use 15

Procedural notes 15

Running **cobas**® SARS-CoV-2 Qualitative utilizing swab specimens 15

Specimens collected in **cobas**® PCR Media, 0.9% physiological saline, UTM-RT or UVT 15

Specimens collected using **cobas**® PCR Media Uni or Dual Swab Sample Kit 16

Running **cobas**® SARS-CoV-2 Qualitative on the **cobas**® 5800 system 17

Results 19

Quality control and validity of results on the **cobas**® 5800 system and **cobas**® 6800/8800 systems with software version 2.0 19

Interpretation of results on the **cobas**® 5800 system and **cobas**® 6800/8800 systems with software version 2.0 20

Quality control and validity of results on the **cobas**® 6800/8800 systems with software version 1.4 21

Interpretation of results on the **cobas**® 6800/8800 systems with software version 1.4. 21

cobas® SARS-CoV-2 Qualitative results interpretation on **cobas**® 5800/6800/8800 systems 22

Procedural limitations 23

Non-clinical performance evaluation 24

System equivalency 24

Key performance characteristics 24

Analytical sensitivity (Limit of Detection) 24

Inclusivity 25

Precision 26

Reproducibility 27

Analytical specificity / cross-reactivity 29

Interference 31

Matrix equivalency 32

Collection media equivalency – UTM-RT, **cobas**® PCR Media and 0.9% physiological saline 32

Expected Values 33

Clinical performance evaluation performed on the cobas® 6800/8800 systems 34

Symptomatic Population 34

Nasopharyngeal and nasal swab specimens 34

Asymptomatic Population 35

Real-world evidence 35

Clinical study 35

Additional information 37

Key test features 37

Symbols 38

Technical support 39

Manufacturer and distributor 39

Trademarks and patents 39

Copyright 39

References 40

Document revision 41

Intended use

cobas® SARS-CoV-2 Qualitative for use on the **cobas**® 5800/6800/8800 systems is a real-time RT-PCR test intended for the qualitative detection of nucleic acids from SARS-CoV-2 in nasopharyngeal swab specimens collected from individuals with signs and symptoms of COVID-19 and in anterior nasal swab specimens collected from any individuals with or without signs and symptoms of COVID-19.

Positive results are indicative of the presence of SARS-CoV-2 RNA. Positive results do not rule out bacterial infection or co-infection with other pathogens.

Negative results do not preclude SARS-CoV-2 infection and should not be used as the sole basis for patient management decisions. Results are meant to be used in conjunction with clinical observations, patient history, recent exposures, epidemiological information, and laboratory data, in accordance with the guidelines provided by the relevant public health authorities.

Summary and explanation of the test

Explanation of the test

cobas® SARS-CoV-2 Qualitative is a qualitative nucleic acid test for use on the **cobas**® 5800/6800/8800 systems for the detection of the 2019 novel coronavirus (SARS-CoV-2) RNA in individual nasal and nasopharyngeal swab samples collected in transport media (refer to **Sample collection, transport and storage** section for details). 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 Qualitative is based on fully automated sample preparation (nucleic acid extraction and purification) followed by PCR amplification and detection. The **cobas**® 5800 system is designed as one integrated instrument. 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**® 5800 or **cobas**® 6800/8800 systems software(s), which assigns test 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.

Selective amplification of target nucleic acid from the sample is achieved by the use of target-specific forward and reverse primers for ORF1 a/b non-structural region that is unique to SARS-CoV-2. Additionally, a conserved region in the structural protein envelope E-gene were chosen for pan-Sarbecovirus detection. The pan-Sarbecovirus detection sets will also detect SARS-CoV-2 virus.

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 genome. A thermostable DNA polymerase enzyme is used for amplification.

The **cobas**® SARS-CoV-2 Qualitative master mix contains detection probes which are specific for the coronavirus type SARS-CoV-2, members of the Sarbecovirus subgenus, and the RNA Internal Control nucleic acid. The coronavirus 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 target 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 Qualitative can be found in Table 1. Materials required, but not provided can be found in Table 2 through Table 4, Table 9 through Table 11.

cobas® SARS-CoV-2 Qualitative 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 Qualitative

Store at 2-8°C
192 test cassette (P/N 09446109190)
480 test cassette (P/N 09448870190)

Kit components	Reagent ingredients	Quantity per kit 192 tests	Quantity per kit 480 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 from Bacillus subtilis. May produce an allergic reaction.	22.3 mL	38 mL
RNA Internal Control (RNA IC)	Tris buffer, < 0.05% EDTA, < 0.001% non-Sarbecovirus related armored RNA construct containing primer and probe specific primer sequence regions (non-infectious RNA in MS2 bacteriophage), < 0.1% sodium azide	21.2 mL	38 mL
Elution Buffer (EB)	Tris buffer, 0.2% methyl-4 hydroxybenzoate	21.2 mL	38 mL
Master Mix Reagent 1 (MMX-R1)	Manganese acetate, potassium hydroxide, < 0.1% sodium azide	7.5 mL	14.5 mL
SARS-CoV-2 QL Master Mix Reagent 2 (SARS-CoV-2 QL 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 and Sarbecovirus primers, < 0.01% Internal Control forward and reverse primers, < 0.01% fluorescent-labeled oligonucleotide probes specific for SARS-CoV-2, Sarbecovirus, 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	9.7 mL	17.5 mL

Table 2 cobas® SARS-CoV-2 Qualitative Control Kit

Store at 2–8°C

(P/N 09446117190)

Kit components	Reagent ingredients	Quantity per kit
SARS-CoV-2 QL Positive Control (SARS-CoV-2 QL (+)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	16 mL (16 x 1 mL)

Table 3 cobas® Buffer Negative Control Kit

Store at 2-8°C

(P/N 09051953190)

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 1 mL)

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: Harmful if swallowed. H314: Causes severe skin burns and eye damage. H412: Harmful to aquatic life with long lasting effects. EUH032: Contact with acids liberates very toxic gas. EUH071: Corrosive to the respiratory tract. P273: Avoid release to the environment. P280: Wear protective gloves/ protective clothing/ eye protection/ face protection/ hearing protection. P301 + P330 + P331: IF SWALLOWED: Rinse mouth. Do NOT induce vomiting. 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 Poly(oxy-1,2-ethanediyl), α-dodecyl-ω-hydroxy- 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

*Product safety labeling primarily follows EU GHS guidance.
**Hazardous substance.

Reagent storage requirements

Reagents shall be stored and will be handled as specified in Table 5, Table 6 and Table 7.

When reagents are not loaded on the **cobas**® 5800 or **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 Qualitative 192T	2–8°C
cobas® SARS-CoV-2 Qualitative 480T	2–8°C
cobas® SARS-CoV-2 Qualitative 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

Reagent handling requirements for the cobas® 5800 system and cobas® 6800/8800 systems

Reagents loaded onto the **cobas**® 5800 system or **cobas**® 6800/8800 systems are stored at appropriate temperatures, their expiration is monitored and enforced by the system. The system allows reagents to be used only if all of the reagent handling conditions shown in Table 6, Table 7 and Table 8 are met. The system automatically prevents use of expired reagents. Remaining open-kit stability and number of kit uses information for assay specific reagents is accessible through the system user interface.

Table 6 Reagent expiry conditions monitored and enforced by the **cobas**® 5800 system

Reagent	Open-kit stability	Number of kit uses	On-board stability
cobas® SARS-CoV-2 Qualitative 192T	90 days from first usage	40	36 days from loading
cobas® SARS-CoV-2 Qualitative 480T	90 days from first usage	40	36 days from loading
cobas® SARS-CoV-2 Qualitative Control Kit	single use vial	16	36 days from loading
cobas® Buffer Negative Control Kit	single use vial	16	36 days from loading

Table 7 Reagent expiry conditions monitored and enforced by the **cobas**® 6800/8800 systems

Reagent	Open-kit stability	Number of kit uses	On-board stability (outside on board refrigerator)
cobas® SARS-CoV-2 Qualitative 192T	90 days from first usage	40	40 hours from loading
cobas® SARS-CoV-2 Qualitative 480T	90 days from first usage	20	20 hours from loading
cobas® SARS-CoV-2 Qualitative Control Kit	single vial use	16	8 hours from loading
cobas® Buffer Negative Control Kit	single vial use	16	10 hours from loading

Table 8 shows the open-kit stability of the **cobas**® **omni** reagents. Prior to each run, the system verifies the open-kit stability and ensures sufficient fill volume. Therefore, these reagents have no number of kit uses or on-board stability assigned.

Table 8 **cobas**® **omni** reagent expiry condition enforced by the **cobas**® 5800/6800/8800 systems

Reagent	Open-kit stability
cobas® **omni** Lysis Reagent	30 days from loading
cobas® **omni** MGP Reagent	30 days from first usage
cobas® **omni** Specimen Diluent	30 days from loading
cobas® **omni** Wash Reagent	30 days from loading

Additional materials required for the cobas® 5800/6800/8800 systems

Table 9 Materials for use on the **cobas**® 5800/6800/8800 systems

Material	P/N
cobas® **omni** Lysis Reagent	06997538190
cobas® **omni** MGP Reagent	06997546190
cobas® **omni** Specimen Diluent	06997511190
cobas® **omni** Wash Reagent	06997503190

Table 10 Consumables for use on the **cobas**® 5800 system*,**

Material
cobas® **omni** Processing Plate 24
cobas® **omni** Amplification Plate 24
cobas® **omni** Liquid Waste Plate 24
Tip CORE TIPS with Filter, 1mL
Tip CORE TIPS with Filter, 300µL
cobas® **omni** Liquid Waste Container
Solid Waste Bag or Solid Waste Bag With Insert
cobas® **omni** Secondary Tubes 13x75 (optional)
cobas® PCR Media Tube Replacement Cap Kit
cobas® PCR Media Disposable Tube Stand (Optional)

*Please contact your local Roche representative for a detailed order list for sample racks, racks for clotted tips and rack carriers accepted on the instruments and compatible with the assay.

For Part Numbers please refer to the **cobas® 5800 system User Assistance.

Table 11 Consumables for use on the **cobas**® 6800/8800 systems*,**

Material
cobas® **omni** Processing Plate
cobas® **omni** Amplification Plate
cobas® **omni** Pipette Tips
cobas® **omni** Liquid Waste Container
Solid Waste Bag and Solid Waste Container or Solid Waste Bag with Insert and Kit Drawer
cobas® **omni** Secondary Tubes 13x75 (optional)
cobas® PCR Media Tube Replacement Cap Kit
cobas® PCR Media Disposable Tube Stand (Optional)

[a]Please contact your local Roche representative for a detailed order list for sample racks, racks for clotted tips and rack carriers accepted on the instruments and compatible with the assay.

** For Part Numbers please refer to the **cobas**® 6800/8800 systems User Assistance.

Instrumentation and software required

The **cobas**® 5800 software, the **cobas**® 6800/8800 systems software and **cobas**® SARS-CoV-2 Qualitative analysis package (ASAP) for the **cobas**® 5800/6800/8800 systems must be installed on the instrument.

For the **cobas**® 5800 and the **cobas**® 6800/8800 systems with software version 2.0, the x800 Data Manager software and PC (or server) will be provided with the system.

For the **cobas**® 6800/8800 systems with software 1.4 the Instrument Gateway (IG) server will be provided with the system.

Table 12 Instrumentation

Equipment	P/N
cobas® 5800 system	08707464001
cobas® 6800 system	05524245001 and 09575154001
cobas® 8800 system	05412722001 and 09575146001
Sample Supply Module for **cobas**® 6800/8800 systems	06301037001 and 09936882001

Refer to the **cobas**® 5800 system or **cobas**® 6800/8800 systems – User Assistance for additional information.

Note: Contact your local Roche representative for a detailed order list for primary and secondary sample tubes, 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.
- Positive results are indicative of the presence of SARS-CoV-2 RNA.
- 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 Qualitative and the **cobas**® 5800/6800/8800 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 or potassium hypochlorite in distilled or deionized water 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.
- Inform your local competent authority and manufacturer about any serious incidents which may occur when using this assay.

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 Qualitative, **cobas**® SARS-CoV-2 Qualitative 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 or potassium hypochlorite 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.
- Avoid collecting or handling specimens in areas that are exposed to SARS-CoV-2 vaccine material. Some vaccines may contain PCR-detectable genomic material. Contamination of specimens or testing materials with vaccine can cause false-positive results.

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 Qualitative kits, **cobas**® SARS-CoV-2 Qualitative 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 or potassium hypochlorite in distilled or deionized water. Follow by wiping the surface with 70% ethanol.
- If spills occur on the **cobas**® 5800 or **cobas**® 6800/8800 instrument, follow the instructions in the **cobas**® 5800 or **cobas**® 6800/8800 systems – User Assistance to properly clean and decontaminate the surface of instrument(s).
- Laboratory personnel should wear a standard surgical mask (or equivalent) and should avoid touching the mask while handling specimens to mitigate potential specimen contamination.

Sample collection, transport, and storage

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

Sample collection – swab specimen types

Ensure that the correct collection device is used with the appropriate sample type by referring to the table below:

Table 13 Collection media and sample types evaluated in the analytical and clinical performance studies

Collection Media	Nasopharyngeal	Nasal
Copan Universal Transport Media (UTM-RT®)	√	√
BD™ Universal Viral Transport (UVT)	√	√

The following additional collection media for use with **cobas**® SARS-CoV-2 Qualitative have been evaluated in analytical studies, and may be acceptable. These media have not been evaluated in the clinical study.

Table 14 Alternative collection media evaluated in the analytical studies

Collection Media	Nasopharyngeal	Nasal
0.9% Physiological saline	√	√
cobas® PCR Media*	-	√

* **cobas**® PCR Media is a component of the **cobas**® PCR Media Uni Swab Sample Kit and Dual Swab Sample Kits. The performance of the **cobas**® PCR Media Uni Swab Sample Kit (P/N 07958030190) and the **cobas**® PCR Media Dual Swab Sample Kit (P/N 07958021190) for use with **cobas**® SARS-CoV-2 Qualitative on the **cobas**® 6800/8800 systems has been evaluated in analytical studies. Clinical performance of the assay with the samples collected using the two kits was not evaluated.

- 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), BD™ Universal Viral Transport (UVT), **cobas**® PCR media or 0.9% physiological saline, as appropriate.
- Refer to the Instructions for Use of the Collection Devices for hazard information.

Transport and storage – swab specimen types

- Transportation of collected specimens must comply with all applicable regulations for the transport of etiologic agents.
- Samples collected in UTM-RT® or UVT,
    - 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 and at ≤ -70°C for up to 30 days.
    - Specimens are stable for up to **two freeze/thaw** cycles when frozen at ≤ -70°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 and at ≤ -70°C for up to 30 days.
    - Specimens are stable for up to **one freeze/thaw** cycle when frozen at ≤ -70°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 and at ≤ -70°C for up to 30 days.
    - Specimens are stable for up to **one freeze/thaw** cycle when frozen at ≤ -70°C.

Instructions for use

Procedural notes

- Do not use **cobas**® SARS-CoV-2 Qualitative reagent, **cobas**® SARS-CoV-2 Qualitative 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.

Running cobas® SARS-CoV-2 Qualitative utilizing swab specimens

For testing swab specimens, **cobas**® SARS-CoV-2 Qualitative 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 tubes compatible with the **cobas**® 5800 and **cobas**® 6800/8800 systems may be loaded directly onto the **cobas**® 5800 and **cobas**® 6800/8800 systems. The swab must be removed from the sample tube prior to direct loading onto the system. Specimens collected tubes which are not compatible with the **cobas**® 5800 and **cobas**® 6800/8800 systems must be transferred into a secondary tube prior to processing on the **cobas**® 5800/6800/8800 systems. The **cobas**® **omni** Secondary Tube is the preferred option. If using frozen samples in secondary tubes, place the samples at room temperature (15-30°C) until completely thawed and then briefly mix (e.g., vortex for 3-5 seconds) and centrifuge to collect all sample volume at the bottom of the tube. Samples should be processed using the 'sample type selection in the user interface (UI) as described in Table 15. Additional tubes for testing **cobas**® SARS-CoV-2 Qualitative are available. Contact your local Roche representative for detailed testing instructions and an order list of primary tubes and secondary tubes compatible with the instruments.

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**® 5800/6800/8800 systems. Transfer into a secondary tube is not necessary. **cobas**® PCR Media tubes fit on to the MPA RACK 16 MM or the 16-position tube carrier on the **cobas**® 5800 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 **cobas**® SARS-CoV-2 Qualitative as described in Table 15.

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**® 5800/6800/8800 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 instruction for use 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**® 5800/6800/8800 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**® 5800/6800/8800 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.

Table 15 Sample type selection in the user interface of the **cobas**® SARS-CoV-2 Qualitative utilizing swab specimens

Collection kit/Matrix type	**Minimum volume (mL) Processing tube**	**Process as Sample Type**
Copan Universal Transport Medium (UTM-RT®) BD™ Universal Viral Transport 0.9% Physiological saline **cobas**® PCR Media Kit	0.6 mL **cobas**® **omni** Secondary Tube	**VTM (on cobas® 6800/8800)** **Viral transport medium (on cobas® 5800 and cobas® 6800/8800 SW2.0)**
	Compatible tubes without swab inside the tube; for dead volume contact your local Roche representative	**VTM (on cobas® 6800/8800)** **Viral transport medium (on cobas® 5800)**
cobas® PCR Media Uni or Dual Swab Sample Kit	1.0 mL Primary tube	**cobas® PCR media swab**

Running cobas® SARS-CoV-2 Qualitative on the cobas® 5800 system

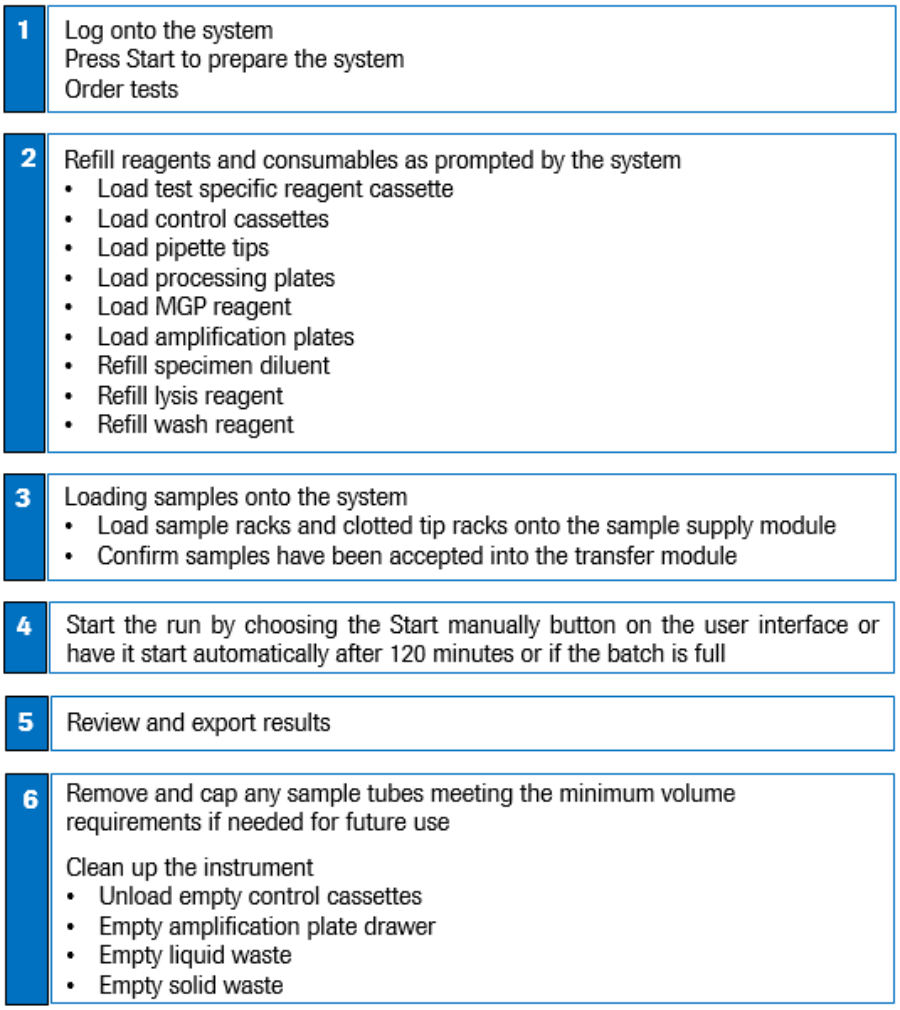
- Ensure that specimen barcode labels on sample tubes are visible through the openings on the side of the sample racks. Refer to the **cobas**® 5800 system or **cobas**® 6800/8800 systems User Assistance for proper barcode specifications and additional information on loading sample tubes.
- Refer to the **cobas**® 5800 system or **cobas**® 6800/8800 systems – User Assistance for proper maintenance of instruments.

Figure 1 and Figure 2 below summarizes the procedure.

Figure 1 **cobas**® SARS-CoV-2 Qualitative test procedure on the **cobas**® 5800 system

1	Log onto the system
2	Loading samples onto the system • Load sample racks onto the system • The system prepares automatically • Order tests
3	Refill reagents and consumables as prompted by the system • Load test specific reagent cassette(s) • Load control mini racks • Load processing tips • Load elution tips • Load processing plates • Load liquid waste plates • Load amplification plates • Load MGP cassette • Refill specimen diluent • Refill lysis reagent • Refill wash reagent
4	Start the run by choosing the Start processing button on the user interface, all subsequent runs will start automatically if not manually postponed
5	Review and export results
6	Remove and cap any sample tubes meeting the minimum volume requirements if needed for future use Clean up the instrument • Unload empty control mini racks • Unload empty test specific reagent cassette(s) • Empty amplification plate drawer • Empty liquid waste • Empty solid waste

Figure 2 **cobas**® SARS-CoV-2 Qualitative test procedure on the **cobas**® 6800/8800 systems



Results

The **cobas**® 5800/6800/8800 systems automatically detect the SARS-CoV-2, for each individually processed sample and control, displaying individual target results for samples as well as test validity for controls.

Quality control and validity of results on the cobas® 5800 system and cobas® 6800/8800 systems with software version 2.0

- The results of the controls are shown in the **cobas**® 5800 software in the "Controls" app.
- One **cobas**® Buffer Negative Control [(-) Ctrl] and one **cobas**® SARS-CoV-2 Qualitative Positive Control [SARS-CoV-2 QL (+) C] are processed at least every 72 hours and with every new kit lot. Positive and/or negative controls can be scheduled more frequently based on laboratory procedures and/or local regulations.
- In the software and/or report, check for flags and their associated results to ensure the result validity (refer to the x800 Data Manager User Assistance for a 'List of flag codes').
- Controls are marked with "Valid" in the column "Control result" if the respective targets of the control is reported valid. Controls are marked with "Invalid" in the column "Control result" if the respective target of the control is reported invalid.
- Controls marked with "Invalid" show a flag in the "Flags" column. More information on why the control is reported invalid including flag information is shown in the detail view.
- If one of the controls is invalid, repeat testing of all controls and all associated samples is required.

Validation of results is performed automatically by the instrument based on control results.

NOTE: The **cobas**® 5800 system and the **cobas**® 6800/8800 systems with software version 2.0 will be delivered with the standard setting of running a set of controls (positive and negative) with every run, but can be configured to a less frequent scheduling up to every 72 hours based on laboratory procedures and/or local regulations. Please contact your Roche service engineer and/or Roche customer technical support for more information.

Interpretation of results on the cobas® 5800 system and cobas® 6800/8800 systems with software version 2.0

The results of the samples are shown in the "Results" app of the software.

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

Table 16 Example of **cobas**® SARS-CoV-2 Qualitative results display **cobas**® 5800 system

Sample ID*	Test	Control Result	Flags **	Status		Result		Creation date/time
Sample_01	SCoV2-QL	Valid		Released		SCoV2 Negative	PanSarb Negative	7/7/2021 8:27:39 AM
Sample _C1	SCoV2-QL	Invalid		Released		Invalid	Invalid	7/7/2021 8:27:39 AM
Sample _B1	SCoV2-QL	Valid		Released		SCoV2 Negative	PanSarb Positive	7/7/2021 8:27:39 AM
Sample _B2	SCoV2-QL	Valid		Released		SCoV2 Positive	PanSarb Positive	7/7/2021 8:27:39 AM
Sample _D1	SCoV2-QL	Valid		Released		SCoV2 Negative	PanSarb Negative	7/7/2021 8:27:39 AM
Sample _A6	SCoV2-QL	Valid		Released		SCoV2 Positive	PanSarb Negative	7/7/2021 8:27:39 AM
Sample _E1	SCoV2-QL	Valid		Released		SCoV2 Positive	Invalid	7/7/2021 8:27:39 AM
Sample _A2	SCoV2-QL	Valid		Released		Invalid	PanSarb Positive	7/7/2021 8:27:39 AM

*Table applies for all sample types used.

** The result overview shows a flag symbol in case of invalid results. Detailed flag descriptions are available in the result details.

- Samples associated with a valid control batch are shown as 'Valid' in the "Control result" column if all Control Target Results reported valid. Samples associated with a failed control batch are shown as 'Invalid' in the "Control result" column if all Control Target Results reported invalid.
- If the associated controls of a sample result are invalid, a specific flag will be added to the sample result as follows:
    - Q05D : Result validation failure because of an invalid positive control
    - Q06D : Result validation failure because of an invalid negative control
- The values in "Results" column for individual sample target result should be interpreted as shown in Table 18 below.
- If one or more sample targets are marked with "Invalid" the software shows a flag in the "Flags"column. More information on why the sample target(s) is reported invalid including flag information is shown in the detail view.

Quality control and validity of results on the cobas® 6800/8800 systems with software version 1.4

- One **cobas**® Buffer Negative Control [(-) Ctrl] and one **cobas**® SARS-CoV-2 Qualitative Positive Control [SARS-CoV-2 QL (+) C] are processed with each batch.
- In the 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 Assistance.
- The batch is valid if no flags appear for all controls. If the batch is invalid, repeat testing of the entire batch is required.

Validation of results is performed automatically by the instrument software based on control results.

Interpretation of results on the cobas® 6800/8800 systems with software version 1.4.

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

- A valid batch may include both valid and invalid sample results.
- Results display examples for **cobas**® SARS-CoV-2 Qualitative are shown in Table 17.
- The "Valid" and "Overall Result" columns are not applicable to sample results for **cobas**® SARS-CoV-2 Qualitative.
- 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 Table 18.

Table 17 Example of **cobas**® SARS-CoV-2 Qualitative results display on **cobas**® 6800/8800 systems with software version 1.4

Test	Sample ID	Valid*	Flags	Sample type	Overall result*	Target 1	Target 2
SCoV2-QL	Sample _01	NA		VTM	NA	SCoV2 Negative	PanSarb Negative
SCoV2-QL	Sample _C1	NA	Y40T	VTM	NA	**Invalid**	**Invalid**
SCoV2-QL	Sample _B1	NA		VTM	NA	SCoV2 Negative	**PanSarb Positive**
SCoV2-QL	Sample _B2	NA		VTM	NA	**SCoV2 Positive**	**PanSarb Positive**
SCoV2-QL	Sample _D1	NA		VTM	NA	SCoV2 Negative	PanSarb Negative
SCoV2-QL	Sample _A6	NA		VTM	NA	**SCoV2 Positive**	PanSarb Negative
SCoV2-QL	Sample _E1	NA	C01H2	VTM	NA	**SCoV2 Positive**	**Invalid**
SCoV2-QL	Sample _A2	NA	C01H1	VTM	NA	**Invalid**	**PanSarb Positive**
SCoV2-QL	C161420284090428828404	Yes		(-) Ctrl	Valid	Valid	Valid
SCoV2-QL	C16142028409300958026 4	Yes		SCoV2-QL (+) C	Valid	Valid	Valid

*The "Valid" and "Overall Result" columns are not applicable to sample results for the **cobas**® SARS-CoV-2 Qualitative. 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 18, **cobas**® SARS-CoV-2 Qualitative results interpretation, for specific instructions on test results interpretation.

cobas® SARS-CoV-2 Qualitative results interpretation on cobas® 5800/6800/8800 systems

Results and their corresponding interpretation for detecting SARS-CoV-2 by the **cobas**® SARS-CoV-2 Qualitative on **cobas**® 5800/6800/8800 systems is described in Table 18 below.

Table 18 cobas® SARS-CoV-2 Qualitative results interpretation

Target 1 (SCoV2)	Target 2 (PanSarb)	Interpretation
Positive	**Positive**	All Target Results were valid. Result for SARS-CoV-2 RNA is Detected.
Positive	**Negative**	All Target Results were valid. Result for SARS-CoV-2 RNA is Detected. A positive Target 1 result and a negative Target 2 result is suggestive of 1) a sample at concentrations near or below the limit of detection of the test, 2) a mutation in the Target 2, target region, or 3) other factors.
Negative	**Positive**	All Target Results were valid. Result for SARS-CoV-2 RNA is Presumptive Positive. A negative Target 1 result and a positive Target 2 result is suggestive of 1) a sample at concentrations near or below the limit of detection of the test, 2) a mutation in the Target 1 target region in the oligo binding sites, or 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**	All Target Results were valid. Result for SARS-CoV-2 RNA is Not Detected.
Positive	**Invalid**	Not all Target Results were valid. Result for SARS-CoV-2 RNA is Detected.
Invalid	**Positive**	Not all Target Results were valid. Result for SARS-CoV-2 RNA is Presumptive Positive. 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	**Invalid**	Not all Target Results were valid. Sample should be retested. If the result is still invalid, a new specimen should be obtained.
Invalid	**Negative**	Not all Target Results were valid. Sample should be retested. If the result is still invalid, a new specimen should be obtained.
Invalid	**Invalid**	All Target Results were invalid. Sample should be retested. If the result is still invalid, a new specimen should be obtained.

Procedural limitations

- For prescription use only.
- A negative test result does not exclude the possibility of viral or bacterial infection.
- Results from this test must be used in conjunction with the clinical history, epidemiological data, or laboratory data available to the clinician evaluating the patient.
- Positive and negative predictive values are highly dependent on disease prevalence.
- FluMist was not evaluated to assess potential interference.
- Test results may also be affected by concurrent antiviral/antibacterial therapy or levels of organism in the specimen that are below the limit of detection for the test.
- **cobas**® SARS-CoV-2 Qualitative has been evaluated only for use in combination with the **cobas**® SARS-CoV-2 Qualitative 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**® 5800/6800/8800 systems.
- Reliable results depend on proper sample collection, storage and handling procedures. Failure to observe proper procedures in any one of these steps can lead to incorrect results.
- This test is intended to be used for the detection of SARS-CoV-2 RNA in nasal and nasopharyngeal swab samples collected as appropriate and described in Table 13 and Table 14. Other sample types were not evaluated with **cobas**® SARS-CoV-2 Qualitative.
- Detection of SARS-CoV-2 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 Qualitative 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 Qualitative 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 Qualitative 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.
- Clinical performance has not been established with all circulating variants but is anticipated to be reflective of the common 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.
- Performance of the **cobas**® SARS-CoV-2 Qualitative has not been established for monitoring treatment of infection.

Non-clinical performance evaluation

System equivalency

System equivalency of the **cobas**® 5800, **cobas**® 6800 and **cobas**® 8800 systems was demonstrated via performance studies. The data presented in this Instructions for Use support equivalent performance for all systems.

Key performance characteristics

Analytical sensitivity (Limit of Detection)

The Limit of Detection (LoD) for **cobas**® SARS-CoV-2 Qualitative was determined using an inactivated quantified SARS-CoV-2 virus (WHO International Standard for SARS-CoV-2, NIBSC code: 20/146). LoD is defined as the lowest concentration of SARS-CoV-2 RNA that can be detected at a rate of at least 95%. A total of 5 concentration levels (500, 250, 125, 62.5, and 31.25 IU/ml) were prepared by diluting the SARS-CoV-2 target in negative simulated clinical matrix stabilized in UTM. Three independent dilution series with three lots of reagents were tested with a total of 24 replicates per concentration.

The concentration level with observed hit rates greater than or equal to 95% was determined to be the LoD for each of the two targets (SARS-CoV-2 and pan-Sarbecovirus) as described in Table 19 and Table 20.

Table 19 Summary of LoD for SARS-CoV-2 using WHO International Standard (NIBSC code: 20/146)

Viral Strain	Kit lot	Hit rate ≥ 95% [IU/mL]	Mean Ct at ≥ 95% Hit rate
WHO International Standard for SARS-CoV-2 RNA (NIBSC code: 20/146)	Lot 1	**250 (24/24)**	33.2
	Lot 2	**125 (23/24)**	34.1
	Lot 3	**250 (23/24**	33.2

The LoD was confirmed at 250 IU/mL for SARS-CoV-2 (Target 1). For all three reagent lots, at least 23/24 replicates detected the target at 250 IU/ml.

Table 20 Summary of LoD for pan-Sarbecovirus using WHO International Standard (NIBSC code: 20/146)

Viral Strain	Kit lot	Hit rate ≥ 95% [IU/mL]	Mean Ct at ≥ 95% Hit rate
WHO International Standard for SARS-CoV-2 RNA (NIBSC code: 20/146)	Lot 1	**125 (24/24)**	35.2
	Lot 2	**125 (24/24)**	36.0
	Lot 3	**125 (23/24)**	34.8

The LoD was confirmed at 125 IU/mL for pan-Sarbecovirus (Target 2). For all three reagent lots, at least 23/24 replicates detected the target at 125 IU/ml.

Inclusivity

The inclusivity of **cobas**® SARS-CoV-2 Qualitative for the detection of SARS-CoV-2 was confirmed by testing nine SARS-CoV-2 strains, including six variant strains. The lowest target analyte at which all four tested replicates were positive are reported in Table 21. In silico analysis of additional SARS-CoV-2 sequences indicates that >99.9% of sequences for SARS-CoV-2 have no changes in primer/probe binding sites at both target regions simultaneously. All known sequences are predicted to be detected by at least one of the two target regions.

Table 21 Summary of inclusivity

Strain	Catalog Number	Lot Number	Test Concentration with 100% Positivity
Hong Kong/VM20001061/2020	0810590CFHI	325659	1.06E+02 cp/mL
Italy-INMI1	0810589CFHI	325658	1.00E+02 cp/mL
USA-WA1/2020	0810587CFHI	325656	5.03E+01 cp/mL
UK (B.1.1.7)	0810614CFHI	326230	2.4E+01 cp/mL
Japan / Brazil (P.1)	NR-54982	70042875	1.9E+02 cp/mL
South Africa (B.1.351)	0810613CFHI	326229	2.4E+01 cp/mL
US NY (B.1.526)	NR-55359	70043342	1.9E+02 cp/mL
India (B.1.617.1)	NR-55486	70044706	2.5E+02 cp/mL
India (B.1.617.2)	NR-55611	70045238	7.0E+01 cp/mL

An updated in-silico analysis was performed in January 2025 using all SARS-CoV-2 sequences submitted to the GISAID database till date (as of January 15, 2025) and are reported in Table 22. The in-silico analysis results indicates that >99.9% of sequences for SARS-CoV-2 have no changes in primer/probe binding sites at both target regions simultaneously. All sequences are predicted to be detected by at least one of the two target regions.

Table 22 In silico analysis of **cobas**® SARS-CoV-2 Qualitative Oligo Design

Target	Orf1ab		E-gene		Orf1ab & E-gene	
Database	**GISAID**		**GISAID**		**GISAID**	
total	16156883	100.00%	16156883	100.00%	16156883	100.00%
with_mismatch	549763	3.40%	87773	0.54%	3560	0.02%
dCp>5 or Tm<65	545	0.00%	1175	0.01%	3*	0.00%

* The three sequences have several frameshifts, significantly long truncations and nucleotide gaps, and thus are considered to be submissions of lower sequencing quality.

Precision

Within-laboratory precision was examined using a panel of SARS-CoV-2 (USA-WA1/2020, heat-inactivated) cultures diluted in simulated clinical matrix in universal transport media. Sources of variability were examined with a panel consisting of three concentration levels, using three lots of **cobas**® SARS-CoV-2 Qualitative reagents and three instruments over a course of 15 instrument days (2 runs/day x 3 instruments x 5 days/instrument x 3 replicates) for a total of 30 runs containing a total of 90 replicates per concentration. A description of the precision panel and the observed positivity rates are shown in Table 22. 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 24) yielded overall CV percentage ranging from 1.1% to 2.2% for **cobas**® SARS-CoV-2 Qualitative. This data was generated on **cobas**® 6800/8800 systems, and is representative of the precision on **cobas**® 5800 system.

Table 23 Summary of within laboratory precision

Target	Panel Member	Level (x LoD)	Positive Results	Total Results	Positivity %	Two-sided 95% CI Lower Bound	Two-sided 95% CI Upper Bound
Target 1 (SARS-CoV-2)	Weak positive	~0.3x	9	90	10%	5%	18%
Target 1 (SARS-CoV-2)	Low positive	~1.0x	82	90	91%	83%	96%
Target 1 (SARS-CoV-2)	Moderate positive	~3.0x	90	90	100%	96%	100%
Target 2 (pan-Sarbecovirus)	Weak positive	~0.3x	31	90	34%	25%	45%
Target 2 (pan-Sarbecovirus)	Low positive	~1.0x	84	90	93%	86%	97%
Target 2 (pan-Sarbecovirus)	Moderate positive	~3.0x	90	90	100%	96%	100%
N/A	Negative	Blank	0	90	0%	0%	4%

Table 24 Overall mean, standard deviation, and percent coefficient of variation for Ct values by positive panel member

Target	Level (x LoD)	Hit rate	Mean Ct	Instrument -to- Instrument SD	Instrument -to- Instrument CV%	Lot- to-Lot SD	Lot- to-Lot CV%	Day- to- Day SD	Day- to- Day CV%	Run- to- Run SD	Run- to- Run CV%	Within Run SD	Within Run CV%	Total SD	Total CV%
Target 1 (SARS-CoV-2)	~0.3x	10.0%	32.51	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.5	1.4	0.5	1.4
Target 1 (SARS-CoV-2)	~1.0x	91.1%	32.1	0.0	0.0	0.2	0.6	0.1	0.3	0.0	0.0	0.6	1.8	0.6	1.9
Target 1 (SARS-CoV-2)	~3.0x	100.0%	31.18	0.0	0.0	0.2	0.7	0.0	0.0	0.0	0.0	0.3	0.9	0.4	1.1
Target 2 (pan-Sarbeco- virus)	~0.3x	34.4%	35.36	0.0	0.0	0.5	1.3	0.3	0.8	0.1	0.2	0.5	1.5	0.8	2.2
Target 2 (pan-Sarbeco- virus)	~1.0x	93.3%	34.21	0.0	0.0	0.1	0.3	0.2	0.6	0.0	0.0	0.7	2	0.7	2.2
Target 2 (pan-Sarbeco- virus)	~3.0x	100.0%	32.9	0.0	0.1	0.0	0.0	0.0	0.0	0.0	0.0	0.4	1.1	0.4	1.1

Reproducibility

The reproducibility of **cobas**® SARS-CoV-2 Qualitative was evaluated across multiple variables that theoretically could affect reported results, including: reagent lot, testing site/instrument, day, and run. The evaluation was conducted at 3 testing sites, using 3 reagent lots, with a 4-member panel of positive and negative samples resulting in a total number 216 tests per concentration (not including controls). The positive panel members contained SARS-CoV-2 viral culture material [WHO International Standard for SARS-CoV-2 RNA (NIBSC code: 20/146)] at 3 different concentrations in universal transport medium (UTM) based simulated clinical matrix. Each site tested two reagent lots for 6 days. Two runs were performed each day and 3 replicates of each panel member were performed for each run. An overall SARS-CoV-2 positive result was determined by a positive detection in either or both of the SARS-CoV-2 or/and pan-Sarbecovirus channels. The evaluation results are summarized in Table 25.

The system showed a 99.1% negative percent agreement with a 95% CI of 96.7%-99.9%. The test results showed good lot-to-lot, instrument-to-instrument (site), day-to-day, and between run variation for the ~0.3x LoD, ~1x LoD, and ~3x LoD panel members (Table 25). This data was generated on **cobas**® 6800/8800 systems, and is representative of the Reproducibility on **cobas**® 5800 system.

Table 25 Overall percentage agreement, mean estimate, standard deviations, and coefficients of variation (%) for cycle threshold values by viral target and expected viral concentration

Viral Target	Panel Member Concentration	n[a]/N	Percent Agreement* (%)[b]	Mean Ct	Site SD	Site CV(%)	Lot SD	Lot CV(%)	Day SD	Day CV(%)	Run SD	Run CV(%)	Within Run SD	Within Run CV(%)	Total SD	Total CV(%)
Negative	0	214/216[c]	99.1	nc	nc	nc	nc	nc	nc	nc	nc	nc	nc	nc	nc	nc
SARS-CoV-2	~0.3x LoD	45/216	20.8	33.6	0.00	0.0	0.00	0.0	0.11	0.3	0.00	0.0	0.35	1.1	0.37	1.1
SARS-CoV-2	~1x LoD	196/216	90.7	33.2	0.00	0.0	0.09	0.3	0.00	0.0	0.17	0.5	0.37	1.1	0.42	1.3
SARS-CoV-2	~3x LoD	216/216	100.0	32.2	0.05	0.2	0.02	0.1	0.00	0.0	0.03	0.1	0.24	0.8	0.25	0.8
pan-Sarbecovirus	~0.3x LoD	158/216	73.1	36.5	0.18	0.5	0.00	0.0	0.00	0.0	0.00	0.0	0.71	2.0	0.74	2.0
pan-Sarbecovirus	~1x LoD	214/216	99.1	35.4	0.00	0.0	0.00	0.0	0.00	0.0	0.00	0.0	0.67	1.9	0.67	1.9
pan-Sarbecovirus	~3x LoD	216/216	100.0	34.1	0.11	0.3	0.05	0.2	0.00	0.0	0.00	0.0	0.32	0.9	0.34	1.0

Ct = cycle threshold, LoD = limit of detection, SD = standard deviation, CV(%) = percent coefficient of variation, SARS-CoV-2 = severe acute respiratory syndrome coronavirus 2, nc = not calculable

Note: SARS-CoV-2 is a dual target assay. Inactivated viral culture material was diluted to ~0.3/1/3x LoD based on the target 2 (SARS-CoV-2) LoD.

[a] n is the number of positive tests which contribute Ct values to the analysis. N is the total number of valid tests for the panel member.

[b] Percent agreement with expected results.

[c] 2 negative panel members were tested positive. Sequencing showed that one of these samples was positive and the other was negative. The Ct values and the curve analysis of these samples may suggest a low level of contamination during specimen handling.

Analytical specificity / cross-reactivity

A panel of 47 viruses, bacteria, and fungi (including those commonly found in respiratory tract) and pooled human nasal wash were tested with **cobas**® SARS-CoV-2 Qualitative to assess analytical specificity. The organisms listed in Table 26 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 SARS-CoV-2 target (spiked at ~3x LoD). None of the organisms interfered with the test performance by generating false-negative or false-positive results. Testing of SARS-CoV-1 generated an expected pan-Sarbecovirus positive result.

Additional in silico analysis conducted with other coronaviruses and respiratory flora indicated no concerns with the test performance by predicting any false-negative or false-positive results.

Table 26 Cross-reactivity test results

Microorganism	Concentration
Human coronavirus 229E	1.0E+05 $TCID_{50}$/mL
Human coronavirus OC43	1.0E+05 $TCID_{50}$/mL
Human coronavirus HKU1	1.0E+05 $TCID_{50}$/mL
Human coronavirus NL63	1.0E+05 $TCID_{50}$/mL
MERS coronavirus	1.0E+05 genomic equivalent/mL
SARS coronavirus	1.0E+05 PFU/mL
Adenovirus B (Type 34)	1.0E+05 $TCID_{50}$/mL
Bocavirus	1.0E+05 cp/mL
Cytomegalovirus	1.0E+05 $TCID_{50}$/mL
Epstein Barr virus	1.0E+05 cp/mL
Human Metapneumovirus (hMPV)	1.0E+05 $TCID_{50}$/mL
Measles virus	1.0E+05 $TCID_{50}$/mL
Mumps virus	1.0E+05 $TCID_{50}$/mL
Parainfluenza virus Type 1	1.0E+05 $TCID_{50}$/mL
Parainfluenza virus Type 2	1.0E+05 $TCID_{50}$/mL
Parainfluenza virus Type 3	1.0E+05 $TCID_{50}$/mL
Parainfluenza virus Type 4	1.0E+05 $TCID_{50}$/mL
Influenza A (H1N1)	1.0E+05 $TCID_{50}$/mL
Influenza A virus (H1N1-2009, H1N3, H3N2)	1.0E+05 $TCID_{50}$/mL
Influenza B	1.0E+05 $TCID_{50}$/mL
Enterovirus E (Type 1)	1.0E+05 $TCID_{50}$/mL
Parechovirus	1.0E+05 $TCID_{50}$/mL
Respiratory syncytial virus	1.0E+05 PFU/mL

Microorganism	Concentration
Rhinovirus	1.0E+05 $TCID_{50}$/mL
Candida albicans	1.0E+06 CFU/mL
Chlamydia pneumoniae	1.0E+06 $TCID_{50}$/mL
Corynebacterium diphtheriae	1.0E+06 CFU/mL
Escherichia coli	1.0E+06 CFU/mL
Haemophilus influenzae	1.0E+06 CFU/mL
Lactobacillus gasseri	1.0E+06 CFU/mL
Legionella pneumophila	1.0E+06 CFU/mL
Legionella jordanis (non-pneumophila)	1.0E+06 CFU/mL
Moraxella catarrhalis	1.0E+06 CFU/mL
Mycobacterium tuberculosis	1.0E+06 cells/mL
Neisseria elongata	1.0E+06 CFU/mL
Neisseria meningitidis	1.0E+06 CFU/mL
Pseudomonas aeruginosa	1.0E+06 CFU/mL
Pneumocystis jirovecii	1:20 of Patient Sample
Staphylococcus aureus	1.0E+06 CFU/mL
Staphylococcus epidermidis	1.0E+06 CFU/mL
Streptococcus pneumoniae	1.0E+06 CFU/mL
Streptococcus pyrogenes	1.0E+06 CFU/mL
Streptococcus salivarius	1.0E+06 CFU/mL
Bordetella pertussis	1.0E+06 CFU/mL
Mycoplasma pneumoniae	1.0E+06 CFU/mL

Interference

The effect of exogenous substances potentially secreted into respiratory specimens was evaluated (Table 27). Each potentially interfering substance was tested at or above clinically relevant levels in negative simulated clinical matrix stabilized in universal transport media in absence and presence of SARS-CoV-2 target (spiked at ~3x LoD).

None of the substances interfered with the test performance by generating false-negative, false-positive or invalid results at the concentrations shown below.

Table 27 List of exogenous substances tested for interference

Substance*	Product Name	Concentration
Oxymetazoline	Afrin Nasal Spray	0.011 mg/mL
Galphimia glauca, Luffa operculata, Sabadilla	Zicam nasal spray	0.023 mg/mL
Lidocaine and Phenylephrine	Liposomal NUMB520 Spray	2.68 mg/mL
Budesonide	Budesonide Nasal spray	0.039 mg/mL
Phenol	Chloraseptic	0.47 mg/mL
Fluticasone propionate	Flovent DisKus	166.67 µg/mL
Mupirocin	Mupirocin onitment UPS (each gram contacin 20 mgs)	0.20 mg/mL
Zanamivir	Relenza (Inhalation powder)	0.0015 mg/mL
Oseltamivir	Antiviral drug – Tamiflu	0.0073 mg/mL
Benzocaine and Menthol	Cepacol (Sore throat Lozenges)	5.00 mg/mL
Tobramycin	Tobramycin ophthalmic solution	0.018 mg/mL
Petroleum Jelly	Vaseline	1% (w/v)
Nicotine	Snuff Tobacco	1% (w/v)
Camphor-synthetic eucalyptus oil and menthol ointment	Analgesic ointment (Vicks@VapoRubR)	1% (w/v)
0.65% NaCl, Phenylcarbino, Benzalkonium chloride	Saline Nasal Spray with Preservatives	1% (w/v)

* FluMist was not evaluated to assess potential interference.

Endogenous substances that may be present in respiratory specimens were tested for interference (Table 28). Each potentially interfering substance was tested at or above clinically relevant levels in negative simulated clinical matrix stabilized in universal transport media in absence and presence SARS-CoV-2 target (spiked at ~3x LoD).

None of the substances interfered with the test performance by generating false-negative, false-positive or invalid results at the concentrations shown below.

Table 28 List of endogenous substances tested for interference

Substance	Concentration
Human Genomic DNA	20 ng/µL
Mucus	One sputum swab/mL
Human Peripheral Blood Mononuclear Cells (PBMC)	1.0E+03 cells/µL
Human Whole Blood	1% (v/v)
Human Whole Blood	2% (v/v)
Human Whole Blood	5% (v/v)

Matrix equivalency

Equivalence between simulated and real clinical matrix was evaluated using nasophyrangeal and nasal swabs. The WHO International Standard was used to formulate panels to a target concentration of approximately 3x LoD (above LoD), 1x LoD (at LoD) and 0.3x LoD (below LoD) into pooled negative clinical samples of each sample type (NPS, NS, and simulated), stabilized in universal transport media. Twenty-five replicates per concentration were tested for each sample type. All replicates tested at the 1x LoD and 3x LoD concentrations were positive for SARS-CoV-2 for all three sample types. Simulated clinical matrix, nasopharyngeal, and nasal swab sample types are acceptable for use with **cobas**® SARS-CoV-2 Qualitative.

Collection media equivalency – UTM-RT, cobas® PCR Media and 0.9% physiological saline

Equivalence between different collection media (UTM-RT, **cobas**® PCR Media, and saline) was evaluated using using the WHO International Standard for SARS-CoV-2 RNA (NIBSC code: 20/146). The WHO International Standard was used to formulate to a target concentration of approximately 2x LoD (low positive) and 4x LoD (moderate positive) into paired individual negative clinical samples, stabilized either in Universal Transport Media (UTM-RT), **cobas**® PCR Media (CPM), or 0.9% physiological saline (NaCl). At least 20 replicates per low positive sample and 10 replicates per moderate positive sample were tested for each collection media type. All replicates tested were positive for SARS-CoV-2 in all the three collection media types. UTM-RT, **cobas**® PCR Media, and 0.9% physiological saline are acceptable for use with **cobas**® SARS-CoV-2 Qualitative. The performance of **cobas**® SARS-CoV-2 Qualitative for use on the **cobas**® 6800/8800 systems in **cobas**® PCR Media and 0.9% physiological saline has been established in analytical studies. Clinical performance of the assay in these media types was not established.

Expected Values

The clinical performance of **cobas**® SARS-CoV-2 Qualitative in symptomatic population was evaluated in a prospective clinical study between March 2021 and June 2021.A summary of the positivity rate for the detection of SARS-CoV-2 by the **cobas**® SARS-CoV-2 Qualitative during the clinical study, for both nasopharyngeal swab specimens (NPS) and nasal swabs (NS) by collection site is presented in Table 29. The SARS-CoV-2 positivity ranged from 0% - 16.2% for NPS and 0% - 15.8% for NS respectively.

Table 29 Positivity Rate by collection site for **cobas**® SARS-CoV-2 Qualitative in Symptomatic Population

Site location	NPS with valid results	NPS Positivity Rate	NS with valid results	NS Positivity Rate
Oakland, CA	114	0.0% (0/114)	117	0.0% (0/117)
St.Louis, MO	117	11.1% (13/117)	117	10.3% (12/117)
Syracuse, NY	11	9.1% (1/11)	11	9.1% (1/11)
Bronx, NY	64	7.8% (5/64)	64	9.4% (6/64)
Nashville, TN	92	12.0% (11/92)	93	11.8% (11/93)
Easley, SC	127	13.4% (17/127)	128	12.5% (16/128)
Powdersville, SC	117	16.2% (19/117)	114	15.8% (18/114)
Dallas, TX	147	6.8% (10/147)	147	6.8% (10/147)
Dallas, TX	31	0.0% (0/31)	31	0.0% (0/31)
New Orleans, LA	46	4.3% (2/46)	46	2.2% (1/46)
Statesville, NC	33	6.1% (2/33)	34	5.9% (2/34)
Moorseville, NC	42	0.0% (0/42)	42	0.0% (0/42)
-	941	8.5% (80/941)	944	8.2% (77/944)

The clinical performance of **cobas**® SARS-CoV-2 Qualitative in asymptomatic population was evaluated in a prospective clinical study between October 2021 and April 2022. The SARS-CoV-2 positivity was 1.8% for asymptomatic NS specimens.

Clinical performance evaluation performed on the cobas® 6800/8800 systems

Symptomatic Population

Nasopharyngeal and nasal swab specimens

The performance of **cobas**® SARS-CoV-2 Qualitative was evaluated in a multi-center study with three external testing sites evaluating prospectively collected clinical specimens in UTM-RT® or UVT from individuals with signs and symptoms of respiratory infection. Participants from 12 geographically distributed enrollment centers each provided nasopharyngeal swab (NPS) and nasal swab (NS, anterior nares) specimens as part of a dual collection where (a) the collection order (first specimen collected) was alternated between the NPS and NS specimen, and (b) the collection method for NS specimens was also alternated with 50% of the NS specimens were self-collected on-site with healthcare provider (HCP) instructions while the other 50% were collected by the healthcare provider. The study used a composite comparator method wherein laboratory sites used up to three highly sensitive EUA SARS-CoV-2 molecular assays, testing NPS specimen from each subject . The composite comparator result was defined as the concordant results from two comparator assays (test A and test B). In case of discordance between the initial two comparator assays, the sample was tested by a third assay (test C) and the result of the third test determined the composite comparator result. The composite comparator result was indetermined when valid results could not be obtained from two assays (i.e., insufficient volume for repeat testing of invalid/failed results).

From March to June 2021, a total of 1,154 participants were enrolled, of which samples from 968 participants were included in the evaluation. Samples from 186 participants were not included: 184 specimens were excluded due to issues associated with specimen shipments and/or being unable to complete testing within the times identified by manufacturer's instructions, and two subjects were excluded for being previously enrolled in the study (exclusion criteria). When self-reporting COVID-19 vaccination status, 207 (21.4%) of the 968 participants were fully vaccinated.

Of the 968 participants, 961 contributed a NPS specimen which resulted in 942 participants with a confirmed infected status. For NPS, 4 specimens had failed/invalid **cobas**® SARS-CoV-2 Qualitative results, resulting in 938 evaluable NPS results. For NS, 8 specimens were invalid/missing **cobas**® SARS-CoV-2 Qualitative NS results, resulting in 934 evaluable results.

When compared with the NPS composite comparator result, **cobas**® SARS-CoV-2 Qualitative yielded a positive percent agreement (PPA) of 98.7% for NPS and 97.4% for NS specimens. The negative percent agreement (NPA) was 99.7% and 99.9% for NPS and NS specimens, respectively (Table 30).

Table 30 Summary of clinical performance of **cobas**® SARS-CoV-2 Qualitative for nasopharyngeal (NPS) and nasal swabs (NS) versus the NPS composite comparator

Specimen Type	Total (N)	PPA	PPA 2-sided 95% Score CI	NPA	NPA 2-sided 95% Score CI
Nasopharyngeal (NPS)	938	98.7% (77/78)	(93.1 %, 99.8 %)	99.7% (857/860)	(99.0 %, 99.9 %)
Nasal Swab (NS)*	934	97.4% (76/78)	(91.1 %, 99.3 %)	99.9% (855/856)	(99.3 %, 100 %)

*Healthcare provider-collected nasal swab specimens and nasal swab specimens self-collected on-site with healthcare provider instructions.

Asymptomatic Population

The clinical performance evaluation of the **cobas**® SARS-CoV-2 Qualitative on asymptomatic subjects was assessed using real world data and clinical study data.

Real-world evidence

The clinical performance of the **cobas**® SARS-CoV-2 Qualitative with asymptomatic subjects was assessed using real-world data collected from the 2020 National Football League (NFL) COVID-19 Surveillance Program where samples were collected and tested between August 2020 and January 2021 as part of an Occupational Testing protocol.[3] Anterior nasal swab samples were prospectively collected on a near-daily basis from NFL players and staff.

The performance of **cobas**® SARS-CoV-2 Qualitative was estimated using a comparator algorithm that was based on molecular comparator test results and/or clinical adjudication performed within the NFL testing program. A total of 1776 samples were selected for analysis where the **cobas**® SARS-CoV-2 Qualitative candidate test and comparator test results, were evaluable to establish the COVID-19 status for each sample. The results are shown in Table 31 below.

Table 31 Performance estimates for the **cobas**® SARS-CoV-2 Qualitative in anterior nasal swabs in asymptomatic individuals (NFL)

	Comparator algorithm		**Total**
	Positive	**Negative**	
Candidate Positive	11	3	14
Candidate Negative	0	1,762	1,762
Total	11	1,765	1,776
PPA (n/N) (95% Confidence Interval)	100.0% (11/11) (95% CI: 74.1% - 100%)		
NPA (n/N) (95% Confidence Interval)	99.8% (1762/1765) (95% CI: 99.5% - 99.9%)		

Note: CI = confidence interval, PPA = positive percent agreement, NPA = negative percent agreement

Clinical study

The clinical performance of the **cobas**® SARS-CoV-2 Qualitative with asymptomatic subjects was also assessed using data collected from the 2021 Test Us At Home (TUAH) study where samples were collected and tested for SARS-CoV-2 between October 2021 and April 2022 as part of longitudinal study.[4] Anterior nasal swab samples were prospectively collected every 48 hours from each participant over 15 days.

The performance of **cobas**® SARS-CoV-2 Qualitative was estimated using a comparator algorithm where two consecutive test results (molecular comparator) over 48 hours were used to determine comparator result. All samples (38,192) from the TUAH study had a valid comparator algorithm result and a valid candidate test result were included in the calculation of performance estimates of **cobas**® SARS-CoV-2 Qualitative. The results are shown in Table 32 below.

Table 32 Performance estimates for the **cobas**® SARS-CoV-2 Qualitative in anterior nasal swabs in asymptomatic individuals (TUAH study)

	Comparator algorithm		Total
	Positive	Negative	
Candidate Positive	315	272	587
Candidate Negative	19	37,586	37,605
Total	334	37,858	38,192
PPA (n/N) (95% Confidence Interval)	94.3% (315/334) (95% CI: 91.4% - 96.8%)*		
NPA (n/N) (95% Confidence Interval)	99.2% (37,586/37,858) (95% CI: 99.2% - 99.4%)*		

* Confidence intervals were estimated using a bootstrapping method.

Note: CI = confidence interval, PPA = positive percent agreement, NPA = negative percent agreement

Additional information

Key test features

Sample type	Nasopharyngeal swab samples collected in the Copan UTM-RT System, the BD™ UVT System and 0.9% physiological saline 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	Swab specimen types: 0.6 or 1.0 mL*
Sample processing volume	Swab specimen types: 0.4 mL

*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**® 5800 and **cobas**® 6800/8800 systems (consult User Assistance) 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 33 Symbols used in labeling for Roche PCR diagnostics products

Age/DOB Age or Date of Birth	Device not for near-patient testing	QS IU/PCR QS IU per PCR reaction, use the QS International Units (IU) per PCR reaction in calculation of the results.
SW Ancillary Software	Device not for self-testing	
Assigned Range [copies/mL] Assigned Range (copies/mL)	Distributor *(Note: The applicable country/region may be designated beneath the symbol)*	SN Serial number
Assigned Range [IU/mL] Assigned Range (IU/mL)	Do not re-use	Site Site
EC REP Authorized representative in the European Community	Female	Procedure Standard Standard Procedure
BARCODE Barcode Data Sheet	For IVD performance evaluation only	STERILE EO Sterilized using ethylene oxide
LOT Batch code	GTIN Global Trade Item Number	Store in dark
Biological risks	Importer	Temperature limit
REF Catalogue number	IVD In vitro diagnostic medical device	TDF Test Definition File
CE CE marking of conformity; this device is in conformity with the applicable requirements for CE marking of an in vitro diagnostic medical device	LLR Lower Limit of Assigned Range	This way up
	Male	Procedure UltraSensitive Ultrasensitive Procedure
Collect Date Collect date	Manufacturer	UDI Unique Device Identifier
Consult instructions for use	CONTROL − Negative control	ULR Upper Limit of Assigned Range
Σ Contains sufficient for <*n*> tests	NON STERILE Non-sterile	Urine Fill Line Urine Fill Line
CONTENT Content of kit	Patient Name	Rx only For USA: Caution: Federal law restricts this device to sale by or on the order of a physician.
CONTROL Control	Patient number	Use-by date
Date of manufacture	Peel here	
Device for near-patient testing	CONTROL + Positive control	
Device for self-testing	QS copies / PCR QS copies per PCR reaction, use the QS copies per PCR reaction in calculation of the results.	

Technical support

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

Manufacturer and distributor

Table 34 Manufacturer and distributor

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

Made in USA

Distributed by

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 https://diagnostics.roche.com/us/en/about-us/patents

Copyright

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.
3. Mack CD, Osterholm M, Wasserman EB, et al. Optimizing SARS-CoV-2 Surveillance in the United States: Insights From the National Football League Occupational Health Program. *Ann Intern Med*. 2021;174:1081-9. PMID: 34125571.
4. Soni, Apurv, et al. "Performance of rapid antigen tests to detect symptomatic and asymptomatic SARS-CoV-2 Infection: A prospective cohort study." Annals of internal medicine 176.7 (2023): 975-982.

Document revision

Document Revision Information	
Doc Rev. 3.0 05/2025	Updated **Intended Use** section.Updated **cobas**® **omni** Lysis Reagent hazard information. Updated **Additional materials required for the cobas**® **5800 System** sections. Updated **Precautions and handling requirements** section Update **Good laboratory practice** section. Updated **Instructions for Use** section. Updated **Results section** to add **cobas**® SARS CoV-2 Qualitative results interpretation of the **cobas**® 5800/6800/8800 Systems information. Updated **Procedural Limitations section** to remove clinical reference of asymptomatic individuals.Updated Inclusivity section to add data based on GISAID database. Added **Expected values** section to include clinical performance in asymptomatic population study information. Updated **Clinical performance section** to distinguish between Real World evidence and Clincal study information for Asymptomatic population. Updated **cobas**® branding. Updated Reference section. Please contact your local Roche Representative if you have any questions.
Doc Rev. 4.0 11/2025	Added system software version 2.0 information for **cobas**® 6800/8800 systems. P/Ns of consumables removed, detailed information on consumables are referenced in the **cobas**® 5800 and **cobas**® 6800/8800 systems User Assistance. Precautions and handling Requirements section: added potassium hypochlorite as additional disinfect. Please contact your local Roche representative if you have any questions.