Rx Only

cobas omni Utility Channel Reagent Kit

for use on the cobas® 5800/6800/8800 Systems

For in vitro diagnostic use

cobas omni Utility Channel Reagent Kit	P/N: 09052011190
cobas® Buffer Negative Control Kit	P/N: 07002238190 -or- P/N: 09051953190

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Intended use

The **cobas omni** Utility Channel Reagent Kit provides the reagents and internal-control primers and probes necessary to utilize the open channel functionality of the **cobas**® 5800/6800/8800 Systems for the automated Polymerase Chain Reaction based Nucleic Acid Testing in order to developed tests for in vitro diagnostic use. The reagent kit is intended for use by trained professionals in the laboratory setting.

Summary and explanation of the test

Background

The **cobas omni** Utility Channel Reagent Kit supports real-time PCR applications in combination with sets of reagents and consumables supplied by Roche. Test-specific reagents (target-specific primers and probes) are not provided by Roche, and must be designed and/or purchased by the customer.

The sample type for the tests must be determined and validated by the customer, based on their test-specific needs.

Principles of the procedure

Tests performed using the **cobas omni** Utility Channel Reagent Kit are based on fully-automated sample preparation (nucleic acid extraction and purification), PCR amplification, and target detection technologies found in the **cobas**® 5800/6800/8800 Systems. 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(s), and the analytic module(s). Automated data management is performed by the **cobas**® 5800/6800/8800 Systems softwares which assigns test results. Results can be reviewed directly on the system screen, exported, or printed as a report.

Performance of tests using the **cobas omni** Utility Channel Reagent Kit relies on the **cobas omni** reagent concept, which is exclusive to the **cobas**® 5800/6800/8800 Systems. This concept enables use of the same sample preparation reagents (**cobas omni** MGP Reagent, **cobas omni** Lysis Reagent, **cobas omni** Wash Reagent, **cobas omni** Specimen Diluent, Proteinase, RNA internal control, Elution Buffer, and MMX-R1) for all tests run on the systems.

All tests performed on the **cobas**® 5800/6800/8800 Systems furthermore utilize a single sample preparation process, the **cobas omni** sample preparation process. In summary, nucleic acid from samples, external controls, and added armored RNA (internal control) is simultaneously extracted; the nucleic acid is released by addition of proteinase and lysis reagent to the sample. The released nucleic acid then 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 an elevated temperature.

Selective amplification of target nucleic acid from the sample is achieved by the use of target-specific forward and reverse primers provided by the customer. The **cobas omni** Utility Channel Master Mix Reagent 2 (UC MMX-R2), provided by Roche as part of the **cobas omni** Utility Channel Reagent Kit, includes an internal control. Selective amplification of the internal control is achieved by the use of sequence-specific forward and reverse primers that also are included in the UC MMX-R2 reagent. A thermostable DNA polymerase enzyme is used for both reverse transcription and PCR amplification. The master mix includes deoxyuridine triphosphate (dUTP), instead of deoxythimidine triphosphate (dTTP), that is incorporated into the newly synthesized DNA (amplicon).[1-3] Any contaminating amplicon from previous PCR runs is eliminated by the AmpErase enzyme included in the master mix during the first thermal cycling step. However, newly formed amplicon is not eliminated since the AmpErase enzyme is inactivated once exposed to temperatures above 55°C.

Reagents and materials

cobas omni Utility Channel reagents and controls

The materials provided for **cobas omni** Utility Channel Reagent Kit can be found in Table 1. Materials required, but not provided can be found in Table 2, Table 3, 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.

Table 1 cobas omni Utility Channel Reagent Kit

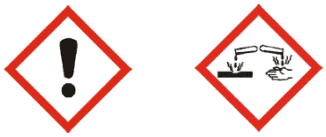
cobas omni Utility Channel Reagent Kit **(UC)** Store at 2-8°C (P/N 09052011190)		
Kit components	**Reagent ingredients**	**Quantity per kit 192 tests**
192 test cassette		
Proteinase Solution (PASE)	Tris buffer, < 0.05% EDTA, calcium chloride, calcium acetate, 8% (w/v) proteinase EUH210: Safety data sheet available on request. EUH208: Contains Subtilisin. May produce an allergic reaction.	22.3 mL
RNA Internal Control (RNA-QS)	Tris buffer, < 0.05% EDTA, armored RNA construct containing primer and probe-specific sequence regions (non-infectious RNA in MS2 bacteriophage), < 0.1% sodium azide	21.2 mL
Elution Buffer (EB)	Tris buffer, 0.2% methyl-4 hydroxybenzoate	21.2 mL
Master Mix Reagent 1 (MMX-R1)	Manganese acetate, potassium hydroxide, < 0.1% sodium azide	7.5 mL
Master Mix Reagent 2 bottle		
cobas omni Utility Channel Master Mix Reagent 2 (UC MMX-R2)	Tricine buffer, potassium acetate, < 18% dimethyl sulfoxide, glycerol, < 0.1% Tween 20, EDTA, < 0.12% dATP, dCTP, dGTP, dUTPs, < 0.01% internal control forward and reverse primers, < 0.01% fluorescent-labeled oligonucleotide probes specific for RNA-IC, < 0.01% oligonucleotide aptamer, < 0.01% Z05D DNA polymerase, < 0.1% AmpErase (uracil-N-glycosylase) enzyme (microbial), < 0.1% sodium azide	19.6 mL (2 x 9.8 mL)

Table 2 **cobas®** Buffer Negative Control Kit

cobas® Buffer Negative Control Kit (BUF (–)C) Store at 2-8°C For use with core software 1.2 or higher on **cobas®** 6800/8800 Systems (P/N 07002238190) -or- For use with core software 1.0 or higher on **cobas®** 5800 System, 1.4 or higher on **cobas®** 6800/8800 Systems (P/N 09051953190)		
Kit components	**Reagent ingredients**	**Quantity per kit**
cobas® Buffer Negative Control Kit (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 3 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)	42.56% (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 serious skin 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

* Product safety labeling primarily follows EU GHS guidance

**Hazardous substance

Reagent storage and handling requirements

Reagents must be stored and handled as specified in Table 4 and Table 6.

When reagents are not loaded on the **cobas**® 5800/6800/8800 Systems, store them at the corresponding temperature specified in Table 4.

Table 4 Reagent storage (when reagent is not on the system)

Reagent	Storage temperature
cobas omni Utility Channel Reagent 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 cobas® 5800 System

Reagents loaded onto the **cobas**® 5800 System are stored at appropriate temperatures and their expiration is monitored by the system. The **s**ystem allows reagents to be used only if all of the conditions shown in Table 5 are met. The system automatically prevents use of expired reagents. Table 5 allows the user to understand the reagent handling conditions enforced by the **cobas**® 5800 System.

Table 5 Reagent expiry conditions enforced by the **cobas**® 5800 System

Reagent	Kit expiration date	Open-kit stability	Number of runs for which this kit can be used	On-board stability
cobas omni Utility Channel Reagent Kit	Date not passed	90 days from first usage	Max 40 runs	Max 36 days*
cobas® Buffer Negative Control Kit	Date not passed	Not applicable[a]	Not applicable	Max 36 days*
cobas omni Lysis Reagent	Date not passed	30 days from loading*	Not applicable	Not applicable
cobas omni MGP Reagent	Date not passed	30 days from loading*	Not applicable	Not applicable
cobas omni Specimen Diluent	Date not passed	30 days from loading*	Not applicable	Not applicable
cobas omni Wash Reagent	Date not passed	30 days from loading*	Not applicable	Not applicable

[a] Single use reagents

* Time is measured from the first time that reagent is loaded onto the **cobas**® 5800 System.

Note: The on-board reagent stability of the **cobas omni** Utility Channel Master Mix Reagent 2, as well as the other reagents, was tested by Roche. The addition of test-specific reagents (target-specific primers and probes) may change the stability of the final **cobas omni** Utility Channel Master Mix Reagent 2. The recommendation is to establish a test-specifc positive control and to process that positive control with each batch.

Reagent handling requirements for cobas® 6800/8800 Systems

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 omni Utility Channel Reagent Kit	Date not passed	90 days from first usage	Max 40 runs	Max 40 hours
cobas® Buffer Negative Control Kit	Date not passed	Not applicable[a]	Not applicable	Max 10 hours
cobas omni Lysis Reagent	Date not passed	30 days from loading*	Not applicable	Not applicable
cobas omni MGP Reagent	Date not passed	30 days from loading*	Not applicable	Not applicable
cobas omni Specimen Diluent	Date not passed	30 days from loading*	Not applicable	Not applicable
cobas omni Wash Reagent	Date not passed	30 days from loading*	Not applicable	Not applicable

[a] Single use reagents

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

For **cobas omni** Utility Channel Reagent Kit the stability after opening time is measured from the first time the reagents are pipetted out of the cassette.

Note: The on-board reagent stability of the **cobas omni** Utility Channel Master Mix Reagent 2, as well as the other reagents, was tested by Roche. The addition of test-specific reagents (target-specific primers and probes) may change the stability of the final **cobas omni** Utility Channel Master Mix Reagent 2. The recommendation is to establish a test-specifc positive control and to process that positive control with each batch.

Additional materials required for cobas® 5800 System

Table 7 Material and consumables for use on **cobas**® 5800 System

Material	P/N
cobas omni Processing Plate 24	08413975001
cobas omni Amplification Plate 24	08499853001
cobas omni Liquid Waste Plate 24	08413983001
Tip CORE TIPS with Filter, 1mL	04639642001
Tip CORE TIPS with Filter, 300uL	07345607001
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 or Solid Waste Bag With Insert	07435967001 or 08030073001

Additional materials required for cobas® 6800/8800 Systems

Table 8 Material 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 Solid Waste Bag	07435967001 and 07094361001 or 08030073001 and 08387281001

Instrumentation and software required

The **cobas**® 5800 System software must be installed on the system. The Data Manager software and PC for the **cobas**® 5800 System will be provided with the system.

The **cobas**® 6800/8800 Systems software must be installed on the system. The Instrument Gateway (IG) server will be provided with the system.

Table 9 Instrumentation

Equipment	P/N
cobas® 5800 System	08707464001
cobas® 6800 System (Option Moveable)	05524245001 and 06379672001
cobas® 6800 System (fix)	05524245001 and 06379664001
cobas® 8800 System	05412722001
Sample Supply Module	06301037001

Refer to the **cobas**® 5800 System or **cobas**® 6800/8800 Systems – User Assistance and/or User Guides for additional information.

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.

Note: Refer to the **cobas omni** Utility Channel User Assistance for Utility Channel Software and Hardware use and ordering information.

Precautions and handling requirements

Warnings and precautions

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

- All 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.[4,5]
- Only personnel proficient in handling infectious materials and the use of the **cobas omni** Utility Channel Reagent Kit 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 hypochlorite in distilled or deionized water (dilute household bleach 1:10) or follow appropriate site procedures.
- 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 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, control cassette, MGP 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.
- The **cobas omni** Utility Channel Reagent 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 the **cobas omni** Utility Channel Reagent Kit or **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**® 5800 instrument, follow the instructions in the **cobas**® 5800 System User Assistance and/or User Guide to properly clean and decontaminate the surface of instrument(s).
- If spills occur on the **cobas**® 6800/8800 Systems, follow the instructions in the **cobas**® 6800/8800 Systems User Assistance and/or User Guide to properly clean and decontaminate the surface of instruments.

Instructions for use

Procedural notes

- Do not use the **cobas omni** Utility Channel Reagent Kit, **cobas**® Buffer Negative Control Kit, or reagents after their expiry dates.
- Do not reuse consumables. They are for one-time use only.
- Refer to the **cobas**® 5800 System or **cobas**® 6800/8800 Systems User Assistance and/or User Guides for proper maintenance of the system.

Running a test using cobas omni Utility Channel Reagent Kit on cobas® 5800 System

Tests performed using the **cobas omni** Utility Channel Reagent Kit can be run with different sample volumes. Depending on the sample type chosen, not all processing volumes may be available. The test procedure is described in detail in the **cobas**® 5800 System User Assistance and/or User Guide. The following figure summarizes the procedure.

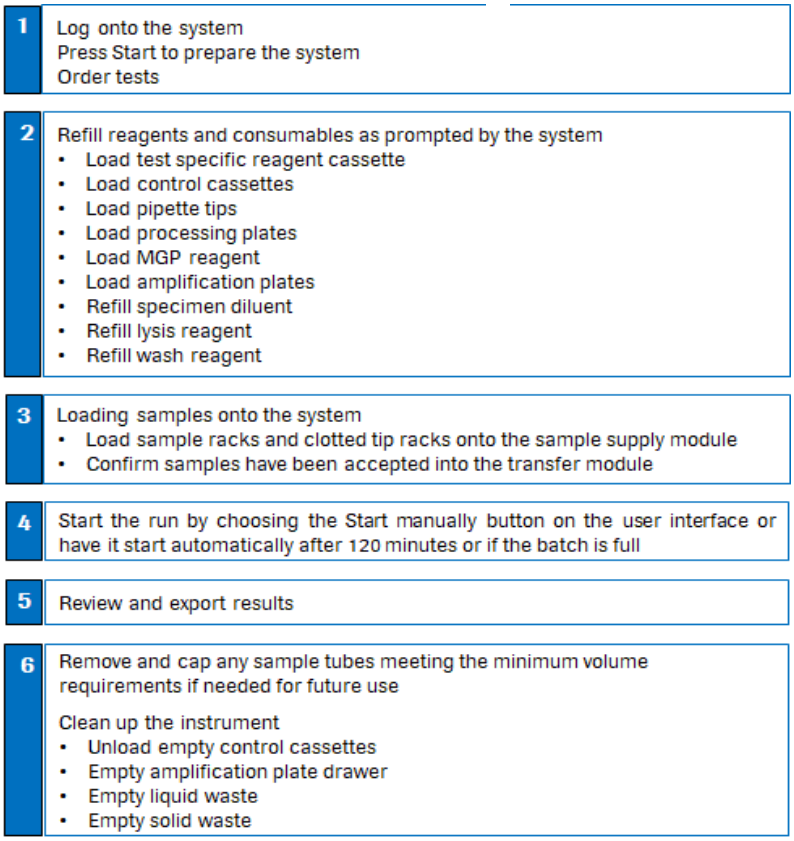
Figure 1 **cobas omni** Utility Channel Reagent Kit test procedure on **cobas**® 5800 System

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

Running a test using the cobas omni Utility Channel Reagent Kit on cobas® 6800/8800 Systems

Tests performed using the **cobas omni** Utility Channel Reagent Kit can be run with different sample volumes. Depending on the sample type chosen, not all processing volumes may be available. The test procedure is described in detail in the **cobas**® 6800/8800 Systems User Assistance and/or User Guides. The following figure summarizes the procedure.

Figure 2 cobas omni Utility Channel test procedure on the **cobas**® 6800/8800 Systems



Results

Quality control and validity of results on the cobas® 5800 System

- One negative control [(–) Ctrl] is processed at least every 72 hours or with every new kit lot on the **cobas**® 5800 System. Negative control can be scheduled more frequently based on laboratory procedures and/or local regulations.
- In the **cobas**® 5800 System software and/or report, check for flags and their associated results to ensure the batch validity.
- The batch is valid if no flags appear for the negative control. The negative control result is displayed as (–) Ctrl.

Invalidation of results is performed automatically by the **cobas**® 5800 System software based on negative control failures.

NOTE: The **cobas**® 5800 System will be delivered with the standard setting of running a negative control 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.

Control results on cobas® 5800 System

The results of the controls are shown in the **cobas**® 5800 software in the "Controls" app.

- Controls are marked with "Valid" in the column "Control result" if all Targets of the control are reported valid. Controls are marked with 'Invalid' in the column "Control result" if all or one Target of the control are 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 will be shown in the detail view.
- If the negative control is invalid, repeat testing of all associated samples.

Quality control and validity of results on the cobas® 6800/8800 Systems

- One negative control [(–) Ctrl] is processed with each batch on the **cobas**® 6800/8800 Systems.
- In the **cobas**® 6800/8800 Systems softwares and/or reports, check for flags and their associated results to ensure the batch validity.
- The batch is valid if no flags appear for the negative control. The negative control result is displayed as (–) Ctrl.

Invalidation of results is performed automatically by the **cobas**® 6800/8800 Systems softwares based on negative control failures.

Control flags on cobas® 6800/8800 Systems

Table 10 Control flag for negative control processed on **cobas**® 6800/8800 Systems

Negative Control	Flag	Result	Interpretation
(–) Ctrl	Q02 (Control batch failed)	Invalid	An invalid result or the calculated Ct result for the negative control is not negative.

If the batch is invalid, repeat testing of the entire batch including samples and controls.

(-) Ctrl stands for **cobas**® Buffer negative control

Interpretation of results

For a valid control batch, check each individual sample for flags in the **cobas**® 5800 System and **cobas**® 6800/8800 Systems softwares and/or reports. The result interpretation should be as follows:

- A valid batch may include both valid and invalid sample results.

Table 11 Target results for individual target result interpretation

Results	Interpretation
UC_Negative	Target-specific nucleic acid has not been detected.
UC_Positive	Target-specific nucleic acid has been detected.
Ct	Threshold cycle (Ct) determined by algorithm for positive sample.

Procedural limitations

- The **cobas omni** Utility Channel Reagent Kit has been evaluated only for use in combination with the **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.
- 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. Users should follow their own specific policies/procedures.

Non-clinical performance evaluation

Key performance characteristics performed on the cobas® 6800/8800 Systems

cobas omni Utility Channel Reagent Kit enables users to add their own primers and probes. The data presented in this section describes the key performance characteristics of the reagent kit based on the RNA internal control performance.

Whole system failure

The whole system failure rate for the **cobas omni** Utility Channel Reagent Kit was determined by running 102 individual clinical EDTA plasma specimens, tested negatively for HBV, HCV and HIV. The study was performed using the **cobas**® 6800 System.

The results of this study determined that all RNA internal control signals were detected in all individual negative clinical specimens, resulting in a whole system failure rate 0%. The two-sided 95% exact confidence interval was 0% for the lower bound and 3.55% for the upper bound [0%: 3.55%].

Endogenous interference

Ten individual clinical EDTA plasma specimens tested negatively for HBV, HCV and HIV with abnormally high levels of either triglycerides (up to 33 g/L), hemoglobin (up to 2 g/L), unconjugated and conjugated bilirubin (up to 0.2 g/L), albumin (up to 60 g/L), or human DNA (up to 0.004g/L) were tested. The presence of these substances did not interfere with the RNA internal control performance.

Reproducibility

Reproducibility was exemplified on the basis of a lab-developed test for Epstein-Barr-Virus (EBV), using cell culture spiked into NHP as sample material. This study consisted of testing 3 panels of EBV at concentrations of approximately 8.9E+02, 2.2E+03 and 4.4E+03 copies/mL. Testing was performed for the following variability components:

- day-to-day variability over 12 days
- lot-to-lot variability using 3 different reagent lots of the **cobas omni** Utility Channel Reagent Kit
- instrument-to-instrument variability using 2 different **cobas**® 6800 Systems

Twenty-two replicates (distributed over 2 runs) were tested with each of the 3 panels for a total of 84 replicates with each reagent lot. All valid reproducibility data were evaluated by calculating the percentage of reactive test results for each concentration level across all variable components.

The limits of two-sided 95% confidence intervals for each reactive rate were calculated for each of the 3 levels of EBV tested across 12 days, 3 reagent lots, and 2 **cobas**® 6800 Systems. The **cobas omni** Utility Channel EBV test is reproducible over multiple days, reagent lots and instruments. The results from reagent lot-to-lot variability are summarized in Table 12.

Table 12 Summary of reproducibility results, reagent lot-to-lot variability

EBV Concentration (cp/mL)	Reagent Lot	Reactive results by reagent lot (number of reactive/number of valid samples)	95% Lower CI	95% Upper CI
4.4E+03	Lot 1	100% (88/88)	94.7%	100.0%
	Lot 2	100% (88/88)	94.7%	100.0%
	Lot 3	100% (88/88)	94.7%	100.0%
2.2E+03	Lot 1	100% (88/88)	94.7%	100.0%
	Lot 2	100% (88/88)	94.7%	100.0%
	Lot 3	100% (88/88)	94.7%	100.0%
8.9E+02	Lot 1	100% (88/88)	94.7%	100.0%
	Lot 2	100% (88/88)	94.7%	100.0%
	Lot 3	100% (88/88)	94.7%	100.0%

RNA internal control failure rate

RNA internal control failure rate was evaluated including data of 32 runs and 1163 plasma and serum samples.

All RNA internal control signals were detected in all samples, resulting in a RNA internal control failure rate of 0%. The upper one-sided 95% exact confidence interval was 0.26%.

System equivalency / system comparison

System equivalency of the **cobas**® 5800, **cobas**® 6800 and **cobas**® 8800 Systems was demonstrated via performance studies.

The results presented in the Instructions for Use support equivalent performance for all systems.

Additional information

Key features

Amount of sample required	Amount of sample processed + minimally 150 µL in **cobas omni** secondary tubes
Amount of sample processed	Indicated as Processing volume (µL) in the Utility Channel Tool

Symbols

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

Table 13 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 US Only: 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 distributors

Table 14 Manufacturer and distributors

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

Made in USA

Roche Diagnostics GmbH
Sandhofer Strasse 116
68305 Mannheim, Germany

Trademarks and patents

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

Copyright

Roche Diagnostics GmbH
Sandhofer Str. 116
68305 Mannheim
Germany

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Document revision

Document Revision Information	
Doc Rev. 2.0 05/2021	Increased volume of MMx-R2 from 9.8 mL to 19.6 mL. Added Made in statement. Please contact your local Roche Representative if you have any questions.
Doc Rev. 3.0 07/2021	Added **cobas**® 5800 specific information ands added new BUFF NEG M/N. Added importer address. Removed distributors addresses. Updated the harmonized symbol page. Please contact your local Roche Representative if you have any questions.