Rx Only

cobas® ADV/hMPV/EV-RV UC

Qualitative nucleic acid test
for use on the cobas® 6800/8800 Systems

For in vitro diagnostic use

cobas® ADV/hMPV/EV-RV UC	P/N: 09555625190
cobas® ADV/hMPV/EV-RV UC Control Kit	P/N: 09555595190
cobas omni Utility Channel Reagent Kit	P/N: 09052011190
cobas® Buffer Negative Control Kit	P/N: 09051953190

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Intended use

The **cobas**® ADV/hMPV/EV-RV UC Qualitative Nucleic Acid test for use with the **cobas omni** Utility Channel on the **cobas**® 6800/8800 Systems is an automated, multiplex, real-time reverse transcription polymerase chain reaction (PCR) assay for the timely in vitro qualitative detection and discrimination of human Adenovirus (ADV), Metapneumovirus (hMPV) and Enterovirus/Rhinovirus (EV-RV).

This test is intended for the use as an aid in the diagnosis and differentiation of ADV, hMPV and EV-RV in nasopharyngeal swab specimens from patients with signs and symptoms of a respiratory infection.

The results from **cobas**® ADV/hMPV/EV-RV UC must be interpreted within the context of all relevant clinical, epidemiological, and laboratory data. Negative results do not preclude viral infection and should not be used as the sole basis for treatment or other patient management decisions. Conversely, positive results do not rule out bacterial infection or co-infection with other viruses. The agent detected may not be the definite cause of disease.

The **cobas**® ADV/hMPV/EV-RV UC Qualitative Nucleic Acid test for use with the **cobas omni** Utility Channel on the **cobas**® 6800/8800 Systems is intended for professional use in a clinical laboratory setting.

Summary and explanation of the test

Background

Acute respiratory tract infection is the most common illness worldwide regardless of age or sex[1] and the second leading cause of death for children less than 5 years of age.[2] Timely identification of common non-influenza and non-SARS-CoV-2 respiratory viruses in acutely ill individuals can aid in the avoidance of costly monitoring, isolation, treatment, and hospitalization.

Human adenoviruses are non-enveloped viruses with an icosahedral nucleocapsid containing a double stranded DNA genome. At present, eight subgroups have been identified (A-G).[3] Adenoviruses are unusually stable to chemical or physical agents and adverse pH conditions, allowing for prolonged survival outside of the body and water. Adenoviruses spread primarily via respiratory droplets. They have a worldwide distribution and are commonly associated with diseases such as conjunctivitis, gastroenteritis, rash illness, neurologic diseases and respiratory infections.[4] The symptoms of the disease depend on the preferred tissue tropism of the virus. For example, adenovirus 40 and 41 belonging to subgroup F cause gastroenteritis, usually in children.[4] Epidemic keratoconjunctivitis is associated with subgroups D and E and respiratory diseases commonly associated with species B, C or E.[5] Adenovirus infection is usually acquired during childhood and the virus may remain latent in human lymphoid tissue for years.[3]

Human metapneumovirus (hMPV) is an RNA virus in the paramyxovirus family and can cause upper and lower respiratory disease in people of all ages, especially among young children, older adults, and people with weakened immune systems.[6] hMPV is the primary etiological agent responsible for approximately 5% to 10% of hospitalizations of children suffering from acute respiratory tract infections. Initial infection with hMPV usually occurs during early childhood and can cause bronchiolitis and pneumonia, but re-infections are common throughout life. Due to the slow growth of the virus in cell culture, molecular methods, such as RT-PCR, are the preferred diagnostic modality for detecting hMPV.[6]

Human rhinoviruses (RVs) and enteroviruses (EVs) are leading causes of infection in humans. These two picornaviruses share an identical genomic organization, have similar functional RNA secondary structures, and are classified within the

same genus because of their high sequence homology.[7] However, despite their common genomic features, these two groups of viruses have different phenotypic characteristics. In vivo, rhinoviruses are restricted to the respiratory tract, are responsible for more than one-half of upper respiratory tract infections (URTI), and therefore considered to be among the most frequent infectious agents in humans worldwide.[8] Most cases of RV infections are benign, self-limited cold-like illnesses. However, these viruses can also cause severe pneumonia in elder and immunocompromised patients, as well as exacerbations of chronic obstructive pulmonary disease and asthma.[8] Enteroviruses infect primarily the gastrointestinal tract and can spread to other sites such as the central nervous system. However, some enteroviruses, such as D68, exhibit specific respiratory tropism and thus have properties similar to rhinoviruses.[9-11]

Rationale for PCR testing

Real-time Polymerase Chain Reaction (PCR) is a nucleic acid amplification method used to detect specific DNA sequences obtained after extraction and by reverse transcription of RNA. Real-time PCR technology allows a rapid and specific measurement of the presence of genes from microorganisms associated with infectious diseases. One of the primary benefits of this technology is a combination of speed and sensitivity unrivaled by antigen detection or viral culture.[12,13]

Explanation of the test

cobas® ADV/hMPV/EV-RV UC for use with the **cobas omni** Utility Channel on the **cobas**® 6800/8800 Systems is an automated, multiplex, real-time reverse transcription polymerase chain reaction (RT-PCR) assay for the rapid in vitro qualitative detection and discrimination of human ADV, hMPV and EV-RV in nasopharyngeal swab (NPS) specimens collected in Copan Universal Transport Medium System (UTM-RT), BD™ Universal Viral Transport System (UVT), or equivalent. 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® ADV/hMPV/EV-RV UC for use with the **cobas omni** Utility Channel, is based on fully automated sample preparation (nucleic acid extraction and purification) followed by PCR amplification and detection. The **cobas**® 6800/8800 Systems consist of the sample supply module, the transfer module, the processing module, and the analytic module. Automated data management is performed by the **cobas**® 6800/8800 Systems software, 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 RNA Internal Control (RNA IC) molecules are simultaneously extracted. Nucleic acid is released by addition of proteinase and lysis reagent to the sample. The released nucleic acid binds to the silica surface of the added magnetic glass particles. Unbound substances and impurities, such as denatured protein, cellular debris and potential PCR inhibitors are removed with subsequent wash steps and purified nucleic acid is eluted from the magnetic glass particles with elution buffer at elevated temperature. External controls (positive and negative) are processed in the same way with each **cobas**® ADV/hMPV/EV-RV UC run.

cobas® ADV/hMPV/EV-RV UC contains the ADV, hMPV and EV-RV primers and probes which are used in combination with the **cobas omni** Utility Channel Master Mix Reagent 2 (UC MMX-R2) and the 192-test cassette included in the **cobas omni** Utility Channel Reagent Kit. The 192-test cassette contains an Internal Control recognized by specific primers and probes included in the **cobas omni** Utility Channel Master Mix Reagent 2 (UC MMX-R2).

Selective amplification of target nucleic acid from the sample, and the positive control is achieved by the use of target

virus-specific forward and reverse primers which are selected from conserved regions of the ADV (Capsid protein precursor pVI and Terminal protein precursor pTP), hMPV (Matrix protein) and EV-RV (polyprotein) genes. Selective amplification of the RNA Internal Control is achieved by the use of non-competitive sequence specific forward and reverse primers, which have no homology with the ADV, hMPV and EV-RV genomes. Amplified target is detected by cleavage of fluorescently labeled oligonucleotide probe. A DNA polymerase enzyme is used for amplification.

The prepared **cobas**® ADV/hMPV/EV-RV UC master mix contains detection probes which are specific for human Adenovirus, Metapneumovirus and Enterovirus/Rhinovirus and the RNA Internal Control nucleic acid. ADV, hMPV, EV-RV 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 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**® ADV/hMPV/EV-RV UC can be found in Table 1. Materials required, but not provided can be found in Table 2, Table 3, Table 4, Table 5, and Table 9.

cobas® ADV/hMPV/EV-RV UC reagents and controls

All unopened reagents and controls shall be stored as recommended in Table 1 to Table 5.

Table 1 cobas® ADV/hMPV/EV-RV UC (primers and probes)

Store at 2-8°C

(P/N 09555625190)

Kit components	Reagent ingredients	Quantity per kit 192 tests
ADV/hMPV/EV-RV UC PP	10 mM Tris, 0.1 mM EDTA, 0.09% sodium azide upstream and downstream primers for ADV, hMPV, EV-RV, fluorescent-labeled oligonucleotide probes specific for ADV, hMPV, EV-RV	1 x 0.65 mL

Table 2 cobas® ADV/hMPV/EV-RV UC Control Kit

Store at 2–8°C

(P/N 09555595190)

Kit components	Reagent ingredients	Quantity per kit
ADV/hMPV/EV-RV UC (+) C	0.005% v/v of linear synthetic ADV, MPV and EV/RV DNA in 99.9% w/v of diluent composed of 0.05% wt/vol. Sodium azide, 20 µg/mL Poly r A, 0.10 mM EDTA, 10 mM Tris, pH 8.0	16 mL (10 x 1.6 mL)

Table 3 cobas omni Utility Channel Reagent Kit (UC)

Store at 2–8°C
(P/N 09052011190)

Reagents	Reagent ingredients	Quantity per kit 192 tests
192 test cassette		
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
RNA Internal Control (RNA-QS)	Tris buffer, <0.05% EDTA, <0.001% 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
R2 Empty Vessel (R2 EV)	Not applicable	1
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 4 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 5 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 severe skin burns and eye damage. H411: Toxic to aquatic life with long lasting effects. EUH032: Contact with acids liberates very toxic gas. P273: Avoid release to the environment. P280: Wear protective gloves/protective clothing/eye protection/face protection/hearing 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. P391: Collect spillage. 593-84-0 Guanidinium thiocyanate 9002-92-0 Polidocanol 3483-12-3 (R*,R*)-1,4-dimercaptobutane-2,3-diol
cobas omni Wash Reagent (WASH) Store at 15–30°C (P/N 06997503190)	Sodium citrate dihydrate, 0.1% methyl-4 hydroxybenzoate	4.2 L	Not applicable

* These reagents are not included in the **cobas**® ADV/hMPV/EV-RV UC kit. See listing of additional materials required (Table 8).

** Product safety labeling primarily follows EU GHS guidance

***Hazardous substance

Reagent storage and handling requirements

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

When reagents are not loaded on the **cobas**® 6800/8800 Systems, store them at the corresponding temperature specified in Table 6.

Table 6 Reagent storage (when reagent is not on the system)

Reagent	Storage temperature
cobas® ADV/hMPV/EV-RV UC[a]	2–8°C
cobas® ADV/hMPV/EV-RV UC Control Kit	2–8°C
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

[a] The prepared reagent cassette can be stored for up to 7 days at 2-8 °C before first usage. After first usage, please refer to expiry conditions of the **cobas omni** Utility Channel Reagent Kit in Table 7.

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 7 are met. The system automatically prevents use of expired reagents. Table 7 allows the user to understand the reagent handling conditions enforced by the **cobas**® 6800/8800 Systems.

Table 7 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[b]	Not applicable	Not applicable
cobas omni MGP Reagent	Date not passed	30 days from loading[b]	Not applicable	Not applicable
cobas omni Sample Diluent	Date not passed	30 days from loading[b]	Not applicable	Not applicable
cobas omni Wash Reagent	Date not passed	30 days from loading[b]	Not applicable	Not applicable

[a] Single use reagents

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

Additional materials required

Table 8 Materials and consumables for use on **cobas**® 6800/8800 Systems

Material	P/N
cobas omni Processing Plate	05534917001
cobas omni Amplification Plate	05534941001
cobas omni Pipette Tips	05534925001
cobas omni Liquid Waste Container	07094388001
cobas omni Lysis Reagent	06997538190
cobas omni MGP Reagent	06997546190
cobas omni Specimen Diluent	06997511190
cobas omni Wash Reagent	06997503190
Solid Waste Bag and Solid Waste Container or Solid Waste Bag With Insert and Kit Drawer Solid Waste Update	07435967001 and 07094361001 or 08030073001 and 08387281001
cobas omni Secondary Tubes 13x75 (optional)	06438776001

Instrumentation and software required

The **cobas**® 6800/8800 software and **cobas**® ADV/hMPV/EV-RV UC analysis package shall be installed on the instrument(s). The Instrument Gateway (IG) server will be provided with the system.

Table 9 Instrumentation

Equipment	P/N
cobas® 6800 System (Option Moveable)	05524245001 and 06379672001
cobas® 6800 System (Fix)	05524245001 and 06379664001
cobas® 8800 System	05412722001
Sample Supply Module	06301037001
Instrument Gateway	06349595001
TWN3 Legic NFC USB (RFID Reader/Writer)	07450460001
External PC with remote connection provided by the customer	N/A
Barcode Printer	N/A

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

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

Precautions and handling requirements

Warnings and precautions

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

- For in vitro diagnostic use only.
- **cobas**® ADV/hMPV/EV-RV UC is not evaluated for use as a screening test for the presence of ADV, hMPV and EV-RV in other samples than NPS specimens.
- 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.[14,15] Only personnel proficient in handling infectious materials and the use of **cobas**® ADV/hMPV/EV-RV UC and **cobas**® 6800/8800 Systems should perform this procedure.
- All human-sourced materials should be considered potentially infectious and should be handled with universal precautions. If spillage occurs, disinfect immediately with a freshly prepared solution of 0.5% sodium hypochlorite in distilled or deionized water (dilute household bleach 1:10) or follow appropriate site procedures.
- The use of sterile disposable pipettes and nuclease-free pipette tips is recommended. Use only supplied or specified required consumables to ensure optimal test performance.
- Safety Data Sheets (SDS) are available on request from your local Roche representative.
- Closely follow procedures and guidelines provided to ensure that the test is performed correctly. Any deviation from the procedures and guidelines may affect optimal test performance.
- False positive results may occur if carryover of samples is not adequately controlled during sample handling and processing.
- 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 reagent cassette and vials, 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, wash immediately with generous amounts of water; otherwise, burns can occur.
- **cobas**® ADV/hMPV/EV-RV UC, **cobas omni** Utility Channel Reagent 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, wash immediately with generous amounts of water; otherwise, burns can occur. If these reagents are spilled, dilute with water before wiping dry.
- Do not allow **cobas omni** Lysis Reagent, which contains guanidine thiocyanate, to contact sodium hypochlorite (bleach) solution. This mixture can produce a highly toxic gas.
- Dispose of all materials that have come in contact with samples and reagents in accordance with country, state, and local regulations.

Good laboratory practice

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

Sample collection, transport, and storage

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

Store all samples at specified temperatures.
Sample stability is affected by elevated temperatures.
Ensure samples are equilibrated to room temperature prior to transfer into a **cobas omni** Secondary Tube.

Sample collection

- Nasopharyngeal specimens should be collected according to standard collection technique using flocked swabs and immediately placed in 3 mL of UTM-RT, UVT, or equivalent.
- Refer to the Instructions for Use of the Collection Devices for hazard information.

Transport and storage

- Transportation of collected specimens must comply with all applicable regulations for the transport of etiologic agents.
- After collection, specimens can be stored in primary tubes for up to 4 hours at 15-25°C, up to 3 days at 2-8°C or up to 30 days at -20°C to -80°C with maximum 3 freeze and thaw cycles.

Instructions for use

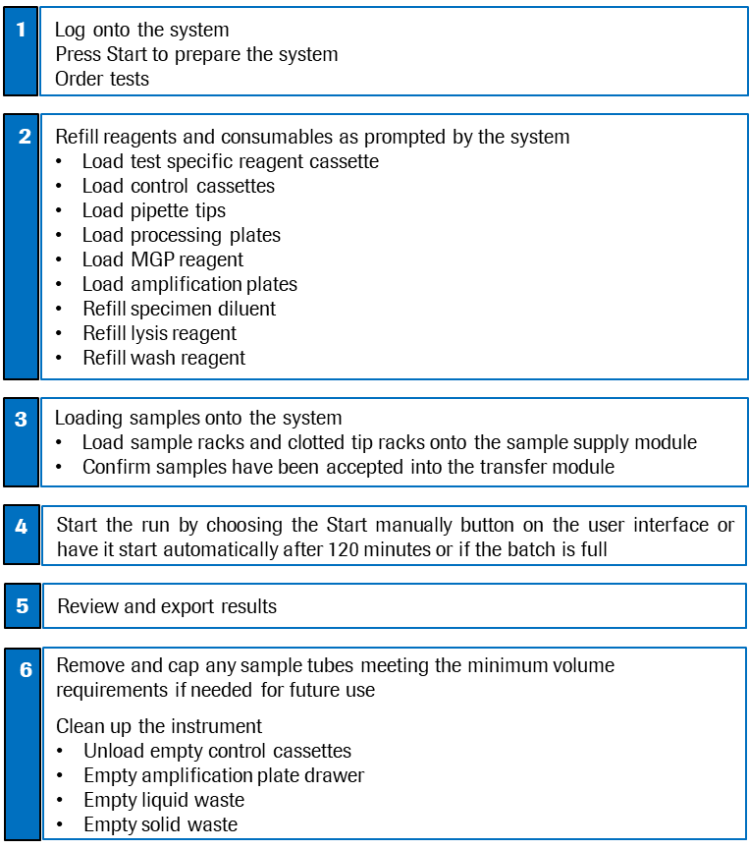
Procedural notes

- The assay is only intended for use with **cobas**® ADV/hMPV/EV-RV UC USAP from Roche.
- Do not use **cobas omni** Utility Channel Reagent Kit, **cobas**® Buffer Negative Control kit, **cobas**® ADV/hMPV/EV-RV UC, **cobas**® ADV/hMPV/EV-RV UC Control Kit or **cobas omni** reagents after their expiry dates.
- Only use the UC MMX-R2 bottles provided with the reagent cassette.
- Do not reuse consumables. They are for one-time use only.
- Ensure that specimen barcode labels on sample tubes are visible through the openings on the side of the sample racks. Refer to the **cobas**® 6800/8800 Systems User Guide for proper barcode specifications and additional information on loading sample tubes.
- Refer to the **cobas**® 6800/8800 Systems – User Assistance and/or User Guide for proper maintenance of instruments.

Running cobas® ADV/hMPV/EV-RV UC

cobas® ADV/hMPV/EV-RV UC can be run with a minimum required sample volume of 0.6 mL in the **cobas omni** Secondary Tube for specimens collected in UTM-RT, UVT, or equivalent.

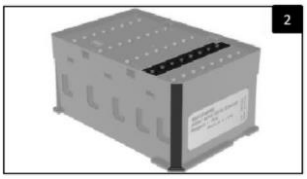
Figure 1 **cobas**® ADV/hMPV/EV-RV UC test procedure



Preparing the reagent cassette

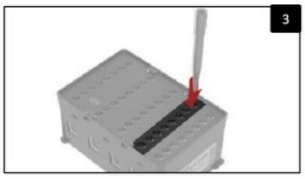
The PCR MMX R2 is prepared from the mix of Master Mix Reagent 2 (UC-MMX-R2) and **cobas**® ADV/hMPV/EV-RV UC primers and probes loaded in the **cobas omni** Utility Channel Reagent kit 192-test cassette.

- Remove the Master Mix Reagent 2 (UC-MMX-R2, see picture 1) from **cobas omni** Utility Channel Reagent Kit and **cobas**® ADV/hMPV/EV-RV UC primers and probes from their 2-8°C storage location.
- Mix UC-MMX-R2 on the roller mixer for 5 minutes at room temperature.
  Note: If no roller mixer is available, invert the bottle 20 times.
- Transfer 10 mL of UC-MMX-R2 reagent to a light-protected polypropylene tube.
  Note: Refer to the **cobas omni** Utility Channel User Assistance for details on transfer option steps.
- Mix and spin the **cobas**® ADV/hMPV/EV-RV UC primers and probes.
- Add 0.600 mL of the **cobas**® ADV/hMPV/EV-RV UC primers and probes (refer Table 1) to the light-protected polypropylene tube.
- Mix the polypropylene tube for 5 minutes on the roller mixer.
  Note: If no roller mixer is available, invert the bottle 20 times.



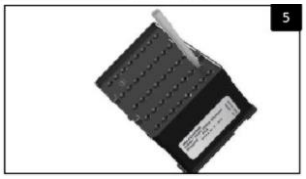
The reagent cassette is prepared by loading the PCR Mix into the reagent cassette from the **cobas omni** Utility Channel Reagent Kit.

- Position the reagent cassette by placing the slanted edge to the lower right corner (see picture 2).
  Note: The second row from the right side contains the empty MMX container.



- Place a 1 mL pipette tip into the top septum hole of row 2 (see picture 3).
  Note: The pipette tip allows air pressure in the vessel to adjust while the prepared PCR Mix is added.
- Take a repeater pipette with a 10 mL pipette tip. Load the pipette tip with 9.7 mL of the prepared PCR Mix.

- Insert the loaded pipette into the bottom septum hole of the reagent cassette. Puncture the septum deeply enough to avoid spillage in row 2 (see picture 4).
- Tilt the reagent cassette to a 45° angle lengthwise from the bottom. Make sure the cassette is tipped along the edge where the pipette with the 10 mL tip is inserted (see picture 5).



- Slowly and carefully pipette 9.7 mL of the prepared PCR Mix through the bottom septum into the empty container in row 2 (see picture 5). If possible, dispense the prepared PCR Mix in a single movement. Ensure that the correct volume of prepared PCR Mix is pipetted.
- Ensure that there is no fluid in the 1 mL pipette tip and then remove it from the septum.
  Note: If there is fluid in the tip, carefully rotate the tip to release the fluid from the tip back into the cassette. If fluid still remains in the 1 mL tip, perform the following: Using the repeater pipette with a 10 mL tip, remove some of the pipetted PCR Mix from the cassette vessel until no fluid remains in the 1 mL tip. Slowly and carefully pipette any fluid in the 10 mL pipette tip back into the vessel. Once both tips are empty, the tips can be removed from the cassette.

- Slowly tilt the reagent cassette 20 times to remove any air bubbles from the newly filled container (see picture 6).
- On the label of the 192-test **cobas omni** Utility Channel Reagent Kit, document the assay name (**cobas**® ADV/hMPV/EV-RV UC), the date the cassette was prepared, the lot number of the assay kits primers and probes

used (P&P Mix Lot) and check the box 'P&P Added' to confirm primers and probes mix has been added.

The RFID label of the prepared **cobas omni** Utility Channel Reagent Kit reagent cassette is labeled as follows:

- Open the **cobas omni** Utility Channel Tool using the Roche Utility Channel Tool start icon on the desktop.
- Click the "Open UC analysis package" button and select the USAP.zip file from the Recently used UC specific analysis packages section or load the UC_AMER USAP via "Open published UC analysis package to write on reagent cassette RFID tag." The UC analysis package screen in UCAP tab opens up.
- On the UC analysis package panel, click the "Reagent cassette" button.
- Enter the **cobas omni** Utility Channel Reagent Kit lot number in the field corresponding to Reagent cassette lot ID.
- Place the RFID reader/writer next to the RFID tag of the Utility Channel reagent cassette to be written on.
- Click the "Write data on the RFID tag" button to write the RFID label.
- Load the prepared reagent cassette onto the **cobas**® 6800/8800 Systems.
- The prepared reagent cassette can be stored for up to 7 days at 2-8°C before first usage. After first usage, please refer to expiry conditions of the **cobas omni** Utility Channel Reagent Kit in Table 7.

Prepare samples and controls

One positive control has to be performed as a sample in each run and for each new reagent cassette. To guarantee that each control batch contains a positive control, it is recommended to use the entire **cobas omni** Utility Channel reagent cassette before loading a new **cobas omni** Utility Channel reagent cassette.

Specimens collected in UTM-RT, UVT, or equivalent and positive control must be vortexed and transferred into separate **cobas omni** Secondary Tubes (0.6 mL) prior to processing on the **cobas**® 6800/8800 Systems. Samples transferred to **cobas omni** Secondary Tubes should be processed using the 'VTM' sample type selection.

Note: If using frozen NPS specimens, place the samples at room temperature until completely thawed and vortex for 3 to 5 seconds before use.

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.

Define test ordering

Create a test order as described in **cobas**® 6800/8800 Systems User Guide.

- In the Sample type field, select "VTM" from the drop down menu.
- In the Test region, select "UC_AMER" from the drop down menu.
- In the Volume region, ensure that the volume equals "400 µL".
- Save and perform the test as described in the **cobas**® 6800/8800 Systems User Guide.

Refer to the **cobas**® 6800/8800 Systems User Guide for more details.

Results

The **cobas**® 6800/8800 Systems automatically detect ADV, hMPV and EV-RV, for each individually processed sample and control, displaying individual target results for samples and the positive control, as well as test validity and overall results for the negative control.

Quality control and run validity of results

- One **cobas**® Buffer Negative Control [BUF (-) C] and one **cobas**® ADV/hMPV/EV-RV UC Control [ADV/hMPV/EV-RV UC (+) C] need to be processed with each batch.
- In the **cobas**® 6800/8800 software and/or report, check for flags and their associated results to ensure the batch validity.
- All flags are described in the **cobas**® 6800/8800 Systems User Guide.
- The batch is valid if no flags appear for the negative control and if the positive control is positive for all targets. If the batch is invalid, repeat testing of the entire batch.

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

The positive control validation has to be performed by the operator based on the positive control performance.

To determine this validity, interpret the results from the controls and IC as described in Table 10 below.

Table 10 Run and result validity interpretation

Validity	Control	Valid	Invalid	Validation
Run	(-) Ctrl	Indicated as "Valid" in Test Result column	Indicated as "Invalid" in Test Result column (All samples of the run must be retested)	**cobas**® 6800/8800 Systems
	(+) Ctrl	Ct value indicated in each Target column	Indicated as “Invalid” or "Negative" in one of the Target columns (1, 2 OR 3) (All samples of the run must be retested)	Operator
Sample	IC	Indicated as "Yes" in Valid column	Indicated as "No" in Valid column AND Target 1, 2 AND 3: Invalid (Invalidated sample must be retested)	**cobas**® 6800/8800 Systems

Interpretation of results

If the run and sample are valid, the result interpretation for each target is based on the results provided by the **cobas**® 6800/8800 Systems and described in Table 11. Invalid results for one or more target combinations are possible and are reported out specifically for each channel on the **cobas**® 6800/8800 Systems. In these cases, the original sample should be re-tested to obtain a valid target result. If the target result is still invalid, a new sample should be obtained.

Results and their corresponding interpretation for detecting ADV, hMPV and EV-RV are shown below (Table 11).

Table 11 cobas® ADV/hMPV/EV-RV UC result interpretation

Target 1 (MPV)	Target 2 (ADV)	Target 3 (EVRV)	Interpretation
MPV Negative	Any	Any	Target Result for MPV is valid. Result for MPV RNA is Not Detected.
MPV Ct value	Any	Any	Target Result for MPV is valid. Result for MPV RNA is Detected.
Invalid	Any	Any	Target Result for MPV is invalid. Sample should be retested. If the result is still invalid, a new specimen should be obtained.
Any	**ADV Negative**	Any	Target Result for ADV is valid. Result for ADV DNA is Not Detected.
Any	**ADV Ct value**	Any	Target Result for ADV is valid. Result for ADV DNA is Detected.
Any	**Invalid**	Any	Target Result for ADV is invalid. Sample should be retested. If the result is still invalid, a new specimen should be obtained.
Any	Any	**EVRV Negative**	Target Result for EVRV is valid. Result for EVRV RNA is Not Detected.
Any	Any	**EVRV Ct value**	Target Result for EVRV is valid. Result for EVRV RNA is Detected.
Any	Any	**Invalid**	Target Result for EVRV is invalid. Sample should be retested. If the result is still invalid, a new specimen should be obtained.
Invalid	**Invalid**	**Invalid**	None of the Targets Results are valid. Sample should be retested. If the result is still invalid, a new specimen should be obtained.

Procedural limitations

- **cobas**® ADV/hMPV/EV-RV UC has been evaluated only for use in combination with the **cobas**® ADV/hMPV/EV-RV UC Control Kit, **cobas omni** Utility Channel Reagent kit, **cobas**® Buffer Negative Control Kit, **cobas omni** MGP Reagent, **cobas omni** Lysis Reagent, **cobas omni** Specimen Diluent, and **cobas omni** Wash Reagent for use on the **cobas**® 6800/8800 Systems.
- The assay is only intended for use with the UC_AMER USAP from Roche.
- Reliable results depend on proper sample collection, storage and handling procedures.
- This test is to be used for the detection of ADV, hMPV and EV-RV (serotypes/species outlined in non-clinical performance evaluation study Inclusivity) in nasopharyngeal swab samples collected in a UTM-RT, UVT or equivalent. Testing of other sample types with **cobas**® ADV/hMPV/EV-RV UC may result in inaccurate results.
- Detection of ADV, hMPV and EV-RV nucleic acid 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**® ADV/hMPV/EV-RV UC could affect primer and/or probe binding resulting in failure to detect the presence of virus.
- False negative or invalid results may occur due to interference. The Internal Control is included in **cobas**® ADV/hMPV/EV-RV UC (in the **cobas omni** Utility Channel Reagent kit) 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 omni** Utility Channel Master Mix reagent enables selective amplification of target nucleic acid; however, good laboratory practices and careful adherence to the procedures specified in this Instructions For Use document are necessary to avoid contamination of reagents.

Non-clinical performance evaluation

Key performance characteristics

Limit of Detection (LoD)

The limits of detection of **cobas**® ADV/hMPV/EV-RV UC were determined by analyzing serial dilutions of hMPV A1_9, ADV C2 and Cox A21 strains supplied and quantified in $TCID_{50}$/mL (ZeptoMetrix), in a pool of ADV-hMPV-EV-RV-negative NPS specimens. Panels of six concentration levels including a negative panel member were tested with three reagent lots of **cobas**® ADV/hMPV/EV-RV UC (Table 12). The study demonstrates that **cobas**® ADV/hMPV/EV-RV UC detects hMPV A1_9, ADV C2 and Cox A21 at respective concentrations of 0.81, 3.29 and 2.05 TCID50/mL (Table 13).

Table 12 LoD determination

Viral Strain	Kit Lot	$LoD_{95\%}$ [$TCID_{50}$/mL]	95% CI of LoD [$TCID_{50}$/mL]	Hit Rate ≥ 95% [$TCID_{50}$/mL]	Mean Ct at ≥ 95% Hit Rate
hMPV A1_9	Lot 1	0.27	0.27 – 0.27	0.67	42.40
	Lot 2	0.81	0.45 – 1.17	2.00	38.80
	Lot 3	0.23	0.23 – 0.23	0.67	41.43
	Lot 1-3	0.57	0.43 – 0.72	0.67	42.21
ADV C2	Lot 1	2.23	1.57 – 2.90	5.00	34.68
	Lot 2	3.29	1.57 – 5.00	5.00	34.37
	Lot 3	2.39	1.58 – 3.19	5.00	34.02
	Lot 1-3	2.61	1.58 – 3.64	5.00	34.36
Cox A21	Lot 1	1.48	0.17 – 2.78	1.67	36.60
	Lot 2	2.05	0 – 7.03	5.00	34.28
	Lot 3	1.62	0.34 – 2.89	1.67	35.86
	Lot 1-3	0.65	0 – 1.93	1.67	36.23

Table 13 LoD summary of least sensitive reagent lot

Viral strain	Matrix	$LoD_{95\%}$	Lower - Upper $LoD_{95\%}$
hMPV A1_9	NPS	0.81 $TCID_{50}$/mL	0.45 - 1.17
ADV C2	NPS	3.29 $TCID_{50}$/mL	1.57 - 5.00
Cox A21	NPS	2.05 $TCID_{50}$/mL	0 - 7.03

Precision – within laboratory

The precision of the **cobas**® ADV/hMPV/EV-RV UC was determined by analyzing two concentrations (3 x and 5 x $LoD_{95\%}$) of the ADV C2, hMPV A1_9 and Cox A21 isolates individually spiked into UTM supplemented with relevant concentrations of genomic DNA and mucin to mimic NPS specimen (UTM Matrix). The samples were tested over five days, using three **cobas**® ADV/hMPV/EV-RV UC reagent lots and three operators on one instrument. Each sample was carried through the entire **cobas**® ADV/hMPV/EV-RV UC procedure on fully automated **cobas**® 6800/8800 System. The results are shown in Table 14.

Table 14 Summary of precision

Target	Spiking Level	Variability Between Operators			Variability Between cobas® ADV/hMPV/EV-RV UC Reagent Lots			Variability Between Days / Runs		
		Mean Ct	SD	CV (%)	Mean Ct	SD	CV (%)	Mean Ct	SD	CV (%)
ADV C2	3 x $LoD_{95\%}$	31.91	0.09	0.28	32.07	0.21	0.65	31.90	0.27	0.85
	5 x $LoD_{95\%}$	30.18	0.11	0.38	30.11	0.26	0.88	30.12	0.21	0.69
hMPV A1_9	3 x $LoD_{95\%}$	37.88	0.17	0.46	36.97	0.44	1.20	37.26	1.03	2.76
	5 x $LoD_{95\%}$	33.59	0.27	0.81	33.70	0.09	0.26	33.35	1.06	3.18
Cox A21	3 x $LoD_{95\%}$	34.74	0.15	0.44	34.47	0.20	0.58	34.39	0.14	0.40
	5 x $LoD_{95\%}$	32.68	0.21	0.65	32.89	0.13	0.41	32.73	0.49	1.49

Reproducibility

The reproducibility of **cobas**® ADV/hMPV/EV-RV UC was determined by testing positive panel members at two concentrations (3 x and 5 x $LoD_{95\%}$) of the ADV, hMPV and Cox A21 strains separately spiked into UTM Matrix. The samples were tested on two instruments/sites. Each sample was carried through the entire **cobas**® ADV/hMPV/EV-RV UC procedure on fully automated **cobas**® 6800/8800 System. The results are shown in Table 15.

Table 15 Summary of reproducibility

Target	Spiking Level	Reproducibility		
		Mean Ct	SD	CV (%)
ADV	3 x $LoD_{95\%}$	32.14	0.45	1.40
	5 x $LoD_{95\%}$	30.54	0.33	1.08
hMPV	3 x $LoD_{95\%}$	37.91	0.17	0.46
	5 x $LoD_{95\%}$	34.18	0.61	1.78
Cox A21	3 x $LoD_{95\%}$	35.07	0.29	0.82
	5 x $LoD_{95\%}$	33.01	0.14	0.42

Inclusivity

Ten ADV (species B, C and E), eight hMPV (serotypes A1, A2, B1 and B2), seven RV (RV species A and B) and ten EV (EV species A, B, C and D) strains were tested at 3 x $LoD_{95\%}$ in UTM Matrix. The results show that **cobas**® ADV/hMPV/EV-RV UC detects the strains listed in Table 16.

Table 16 Summary of inclusivity

Target Pathogen	Isolate
ADV	ADV B3
	ADV B7
	ADV B11
	ADV B14
	ADV B21
	ADV C1
	ADV C2
	ADV C5
	ADV C6
	ADV E4
hMPV	hMPV9 A1
	hMPV16 A1
	hMPV27 A2
	hMPV 3 B1
	hMPV 5 B1
	hMPV 4 B2
	hMPV 8 B2
	hMPV 18 B2
EV-RV	Rhinovirus B14
	Rhinovirus A16
	Rhinovirus B42
	Rhinovirus B70
	Rhinovirus A80
	Rhinovirus A2
	Rhinovirus 1A
	Coxsackievirus A21
	Coxsackievirus A10
	Enterovirus 68
	Echovirus 6
	Echovirus 9
	Echovirus 11
	Enterovirus 71
	Coxsackievirus B3
	Coxsackievirus B4
	Coxsackievirus A9

Analytical specificity (cross-reactivity and microbial interference)

The analytical specificity of **cobas**® ADV/hMPV/EV-RV UC was evaluated by diluting viruses, bacteria, fungi or yeasts (listed in Table 17) with and without ADV C2, hMPV A1_9 and Cox A21 strains (co-formulated at 3 x $LoD_{95\%}$) into UTM Matrix. Viruses were tested at either 1.00E+04 or 1.00E+05 $TCID_{50}$/mL or c/mL. Bacteria, yeasts and fungi were tested at 1.00E+06 CFU/mL, IFU/mL or CCU/mL. None of these non-targeted pathogens interfered with the **cobas**® ADV/hMPV/EV-RV UC performance. In total, 100% of negative results were obtained with **cobas**® ADV/hMPV/EV-RV UC for all ADV/hMPV/EV-RV-negative samples and 100% of positive results were obtained for all ADV/hMPV/EV-RV positive samples.

Table 17 Microorganisms tested for analytical specificity/cross-reactivity

Microorganism Name	Tested Concentration
Aspergillus fumigatus	1.00E+06 CFU/mL
Candida albicans	1.00E+06 CFU/mL
Chlamydia pneumoniae	1.00E+06 IFU/mL
Coronavirus-SARS-Cov-2	1.00E+05 $TCID_{50}$/mL
Corynebacterium diphtheriae	1.00E+06 CFU/mL
Cytomegalovirus (CMV)	1.00E+05 $TCID_{50}$/mL
Epstein-Barr Virus (EBV)	1.00E+05 c/mL
Escherichia coli	1.00E+06 CFU/mL
Haemophilus influenzae	1.00E+06 CFU/mL
Herpes Simplex Virus 1 (HSV-1)	1.00E+05 $TCID_{50}$/mL
Herpes Simplex Virus 2 (HSV-2)	1.00E+04 $TCID_{50}$/mL
Influenza virus A H1N1	1.00E+05 $TCID_{50}$/mL
Influenza virus B	1.00E+05 $TCID_{50}$/mL
Klebsiella pneumoniae	1.00E+06 CFU/mL
Lactobacillus acidophilus	1.00E+06 CFU/mL
Legionella pneumophila	1.00E+06 CFU/mL
Measles virus	1.00E+05 $TCID_{50}$/mL
Moraxella catarrhalis	1.00E+06 CFU/mL
Mumps virus	1.00E+05 $TCID_{50}$/mL
Mycobacterium avium	1.00E+06 CFU/mL
Mycobacterium tuberculosis	1.00E+06 CFU/mL
Mycoplasma pneumoniae	1.00E+06 CCU/mL
Neisseria elongata	1.00E+06 CFU/mL
Neisseria meningitidis	1.00E+06 CFU/mL
Parainfluenza 1	1.00E+05 $TCID_{50}$/mL
Parainfluenza 2	1.00E+05 $TCID_{50}$/mL
Parainfluenza 3	1.00E+05 $TCID_{50}$/mL
Parainfluenza 4 b	1.00E+05 $TCID_{50}$/mL
Pseudomonas aeruginosa	1.00E+06 CFU/mL
Respiratory Syncytial Virus A (RSV-A)	1.00E+05 $TCID_{50}$/mL
Respiratory Syncytial Virus B (RSV-B)	1.00E+05 $TCID_{50}$/mL
Staphylococcus aureus	1.00E+06 CFU/mL
Staphylococcus epidermidis	1.00E+06 CFU/mL
Streptococcus pneumoniae	1.00E+06 CFU/mL
Streptococcus pyogenes	1.00E+06 CFU/mL
Streptococcus salivarius	1.00E+06 CFU/mL
Varicella Zoster Virus (VZV)	1.00E+05 c/mL

Interfering substances

The impact of potentially interfering substances on the **cobas**® ADV/hMPV/EV-RV UC performance was evaluated by testing ten exogenous and two endogenous substances, with and without ADV, hMPV, EV-RV strains into UTM Matrix (co-formulated at 3 x $LoD_{95\%}$). Both exogenous and endogenous substances were tested at clinically relevant concentrations (Table 18). None of these substances interfered with the **cobas**® ADV/hMPV/EV-RV UC performance at the tested concentrations. In total, 100% of negative results were obtained with **cobas**® ADV/hMPV/EV-RV UC for all ADV, hMPV, EV-RV-negative samples and 100% of positive results were obtained for all ADV, hMPV, EV-RV positive samples.

Table 18 Exogenous and endogenous substances tested for interference

Substance	Final Concentration
Zanamivir	5 mg/mL
Fluticasone (Flixotide Nebules)	5% (v/v)
Budesonide	0.039 mg/mL
Mupirocin	5 mg/mL
Oxymetazoline (Nasivin)	5% (v/v)
Oseltamivir phosphate	8 mg/mL
Tobramycin	4 µg/mL
Lidocaine	2.68 mg/mL
Benzocaine	5 mg/mL
Galphimia clauca, Histaminum hydrochloricum, Luffa operculata, Sulfur (Luffeel)	5% (v/v)
Mucin	0.5% (v/v)
Whole Blood	1.5% (v/v)

Co-infection (competitive interference)

The co-infection rate among patients presenting respiratory symptoms can be high, especially co-infections with rhinoviruses/enteroviruses as described in the literature.[16,17] One low concentrated (3 x $LoD_{95\%}$) target co-infected with two high concentrated (1000 x $LoD_{95\%}$) targets were tested. The reference with individually spiked target (3 x $LoD_{95\%}$) and the negative NPS specimens were also tested. The results demonstrate that **cobas**® ADV/hMPV/EV-RV UC is able to detect ADV, hMPV and EV-RV targets either in individual or co-spiked condition.

Clinical performance evaluation

The performance of **cobas**® ADV/hMPV/EV-RV UC was evaluated in comparison with three CE-IVD kits for detection of ADV (Diagenode R-DiaADV), hMPV (Diagenode R-DiaRes), and EV-RV (Altona RealStar Enterovirus PCR Kit 1.0) internally using archived nasopharyngeal swabs (NPS).

The clinical evaluation study included 188 samples including 96 pre-selected NPS clinical specimens with a known status and 92 NPS clinical specimens with an unknown status.

As shown in Table 19, the **cobas**® ADV/hMPV/EV-RV UC demonstrated high percent agreement with the comparator tests for the detection of ADV, hMPV and EV-RV.

Table 19 Summary of clinical performance of **cobas**® ADV/hMPV/EV-RV UC

Virus	Number of Samples	Test Results				Agreement Statistics		
		Concordant Positive (N)	Discordant Positive (N)	Concordant Negative (N)	Discordant Negative (N)	Agreement Parameter	Percent Agreement (%)	95% CI (LCL, UCL)*
ADV	186	22	4	159	1	PPA	95.7%	(79.0%, 99.2%)
						NPA	97.5%	(93.9%, 99.0%)
hMPV	188	22	2	164	0	PPA	100.0%	(85.1%, 100.0%)
						NPA	98.8%	(95.7%, 99.7%)
EV-RV	188	40	7	139	2	PPA	95.2%	(84.2%, 98.7%)
						NPA	95.2%	(90.4%, 97.7%)

* Two samples were excluded from the analysis as confirmed belonging to ADV species D and F.

Discordant results between the **cobas**® ADV/hMPV/EV-RV UC and the comparator assays were observed for 16 samples. For ADV, there were 4 discordant positives for which sequencing did not yield interpretable results but 1 of the 4 was confirmed ADV positive by the supplier. The discordant negative ADV sample was sequenced but the results were not interpretable. For hMPV, the 2 discordant positive samples were sequenced but did not yield interpretable results; one of these 2 positives was confirmed hMPV positive by the supplier. For EV-RV, among the 7 discordant positive samples sequenced, three had interpretable results which confirmed RV positivity. The sequencing results were not interpretable for four samples but the supplier confirmed three of these as EV-RV positive. The 2 discordant negative results were confirmed ER/RV positive by the supplier.

Additional information

Key test features

Sample type	Nasopharyngeal swab samples collected in the UTM-RT System or the UVT System, or equivalent
Minimum amount of sample required	0.6 mL*
Sample processing volume	0.4 mL
Test duration	Results are available within less than 3.5 hours after loading the sample on the system.

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

Symbols

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

Table 20 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 importer

Table 21 Manufacturer and importer

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

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Copyright

IVD

EC REP

Roche Diagnostics GmbH
Sandhofer Str. 116
68305 Mannheim
Germany

CE

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Document revision

Document Revision Information	
Doc Rev. 1.0 03/2022	First Publishing.
Doc Rev. 2.0 05/2022	Updated **Intended use** section to include the use of the test as an aid in the diagnosis and differentiation of ADV, hMPV and EV-RV. Error in Table 10 corrected. Typographical errors corrected throughout the document. Please contact your local Roche Representative if you have any questions.