Product Reference:
UC-TIB-HSV/VZV **40-0401-UC** **09838902001**
UC_TIB_HSV_VZV_v01.00 USAP **09915460001**

Version 5.1
Last revision date: 11.11.2025

UC-TIB-HSV/VZV

Real time PCR kit for qualitative detection of human Herpes Simplex Virus 1/2 and Varicella Zoster Virus

For use with the **cobas**® **omni** utility channel on the **cobas**® 6800/8800 Systems

Instructions For Use

CE
IVD

TIB MOLBIOL

REVISION NOTE COMPARED TO THE PREVIOUS VERSION

Revision date	Description
07/09/2021	Initial release
04/08/2023	Change of Legal Manufacturer and Adjustments to latest recommendations, e.g. material-numbers
16/05/2024	e-labdoc availability of the USAP deleted
04/03/2025	integration of **cobas®** 6800/8800 systems with software version 2.0 or higher
04/11/2025	availability of UCAP for cobas® 6800/8800 software version 2.0 integrated
11/11/2025	Typo on page 9 in description of table 4.2

This Instructions For Use can be downloaded by following the procedure below:

- Go to the website : http://e-labdoc.roche.com

- Search for Method Sheet Catalog No.:

- **09838902001 Doc Ver. 5.1 (UC-TIB-HSV/VZV)**

- Download the Instructions For Use

Please contact your local Roche Representative if you have any questions.

TABLE OF CONTENTS

GLOSSARY

(-) Ctrl	Negative Control
(+) Ctrl	Positive Control
CFR635	CAL Fluor Red 635
c/mL	Copies/mL
Ct	Cycle threshold
DNA	DeoxyriboNucleic Acid
EDTA	EthyleneDiamineTetraacetic Acid
dTTP	DeoxyThimidine Triphosphate
dUTP	DeoxyUridine Triphosphate
Em.	Emission
Ex.	Excitation
HSV	Herpes Simplex Virus
GTIN	Global Trade Item Number
IC	Internal Control
IU/mL	International Units/mL
IVD	*In vitro* Diagnostics
IVDMD	*In vitro* Diagnostic Medical Device
LoD	Limit of Detection
$LoD_{95\%}$	Limit of Detection at 95 % of targets
MGP	Magnetic Glass Particle
MMX	Master Mix
PC	Positive Control
PCR	Polymerase Chain Reaction
P/N	Part Number
PP	Primers and Probes
PROBIT	Probability + Unit
RNA	RiboNucleic Acid
RUI	Remote User Interface
UC	utility channel
$TCID_{50}$/mL	Fifty-Percent Tissue Culture Infective Dose/mL
USAP	utility channel Analysis Package
VZV	Varicella Zoster Virus

1. INTRODUCTION

Real Time Polymerase Chain Reaction is a nucleic acid amplification method used to detect specific DNA sequences obtained after extraction or 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, cancer, and genetic abnormalities. TIB Molbiol kits are based on this powerful technology to accurately detect the presence of pathogens for a number of infectious diseases.

One of the primary benefits of this technology is the ability to detect the amplified DNA during the reaction in real time, resulting in a more accurate detection of genetic sequences. TIB Molbiol assays use TaqMan® DNA probes that hybridize with the target DNA strand. These probes are labeled with a fluorescent dye allowing real time measurements during the PCR process. The generated fluorescent signals are then detected and quantified using an instrument such as a thermal cycler.

2. GENERAL INFORMATION

2.1. INTENDED USE

UC-TIB-HSV/VZV is an automated *in vitro* nucleic acid amplification test for the qualitative detection of human Herpes Simplex Virus-1 (HSV-1), Herpes Simplex Virus-2 (HSV-2) and Varicella Zoster Virus (VZV) DNA in human EDTA plasma samples. This test utilizes the open channel functionality (**cobas® omni** utility channel) of the **cobas®** 6800/8800 Systems.

This test is intended for use as an aid in the diagnosis of human HSV and VZV infections such as in transplanted and immunocompromised patients. The results from **UC-TIB-HSV/VZV** must be interpreted within the context of all relevant clinical and laboratory findings.

2.2. PATHOGEN INFORMATION

2.2.1. Herpes Simplex Virus 1 and 2 (HSV-1/2)

Infection with herpes simplex virus type-1 and 2 (HSV-1 and HSV-2), two members of the human Herpesviridae family and alphaherpesvirus subgroup, can cause oral and genital mucocutaneous ulcers, also known as oral and genital herpes. HSV-1 is predominantly associated with oral herpes, but has to a lesser extent been known to cause genital herpes. On the other hand, HSV-2 is mainly responsible for genital herpes ①.

In one 2016 study, around 65% of the global population under 50 years of age was estimated to have HSV-1 infection, whereas around 13% were infected with HSV-2 . However, prevalence varied greatly by region and age. HSV infections usually occur early in life and are lifelong and incurable. Both viruses primarily infect nerve cells in their latent forms and symptoms often appear after reactivation ②③.

In immunocompetent individuals, HSV infections are mostly asymptomatic. However, in some cases HSV-related symptoms, such as orolabial (HSV-1) or genital and perianal (HSV-1 and HSV-2) painful blisters or open sores called ulcers, can occur. In comparison, immunocompromised patients are at higher risk to develop HSV infections. In fact, in immunocompromised patients, reactivation of previously acquired HSV virus is one of the most common causes of viral infection after solid organ transplantation or hematopoietic stem cell transplantation. Transplant patients will shed the virus more often than immunocompetent individuals, leading to more recurrent and severe HSV-related symptoms in these patients. In some rare cases, HSV-infection can also occur due to primary infections following transplantation ①③④.

The most common clinical manifestation of HSV infection in immunocompromised patients is mucocutaneous ulcers, however HSV infection can affect visceral organs and the central nervous system. In such cases, severe disseminated infections such as esophagitis, hepatitis, encephalitis, pneumonitis or keratitis can occur ①③④.

Antiviral medications such as acyclovir and valacyclovir are currently the most effective drugs for the prevention and treatment of HSV infections in post-transplant patients.①③④.

2.2.2. Varicella Zoster Virus (VZV)

Human alphaherpesvirus 3 (HHV-3), usually referred to as the Varicella Zoster Virus (VZV), is a member of the Herpesviridae family and the alphaherpesvirus subgroup, and can cause acute varicella or “chickenpox” in children, teens and young adults after primary infection. VZV then lies dormant in nerve cells and can reactivate years to decades later, leading to a disease known as shingles or herpes zoster. VZV infections are common and it is estimated that around 90% of the global adult population acquired the virus during childhood ⑤.

Varicella is usually a mild disease presenting with cold-like symptoms, followed by a fever and disseminated pruritic rash. On the other hand, development of shingles usually results in a rash of blisters around the affected nerve, often on the chest ⑤.

VZV infection is often observed in immunocompromised patients, such as post-transplant patients. Approximately, 1% to 20% of solid organ transplant patients will develop VZV-related symptoms due to either virus reactivation or primary infection. In comparison, the percentage of hematopoietic stem cell transplant patients developing VZV infection is higher, reaching around 40% ③.

The most common clinical manifestation of VZV infection in immunocompromised patients is the development of a cutaneous infection, however VZV can rapidly evolve and affect visceral organs and the central nervous system. In such cases, severe skin disease, encephalitis, postherpetic neuralgia, and pneumonitis, can occur ③④⑤.

Treatment is generally recommended for all transplant patients. Localized and disseminated VZV infections are typically treated with high-dose acyclovir or its analogues (valacyclovir, famciclovir).③④⑤.

Note: See Section 12 for the corresponding publications ①②③④⑤.

2.3. PRINCIPLE

The HSV/VZV detection is performed on the **cobas®** 6800/8800 Systems with the **UC-TIB-HSV/VZV** on human EDTA plasma samples. The test utilizes two external controls: a Positive Control provided in this kit and a Negative Control (Roche P/N 09051953190).

The **UC-TIB-HSV/VZV** used in combination 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 **UC-TIB-HSV/VZV** works with the optimal conditions (defined parameters from sample preparation to result analysis) included in the USAP (utility channel Specific Analysis Package). The **UC-TIB-HSV/VZV** is assigned to the **cobas® omni** Utilily Channel 192 Reagent Kit (192-test cassette) and then transferred to the **cobas®** 6800/8800 Systems in order to perform the **UC-TIB-HSV/VZV**.

Nucleic acid from patient samples, external controls (Positive and Negative) and the added internal control is extracted simultaneously. Nucleic acid is released by addition of proteinase and lysis reagent to the sample and the released nucleic acid binds to the silica surface of the added magnetic glass particles. Unbound substances and impurities, such as denatured protein, cell debris and potential PCR inhibitors are removed with subsequent wash reagent steps, and purified nucleic acid is eluted from the glass particles with elution buffer at elevated temperature.

The **UC-TIB-HSV/VZV** contains the HSV-1, HSV-2 and VZV 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 provided by Roche. 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 HSV-1 (UL5), HSV-2 (UL30) and VZV (ORF-31) genes.

The 192-test cassette contains an internal control (IC) recognized by specific primers and probes included in the **cobas® omni** utility channel Master Mix Reagent 2 (UC MMX-R2). Selective amplification of the IC is achieved by the use of sequence-specific forward and reverse primers which have no homology with the HSV and VZV genomes. A thermostable DNA polymerase enzyme is used for amplification. The target and internal control sequences are

amplified simultaneously utilizing a universal PCR amplification profile with predefined temperature steps and number of cycles. The master mix includes deoxyuridine triphosphate (dUTP), instead of deoxythimidine triphosphate (dTTP), which is incorporated into the newly synthesized DNA (amplicon). Any contaminating amplicon from previous PCR runs is eliminated by the AmpErase enzyme, which is included in the PCR mix.

The probes are labeled with target-specific fluorescent reporter dyes allowing simultaneous detection and differentiation of the HSV-1, HSV-2 and VZV targets, and internal control in four target channels. The fluorescent signal of the intact probes is suppressed by the quencher dye. During the PCR amplification step, hybridization of the probe with the specific single-stranded DNA templates results in cleavage by the 5'-to-3' nuclease 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 is concomitantly increased. Real-time detection and discrimination of PCR products is accomplished by measuring the fluorescence of the released reporter dyes for the viral targets and IC.

2.4. TARGET SEQUENCE

The primers are designed to hybridize with specific sequences in the target pathogens.

Pathogen	Target gene
HSV-1	UL5
HSV-2	UL30
VZV	ORF-31

The probes are designed to hybridize with a specific sequence of the target pathogens. They include a fluorescent reporter dye at the 5' end, the fluorescence of which is quenched by an internal second dye. The probes only emit a signal if they are bound to the amplified product.

Pathogen	Detection Channel
HSV-1	FAM
HSV-2	CAL Fluor Red 635
VZV	HEX

2.5. KIT CONTENTS

This kit contains the following reagents to perform up to 192 reactions:

Table 1. UC-TIB-HSV/VZV (09838902001)

Reagents	Cap ID	Ingredients	Quantity per kit	Safety symbol and warning
HSV/VZV Primers and Probes (FAM, CFR635, HEX)		Tris buffer, 0.015 % EDTA, 0.05 % sodium azide	0.600 mL (1 x 0.600 mL) 192 reactions	Not Applicable
HSV/VZV Positive Control		Titered Linear synthetic HSV-1, HSV-2 and VZV DNA, Tris buffer, 0.015 % EDTA, 0.1 % ProClin® 300 preservative, 0.002 % RNA carrier	12.25 mL (8 x 1.75 mL) 40 reactions	 Warning H317: May cause an allergic skin reaction. P261: Avoid breathing dust/fumes/gas /mist/vapors/spray. P272: Contaminated work clothing should not be allowed out of the workplace. P280: Wear protective gloves. P302 + P352: IF ON SKIN wash with plenty of soap and water. P333 + P313: If skin irritation or rash occurs: Get medical advice/attention. P362 + P364: Wash contaminated clothing before reuse.

3. REQUIRED MATERIALS (NOT SUPPLIED)

3.1. MATERIALS AND CONSUMABLES

The table below lists the materials required to run the **UC-TIB-HSV/VZV** on **cobas®** 6800/8800 Systems**.**

Table 2. Materials and consumables for use on **cobas®** 6800/8800 Systems

Material	Roche 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 Sample Diluent Reagent	06997511190
cobas® omni Wash Reagent	06997503190
cobas® Buffer Negative Control Kit	09051953190
cobas® omni utility channel 192 Reagent Kit	09052011190
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
cobas® omni Secondary Tubes 13x75 (optional)	06438776001
Repeater pipette with a 10 mL pipette tip	N/A

► Refer to the **cobas® omni** utility channel Reagent Kit and **cobas® omni** utility channel User Assistance Version 4.4 or higher.
► Refer to the **cobas®** 6800/8800 Systems User Assistance for additional information on secondary tubes.

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.

3.2. INSTRUMENTATION

The table below lists the instruments required to run **UC-TIB-HSV/VZV** on **cobas®** 6800/8800 Systems.

Table 3. Instrumentation

Equipment	Roche 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
TWN3 Legic NFC USB (RFID Reader/Writer)	07450460001
External PC with remote connection provided by the customer	N/A
Barcode Printer	N/A

► Refer to the **cobas®** 6800/8800 Systems User Assistance for proper maintenance of instruments.

3.3. SOFTWARE

The table below lists the software required to run **UC-TIB-HSV/VZV** on **cobas®** 6800/8800 Systems.

Table 4.1 Software 1.4

Instrument	Software	Version
cobas® 6800/8800 Systems	**cobas®** 6800/8800 software	1.4
External computer with remote connection (also called Remote User Interface, RUI)	**cobas® omni** utility channel Tool	3.4 or higher
	UC_TIB_HSV_VZV_v01.00 USAP	1.0 or higher

Table 4.2 Software 2.0 or higher

Instrument	Software	Version
cobas® 6800/8800 Systems	**cobas®** 6800/8800 software	2.0 or higher
External computer with Data Manager	**cobas® omni** RFID tool	1.1 or higher
	UC_TIB_HSV/VZV v02.00 UCAP	2.0 or higher

Note: The UC_TIB_HSV/VZV analysis package (UCAP) for cobas® 6800/8800 systems shall be installed on the instrument(s), for support please contact your Roche Service Representative.

► Refer to the **cobas® omni** utility channel User Assistance Version 4.4 or higher for additional information on the **cobas® omni** utility channel software.

4. REAGENT STORAGE, HANDLING, AND STABILITY

The **UC-TIB-HSV/VZV** and the **cobas® omni** utility channel Reagents should be stored and managed as specified in Tables 5 and 6. Reagents must be used before the expiry date mentioned on the corresponding packaging label.

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

Reagent	Storage conditions
UC-TIB-HSV/VZV	2–8°C, protected from light
cobas® omni utility channel 192 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 Sample Diluent	2–8°C
cobas® omni Wash Reagent	15–30°C

The **cobas**® 6800/8800 Systems allow Roche reagents to be used only if all of the conditions shown in Table 6 are met. Otherwise, the system automatically prevents their use. Table 6 enables the user to understand the reagent handling conditions enforced by the **cobas®** 6800/8800 Systems.

Please note that the **cobas® omni** utility channel 192 Reagent kit cassette loaded with PCR Mix (containing Master Mix Reagent 2 (UC-MMX-R2) and **UC-TIB-HSV/VZV** (Primers and Probes) 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 6. Positive Controls need to be used within 30 days from first use and before the expiry date mentioned on the kit packaging label.

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

Reagent	Expiration date	Opened-kit stability	Number of runs	On-board Stability**
cobas® omni utility channel Reagent Kit	Not passed	90 days from first use	Max 40 runs	Max 40 hours
cobas® Buffer Negative Control Kit	Not passed	Not applicable	Not applicable	Max 10 hours
cobas® omni Lysis Reagent	Not passed	30 days from loading*	Not applicable	Not applicable
cobas® omni MGP Reagent	Not passed	30 days from loading*	Not applicable	Not applicable
cobas® omni Sample Diluent	Not passed	30 days from loading*	Not applicable	Not applicable
cobas® omni Wash Reagent	Not passed	30 days from loading*	Not applicable	Not applicable

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

5. PRECAUTIONS AND HANDLING REQUIREMENTS

►If the package is damaged, please contact your local Roche representative.

5.1. WARNING 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.
- **UC-TIB-HSV/VZV** is not evaluated for use as a screening test for the presence of HSV/VZV in blood or blood products.
- 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. Only personnel proficient in handling infectious materials and the use of **UC-TIB-HSV/VZV** 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 0.6% sodium or potassium hypochlorite in distilled or deionized water or follow appropriate site procedures.
- **Do not freeze whole blood or any samples stored in primary tubes.**
- 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.

5.2. 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 **cobas® omni** reagent cassette, sample 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 this reagent with the skin, eyes, or mucous membranes. If contact does occur, wash immediately with generous amounts of water; otherwise, burns can occur.
- **UC-TIB-HSV/VZV**, **cobas® omni** MGP Reagent, and **cobas® omni** Sample 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.

5.3. GOOD LABORATORY PRACTICES

- 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, **UC-TIB-HSV/VZV** 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 0.6% sodium or potassium hypochlorite in distilled or deionized water. 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 to clean and decontaminate the surface of instrument(s) properly.

6. SAMPLE COLLECTION, STORAGE, AND TRANSPORT

Detection of HSV-1, HSV-2 and VZV by Real Time PCR is dependent upon the quality of the sample collection, timely delivery of the samples to the laboratory in correct containers, and storage under the appropriate conditions before analysis.

- Store all samples at specified temperatures: sample stability is affected by elevated temperatures.
- Repeated freezing and thawing of human samples can compromise PCR sensitivity.
- Blood should be collected in Plasma Preparation Tubes for Molecular Diagnostic Test Methods or in sterile tubes using EDTA as the anticoagulant. Follow the instructions of the sample collection tube manufacturer.
- Whole blood collected in Plasma Preparation Tubes for Molecular Diagnostic Test Methods or in sterile tubes using EDTA as the anticoagulant may be stored and/or transported for up to 24 hours at 2-25°C prior to plasma preparation. Centrifugation should be performed according to the manufacturer's instructions.
- After separation, plasma specimen may be stored in secondary tubes for up to 6 days at 2-8°C or up to 3 weeks at -15°C to -80°C.
- Human samples must be transported according to the regulatory requirements for the transport of potentially infectious substances. To ensure ideal storage and transport conditions, follow the manufacturer's instructions.

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

7. PROTOCOL

7.1. WORKFLOW OVERVIEW

- The assay is only intended for use with **UC_TIB_HSV_VZV_v01.00** USAP.
- Do not use **cobas® omni** utility channel Reagent Kit, **cobas®** Buffer Negative Control kit, **UC-TIB-HSV/VZV**, or **cobas® omni** reagents after their expiry dates.
- Do not reuse consumables which are designed for single use only.

Table 7. Workflow overview

Step	Action	Required material	Reference Document
1	Define Rack-Based Ordering	**cobas®** 6800/8800 Systems	**cobas®** 6800/8800 User Assistance **cobas® omni** utility channel User Assistance
2	Prepare & Load Reagent Cassette		
3	Load Reagents and Consumables		
4	Prepare Samples and Control		
5	Start Run		
6	View Results		
7	Unload Consumables		

7.1.1. DEFINE TESTS ORDERING

- A **UC-TIB-HSV/VZV** can be ordered in any of the ways available for ordering tests on the system (i.e., from the LIS, as a manually entered test order, or as a rack-based order). Create a test order as described in **cobas®** 6800/8800 Systems user documentation. In the Sample type field, choose the sample material.
    - The Sample type field is displayed with LIS orders, manually entered test and rack-based orders.
- In the **Tests** group box, perform the following:
    - From the options in the **Test** field, choose the UC analysis package. Multiple UC analysis packages with identical PCR parameters can be assigned to the same run.
    - In the **Volume** field, choose the sample volumes. The available volumes are defined in the UC analysis package.
- Save and perform the test as described in the **cobas®** 6800/8800 Systems user documentation.

► Refer to the **cobas®** 6800/8800 Systems user documentation for more details.

7.1.2. PREPARING THE REAGENT CASSETTE

7.1.2.1. Prepare Master Mix

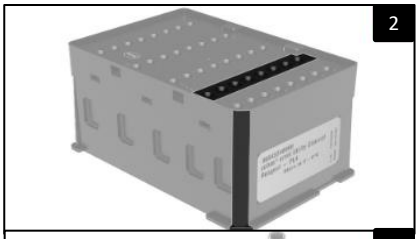
The Master Mix is prepared from the mix of Master Mix Reagent 2 (UC-MMX-R2) and **UC-TIB-HSV/VZV** primers and probes loaded in the 192-test cassette.


1

- Remove the Master Mix Reagent 2 bottles (UC-MMX-R2, see Picture 1), 192-test cassette from **cobas® omni** utility channel 192 Reagent Kit and **UC-TIB-HSV/VZV** primers and probes from their 2°C to 8°C storage location
- Mix the Master Mix Reagent 2 by inverting the bottle 20 times
- Transfer 10.0 mL Master Mix Reagent 2 to a light-protected polypropylene tube
  Note: Refer to the cobas® omni utility channel User Assistance for details on transfer options steps
- Mix and spin **UC-TIB-HSV/VZV** primers and probes
- Add 0.600 mL of **UC-TIB-HSV/VZV** primers and probes
- Mix this polypropylene tube by inverting 20 times

7.1.2.2. Filling the Reagent Cassette

The reagent cassette is prepared by loading the PCR Mix into the reagent cassette from the **cobas® omni** utility channel 192 Reagent Kit.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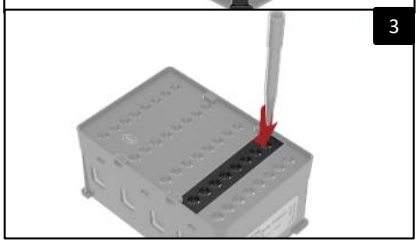
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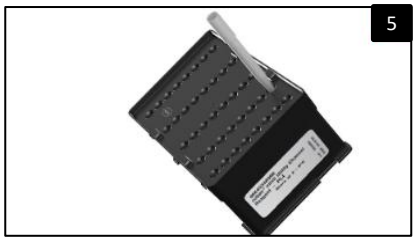
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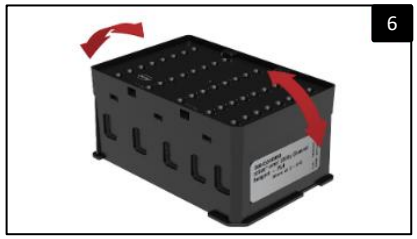
6

- Position the reagent cassette by placing the slanted edge in the lower right corner (see Picture 2).
  Note: The second row from the right now contains the empty container.
- Place a 1 mL plastic pipette tip into the top septum hole of row 2 (see Picture 3).
  Note: This pipette tip allows air pressure in the container 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 10.0 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 the prepared PCR Mix is pipetted. **Insufficient reagent volume can lead to false negative results.**
- 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 cassette from the **cobas® omni** utility channel Reagent Kit, document the assay name (**UC-TIB-HSV/VZV**), the date the cassette was prepared, the lot number of the assay kit primers and probes used (PP Mix Lot) and check the box “P&P Added” to confirm primers and probes mix has been added.

- Write the UCAP on the 192-test cassette, as described in table 8.

Table 8. To write the UCAP on the 192-test cassette

cobas® 6800/8800 Systems v1.4	cobas® x800 Data Manager 2.0 or higher
Using the **cobas® omni** utility channel tool: Start the **cobas® omni** utility channel tool. Choose Open a published UCAP to write a reagent cassette RFID tag button. Select the USAP zip.file in the new window and then Open. Recommended: Add **UC-TIB-HSV/VZV** Lot number to the RFID.	Using the RFID tool: Connect the RFID reader/writer to a USB port on the PC in which you have installed the RFID tool. In the Writing data on RFID tag group box, in the Reagent cassette ID field, enter the UCAP name: **U_UC_TIB_HSV_VZV**. If you have multiple cassettes for the same UCAP, in the Writing data on RFID tag group box, fill in the Custom information field. What you enter is used together with the reagent cassette lot number to track the reagent cassette lot. Recommended: Add **UC-TIB-HSV/VZV** Lot number to the RFID.
To forward the UCAP to the 192-test cassette RFID, use the RFID writer/reader: Place the RFID reader/writer immediately next to the RFID tag on the reagent cassette to be written. Choose the Write data on RFID tag button. To ensure that the RFID tag has been written on, choose the Read data from RFID tag button.	

- 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 6.

► Refer to the **cobas® omni** utility channel User Assistance for more details.

7.1.3. LOAD REAGENTS AND CONSUMABLES

On the Monitoring tab, choose the drawer corresponding to reagents and consumables to be loaded into the **cobas®** 6800/8800 Systems. Check their status and if necessary:

- Load the empty solid waste bag and liquid waste container
- Load the wash reagent, lysis reagent and diluent
- Load the processing plates and amplification plate cassette
- Load the Magnetic Glass Particles
- Load the Negative control cassette
- Load tips racks

Place the rack for clotted tips onto the sample supply module.

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

7.1.4. PREPARE SAMPLES AND CONTROL

Note: If using frozen plasma samples, place the samples at room temperature until completely thawed and vortex for 3 to 5 seconds before use. Controls should be removed from storage at 2°C to 8°C and brought to room temperature before use.

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 an appropriate Positive Control, we recommend using the entire cobas® omni utility channel 192 Reagent Kit cassette before loading a new utility channel 192 Reagent Kit cassette.

► Refer to the **cobas®** 6800/8800 Systems User Assistance to identify sample tubes with barcode.

Prepare the secondary tube for the **UC-TIB-HSV/VZV** Positive Control with the corresponding barcode as described below:

- Vortex the Positive Control vial
- Transfer 0.35 mL (this volume includes 0.15 mL of dead volume) of the Positive Control vial to the secondary tube with the appropriate barcode labeled.

Place the tubes with samples and Positive Control in the sample racks assigned to the assay **UC-TIB-HSV/VZV** on the **cobas®** 6800/8800 Systems.
Please note a negative control (**cobas®** Buffer Negative Control Kit, Roche P/N 09051953190) is automatically performed with each run by the **cobas®** 6800/8800 Systems.

7.1.5. START RUN

A run starts automatically if at least one of the samples for the run is onboard. If the run is not full and you do not want to wait for the timeout to end, start the run manually:

- Make sure that the system is in ”Ready” status
- On the Monitoring tab, next to the system overview, choose the ”Batches” button
  Note: Ensure all samples are scanned before starting the run
- Choose the ”Start manually” button

When the samples are processed, remove the rack tray with the sample racks from the output buffer of sample supply module.

7.1.6. VIEW RESULTS

Once the run finished, all the results obtained are reviewed on the **cobas®** 6800/8800 according to this procedure:

- On the monitoring tab of the **cobas®** 6800/8800, go to the “Routine” tab and choose “Control batch”.
- The **cobas®** 6800/8800 reports run and sample validity, based on negative control and internal control (IC).
- The positive control must be analyzed by the operator to validate or invalidate a run.
- The Ct values for each target are reported for samples with a positive and valid reaction.

7.1.6.1. Quality control and run validity of the results

The negative and the positive controls validate the run while the IC validates each sample. To determine this validity, interpret the results from the controls as described in Table 9 below.

Table 9. Run and reaction validity interpretation

Validity	Control	Valid	Invalid	Validation
Run	(-) Ctrl	Indicated as **"Valid"** in Overall Result column	Indicated as **"Invalid"** in Overall 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 (2, 3 OR 4) ► 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 2, 3 AND 4: Invalid ► Invalidated sample must be retested	**cobas®** 6800/8800 Systems

7.1.6.2. Interpretation of the results

If the run and sample are valid (section 7.1.6.1), the result interpretation for each target is based on the results provided by the **cobas®** 6800/8800 Systems and described in Table 10.

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, original sample should be re-tested to obtain a valid target result (see Section 7). If the target result is still invalid, a new sample should be obtained.

Table 10. Sample result interpretation

Target 2	Target 3	Target 4	Interpretation
HSV-1 Ct Value	VZV Ct Value VZV Negative Invalid	HSV-2 Ct Value HSV-2 Negative Invalid	Target signal detected for HSV-1.
HSV-1 Negative			No target signal detected for HSV-1.
Invalid			Result for HSV-1 is invalid
HSV-1 Ct Value HSV-1 Negative Invalid	VZV Ct Value	HSV-2 Ct Value HSV-2 Negative Invalid	Target signal detected for VZV.
	VZV Negative		No target signal detected for VZV.
	Invalid		Result for VZV is invalid.
HSV-1 Ct Value HSV-1 Negative Invalid	VZV Ct Value VZV Negative Invalid	HSV-2 Ct Value	Target signal detected for HSV-2.
		HSV-2 Negative	No target signal detected for HSV-2.
		Invalid	Result for HSV-2 is invalid.

7.1.7. UNLOAD CONSUMABLES

On the Monitoring tab, choose the drawer for the consumables to be discharged from **cobas®** 6800/8800 Systems.

- Unload the amplification plates from the analytic module
- Unload empty control cassettes
- Empty solid waste bag
- Empty liquid waste container

8. PERFORMANCE EVALUATION

8.1. LIMIT OF DETECTION (LOD)

The limit of detection (LoD) of **UC-TIB-HSV/VZV** was determined by analyzing serial dilutions of the HSV-1 (MacIntyre strain), HSV-2 (MS strain) and VZV (82 strain) strains obtained from Zeptometrix, in HSV/VZV-negative human EDTA plasma. These strains were quantified in c/mL with a calibration curve using quantified genomic DNA from ATCC as standard solutions. Panels of 7 concentration levels, including a negative panel were tested on three lots of **UC-TIB-HSV/VZV**. The study demonstrates that **UC-TIB-HSV/VZV** detects HSV-1, HSV-2 and VZV DNA at respective concentrations of 56.5 c/mL, 67.7 c/mL and 75.1 c/mL (Table 11), determined by PROBIT with a hit rate of 95%.

Table 11. LoD summary

Target	Matrix	$LoD_{95\%}$	95% Confidence Interval
HSV-1	EDTA Plasma	56.5 c/mL	35.5 – 77.4 c/mL
HSV-2	EDTA Plasma	67.7 c/mL	53.9 – 81.5 c/mL
VZV	EDTA Plasma	75.1 c/mL	61.2 – 88.9 c/mL

8.2. ANALYTICAL SPECIFICITY

The analytical specificity of the **UC-TIB-HSV/VZV** was evaluated by diluting microorganisms with and without HSV-1, HSV-2 and VZV strains in HSV/VZV-negative EDTA plasma (Table 12). Yeasts were tested at concentrations of 1.0E6 CFU/mL. Viruses were tested at concentrations ranging from 1.0E5 to 1.0E6 $TCID_{50}$/mL, c/mL or IU/mL, except when mentioned otherwise. None of the non-HSV/VZV pathogens interfered with the **UC-TIB-HSV/VZV** test performance. Negative results were obtained with **UC-TIB-HSV/VZV** for all HSV-1, HSV-2 and VZV-negative samples and positive results were obtained for all HSV-1, HSV-2 and VZV-positive samples.

Table 12. Microorganisms tested for cross-reactivity

Microorganism Name	Tested Concentration
Herpes Simplex Virus 1*	1.0E6 c/mL
Herpes Simplex Virus 2**	1.0E6 c/mL
Varicella Zoster Virus***	1.0E6 c/mL
BK Virus	1.0E6 c/mL
Cytomegalovirus	1.0E5 $TCID_{50}$/mL
Candida albicans	1.0E6 CFU/mL
Candida glabrata	1.0E6 CFU/mL
Epstein-Barr Virus	1.0E6 c/mL
Hepatitis B Virus	1.0E3 IU/mL
Hepatitis C Virus	1.0E3 IU/mL
Human Herpesvirus 6	1.0E6 c/mL
Human Herpesvirus 7	1.0E5 $TCID_{50}$/mL
Human Herpesvirus 8	1.0E5 $TCID_{50}$/mL
Human Immunodeficiency Virus 1	1.0E5 $TCID_{50}$/mL
JC Virus (pBRSV)	1.0E5 $TCID_{50}$/mL
Parvovirus B19	1.0E6 IU/mL
Simian Virus 40	1.0E5 $TCID_{50}$/mL

**For HSV-2 and VZV, **For HSV-1 and VZV, ***For HSV-1 and HSV-2*

8.3. INCLUSIVITY

Four strains of HSV-1, three of HSV-2 and eight of VZV were tested at a concentration close to the $LoD_{95\%}$ in HSV/VZV-negative EDTA plasma. The inclusivity of two HSV-2 and one VZV variants found in the literature was also assessed using synthetic DNA (gBlock). The results demonstrated that **UC-TIB-HSV/VZV** detects all the strains tested (Table 13).

Table 13. Detection of each strain with **UC-TIB-HSV/VZV**

Pathogen	Strains
HSV-1	HF
	F
	KOS
	MP
HSV-2	ATCC-2011-2
	ATCC-2011-4
	MS
	2 variants (synthetic DNA)
VZV	Oka
	Ellen
	Isolate A
	Isolate B
	82
	275
	1700
	9939
	1 variant (synthetic DNA)

8.4. INTERFERING SUBSTANCES

Potential exogenous (antimicrobial, antiviral and immunosuppressive drugs) and endogenous interfering substances were selected and tested at clinically relevant concentrations with the **UC-TIB-HSV/VZV** (Table 14). Interfering substances were tested in the presence and absence of the HSV-1, HSV-2 and VZV strains spiked in HSV/VZV-negative EDTA plasma. All potentially interfering substances were shown not to interfere with the test performance.

Table 14. Potential interfering substances tested for interference with **UC-TIB-HSV/VZV**

Interfering Substance	Final Concentration (µg/mL)
Azathioprine	2.99
Cefotetan disodium	474.00
Cidofovir hydrate	53.60
Cyclosporine A	4.59
Everolimus	0.34
Fluconazole	74.97
Foscarnet sodium	453.15
Ganciclovir	20.80
Mycophenolate mofetil	72.40
Mycophenolic acid	114.40
Piperacillin sodium	596.00
Potassium clavulanate	6.99
Prednisone	0.30
Sirolimus	0.09
Sulfamethoxazole	399.74
Tacrolimus	0.04
Tazobactam sodium	67.60
Ticarcillin disodium	776.00
Trimethoprim	40.02
Valganciclovir hydrochloride hydrate	22.96
Vancomycin hydrochloride	99.98
Bovine serum albumin	58700.00
Conjugated bilirubin	250.00
Hemoglobin human	2900.00
Human DNA	2.00
Triglyceride mix	34500.00
Unconjugated bilirubin	250.00

8.5. PRECISION

The precision of the **UC-TIB-HSV/VZV** was determined by analysis of two concentrations (2 and 5 times the $LoD_{95\%}$) of the HSV-1, HSV-2 and VZV strains spiked separately in HSV/VZV-negative EDTA plasma. The samples were tested for each concentration over 3 lots of **UC-TIB-HSV/VZV** on 1 instrument, 3 operators, 5 days. Each sample was carried through the entire **UC-TIB-HSV/VZV** procedure on fully automated **cobas®** 6800/8800 Systems. Therefore, the precision reported below represents all aspects of the test procedure (Table 15). **UC-TIB-HSV/VZV** showed repeatable and accurate results.

Table 15. Precision of the **UC-TIB-HSV/VZV**

Target	Concentration	Between Reagent Batches			Between Operators			Between Days		
		Mean Ct	SD	CV(%)	Mean Ct	SD	CV(%)	Mean Ct	SD	CV(%)
HSV-1	2 x $LoD_{95\%}$	35.2	0.7	1.9	35.0	0.3	1.0	35.5	0.3	0.8
	5 x $LoD_{95\%}$	34.0	0.2	0.7	33.8	0.1	0.3	34.1	0.3	0.9
HSV-2	2 x $LoD_{95\%}$	35.0	0.3	0.8	34.8	0.1	0.3	35.1	0.4	1.1
	5 x $LoD_{95\%}$	33.6	0.2	0.5	33.4	0.2	0.7	33.4	0.3	0.8
VZV	2 x $LoD_{95\%}$	33.7	0.4	1.1	33.1	0.9	2.6	33.6	0.8	2.5
	5 x $LoD_{95\%}$	32.5	0.5	1.5	32.5	0.0	0.1	32.5	0.1	0.4
Negative (IC)	NA	31.1	0.3	0.9	30.9	0.1	0.4	31.0	0.2	0.5

Target	Concentration	Between runs			Within run			Inter-Assay Precision		
		Mean Ct	SD	CV(%)	Mean Ct	SD	CV(%)	Mean Ct	SD	CV(%)
HSV-1	2 x $LoD_{95\%}$	35.5	0.3	0.8	35.2	0.5	1.4	35.2	0.6	1.8
	5 x $LoD_{95\%}$	34.1	0.3	0.9	34.0	0.5	1.4	34.0	0.5	1.5
HSV-2	2 x $LoD_{95\%}$	35.1	0.4	1.1	35.3	0.2	0.6	35.0	0.7	2.0
	5 x $LoD_{95\%}$	33.4	0.3	0.8	33.6	0.4	1.1	33.5	0.4	1.2
VZV	2 x $LoD_{95\%}$	33.6	0.8	2.5	34.1	1.2	3.5	33.6	1.5	4.4
	5 x $LoD_{95\%}$	32.5	0.1	0.4	32.1	0.4	1.3	32.5	0.6	2.0
Negative (IC)	NA	31.0	0.2	0.5	31.2	0.1	0.5	31.0	0.3	1.0

8.6. REPRODUCIBILITY

The reproducibility of **UC-TIB-HSV/VZV** was determined by analysis of two concentrations (2 and 5 times the $LoD_{95\%}$) of the HSV-1, HSV-2 and VZV strains spiked separately in HSV/VZV-negative EDTA plasma. The samples were tested for each concentration over 1 lot of **UC-TIB-HSV/VZV** on 2 instruments at 2 different sites. Each sample was carried through the entire **UC-TIB-HSV/VZV** procedure on fully automated **cobas®** 6800/8800 Systems. Therefore, the reproducibility reported below represents all aspects of the test procedure (Table 16). **UC-TIB-HSV/VZV** showed reproducible results.

Table 16. Reproducibility of **UC-TIB-HSV/VZV**

Target	Concentration	Reproducibility		
		Mean Ct	SD	CV(%)
HSV-1	2 x $LoD_{95\%}$	35.23	0.93	2.65
	5 x $LoD_{95\%}$	34.41	0.77	2.24
HSV-2	2 x $LoD_{95\%}$	35.06	0.40	1.14
	5 x $LoD_{95\%}$	33.69	0.46	1.36
VZV	2 x $LoD_{95\%}$	34.13	1.00	2.92
	5 x $LoD_{95\%}$	32.14	0.11	0.34
Negative (IC)	NA	31.47	0.93	2.96

8.7. CLINICAL PERFORMANCE

The performance of the **UC-TIB-HSV/VZV** was demonstrated by comparison with a real-time PCR CE-IVD kit for detection of human HSV-1 and HSV-2, and with a real-time PCR CE-IVD kit for detection of VZV on a retrospective collection. A total of 257 samples including 57 pre-selected EDTA plasma clinical specimens, 150 EDTA-plasma contrived samples and 50 plasma specimens with an unknown status were enrolled. All the results were valid.

The positive percent of agreement (PPA) was 100% for HSV-1, 98.4% for HSV-2 and 100% for VZV and the negative percent of agreement (NPA) was 99.5% for each target, as shown in Table 17. The discordants were tested with an alternative CE-IVD real time PCR kit and were detected negative for their respective discordant target pathogen.

Table 17. Summary of Clinical Performance of **UC-TIB-HSV/VZV**

HSV-1		**CE-IVD comparative kit**	
Total	257	+	-
UC-TIB-HSV/VZV	+	75	1
	-	0	181
PPA % (CI95%)	100 (95.1 – 100.0) %		
NPA % (CI95%)	99.5 (96.9 –99.9) %		

HSV-2		**CE-IVD comparative kit**	
Total	257	+	-
UC-TIB-HSV/VZV	+	60	1
	-	1	195
PPA % (CI95%)	98.4 (91.3 – 99.7) %		
NPA % (CI95%)	99.5 (96.9 – 99.9) %		

VZV		**CE-IVD comparative kit**	
Total	256*	+	-
UC-TIB-HSV/VZV	+	74	1
	-	0	181
PPA % (CI95%)	100 (95.1 – 100.0) %		
NPA % (CI95%)	99.5 (96.9 –99.9) %		

**1 clinical sample was reported invalid by the CE-IVD comparative kit. Due to insufficient volume for retest, this sample was excluded from the clinical analysis.*

9. LIMITATIONS

The **UC-TIB-HSV/VZV** has been evaluated only for use in combination with the **cobas®** 6800/8800 Buffer Negative Control Kit, **cobas® omni** MGP Reagent, **cobas® omni** Lysis Reagent, **cobas® omni** Sample Diluent, and **cobas® omni** Wash Reagent for use on the **cobas®** 6800/8800 Systems.

Reliable results depend on correct sample collection, storage and handling procedures.

This test has been validated only for use with EDTA plasma. Testing of other sample types may result in inaccurate results. Plasma viral load measurements are not directly comparable to those of other sample types.

Due to inherent differences between technologies, it is recommended that, prior switching from one technology to another, users perform method correlation studies in their laboratory to qualify technology differences. Users should follow their own specific policies/procedures.

Negative results do not preclude HSV1, HSV2 or VZV infections and should not be used as the sole basis for diagnosis treatment and other patient management decisions. Results of the **UC-TIB-HSV/VZV** need to be interpreted in consideration of all clinical and laboratory findings.

10. QUALITY CERTIFICATION

TIB Molbiol is ISO 13485 certified. The **UC-TIB-HSV/VZV** has been tested against predetermined specifications to ensure product quality.

11. KEY TEST FEATURES

Sample type	EDTA Plasma
Pathogens detected	HSV-1, HSV-2 and VZV
Minimum amount of sample required	350 µL*
Sample processing volume	200 µL
Analytical sensitivity	56.5 c/mL (HSV-1), 67.7 c/mL (HSV-2), 75.1 c/mL (VZV)
Specificity	99.5 %

* recommended for **cobas® omni** secondary tubes, minimum volumes for other tubes may differ

12. REFERENCES

① M.B. Wilck *et al.* (2013). Herpes Simplex Virus in Solid Organ Transplantation. *American Journal of Transplantation 13:121-127*

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③ K. Shiley and E. Blumberg (2011). Herpes Viruses in Transplant Recipients: HSV, VZV, Human Herpes Viruses, and EBV. *Hematology/Oncology Clinics of North America 25:171-191*

④ S.S. Dadwal (2019). Herpes Virus Infections Other than Cytomegalovirus in the Recipients of Hematopoietic Stem Cell Translantation. *Infectious Disease Clinics of North America 33:467-484*

⑤ S.A. Pergam *et al* (2013). Varicella Zoster Virus in Solid Organ Transplantation. *American Journal of Transplantation 13: 138-146*

13. SYMBOLS

REF	Catalog reference number		Refer to user manual
LOT	Batch code	CONTROL +	Positive Control
GTIN	GTIN code		Store in the dark
Σ	Contains sufficient for "n" tests		Manufacturing date (yyyy-mm-dd)
2°C 8°C	Storag range of temperatures		Legal Manufacturer
	Use by date (yyyy-mm-dd)	SW	Ancillary Software
IVD	*In vitro* diagnostic medical device		Warning

14. NOTICE TO PURCHASER

- **UC-TIB-HSV/VZV** is a product from TIB Molbiol Syntheselabor GmbH, exclusively distributed worldwide by Roche Diagnostics GmbH
- **cobas®** is a registered trademark of Roche Diagnostics GmbH

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