Rx Only

cobas® Microbial Inactivation Solution

For in vitro diagnostic use

cobas® Microbial Inactivation Solution (MIS) P/N: 08185476001

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Intended use

The **cobas**® Microbial Inactivation Solution (MIS) is intended to be used for the pre-analytical sample preparation of raw sputum and digested and decontaminated (N-acetyl-L-cysteine/NaOH [NALC-NaOH]-treated) sputum and bronchoalveolar lavage (BAL) sediment specimens before testing with **cobas**® MTB, **cobas**® MAI and **cobas**® MTB-RIF/INH on the **cobas**® 5800/6800/8800 Systems. Refer to test-specific Instructions for Use for assay-specific claims.

Reagents and materials

cobas® Microbial Inactivation Solution

Store MIS at the corresponding temperature specified in Table 1.

Table 1 **cobas**® Microbial Inactivation Solution

cobas® Microbial Inactivation Solution Store at 2-8°C (P/N 08185476001)			
Kit components	**Reagent ingredients**	**Quantity per kit**	**Safety symbol and warning***
cobas® Microbial Inactivation Solution	Tris buffer, 60% (v/v) Isopropanol**, 1% (w/v) Thymol**, 18.9% (w/v) Guanidinium thiocyanate**, 1.4% (w/v) Tris(2-carboxyethyl)-phosphine hydrochloride**, 0.4% (w/v) Tween 20	480 mL (16 x 30 mL)	 **DANGER** H225: Highly flammable liquid and vapour. H314: Causes severe skin burns and eye damage. H336: May cause drowsiness or dizziness. H412: Harmful to aquatic life with long lasting effects. EUH032: Contact with acids liberates very toxic gas. EUH071 Corrosive to the respiratory tract. P210: Keep away from heat, hot surfaces, sparks, open flames and other ignition sources. No smoking. 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. P370 + P378: In case of fire: Use dry sand, dry chemical or alcohol-resistant foam to extinguish. 67-63-0 Propan-2-ol 593-84-0 Guanidinium thiocyanate 51805-45-9 Propanoic acid, 3,3',3"-phosphinidynetris-, hydrochloride 89-83-8 Thymol

* Product safety labeling primarily follows EU GHS guidance

**Hazardous substance or mixture

For details regarding the materials and consumables required for the pre-analytic sample processing with MIS please refer to the test-specific Instructions for Use.

Reagent storage and handling requirements

Unopened MIS is stable until the expiration date indicated. Once opened, this reagent is stable for 30 days when stored at 2-8°C including cumulative 5 hours at 15–30°C (room temperature) or until expiration date, whichever comes first as specified in Table 2.

Table 2 **cobas**® Microbial Inactivation Solution expiry conditions

Reagent	Kit expiration date	Open-kit stability	Stability at 15–30°C (room temperature)
MIS	Date not passed	30 days from first usage	Max. 5 hours

Precautions and handling requirements

Warnings and precautions

As with any test procedure, good laboratory practice is essential for proper test performance. Care should be taken to keep reagents and samples free of contamination.

- For in vitro diagnostic use only.
- Safety Data Sheets (SDS) are available upon request from your local Roche representative.
- All patient samples should be considered potentially infectious. Therefore, all biological specimens should be handled as if infectious, using good laboratory procedures and adequate risk assessment as outlined in Biosafety in Microbiological and Biomedical Laboratories, in the CLSI Document M29-A4 and in the Tuberculosis Laboratory Biosafety Manual by WHO.[1,2,3] Only personnel proficient in handling infectious materials should perform this procedure.
- All personnel should wear protective personal equipment, including laboratory coats, disposable gloves, and eye and respiratory protection according to their institution's safety procedures and practices and should follow their institution's safety procedures for working with chemicals and biological specimens.
- Specimen liquefaction and mycobacterial inactivation by MIS should be performed in line with local and institutional guidelines or regulations and based on an adequate risk assessment.[3]
- If spillage of samples in MIS (which contains guanidinium thiocyanate) occurs, do not allow it to come in contact with sodium hypochlorite containing disinfectants such as bleach. This mixture can produce a highly toxic gas.
- If spillage of samples in MIS occurs, clean with 70% alcohol.
- MIS is light-sensitive and shipped in light-protective bottles. MIS must be stored upright.
- Do not use MIS kits after their expiration dates.
- Do not use MIS kits if any leaks or liquids are detected or components are visibly damaged.
- Inform your local competent authority about any serious incidents which may occur when using this product.

Reagent handling

- Before use, visually inspect the MIS bottle container to ensure that there are no signs of leakage. If there is any evidence of leakage, do not use that material for pre-analytic sample processing.
- MIS contains guanidine thiocyanate, a potentially hazardous chemical. Avoid contact of reagents with the skin, eyes, or mucous membranes. If contact does occur, immediately wash with generous amounts of water; otherwise, burns can occur.
- Do not allow MIS, 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 MIS 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.

Specimen type, transport, and storage

Specimen type

Raw sputum, and NALC-NaOH-treated sputum and BAL sediment specimens may be processed with MIS before testing with **cobas**® MTB, **cobas**® MAI and **cobas**® MTB-RIF/INH on the **cobas**® 5800/6800/8800 Systems.

Specimen transport and storage

Raw sputum specimens may be stored and/or transported for up to 3 days at 2°C to 35°C, followed by up to 7 days at 2°C to 8°C prior to sample liquefaction and inactivation by MIS. For long-term storage of MIS untreated raw sputum specimens, temperatures at ≤ -20°C are recommended.

NALC-NaOH-treated sputum and BAL sediment specimens may be stored for up to 7 days at 2°C to 8°C prior to sample inactivation by MIS. For long-term storage of MIS untreated sputum and BAL sediment specimens, samples may be stored frozen at temperatures ≤ -20°C for up to 9 months including two freeze/thaw cycles.

If samples are to be shipped, they should be packaged and labeled in compliance with applicable country and/or international regulations covering the transport of infectious samples and etiologic agents.

Inactivated specimen storage

Raw sputum and NALC-NaOH-treated sputum and BAL sediment specimens treated with MIS (inactivated) may be stored for up to 8 hours at 15°C to 35°C, followed by up to 7 days at 2°C to 8°C and 30 days at ≤ -20°C including two freeze/thaw cycles prior to processing on the **cobas**® 5800/6800/8800 Systems.

Note: MIS-treated specimens may not freeze due to high isopropanol content.

Instructions for use

For details regarding the processing of raw sputum and/or NALC-NaOH-treated sputum and BAL sediment specimens please refer to the test-specific Instructions for Use.

Procedural notes

- Invert the MIS bottles two to four times before use.
- Close the MIS bottles immediately after use.

Procedural limitations

Success in mycobacterial inactivation depends on adherence to procedures outlined in the test-specific Instructions for Use and complete mixing of sample with MIS. Pre-analytic treatment of patient samples by MIS reduces, but may not completely eliminate the risk of mycobacterial infection. The **cobas**® Microbial Inactivation Solution has been validated only for pre-analytical sample preparation of raw sputum and digested and decontaminated (N-acetyl-L-cysteine/NaOH [NALC-NaOH]-treated) sputum and bronchoalveolar lavage (BAL) sediment specimens before testing with **cobas**® MTB, **cobas**® MAI and **cobas**® MTB-RIF/INH on the **cobas**® 5800/6800/8800 Systems.

Performance evaluation

Sample inactivation

The reduction of mycobacterial infection risk by treating samples with MIS was evaluated using high positive cultures of two MTB complex strains (MTB CDC268 and MTB H37) at three different sites and using three different MIS reagent lots. For each condition five culture aliquots of concentration levels up to 5 x 10^7 CFU/mL were treated with MIS in a 1:2 ratio for 60 minutes at room temperature. The samples were then centrifuged for 15 minutes at 3000 x *g*, washed twice with sterile PBS and finally resuspended in 0.5 mL of sterile PBS. At two sites, the entire inactivated sample was inoculated and tested for growth using the BACTEC™ MGIT™ 320 Mycobacterial Detection System (Becton Dickinson). At the third site, MTB viability was tested on solid Löwenstein-Jensen (LJ) medium. None of the inactivated samples showed growth of M. tuberculosis complex bacteria at the end of the 56-day incubation period.

Additional information

Symbols

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

Table 3 Symbols used in labeling for Roche diagnostic 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

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References

1. Centers for Disease Control and Prevention. Biosafety in microbiological and biomedical laboratories, 5th ed. U.S. Department of Health and Human Services, Public Health Service, Centers for Disease Control and Prevention, National Institutes of Health HHS Publication No. (CDC) 21-1112, revised December 2009.
2. Clinical and Laboratory Standards Institute (CLSI). Protection of laboratory workers from occupationally acquired infections. Approved Guideline-Fourth Edition. CLSI Document M29-A4:Wayne, PA; CLSI, 2014.
3. World Health Organization. Tuberculosis laboratory biosafety manual. Geneva, Switzerland; WHO, 2012.

Document revision

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