

INSTRUCTIONS FOR USE



■ QC Microbiology Slides

INTENDED USE

QC Microbiology Slides are intended for use as non-viable, external control materials to evaluate the performance of formal quality assurance programs that involve the organisms and products listed in Table 1. These products are microscope slide preparations containing specific organism populations with known and predictable characteristics. These products are quality control challenges to verify performance of stain reagents, staining methods, and the performance of personnel interpreting microscopic examinations. These products have no qualitative or quantitative assigned value. These control materials are nonautomated and not intended to be used for screening, monitoring, or diagnosis. These controls are not intended for any specific patient population or specimen.

SUMMARY AND EXPLANATION

A reliable source of microbiology quality control slides is essential. QC Microbiology Slides containing specific microorganism populations of known and predictable staining characteristics and microscopic morphology are used in quality control, education, and proficiency programs. The organisms listed in Table 1 have been rendered non-viable through chemical fixation methods.

The use of prepared slides with fixed challenge microorganisms is well-documented and recommended as quality control challenges. QC Microbiology Slides consist of six groups of microscope slide preparations including:

- Acid-Fast Stain Controls
- Blood Parasites
- Tissue Fungi
- Intestinal Parasites
- Gram Stain Controls
- Mycology Controls

PRINCIPLES

Each Microbiology QC Slide is labeled with the slide description. Table 1 details the challenge material provided on each slide and information regarding the actual use of the challenge material in the laboratory.

COMPOSITION

QC Microbiology Slides are packaged in a box of 10 slides. Each box contains:

- Slides with one or two air-dried, non-viable preserved microorganism populations
- Instructions for Use

The details of the specified microorganism populations and the method of preservation are listed in Table 1.

Table 1: QC Microbiology Slides Product Information

Product Group and Catalog #		Description	Organisms	Preservation Method	Recommended Stain
Gram Stain Controls	SL01-10	Gram Stain Control Slide	Gram-positive <i>Staphylococcus aureus</i> ATCC® 25923™ Gram-negative <i>Escherichia coli</i> ATCC® 25922™	Methanol fixation	Gram Stain
	SL10-10	Zinc PVA-Preserved Fecal Smear Control	Representative intestinal protozoa, usually <i>Giardia lamblia</i>	PVA fixative	Trichrome Stain (Wheatley)
Intestinal Parasites	SL15-10	SAF-Preserved Fecal Smear Control	Representative intestinal protozoa, usually <i>Giardia lamblia</i>	SAF fixative	
	Acid-Fast Stain Controls	SL40-10	Acid Fast Control Slide	<i>Mycobacterium gordonae</i> ATCC® 14470™ <i>Cryptosporidium</i> and intestinal bacteria	Methanol fixation
SL41-10		Mycobacterium Control Slide	<i>Mycobacterium gordonae</i> ATCC® 14470™ <i>Erysipelothrix rhusiopathiae</i> ATCC® 19414™		
SL45-10		Cryptosporidium Control Slide	<i>Cryptosporidium</i> Intestinal bacteria		
Mycology Controls	SL50-10	FYC (Culture Isolates) Control Slide	<i>Candida albicans</i> ATCC® 10231™	Methanol fixation	Lactophenol Cotton Blue
	SL60-10	MYC-D (Clinical Samples) Control Slide	<i>Candida albicans</i> ATCC® 10231™ with Leukocytes		Calcofluor White (KOH)
Tissue Fungi	SL70-10	<i>Pneumocystis carinii</i> Control Slide	<i>Pneumocystis carinii</i>	Methanol fixation	Giemsa, Giemsa Plus, Methenamine Silver Nitrate
	SL75-10	<i>Pneumocystis carinii</i> Two-Well Control Slide	Normal rat lung tissue Rat lung tissue infected with <i>Pneumocystis carinii</i> cysts and trophs		
Blood Parasites	SL90-10	Blood Parasite Control Slide	Plasmodium, Babesia, or Trypanosoma	Methanol fixation	Giemsa Plus, Wright's Stain

WARNINGS AND PRECAUTIONS

- For In Vitro Diagnostic use only.
- For professional use only. To be used by personnel trained in the use of the laboratory protocol.
- QC Microbiology Slides are single-use only. Once stained, do not reuse. If reused, the results may be obscured by overstaining.
- Not intended for human, animal, or pet consumption.
- These products do not contain any hazardous substances listed in 1272/2008/EC.
- This product should be handled using universal laboratory precautions to avoid injuries due to glass breakage. Wear appropriate personal protective equipment. Do not smoke, eat, or drink in areas where specimens are handled. Disinfect any spills and dispose of glass microscope slides in accordance with your laboratory protocol and in compliance with national and local regulations.
- The non-viable nature of these products excludes the materials from a biohazard classification.
- Refer to the SDS for more detailed information. The SDS can be located on the Microbiologics website at www.microbiologics.com or by contacting Technical Support at 1.320.229.7045 or U.S. Toll Free 1.866.286.6691.
- These products are not made with natural rubber latex.
- Report any serious incident that has occurred in relation to the device to Microbiologics and the local regulatory officials in which the user and /or the patient is established.

MATERIALS REQUIRED BUT NOT PROVIDED

- The staining reagents and materials as specified in the laboratory protocol.
- The equipment and materials required for microscopic examination as specified in the laboratory protocol.

INSTRUCTIONS FOR USE

QC Microbiology Slides are ready for staining. No additional manipulations or processing are required.

1. Stain the slide according to the stain reagent manufacturer's directions or according to the laboratory protocol.
2. Examine the stained regions microscopically (for example, oil immersion).
3. Record the test results in compliance with your laboratory quality assurance protocol.

STORAGE AND EXPIRATION



QC Microbiology Slides must be stored under dry conditions at room temperature (15°C – 30°C) in the original container to avoid adverse effects of heat, moisture, and dust. Stored as directed, the microorganism challenges will retain, until the expiration stated on the device label, its specifications and performance within the stated limits. The products are intended to be used immediately after staining.

QC Microbiology Slides should not be used if:

- Stored improperly.
- There is evidence of excessive exposure to heat or moisture.
- The expiration date has passed.

LIMITATIONS

This product may not be suitable for use with all kits and procedures. Please see kit manufacturer instructions for sample details.

MICROBIOLOGICAL STATE

This sample contains fixed, non-viable organisms.

KEY OF SYMBOLS



Authorized Representative in the European Community



Do not re-use



Batch Code (Lot)



In Vitro Diagnostic Medical Device



Catalog Number



Manufacturer



Caution



Telephone Number



CE Mark



Temperature Limit



Consult instructions for use or consult electronic instructions for use



Use-By Date



Contains sufficient for <n> tests



EU Authorized Representative

Please refer to product labels for applicable symbols.

WEBSITE

Visit our website, www.microbiologics.com, for current technical information, product availability, biohazard cleanup, growth requirements and Certificate of Analysis.

BIBLIOGRAPHY

- Morris GB, Ridgway EJ, Suvarna SK. Traditional stains and modern techniques for demonstrating microorganisms in histology. *Bancroft's Theory and Practice of Histological Techniques*. 2019;254-279. doi:10.1016/B978-0-7020-6864-5.00016-5

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REVISION HISTORY ---

Publication History		
Revision	Date	Description of Change
C	2022-08-05	Revised intended use and summary and explanation section verbiage, added Table 1, added EU warnings and precautions, revised material required but not provided section verbiage, added "Single-Use Only" symbol to Key of Symbols section, added revision history table, removed "packaged in a box of 5" from composition section, updated item #'s in table 1 to match website.
D	2025-07	Added Bibliography section, updated MediMark® Address, replaced EC rep Symbol with EU Rep and removed Warranty information.