

MicroBiologics®

MICROBIOLOGY QUALITY CONTROL SLIDES

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

INTENDED USE

The **MICROBIOLOGY QC Slides** are microscope slide preparations containing specific organism populations with known and predictable characteristics.

These slides support formal quality assurance programs by serving as quality control challenges to verify performance of stain reagents, staining methods, and the performance of personnel interpreting microscopic examinations.

SUMMARY AND HISTORY

A reliable source of microbiology quality control slides is essential. Microscope slide preparations containing specific organism populations of known and predictable staining characteristics and microscopic morphology are used in quality control, education and proficiency programs.

The use of prepared slides with fixed challenge organisms is well-documented and recommended as quality control challenges.

The **MICROBIOLOGY QC Slides** consist of six groups of microscope slide preparations. The preparations include:

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

PRINCIPLE

Each **MICROBIOLOGY QC Slide** is labeled with the slide description.

The "**PRODUCT DESCRIPTION**" details the challenge material provided on each slide and the reference notation '(ref . . .)' provides information regarding the actual use of the challenge material in the laboratory.

FORMULA COMPONENTS

Each **MICROBIOLOGY QC Slide** contains one or two air-dried, nonviable, and preserved organism populations. The details of the specified organism populations and the method of preservation or 'fixing' are listed in the "**PRODUCT DESCRIPTION**" section of this product insert.

PRODUCT DESCRIPTION

ACID-FAST STAIN CONTROLS **SL45-10 (ref. Acid Fast Stains)** **Cryptosporidium Control Slide**

The selection of materials for these quality control slides was based on the Acid Fast staining characteristics of *Cryptosporidium*.

This quality control slide provides a single, air-dried and methanol-fixed fecal smear containing Acid Fast-Positive *Cryptosporidium* and Acid Fast-Negative intestinal bacteria.

SL41-10 (ref. Acid Fast Stains) **Mycobacterium Control Slide**

The selection of materials for these quality control slides was based on the Acid Fast staining characteristics of *Mycobacterium*.

This quality control slide provides two air-dried and methanol-fixed droplets within two etched circles. The circle nearest the label contains an Acid Fast-Positive *Mycobacterium* and the circle furthest contains an Acid Fast-Negative 'Coryneform' bacterium.

SL40-10 (ref. Acid Fast Stains) **Acid Fast Control Slide**

The selection of materials for these quality control slides was based on the Acid Fast staining characteristics of *Mycobacterium* and *Cryptosporidium*.

This quality control slide provides two air-dried and methanol-fixed droplets within two etched circles.

The circle **nearest** the label contains a droplet of an Acid Fast-Positive *Mycobacterium*. The circle **furthest** from the label contains a droplet of an Acid Fast-Positive *Cryptosporidium* in a fecal sample and also contains Acid Fast-Negative intestinal bacteria.

Blood Parasites

SL90-10 (ref. Giemsa and Wright Stains) **Blood Parasite Control Slide**

The selection of materials for these quality control slides was based on the use of stains to detect characteristics and identification features of *blood parasites* in blood smear preparations.

This quality control slide provides an air-dried, methanol-fixed, thin blood smear containing *Plasmodium*, *Babesia* or *Trypanosoma*.

Tissue Parasites

SL70-10 (ref. Toluidine Blue O Stain, Giemsa, etc.)

P. carinii Control Slide

The selection of materials for these quality control slides was based on the use of stains such as Toluidine Blue O, Giemsa, and histological stains to detect characteristics and identification features of *Pneumocystis* in tissue samples.

This quality control slide provides a single, air-dried and methanol-fixed rat lung tissue preparation containing *Pneumocystis*.

Intestinal Parasites

SL10-10 (ref. Trichrome and Iron Hematoxylin) Protozoan Control (Zinc PVA)

The selection of materials for these quality control slides was based on the use of permanent stains to detect characteristics and identification features of intestinal protozoa preserved in **Zinc PVA Fixative**.

This quality control slide provides an air-dried, PVA-preserved, fecal smear containing a representative intestinal protozoa.

SL15-10 (ref. Trichrome and Iron Hematoxylin) Protozoan Control (SAF)

The selection of materials for these quality control slides was based on the use of permanent stains to detect characteristics and identification features of intestinal protozoa preserved in **SAF Fixative**.

This quality control slide provides an air-dried, SAF-preserved, fecal smear containing a representative intestinal protozoa.

SL80-10 (ref. Modified Trichrome) Microsporidium Control Slide

This selection of materials for these quality control slides was based on the use of strains such as the Modified Trichrome to detect characteristics and identification features of *Microsporidium*.

This quality control slide provides two air-dried and methanol-fixed droplets within two etched circles. One droplet contains *Microsporidium species* and the other droplet contains a budding yeast.

Gram Stain Controls

SL01-10 (ref. Gram Stain)

Gram Stain Control Slide

The selection of materials for these quality control slides was based on the use of the Gram Stain to detect characteristics and identification features of bacteria.

This quality control slide provides two air-dried and methanol-fixed droplets within two etched circles. The circle **nearest** the label contains a droplet of a Gram-Positive *Staphylococcus aureus derivative of ATCC® 25923™*. The droplet **furthest** from the label contains a droplet of a Gram-Negative *Escherichia coli derivative of ATCC® 25922™*.

Mycology Controls

SL50-10 (ref. Lactophenol Cotton Blue) FYC Control Slide

The selection of materials for these quality control slides was based on the use of lactophenol cotton blue to identify unique staining and morphological characteristics of a fungus or yeast culture isolate.

This quality control slide provides a single, air-dried and methanol-fixed preparation containing a portion of a yeast or fungus culture isolate.

SL60-10 (ref. Calcofluor White & KOH preparations) MYC-D Control Slide

The selection of materials for these quality control slides was based on the use of Calcofluor White to detect mycotic agents in clinical samples and the use of potassium hydroxide to clear cell debris to improve the detection of fungus or yeast elements in clinical samples.

This quality control slide provides a single, air-dried, methanol-fixed, preparation containing host cells and yeast or fungi elements.

PRECAUTIONS AND LIMITATIONS

These products are for in-vitro use only.

The nonviable nature of these products excludes the materials from a biohazard classification.

STORAGE REQUIREMENTS

The **MICROBIOLOGY QC Slides** must be stored at room temperature (15°C to 30°C), under dry conditions, and in the original container to avoid adverse affects 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 **Microbiology QC Slides** should not be used if:

- stored improperly;
- there is evidence of excessive exposure to heat or moisture; or,
- the expiration date has passed.

MATERIALS REQUIRED BUT NOT PROVIDED

- The staining reagents and materials specified in each laboratory's protocol are not provided.
- The equipment and materials required for microscopic examination as specified in each laboratory's protocol are not provided.

PRODUCT WARRANTY

These products are warranted to meet the specifications and performance printed and illustrated in product inserts, instructions, and supportive literature.

The warranty, expressed or implied, is limited when:

- The procedures employed in the laboratory are contrary to printed and illustrated directions or instructions; or,
- The products are employed for applications other than the intended use cited in product inserts, instructions, and supportive literature.

3. Manual of Quality Control Procedures for Microbiology Laboratories. 3rd Ed. 1981. CDC. Atlanta, GA

DIRECTIONS FOR USE

The **Microbiology QC 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 your laboratory staining method.
2. Examine the stained circles microscopically (e.g., oil immersion).
3. Record the test results in compliance with your laboratory quality assurance protocol.

BIOHAZARD CLEANUP

These products are nonviable and do not pose a biohazard threat. Biohazard Cleanup protocols are not indicated.

WASTE DISPOSAL METHOD

Avoiding injuries due to breakage must be considered for proper disposal of glass microscope slides. Dispose of glass microscope slides in accordance with your laboratory protocol and in compliance with regulatory requirements.

QUALITY CONTROL

These products are developed, manufactured and distributed:

- in compliance with the mandates of FDA: Quality System Regulation (QSR), 21CFR Part 820;
- in conformance with the elements of ISO 9001:2000; and,
- in conformance with CE Mark requirements.

Quality control functions include, but are not limited to:










- typical microscopic staining characteristics;
- typical microscopic morphology; and,
- as indicated, the identity and traceability of the microorganism populations to a reference culture.

REFERENCES

The use of microbiology control slides is only one integral part of the overall scheme for QC challenge procedures and techniques. Reference to guidelines for each laboratory's applications is essential. Examples might include:

1. Clinical Microbiology Procedures Handbook. Vol. 1 and Vol. 2. 2nd Ed. 2004. ASM. Washington, D.C.
2. Manual of Clinical Microbiology. Vol. 1 and Vol. 2. 8th Ed. 2003. ASM. Washington, D.C.

KEY OF SYMBOLS

-  Authorized Representative in the European Community
-  Batch Code (Lot)
-  CE Mark
-  Catalog Number
-  Caution consult accompanying documents Attention, see instructions for use
-  In Vitro Diagnostic Medical Device
-  Manufacturer
-  Temperature Limitation
-  Use by

WEB SITE

Visit our Web Site for the most current technical and product availability information.

www.microbiologics.com

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