

# MicroBiologics

## KWIK-QC™ SLIDES

**KWIK-QC™ Gram Stain Slides**  
**KWIK-QC™ GC Slides**  
**KWIK-QC™ Acid Fast Stain Slides**  
**KWIK-QC™ Mycobacterium Slides**

### INTENDED USE

The **KWIK-QC™ Slides** are microscope slide preparations containing specific organism populations of known and predictable characteristics. These slides support formal quality assurance programs by serving as quality control challenges to demonstrate and document satisfactory performance of staining reagents and methods used in staining procedures and to document personnel's ability to perform the procedure and to properly interpret the microscopic test results.

### 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 **KWIK-QC™ Slides** consist of four distinct microscope slide preparations. The preparations include:

**KWIK-QC™ Gram Stain Slides**  
**KWIK-QC™ GC Slides**  
**KWIK-QC™ Acid Fast Stain Slides**  
**KWIK-QC™ Mycobacterium Slides**

### PRINCIPLE

Each **KWIK-QC™ Slide** has a labeled end and a clear glass portion. The design facilitates staining clinical samples or unknown culture isolates concurrent with the designated quality control.

The labeled end identifies the specific **KWIK-QC™ Slide** and contains two (2) circles. Each circle contains an air-dried, nonviable, methanol-fixed, droplet of the specified organism population.

The white silk-screened area of the slide label can be used to identify the slide (pen or pencil).

The remaining clear portion of the slide can be used to prepare clinical sample smears or suspensions of culture isolate for concurrent staining.

### FORMULA COMPONENTS

Each **KWIK-QC™ Slide** contains two (2) air-dried, nonviable, methanol-fixed droplets of a specified organism population. The details of the specified organism populations are listed in the "**PRODUCT DESCRIPTION**" listed below.

### PRODUCT DESCRIPTION

#### A. KWIK-QC™ Gram Stain, SL03-10

The label end of the **KWIK-QC™ Gram Stain Slide** contains two circles.

- The circle labeled "**POSITIVE**" contains an air-dried, nonviable, methanol-fixed, droplet of *Staphylococcus aureus* (derivative of ATCC® 25923™).
- The circle labeled "**NEGATIVE**" contains an air-dried, nonviable, methanol-fixed, droplet of *Escherichia coli* (derivative of ATCC® 25922™).

Properly performed, a Gram Stain procedure will produce anticipated staining results on the **KWIK-QC™ Gram Stain Slide**. The Gram-Positive bacterium, *S. aureus*, will retain the crystal violet-iodine complex and stain purple. The Gram-Negative bacterium, *E. coli*, will not retain the crystal violet-iodine complex due to the decolorizing step and retains the counter stain, and stains red-pink.

#### B. KWIK-QC™ GC Slides, SL04-10

The label end of the **KWIK-QC™ GC Slide** contains two circles.

- The circle labeled "**POSITIVE**" contains an air-dried, nonviable, methanol-fixed, droplet of *Neisseria gonorrhoeae* (derivative of ATCC® 43069™) with a background of leukocytes and protein debris.
- The circle labeled "**NEGATIVE**" contains an air-dried, nonviable, methanol-fixed, admixture droplet of *Candida albicans* (derivative of ATCC® 60193™), and *Staphylococcus aureus* (derivative of ATCC® 25923™).

Properly performed, a Gram Stain procedure will produce anticipated staining results on the **KWIK-QC™ GC Stain Slide**. The *N. gonorrhoeae* will demonstrate typical Gram-negative, 'coffee-bean' shaped diplococci in comparison to the large, Gram-Positive budding yeast demonstrated by *C. albicans* and the smaller Gram-Positive cocci in clusters demonstrated by *S. aureus*.

**C. KWIK-QC™ Acid Fast Stain Slides, SL42-10**

The label end of the **KWIK-QC™ Acid Fast Stain Slide** contains two circles.

- The circle labeled "**AFB**" contains an air-dried, nonviable, methanol-fixed, droplet of *Mycobacterium species*.
- The circle labeled "**CRYPTO**" contains an air-dried, methanol-fixed, fecal smear containing nonviable *Cryptosporidium species* and intestinal bacteria.

Properly performed, the Acid Fast Stain procedure will produce anticipated staining results on the **KWIK-QC™ Acid Fast Stain Slide**. The Acid Fast-Positive *Mycobacterium* and *Cryptosporidium* will retain the primary stain and fail to decolorize with acid alcohol resulting in a red-pink stain (carbol fuchsin) or produce fluorescence (rhodamine/auramine). The Acid Fast-Negative microorganisms will not retain the primary stain due to decolorization by acid alcohol and retains the counterstain or fails to fluoresce.

**D. KWIK-QC™ Mycobacterium Slides, SL43-10**

The label end of the **KWIK-QC™ Mycobacterium Slide** contains two circles.

- The circle labeled "**POSITIVE**" contains an air-dried, nonviable, methanol-fixed, droplet of *Mycobacterium species*.
- The circle labeled "**NEGATIVE**" contains an air-dried, nonviable, methanol-fixed, droplet of 'Coryneform' bacterium.

Properly performed, the Acid Fast Stain procedure will produce anticipated staining results on the **KWIK-QC™ Mycobacterium Stain Slide**. The Acid Fast-Positive *Mycobacterium* will retain the primary stain and fail to decolorize with acid alcohol resulting in a red-pink stain (carbol fuchsin) or produces fluorescence (rhodamine/auramine). The Acid Fast-Negative 'Coryneform' bacterium will not retain the primary stain due to decolorization by acid alcohol and retains the counterstain or fails to fluoresce.

## 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 **KWIK-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 **KWIK-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.

## DIRECTIONS FOR USE

The **KWIK-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. 2<sup>nd</sup> Ed. 2004. ASM. Washington, D.C.
2. Manual of Clinical Microbiology. Vol. 1 and Vol. 2. 8<sup>th</sup> Ed. 2003. ASM. Washington, D.C.
3. Manual of Quality Control Procedures for Microbiology Laboratories. 3<sup>rd</sup> Ed. 1981. CDC. Atlanta, GA.

**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](http://www.microbiologics.com)**

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MicroBioLogics, Inc.  
217 Osseo Avenue North  
St. Cloud, MN 56303 USA  
Tel. 320-253-1640  
Fax. 320-253-6250  
Email. info@mbl2000.com:

 MediMark® Europe  
11, rue Emile Zola B.P. 2332  
38033 Grenoble Cedex 2, France  
Tel. 33 (0)4 76 86 43 22  
Fax. 33 (0)4 76 17 19 82  
Email. info@medimark-europe.com

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