

Acid Fast Stain Control Slides

Intended Use:

SDL Acid Fast Stain Control Slides are intended to be part of a quality control program to monitor microbiological stains and techniques such as Ziehl-Neelsen Stain, Kinyoun Stain, or Fluorescent Stains. Fluorescent Stains include: AcriFluor, Auramine-Rhodamine, Auramine O, & Modified Auramine O Stain. AFB Control Slides are solely intended for use *In Vitro* diagnostic analysis.

Summary and Explanation:

The SDL Acid Fast Stain Control Slide is prepared from standard stock of quality control organisms. Each control slide contains a positive control well with *Mycobacteria tuberculosis* and a negative well containing *Escherichia coli*. The distribution of the background material has been made to simulate patients' specimens.

Principle of the Procedure:

AFB Control Slides are stained either with a Kinyoun Stain, Ziehl-Neelsen Stain, or a Fluorescent Stain.

Components:

AFB Slides are packaged in boxes of 10 or 50.

Warnings:

Do not use product beyond the expiration date.
Avoid Wiping slide dry with cloth or paper towels, let slide air dry.

Storage:

Store at room temperature (15°C to 30°)

Procedure:

Follow laboratory procedure or procedure outlined in stain manufacturer's Instructions For Use.

Expected Results:

When staining with either Kinyoun or Ziehl-Neelsen stain the *Mycobacteria* species stain red to pink in color, and the background will stain either blue or green depending on the counterstain used. The *Escherichia coli* in the negative well will stain blue or green depending on counterstain used. When staining with Fluorescent Stain the *Mycobacteria species* will be orange/red, or yellowish green in color depending on the fluorescent stain used.

Quality Control:

Quality control should be performed each time a patient specimen is stained. Results should be recorded in a quality control manual.

Limitations:

The correct time for staining should be followed.
The preparation of a thin smear is necessary in order to visualize *Mycobacteria species* optimally.
The staining procedure should be performed by a qualified individual.
Patient samples should always be smeared on a separate slide to assure against cross contamination from the positive control well. If questionable results are obtained, test results should not be reported.

Safety:

For *In vitro* diagnostic use.
Gloves should be worn during staining procedure.
Good general microbiology techniques should be followed.









References:

1. V. Balows et al. Manual of Clinical Microbiology 5th ed. chap. 34, Amer. Soc. Micro. 1991.

Related product information:

Catalog # 350: 10 Acid Fast Stain Control Slides
Catalog # 351: 50 Acid Fast Stain Control Slides
Catalog # 384: AcriFluor Stain Set
Catalog # 345: Modified Auramine O Stain
Catalog # 353: AFB Stain/ Kinyoun Stain Set
Catalog # 041-0120 TB Slides for patient smears

SYMBOL LEGEND

	Catalog Number
	In Vitro Diagnostic Medical Device
	Consult Instructions for Use (IFU)
	Temperature Limitations (Storage Temp.)
	Batch Code (Lot Number)
	Use By (Expiration Date)
	Quantity Included
	Dimensions

Supported Products Page **(QUALITY FILE ONLY)**

This Technical Insert is used for the following products:

SDL Prod ID	Description
158	350 Acid Fast Stain Control Slides 10 slides/pkg
159	351 Acid Fast Stain Control Slides 50 slides/pkg

Revision History

CR NUMBER	REVISION
0809-007	00
1009-002	01
1017-003	02
0420-001	03
0121-001	04