

Certificate of Quality

Product Name: Gram Stain Set 4 x 250mL w/ Tray
Lot Number: 539845

Product Number: R40080
Expiration Date: 2021-09-04
 (YYYY-MM-DD)

This product has been manufactured, processed and packaged in accordance with the requirements of the Code of Federal Regulations 21 CFR part 820

Performance characteristics as described require all staining components to be used in the appropriate manner. Consult appropriate IFUs or other references to assure conformance to suitable methodology.

The individual components of this product have met separate performance specifications, and package requirements as a kit.

Challenge Organism:	Results
Gram Positive Control	Purple, Gram Positive Cocci
Gram Negative Control	Pink, Gram Negative Rods

This product was tested using Remel QC Slide catalog number R40142 and using standard Gram Stain Procedure.

Microbial Load Evaluation:

Product is evaluated for performance specifications only.

Contents of Kit:

Gram Crystal Violet	
Appearance:	Dark Purple, Liquid
pH @ 20-25°C:	N/A
Gram Decolorizer	
Appearance:	Colorless, Clear Liquid
pH @ 20-25°C:	N/A
Gram Iodine	
Appearance:	Bottle - Colorless, Clear Liquid Iodine Pouch - Dark Amber, Liquid
Gram Safranin	
Appearance:	Red, Liquid
pH @ 20-25°C:	N/A

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Aime Williams

Senior Quality Assurance Engineer