



PRINCIPLE

QC1™ Gram Slides are designed for the quality control of the Gram stain technique. They utilize Gram-positive bacteria and Gram-negative bacteria as Gram stain reaction controls. QC1 Gram Slides are intended to be used to validate each batch of slides stained by the conventional Gram stain technique.

CLINICAL SIGNIFICANCE

In 1884, Hans Christian Joachim Gram improved a staining method with the intention to differentiate pneumococci from lung tissue. In his procedure, he noticed that certain bacteria retained the stain while others did not. However, he did not realize how this method correlated to the unique attributes of the cells nor its importance as a preliminary means to classify bacteria taxonomically and phenotypically. The Gram stain has since become one of the relied upon methods employed in laboratories for differentiating bacteria.

Upon passing through the cell wall of the organism, crystal violet and iodine will form a complex. Some types of bacteria will retain this complex after a wash with an organic solvent, while others will not. Those that retain the crystal violet are known as Gram-positive (purple in color) while those that only retain the counterstain are known as Gram-negative (pink in color).

QC1 Gram Slides contain substrates (bacterial cell suspensions) at optimum concentrations (CFU/ml) necessary for a positive and negative Gram stain reaction. QC1 Gram Slides consist of two "wells". The positive control *Staphylococcus aureus* displays a Gram-positive staining reaction, and the negative control, *Escherichia coli*, displays a Gram-negative staining reaction.

Various clinical laboratory organizations and Good Laboratory Practices require quality control programs. The performance of equipment, reagents, methods, and techniques must be monitored and documented. The QC1 Gram Slide is used as a control slide for use with the Gram stain test, eliminating the need to maintain in-house stock cultures for preparing slides.

SPECIMEN COLLECTION AND PREPARATION

N/A

FOR IN VITRO DIAGNOSTIC USE ONLY

REAGENTS AND MATERIALS

- Provided**
 - QC1 Gram Slides
- Not Provided**
 - Gram staining reagents
 - Microscope slides
 - Microscope with oil immersion lens
 - Absorbent material
- Storage:** Store at room temperature (15-30° C).
- Stability:** QC1 Gram Slides are stable to the stated expiration date when stored at room temperature (15-30°C).

CALIBRATION

N/A

QUALITY CONTROL

Any product showing discoloration or past the stated expiration date should be discarded.

PROCEDURE

PRECAUTIONS

Handle all slides by the edges. Do not touch the surface of the slide as this may damage the substrates. The control slides contain bacterial concentrations that are air-dried and heated to adhere to the slide surface. Routine bacteriological safety controls should be used when handling the bacterial slides.

- The substrates on the Alpha-Tec QC1 Gram Slides are pre-fixed and do not need to be fixed by heat or alcohols prior to staining.
- If using Alpha-Tec Gram Quality Control Slides that have an area for a patient specimen (#0003231, #0003235, #0003236), it is acceptable to heat fix the patient area(s) of the slide by using the appropriate temperatures.
- Add the Alpha-Tec QC1 Gram Slide at the first stain step of your laboratory's staining procedure.
- Stain following the procedure described by the manufacturer of the stain being used, or consult appropriate references.

CALCULATIONS

N/A

RESULTS

Retention of the purple mordant primary stain indicated a Gram-positive organism. Bacterial cells that decolorize and stain pink/red with counterstain are Gram-negative organisms.

LIMITATIONS

For patient slides, a proper heat fixing technique must be used to prevent change to the cell wall and the chemical structure of the cell wall. Care must be taken not to heat the slide for too long or too hot. A microorganism that is physically disrupted by excess heating will not react to Gram staining as expected.

BIBLIOGRAPHY

1. Todd & Stanford, CLINICAL DIAGNOSIS BY LABORATORY METHODS, 14th Edition.
2. STAIN TECHNOLOGY, Vol VIII, No. 2, January 1932
3. MANUAL FOR MICROBIAL METHODS, NY McGraw-Hill, 1957, pp. 15-18.
4. DIAGNOSTIC MICROBIOLOGY, 2nd Edition, 1966, p. 320.

CONTACT

For Technical Assistance email Technical@AlphaTecSystems.com and for Customer Service, email Sales@AlphaTecSystems.com or call (800) 221-6058 or (360) 260-2779 between 8am and 4pm Monday through Friday, Pacific Time.

WARRANTY

Alpha-Tec Systems, Inc. warrants this product to perform as described in the labeling and literature supplied. Alpha-Tec Systems, Inc. disclaims any implied warranty or merchantability or fitness for any other purpose, and in no event shall Alpha-Tec Systems, Inc. be liable for any consequential damages arising out of aforesaid express warranty.

TRADEMARKS

QC1™ is a trademark of Alpha-Tec Systems, Inc., 1311 SE Cardinal Court, Suite 170, Vancouver, WA 98683 USA

PRODUCT CODES

0003230 QC1 Gram Slides, 40/pk	0003235 QC1 Gram Slides, Three Patient Well, 40/pk
0003231 QC1 Gram Slides, One Patient Well, 40/pk	0003236 QC1 Gram Slides, Three Patient Well, 10/pk
0003233 QC1 Gram Slides, 10/pk	0003238 QC1 Gram Slides, 40/pk



Manufactured by Alpha-Tec Systems Inc., 1311 SE Cardinal Court, Suite 170, Vancouver, WA 98683 USA.



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**GLOSSARY OF SYMBOLS**

Lot number / Número de porción / Numéro de lote / Numerodi lotto / Partienummer / Numéro de sort / Het Aantal van de partij



Catalog number / Número de catálogo / Número de catálogo / Numero di catalogo / Katalogzahl / Numéro de catalogue / Het aantal van de catalogus



For in vitro diagnostic use only / Para el uso diagnóstico in vitro solamente / Para in vitro o uso diagnóstico solamente / Solo per uso diagnostico in vitro / Für nur in vitrodiagnosegebrauch / Pour l'usage diagnostique in vitro seulement / Voor kenmerkend slechts gebruik in vitro



Authorized European representative / Representante europeo autorizado / Representante europeu autorizado / Rappresentante europeo autorizzato / Autorisierter europäischer Repräsentant / Representant européen autorisé / Gemachtigde Europese vertegenwoordiger



Caution, consult accompanying documents / Precaución, consulte los documentos de acompañamiento / Cuidado, consulte originais acompanhando / Attenzione. Consulti i documenti di accompagnamento / Vorsicht, beraten Begleitdokumente / Attention, consultez les documents d'accompagnement / Voorzichtigheid, raadpleeg begeleidende documenten



Store between temperatures indicated / Almacén entre las temperaturas indicadas / Loja entre as temperaturas indicadas / Deposito fra le temperature indicate / Speicher zwischen den Temperaturen angezeigt / Magasin entre les températures indiquées / Opslag tussen vermelde temperature



Consult instructions for use / Consulte las instrucciones para el uso / Consulte instruções para o uso / Consulti le istruzioni per uso / Beraten Sie Anwendungsvorschriften / Consultez les instructions pour l'usage / Raadpleeg instructies voor gebruik



Use by date indicated / Uso por la fecha indicada / Uso pela data indicada / Uso entro la data indicate / Gebrauch bis zum der Dattel angezeigt / Utilisation à la datte indiquée / Gebruik door vermelde datum



Manufacturer / Fabricante / Fabricante / Fornitore / Hersteller / Fabricant / Fabrikant



Contains sufficient for <n> tests / Contiene suficiente para <n> las pruebas / Contem suficiente para <n> testes / Contiene sufficiente per <n> le prove / Enthält genügendes für <n> tests / Contient suffisamment pour <n> des essays / Bevat voldoende voor <n> tests