



Quidel Molecular GBS Control Set

Positive and Negative

QUIDEL



INTENDED USE

The Quidel Molecular GBS Control Set is intended to be used as full process controls in molecular testing. This unassayed Control Set for *in vitro* diagnostic use consists of a highly purified, inactivated Group B Streptococcus. The negative control is Group B Streptococcus free matrix.

INSTRUCTIONS FOR USE

The Quidel Molecular GBS Control Set should be used at the same volume (10-50 µL) as unknown culture samples in a validated molecular test methodology. See table below for suggested volumes in specific Quidel Molecular products.

| Quidel Molecular Assay | Volume |
|------------------------|--------|
| AmpliVue® GBS | 50 µL |
| Solana® GBS | 50 µL |

MATERIALS PROVIDED

Cat. #M116

Control Kit (2 vials) – Store at 2°C to 8°C

| # | Component | Quantity |
|------------------|--|-----------------|
| CONTROL + | Group B Streptococcus Positive Control Part M5081 | 1 vial/kit 1 mL |
| CONTROL - | Negative Control Part M5236 | 1 vial/kit 2 mL |

WARNINGS AND PRECAUTIONS

- Treat all specimens, samples and controls as potentially infectious. Follow universal precautions when handling samples, this kit, and its contents.
- Avoid contact with skin and eyes.
- Use micropipettes with an aerosol barrier or positive displacement tips for all procedures.
- Avoid microbial and cross contamination of the kit reagents. Follow Good Laboratory Procedures.
- Controls contain 0.09% Sodium Azide. Do not empty these controls into drains. Dispose of the containers in a safe way.
- Proper sample collection, storage, and transport are essential for correct results.¹
- Store assay reagents as indicated on their individual labels.
- Testing should be performed in an area with adequate ventilation.
- Dispose of containers and unused contents in accordance with Federal, State and Local regulatory requirements.

- Wear suitable protective clothing, gloves, and eye/face protection when handling the contents of this kit.
- Wash hands thoroughly after handling.
- For additional information on hazard symbols, safety, handling and disposal of the components within this kit, please refer to the Safety Data Sheet (SDS) located at quidel.com.

STORAGE AND HANDLING OF KIT REAGENTS

Store the kit at 2°C to 8°C until the expiration date listed on the labels.

QUALITY CONTROL

The controls included in the Quidel Molecular GBS Control Set are unassayed controls. Control ranges may vary based on testing method. A specific range should be determined for each desired testing method. Each laboratory should establish their own quality control ranges and frequency of QC testing based on applicable local laws, regulations and standard good laboratory practice.

LIMITATIONS

- For *in vitro* diagnostic use.
- This control has been studied using a molecular testing methodology; it is not intended for use with other methodologies.

CUSTOMER AND TECHNICAL SUPPORT

To place an order or for technical support, please contact a Quidel Representative at 800.874.1517 (in the U.S.) or 858.5521100 (outside the U.S.), Monday through Friday, from 8:00 a.m. to 5:00 p.m., Eastern Time. Orders may also be placed by fax at 740.592.9820. For e-mail support contact customerservice@quidel.com or technicalsupport@quidel.com. For services outside the U.S., please contact your local distributor. Additional information about Quidel, our products, and our distributors can be found on our website quidel.com.

REFERENCES

1. CLSI MM13-A: Guidance for the Collection, Transport, Preparation and Storage of Specimens for Molecular Methods (Vol. 25, No. 31) (Dec 2005).



M116 – Quidel Molecular GBS Control Set



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PIM116002EN00 (12/18)

GLOSSARY

REF

Catalogue number



CE mark of conformity

EC REP

Authorized representative
in the European Community

LOT

Batch code



Use by



Manufacturer



Temperature limitation



Intended use



Biological risks



Consult e-labeling
instructions for use

CONT

Contents/Contains

IVD

For *in vitro* diagnostic use

CONTROL +

Control positive

CONTROL -

Control negative
