



# 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.

### MATERIALS PROVIDED

Cat. #M116

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

#	Component	Quantity
<b>CONTROL +</b>	<b>Group B Streptococcus Positive Control</b> Part M5081	1 vial/kit 1 mL
<b>CONTROL -</b>	<b>Negative Control</b> Part M5031	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.
- Wear suitable protective clothing, gloves, eye, and face protection when using this kit.
- 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.<sup>1</sup>
- Store assay reagents as indicated on their individual labels.
- SDS is available upon request or can be accessed on the product website.

### 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 [custserv@quidel.com](mailto:custserv@quidel.com) or [technicalsupport@quidel.com](mailto: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](http://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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## GLOSSARY

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**REF**

Catalogue number



CE mark of conformity

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**EC REP**

Authorized representative  
in the European Community

**LOT**

Batch code

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Use by



Manufacturer

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Temperature limitation



Intended use

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Biological risks



Consult e-labeling  
instructions for use

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**CONT**

Contents/Contains

**IVD**

For *in vitro* diagnostic use

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**CONTROL +**

Control positive

**CONTROL -**

Control negative

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