Quidel Molecular Strep A+G Control Set
Positive and Negative

QUIDEL

INTENDED USE

The Quidel Molecular Strep A+G 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 mix of bacteria which include Group A Streptococcus and Group G Streptococcus. The negative control is Group A Streptococcus and Group G Streptococcus free matrix.

INSTRUCTIONS FOR USE

The Quidel Molecular Strep A+G Control Set should be used at the same volume (10 to 50 µL) as unknown samples in a validated molecular test methodology. The controls should be sampled using the same device as the unknown sample (polyester swab or transfer pipette). See table below for suggested volumes in specific Quidel Molecular products.

Quidel Molecular Assay	Volume
AmpliVue® GAS	50 µL
Solana® GAS	25 µL
Lyra® Direct Strep	25 µL

MATERIALS PROVIDED

Cat. #M111
Control Kit (2 vials) – Store at 2°C to 8°C

#	Component	Quantity
CONTROL +	**Group A+G Streptococci Positive Control** Part M5062	1 vial/kit 0.5 mL per vial
CONTROL −	**Negative Control** Part M5086	1 vial/kit 0.5 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.[1]
- Store assay reagents as indicated on their individual labels.

- 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 Strep A+G 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 858.552.1100 (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 25:31, 2005.

REF M111 – Quidel Molecular Strep A+G Control Set

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CE

EC REP

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GLOSSARY

REF Catalogue number	CE 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