Quidel Molecular Influenza A+B Control Set
Positive and Negative

For *in vitro* diagnostic use.

A symbols glossary can be found at quidel.com/glossary.

INTENDED USE
The Quidel Molecular Influenza A+B 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 mixture of highly purified, inactivated strains of Influenza A/New Caledonia/20/99 (H1N1), Influenza B/Florida/04/06 and an influenza RNA-free matrix.

INSTRUCTIONS FOR USE
The Quidel Molecular Influenza A+B Control Set should be used at the same volume (i.e. 180 µL) as unknown samples in a validated molecular test methodology. See table below for suggested volumes in specific Quidel Molecular products.

Quidel Molecular Assay	Volume
Lyra® Influenza A+B	180 µL

MATERIALS PROVIDED
Cat. #M106
Control Kit (3 vials) – Store at 2°C to 8°C

#	Component	Quantity
CONTROL +	**Influenza A+B Positive Control** Part M5029	2 vials/kit, 1 mL
CONTROL –	**Negative Control** 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.
- 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 Influenza A+B 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

If you have any questions regarding the use of this product, please contact Quidel Technical Support at 1.800.874.1517 (in the U.S.) or technicalsupport@quidel.com. If outside the U.S., further information can be obtained from your distributor, or directly from Quidel at one of the numbers listed below. Reference **quidel.com** to see more options for Support.

Country	**Phone**	**E-Mail Address**
Europe, Middle East and Africa	+353 (91) 412 474 (main) 0 1800 200441 (toll free)	emeatechnicalsupport@quidel.com
Austria	+43 316 231239	
France	0 (805) 371674	
Germany	+49 (0) 7154 1593912	
Netherlands	0 800 0224198	
Switzerland	0 800 554864	
United Kingdom	0 800 3688248	
Italy	+39 (800) 620 549	
North America, Asia-Pacific, Latin America	858.552.1100	technicalsupport@quidel.com
Canada	437.266.1704 (main) 888.415.8764 (toll free)	technicalsupport@quidel.com
China	0400 920 9366 or +86 021 3217 8300	chinatechnicalservice@quidel.com

REFERENCES

1. CLSI MM13-A: Guidance for the Collection, Transport, Preparation and Storage of Specimens for Molecular Methods 25:31, 2005.

REF M106 – Quidel Molecular Influenza A+B Control Set

IVD

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