Quidel Molecular Parainfluenza Virus Control Set
Positive and Negative

QUIDEL

INTENDED USE

The Quidel Molecular Parainfluenza Virus 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 strain of parainfluenza virus types 1, 2 and 3 in a parainfluenza RNA-free matrix.

INSTRUCTIONS FOR USE

The Quidel Molecular Parainfluenza Virus 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® Parainfluenza Virus	180 µL

MATERIALS PROVIDED

Cat. #M115
Control Kit (3 vials) – Store at 2°C to 8°C

#	Component	Quantity
CONTROL +	**Parainfluenza Virus Positive Control** Part M5069	2 vials/kit 1.0 mL
CONTROL –	**Negative Control** Part M5031	1 vial/kit 2.0 mL

WARNINGS AND PRECAUTIONS

- For *in vitro* diagnostic use.
- 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.
- 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 Parainfluenza Virus 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

- 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 M115 – Quidel Molecular Parainfluenza Virus 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