

Birlinn® CoV2-Flu-RSV Control Panel M509

INTENDED USE:

Birlinn® CoV2-Flu-RSV Control Panel M509 is intended for *in vitro* use as an external positive and negative unassayed quality control to monitor the performance of laboratory nucleic acid testing procedures that target the gene segments listed in Table 1 for the qualitative detection of Influenza A, Influenza B, Respiratory Syncytial Virus A/B and SARS-CoV-2.

PRODUCT SUMMARY and PRINCIPLE:

The Birlinn CoV2-Flu-RSV Control Panel M509 contains surrogate material composed of synthetic RNA corresponding to genome segments of Influenza A, Influenza B, Respiratory Syncytial Virus A/B, and SARS-CoV-2, as listed in Tables 1 and 2. Birlinn CoV2-Flu-RSV Control Panel M509 controls do not have assigned concentrations. RNA yield will depend on the individual laboratory's extraction and test methods.

Quality controls can be used for routine monitoring of test systems, validation, verification, proficiency assessment, and training procedures. Quality controls that are consistent from lot to lot assist the laboratory in identifying shifts, trends, and increased frequency of random errors caused by variations in the test system, such as failing reagents or malfunctioning equipment. Early investigation can prevent failed assay runs.

COMPOSITION:

The Birlinn CoV2-Flu-RSV Control Panel M509 is comprised of 12 tubes, 6 tubes of Birlinn CoV2-Flu-RSV Positive Control and 6 tubes of Birlinn CoV2-Flu-RSV Negative Control, 800 μ L each.

Birlinn CoV2-Flu-RSV Positive Control contains synthetic RNA consisting of gene segments of Influenza A, Influenza B, Respiratory Syncytial Virus A/B and SARS-CoV-2 suspended in a non-infectious solution of buffers, preservatives and stabilizers. Birlinn CoV2-Flu-RSV Negative Control contains synthetic RNA consisting of gene segments of the human RNase P gene suspended in a non-infectious solution of buffers, preservatives, and stabilizers.

STORAGE and STABILITY:

Birlinn CoV2-Flu-RSV Control Panel M509 will be shipped on dry ice or cold packs depending on destination and stored refrigerated (2°C to 8°C) upon receipt. Unopened Birlinn CoV2-Flu-RSV Control Panel M509 is stable through the expiration date printed on each tube when consistently stored at 2°C to 8°C. Opened material should be tightly capped and returned to the refrigerator (2°C to 8°C) immediately after use. The material is stable for ninety (90) days from the date of opening when consistently stored at 2°C to 8°C.

ORDERING INFORMATION:

Birlinn CoV2-Flu-RSV Control Panel M509

Part Number: M509

Kit Contains: 12 tubes x 800 μ L

6 Positive controls and 6 Negative controls

PRECAUTIONS, WARNINGS, and LIMITATIONS:

- This product is intended for *in vitro* diagnostic use only.
- Appearance: slightly cloudy.
- This product does not contain any biological material of human or animal origin. Universal Precautions are NOT required when handling this product.
- Quality control materials should be used in accordance with local, state, and federal regulations and accreditation requirements.
- Birlinn CoV2-Flu-RSV Control Panel M509 does not contain the entire genome of Influenza A, Influenza B, Respiratory Syncytial Virus A/B and SARS-CoV-2.
- Birlinn CoV2-Flu-RSV Control Panel M509 cannot be cloned, sold, or transferred without the explicit written consent of MMQCI.

INSTRUCTIONS FOR USE:

Allow controls to come to room temperature (18°C to 25°C), approximately 10-15 minutes.

1. Immediately before use, mix the control thoroughly by first flicking the tube 5 times followed by inverting at least 5 times. Tap the tube 3 times on the bench to remove any control caught in the cap before opening the tube.
2. For sample-to-answer test methods, use the control sample directly, as you would a patient specimen.
3. For use in test methods that are not sample-to-answer, extract the control as you would a patient specimen. Use the same volume that would be used for the extracted patient sample.

Note 1: Certain test methods may require additional processing of the control material, such as dilution prior to analysis.

Note 2: The level of RNA present in the extracted control is not quantifiable by spectrophotometer measurements.

4. Proceed with testing by following manufacturer's instructions.
5. Discard after use according to your local and federal regulations.

Consult MMQCI for assistance with instructions or use of the Birlinn CoV2-Flu-RSV Control Panel M509.

EXPECTED VALUES:

The laboratory should follow Good Laboratory Practice (GLP) and establish its own performance characteristics for Birlinn CoV2-Flu-RSV Control Panel M509 by analyzing data from multiple runs. Recoveries may vary depending on instrumentation, cycle time/temperature, reagents, method variation, and other system specifications. The genome segments in the Birlinn CoV2-Flu-RSV Control Panel M509 are listed in Tables 1 & 2.

Table 1. Birlinn CoV2-Flu-RSV Positive Control

Analyte	Genome Segments
SARS CoV-2	S gene, E gene, M gene, N gene, RdRP gene, ORF7ab, ORF1ab, ORF3a, ORF8 and ORF10
Flu A	PA gene, PB2 gene and M gene
Flu B	M gene, NS1 gene and NS2 gene
RSV A and B	M gene, M2 gene and N gene
Human RNase P	RNase P gene segments

Table 2. Birlinn CoV2-Flu-RSV Negative Control

Analyte	Genome Segments
Human RNase P	RNase P gene segments