



Birlinn™ CoV2-Flu-RSV Control Panel M509

INTENDED USE:

The Birlinn™ CoV2-Flu-RSV Control Panel M509 is intended for use as an external quality control to monitor the performance of *in vitro* 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. The Birlinn CoV2-Flu-RSV Control Panel M509 is an unassayed control and does not have assigned concentrations. RNA yield will depend on 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. The use of quality control materials allows for early investigation of analytical errors that 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, 800µL 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:

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

ORDERING INFORMATION:

Birlinn CoV2-Flu-RSV Control Panel M509

Part Number: M509

Kit Contains: 12 tubes x 800µL

6 Positive controls and 6 Negative controls

PRECAUTIONS and WARNINGS:

- Do not dilute. Use the control as provided.
- This product is intended for *in vitro* analytical testing and is provided for Research Use Only, not for use in diagnostic procedures.
- 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, federal regulations and accreditation requirements.
- The 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.
- The 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° – 25°C) before use.

1. Use the control as provided. **Do Not Dilute.**
2. Immediately before use, **mix the control thoroughly by first flicking the tubes 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.
3. Proceed with testing by following manufacturer's instructions.
4. Discard after use according to your local and federal regulations.

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 extraction method, probes and primers, instrumentation, cycle time / temperature, reagents, and methodology. 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