

LIAISON PLEX RP Control Panel M518

INTENDED USE:

The LIAISON PLEX RP Control Panel M518 is intended for use as an external positive and negative assayed quality control to monitor the performance of the LIAISON PLEX® Respiratory Flex (RSP Flex) Assay on the LIAISON PLEX System. The LIAISON PLEX Respiratory Flex (RSP Flex) Assay qualitatively detects the following pathogens: Adenovirus (A/B/C/D/E/F), *Bordetella parapertussis*, *Chlamydia pneumoniae*, Coronavirus (HKU1/ 229E/ NL63/ OC43), Influenza A (subtype H1), Influenza A, Human Metapneumovirus, Parainfluenza 1, Parainfluenza 3, Respiratory Syncytial Virus (RSV A and RSV B), *Bordetella holmesii*, *Bordetella pertussis*, SARS-CoV-2, Enterovirus/Rhinovirus, Influenza A (subtype H3), Influenza B, *Mycoplasma pneumoniae*, Parainfluenza 2 and Parainfluenza 4. The LIAISON PLEX RP Control Panel M518 positive controls contain synthetic DNA and RNA in stabilizing solution, and the negative control contains buffers and preservatives. This product is not intended to replace manufacturer internal controls provided with LIAISON PLEX devices.

PRODUCT SUMMARY and PRINCIPLE:

The LIAISON PLEX RP Control Panel M518 is composed of 3 controls, LIAISON PLEX RP Positive A, LIAISON PLEX RP Positive B, and LIAISON PLEX RP Negative. LIAISON PLEX RP Positive A and Positive B contain surrogate control material composed of synthetic DNA and RNA corresponding to genome segments of pathogens listed in Table 1. LIAISON PLEX RP Negative does not contain any DNA or RNA corresponding to the pathogens listed in Table 1.

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 LIAISON PLEX RP Control Panel M518 is comprised of 12 single use tubes, 4 tubes of LIAISON PLEX RP Positive A, 4 tubes of LIAISON PLEX RP Positive B, and 4 tubes of LIAISON PLEX RP Negative, 300µL each. The LIAISON PLEX RP Positive controls contain synthetic target DNA and RNA suspended in a non-infectious solution of buffers, preservatives, and stabilizers. The LIAISON PLEX RP Negative control contains a non-infectious solution of buffers, preservatives, and stabilizers, with no target DNA or RNA. Table 1 lists the pathogens that are detected in the LIAISON PLEX RP Control Panel M518 when tested with the LIAISON PLEX RSP Flex Assay. The LIAISON PLEX RP Control Panel M518 does not contain the entire genome of the pathogens listed in Table 1.

PRECAUTIONS, WARNINGS and LIMITATIONS:

- Do not dilute. Use 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.
- This product is for use solely with LIAISON PLEX RSP Flex Assay on the LIAISON PLEX system. It does not contain the entire genome of the pathogens listed in Table 1.
- Quality control materials should be used in accordance with local, state, and federal regulations and accreditation requirements.
- 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.
- LIAISON PLEX RP Control Panel M518 cannot be cloned, sold or transferred without the explicit written consent of MMQCI.

STORAGE and STABILITY:

The LIAISON PLEX RP Control M518 will be shipped on dry ice or cold packs, depending on destination. Place at refrigerated temperature (2°C to 8°C) upon receipt. Unopened LIAISON PLEX RP Control Panel M518 is stable through the expiration date printed on the kit label when consistently stored refrigerated (2°C to 8°C). LIAISON PLEX RP Control Panel M518 kit components are for single use. Discard after use according to your local and federal regulations.

ORDERING INFORMATION:

LIAISON PLEX RP Control Panel M518

Part Number: M518

Kit Contains: 12 tubes x 300µL

4 each of Positive A, Positive B, and Negative

INSTRUCTIONS FOR USE:

Note: Before running a control, External Controls must be created in the software by following instructions in the LIAISON PLEX System User Manual.

- Allow the control to be tested to come to room temperature (18°C to 25°C), approximately 10-15 minutes when stored refrigerated, or approximately 30 minutes if frozen due to dry ice shipping.
- Use the control as provided. **DO NOT DILUTE.**
- Immediately before use, mix the control thoroughly by briefly vortexing for 5 to 10 seconds, or by flicking the tube and inverting 3 to 5 times, and then remove any droplets caught in the cap by tapping the tube gently on the bench, or by shaking the tube down firmly.
- Carefully following the LIAISON PLEX RSP Flex Assay Instructions for Use, use the disposable transfer pipette provided with the assay to pipette 300µL of the well-mixed control sample into the sample port of the assay cartridge.
- After the sample is loaded, close the sample port on the assay cartridge. Gently tap the cartridge on the bench to ensure the sample is in the bottom of the sample port.
- Run the control by selecting "CONTROL".
 - Type a descriptive Control ID.
 - Select the Control Type and scan the cartridge.
 - Select the appropriate External Control and click Confirm.
 - Load the cartridge when prompted.
 - Verify the Control ID and select RUN to start the run.
- Discard after use according to your local and federal regulations.

For complete test system instructions, refer to LIAISON PLEX RSP Flex Assay Instructions for Use and LIAISON PLEX System User Manual provided by Diasorin.

EXPECTED VALUES:

The External Control expected results when the controls are tested with the LIAISON PLEX RSP Flex Assay are listed in Table 1.

Table 1. Expected Results: LIAISON PLEX RP Control Panel M518

Test	Positive A Result	Positive B Result	Negative Result
Adenovirus (A/B/C/D/E/F)	√ Detected	√ Not Detected	√ Not Detected
<i>Bordetella parapertussis</i>	√ Detected	√ Not Detected	√ Not Detected
<i>Chlamydia pneumoniae</i>	√ Detected	√ Not Detected	√ Not Detected
Coronavirus † (HKU1/229E/NL63/OC43)	√ Detected	√ Detected	√ Not Detected
Influenza A (subtype H1)	√ Not Detected	√ Detected	√ Not Detected
Influenza A	√ Not Detected	√ Detected	√ Not Detected
Human Metapneumovirus	√ Detected	√ Not Detected	√ Not Detected
Parainfluenza 1	√ Detected	√ Not Detected	√ Not Detected
Parainfluenza 3	√ Detected	√ Not Detected	√ Not Detected
Respiratory Syncytial Virus (RSV A and RSV B)	√ Not Detected	√ Detected	√ Not Detected
<i>Bordetella holmesii</i>	√ Detected	√ Not Detected	√ Not Detected
<i>Bordetella pertussis</i>	√ Not detected	√ Detected	√ Not Detected
SARS-CoV-2	√ Detected	√ Not Detected	√ Not Detected
Enterovirus/Rhinovirus	√ Detected	√ Not Detected	√ Not Detected
Influenza A (subtype H3)	√ Not Detected	√ Detected	√ Not Detected
Influenza B	√ Not Detected	√ Detected	√ Not Detected
<i>Mycoplasma pneumoniae</i>	√ Not Detected	√ Detected	√ Not Detected
Parainfluenza 2	√ Not Detected	√ Detected	√ Not Detected
Parainfluenza 4	√ Detected	√ Not Detected	√ Not Detected

† Coronavirus 229E, NL63 and HKU1 are Detected for Positive A. Coronavirus OC43 is Detected for Positive B