Simplexa™ COVID-19 & Flu A/B Positive Control Pack
(English)

REF MOL4260
Rev. 01

For *in vitro* diagnostic use
Rx Only

INTENDED USE
The Simplexa™ COVID-19 & Flu A/B Positive Control Pack is intended to be used as a control with the Simplexa™ COVID-19 & Flu A/B Direct kit for use on the LIAISON® MDX instrument. This control is not intended for use with other assays or systems.

MATERIALS PROVIDED
Upon receipt, store at -10 to -30 ºC (do not use a frost-free freezer). Each vial contains sufficient material for one use. Use within 30 minutes of removing from the freezer.

PRODUCT DESCRIPTION

Component Name	REF	Description	Cap Color	Number of Vials	Reactions per Vial/Kit	Volume per Vial
Simplexa™ COVID-19 & Flu A/B Direct Positive Control	MOL4261	Inactivated SARS-CoV-2 virus, inactivated influenza A virus, inactivated influenza B virus	Red	10	1/10	50 µL

MATERIALS REQUIRED BUT NOT SUPPLIED
1. Simplexa™ COVID-19 & Flu A/B Direct kit (REF MOL4250)
2. LIAISON® MDX with LIAISON® MDX Studio Software version 1.1 or higher.
3. Direct Amplification Disc Kit (REF MOL1455).
    a. Direct Amplification Discs for use on the LIAISON® MDX.
4. 50 µL fixed volume pipette (VWR Signature™ Fixed Volume Ergonomic High-Performance Pipette Model VWR FE50 or equivalent).
5. Sterile, nuclease-free disposable pipette tips with filters.
6. Freezer (manual defrost) at -10 to -30 °C (for control pack frozen storage).
7. Disposable, powder-free gloves.

RECOMMENDED MATERIALS
1. Universal Transport Media (UTM) to be used as a No Template Control (NTC).

SHELF LIFE AND HANDLING
1. Store controls at -10 to -30 ºC (do not use a frost-free freezer).
2. Do not use control beyond the expiration date.
3. Allow controls to thaw at room temperature (approximate range 18 to 25 ºC) before use.
4. Do not refreeze.

WARNINGS AND PRECAUTIONS
1. Wear personal protective equipment, such as (but not limited to) gloves and lab coats when handling kit reagents. Wash hands thoroughly when finished performing the test.
2. Contamination of specimens or reagents can produce erroneous results. Use good laboratory practices and control workflow[1, 2].
3. Do not pipette by mouth.
4. Do not smoke, drink, eat, handle contact lenses or apply make-up in areas where kit reagents and/or specimens are being used.
5. Dispose of unused controls and human specimens according to local, state and federal regulations.
6. Viruses in the Simplexa™ COVID-19 & Flu A/B Positive Control Pack have been chemically inactivated, but should be considered potentially infectious and handled accordingly.
7. Avoid touching the underside of the foil that will be in contact with the wells and disc surface.
8. Do not attempt to remove adhesive foil cover from wedges that have been used or attempt to re-use Sample and Reaction ports that have been used in previous runs.
9. Discs may be reused until all eight (8) wedges have been used. Dispose of used discs without detaching foil cover in a biohazardous waste container.

10. After each use store Direct Amplification Disc flat with the numbered foil side up.
11. Store reagents away from light.
12. If kit packaging or contents appear to be broken or damaged, do not use it and contact DiaSorin Molecular. Contact information is on the last page of this document.

INSTRUCTIONS FOR USE

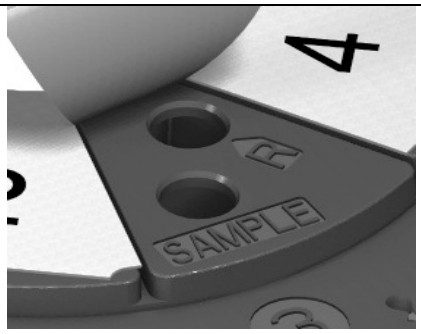
1. REAL-TIME PCR INSTRUMENT SETUP

1. Refer to the LIAISON® MDX Operator Manual for details on how to configure LIAISON® MDX Studio Software to add an assay definition, set up and analyze runs on the LIAISON® MDX.

2. **DIRECT AMPLIFICATION DISC LOADING AND REAL-TIME PCR AMPLIFICATION**

NOTE: No control extraction is needed prior to PCR amplification step.

1. Select controls that need to be tested.
2. Thaw the Positive Control and Reaction Mix vials at room temperature (approximate range 18 to 25 °C). Thaw one Reaction Mix vial for each sample or control to be tested.
3. Scan the barcode on the Simplexa™ COVID-19 & Flu A/B Direct Reaction Mix vial or barcode card**.**
4. Scan the disc barcode from the Direct Amplification Disc (DAD).
5. Scan or type in each control identifier.
6. For one wedge at a time, peel the adhesive foil back to expose the Reaction (R) and Sample (SAMPLE) wells without completely removing the adhesive foil cover (Figure 1 & 2). Avoid touching the under-side of the foil that will be in contact with the wells and disc surface.
7. Ensure that the reaction mix is completely thawed. Briefly spin down the tubes as needed.
8. Use the fixed volume pipette to transfer 50 µL of the reaction-mix into Reaction well (R).
9. Use the fixed volume pipette to transfer 50 µL of the control into Sample well (SAMPLE).
10. Cover and seal the wells with the peeled adhesive foil, pressing down firmly near the edge of the disc. If the original foil is torn do not load the wells in the wedge. Instead load another wedge.
11. Carefully remove the tab portion of the cover at the perforation.
12. Repeat steps 6 to 11 for the next control(s).
13. Load the sealed Direct Amplification Disc into the LIAISON® MDX and start the run.

Figure 1 - Disc with pre-use foil lifted from Reaction [R] and Sample [SAMPLE] Wells for wedge #3	**Figure 2 –Reaction [R] and Sample [SAMPLE] Wells**
	

NOTES (*for informational purposes - no user action/interpretation required):*

DiaSorin Molecular Kits may contain version numbers for Assay Definitions. If the version number exists, it will be appended to the Assay Definition i.e. ‘Sample IVD Assay.2”. When multiple versions exist, the software automatically uses the assay definition associated with the scanned lot number.

QUALITY CONTROL

Quality control ranges have been established as indicated in the table below. If the controls are not within these parameters, results should be considered invalid and the assay repeated. The Simplexa™ COVID-19 & Flu A/B Positive Control Pack may be used as an external control for QC testing, training or proficiency testing. Each laboratory should establish its own QC ranges and frequency of QC testing based on applicable local laws, regulations and standard good laboratory practice.

Expected Control Results

Control Type	COVID-19	Flu A	Flu B	RNA Internal Control (RNA IC)
Simplexa™ COVID-19 & Flu A/B Direct Positive Control [1]	Detected	Detected	Detected	Not applicable[2]
No Template Control (NTC)	Not Detected	Not Detected	Not Detected	Valid

[1] Typical Ct values for the Positive Control range between 24-30.
[2] Detection of the Simplexa™ RNA Internal Control (RNA IC) is not required for a valid result.

LIMITATIONS

1. For use under an Interim Order Authorization Approval 333538 Only
2. For *in vitro* diagnostic use.
3. For professional and prescription use only.
4. This control is not intended for use with donor screening tests.
5. This control has been studied using the Simplexa™ COVID-19 & Flu A/B Direct assay; it is not intended for use with other methodologies.

REFERENCES

1. US Department of Health and Human Services PHS/CDC/NIH. Biosafety in microbiology and biomedical laboratories, Washington DC: US Government Printing Office, 2009.
2. CLSI: MM3-A2 Molecular diagnostic methods for infectious disease; approved guideline, 3rd ed. Wayne, PA: Clinical Laboratory Standards Institute, 2015.

GLOSSARY

	Caution, consult accompanying documents*		Telephone
	Consult instructions for use*		Fax
	Keep away from sunlight	IVD	*In vitro* diagnostic medical device*
	Contains sufficient for <n> tests*	CONT	Kit contents
	Temperature limitation*	REF	Catalog number*
	Manufacturer*	REV	Revision
	Use by*	LOT	Batch code*
	Do not reuse*	CONTROL +	Positive Control*

* ISO 15223-1

The symbols glossary is provided electronically at www.DiaSorin.com

Visit our website at www.DiaSorin.com

DiaSorin Molecular LLC
11331 Valley View Street
Cypress, California 90630
U.S.A.