



Date: February 7, 2024

Product: REDx™ FLOQ® SARS-CoV-2 CONTROL PANEL (Ref. #: RED-S-19/99-P-01)
(Alternate External Control Swabs for the Metrix® COVID-19 Test)

Subject: Location of lot numbers for the REDx™ FLOQ® SARS-CoV-2 CONTROL PANEL

Dear Valued Customer,

The REDx™ FLOQ® SARS-CoV-2 CONTROL PANEL contains one SARS-CoV-2 Swab Positive Control and one SARS-CoV-2 Swab Negative Control, and may be used as alternate External Quality Control samples with the Metrix® COVID-19 Test.

The label on the CONTROL PANEL box displays a lot number for each of the swabs contained in the panel, as shown in the sample below:

Sample:	REF	RED-S-19/99-P-01		
	LOT	12A34567B8 (1xRED-S-19-01)	⌚	20241128
		90X12345Y6 (1xRED-S-99-M4)		20241130

Identified Issue:

Due to an internal system limitation, we are currently unable to display both lot numbers on the Packing List associated with each order. One lot number and the corresponding expiration date will appear on the Packing List, as shown in the example below:

PART NUMBER	DESCRIPTION	ORDERED QTY	UM	SHIP DATE	QUANTITY	HANDLING STATUS
RED-S-19/99-P-01	REDx™ FLOQ® SARS-CoV-2 CONTROL PANEL Lot: 12A34567B8 Expiry: 20241128 Qty: 1	1	EA	mm/dd/yyyy	1	Activated

Occurrence:

This is a temporary measure, as we work to implement a mechanism allowing both lot numbers to appear as expected.

Impact / Actions:

There is no impact to the product, product performance, or traceability at SEKISUI Diagnostics. Please refer to the Control Panel box label for complete lot numbers and expiration dates.

Please do not hesitate to contact Sekisui Diagnostics Technical Support with any questions regarding this notification at 888-341-7206, or via email at techservices@sekisuidiagnostics.com.