



IMPORTANT: CUSTOMER CORRECTION NOTICE
Simplexa™ Flu A/B & RSV Direct
Integrated Cyclor

May 6, 2016

Dear Customer/Distributor,

The purpose of this letter is to advise you that Focus Diagnostics is providing a customer correction notice for the Simplexa Flu A/B & RSV Direct kit (MOL2650) and Integrated Cyclor (IC).

ISSUE:

Focus Diagnostics has received customer complaints of obtaining false Flu B positive results using the MOL2650 kits attributed to spectral bleed-through between channels; however the occurrence of the spectral bleed-through is remote.

The Simplexa Flu A/B & RSV Direct assay is designed to utilize the FAM channel for detection of Flu A and the JOE channel for detection of Flu B. The FAM and JOE fluorescent dye emission spectra are adjacent to one another, and due to the proximity of the emission spectra peaks, spectral bleed-through or “crosstalk” between channels used for detection can occur if instruments are not properly calibrated. In the case of the Simplexa Flu A/B & RSV Direct assay, there is a potential to obtain a false positive Flu B signal in the presence of a strong Flu A (FAM signal) due to spectral bleed-through if instruments are not properly calibrated. Our most current version of the Integrated Cyclor Studio Software (Version 6.0) states that calibration should be performed annually on page C-2. However, based on studies conducted at Focus, we have determined that performing a spectral calibration of the IC every 6 months using the Spectral Calibration Kit (SC1100) will resolve the spectral bleed-through issue.

RECOMMENDATION:

Focus now requires spectral calibration of the IC every 6 months using the SC1100.

Please verify the last time you performed spectral calibration of your IC. If your records indicate that calibration was last conducted 6 or more months ago, please calibrate your IC. If your records indicate that a spectral calibration was performed within the last 6 months, no action is required at this time. Please determine when your IC is due for a spectral calibration and contact Technical Services at Technicalinfo@focusdx.com or call 800-838-4548 to order the SC1100 kit, if you do not have this kit on hand. Orders for the SC1100 will be processed as existing inventory allows. All orders will be processed prior to June 30, 2016.

For Customers running Integrated Cyclor Studio software version 6.0:
Please refer to Attachment 1 for the instructions on how to replace the Integrated Cyclor Operator Manual located on the computer with the revised Integrated Cyclor Operator Manual indicating the 6 month required calibration.

For Customers running Integrated Cyclor Studio software earlier than version 6.0:
Please refer to Attachment 2 for the instructions on how to include this notification with your Integrated Cyclor Operator Manual located on the computer.

If you are not currently using version 6.0, we highly recommend you have your system upgraded. This version contains important updates and features not available in earlier software versions.

Please refer to Attachment 3, SC1100 package insert for spectral calibration instructions. We ask that you conduct a spectral calibration if you have exceeded 6 months since your last spectral calibration.

As noted in the MOL2650 package insert (Section: Limitations), results must be considered in conjunction with the clinical history, epidemiological data, and other data available to the clinician evaluating the patient.

RISK – Potential for false Flu B positive result (in conjunction with a Flu A positive result)

A false positive Flu B result when Flu A has been detected (dual positive) is little risk in most patients, as treatment is usually supportive and is based on symptoms, not lab findings; however, if the false positive Flu B was seen in isolation, it may lead to unnecessary administration of antiviral medications in some cases. In this case, false positive Flu B would be in conjunction with a true positive Flu A, which may be appropriately treated with antivirals, so there would be no additional risk to the patient.

Diagnosis should be made in light of the entire clinical picture, including retesting, if at high risk.

ACTIONS BY THE CUSTOMER/DISTRIBUTOR:

- Verify the last time your instrument was calibrated with SC1100. If it was more than 6 months ago, use the Spectral Calibration kit SC1100 to calibrate the IC.
- Upload the Integrated Cyclor Operator Manual if using Studio software version 6.0 or this notification letter if using any prior versions of the Studio.
- If upon calibration the problem is unresolved, please contact Focus Technical Services department.
- Based on the physician's assessment of the patient, if questions still arise, additional testing may be necessary.
- Acknowledge that you have received this notification by signing the enclosed acknowledgement form and email the form to Technicalinfo@focusdx.com or fax back to Focus Diagnostics Technical Services at 562-240-6526 within 10 business days.

Distributors only: As part of our Quality System we may audit your facility to ensure activities assigned to your facility are properly conducted. If selected, we will contact you prior to scheduling the audit.

Any ICS shipped on or after May 6, 2016 will include the revised ICS Operators Manual.

Please accept our apologies for any inconvenience this may have caused. If you have any questions or require additional information, please contact our Technical Services department at 800-838-4548, select option 3, between the hours of 7am to 5pm (PST) or send an email to Technicalinfo@focusdx.com. Adverse reactions or quality problems experienced with the use of this product may be reported to FDA or appropriate International Ministry of Health:

- <https://www.accessdata.fda.gov/scripts/medwatch/index.cfm?action=reporting.home>, or
- Call FDA 1-800-FDA-1088

Sincerely,



Valerie Cimmarusti
Vice President, Quality, Regulatory and Clinical Affairs

Attachments: Acknowledgement Form
Attachment 1: Instructions to replace Integrated Cyclor Operator Manual
Attachment 2: Instructions to add Notification letter
Attachment 3: SC1100 package insert for calibration instructions
IC Operator Manuals and Notification letter are accessible at the following links:
<http://www.focusdx.com/USCustomersVersion6.0/InVitroDiagnostics.pdf>
<http://www.focusdx.com/USCustomersVersion6.0/UserDefined.pdf>
<http://www.focusdx.com/NONUSCustomersVersion6.0/InVitroDiagnosticsQQD.pdf>
<http://www.focusdx.com/NONUSCustomersVersion6.0/UserDefinedOUS.pdf>
<http://www.focusdx.com/notification/CustomerCorrectionNoticeMay2016.pdf>