IMPORTANT: CUSTOMER CORRECTION NOTIFICATION

Simplexa™ CMV
Simplexa™ CMV Quantitation Standards

February 17, 2016

Dear Customer/Distributor,

The purpose of this letter is to advise you that Focus Diagnostics is providing a customer correction notification for use of the Simplexa™ CMV (MOL2200) and Simplexa™ CMV Quantitation Standards (MOL2210).

ISSUE:
Instrumentation used to quantitate kit controls and calibrators for the Simplexa™ CMV and Simplexa™ CMV Quantitation Standards is no longer functional. Focus Diagnostics qualified new instrumentation and re-established calibration curves in alignment to the 1st WHO International Standard for human cytomegalovirus (HCMV). New controls and calibrators have been manufactured and quantitated with the newly established calibration standard curves. Simplexa™ CMV lot 29529 and Simplexa™ CMV Quantitation Standards lot 30138 were manufactured with the new instrumentation and produced ***expected values*** (within a 0.6 $\log_{10}$ IU/mL range) for the 1st WHO International Standard for HCMV; however the following issues were identified:

- Simplexa™ CMV lot 29529 used with calibration curves generated from new lots of Simplexa™ CMV Quantitation Standards have been shown to produce values approximately 0.2 to 0.5 $\log_{10}$ IU/mL higher than previous lots.
- Simplexa™ CMV lot 29529 used with calibration curves generated from previous lots of Simplexa™ CMV Quantitation Standards may produce Low Positive Control (LPC) and High Positive Control (HPC) values outside of expected ranges, resulting in invalid runs.

RECOMMENDATION:

For use of Simplexa™ CMV lot 29529 and future lots, it is recommended to run new calibration curves using Simplexa™ CMV Quantitation Standards lot 30138 (or later lots).

If using results for the monitoring of pre-emptive therapy to determine initiation, take into consideration that the new lots may produce values from 0.2 to 0.5 $\log_{10}$ IU/mL higher compared to historical values.

If using results for the continued monitoring of patients, repeated monitoring testing using the same new calibration curve provides a better assessment of the trends in viral loads.

RISK – Use of Simplexa™ CMV lot 29529 with new calibration curves

Simplexa™ CMV lot 29529 used with new calibration curves may produce values 0.2 to 0.5 $\log_{10}$ IU/mL higher than previous lots. The risks associated with elevated values may:

- Support the inappropriate assessment that the patient is not responding to antiviral therapy.
- Inappropriately support reduction of immunosuppression in certain patient populations.
- Inappropriately support use or continuation of, or increase in dosing of antiviral therapy in certain patient populations.
- Result in change of antiviral medication if lack of decrease in viral load suggests viral resistance.
- Inappropriately support use or continuation of immune globulin in certain patient populations.
- Initiate or re-initiate potentially toxic antiviral therapy in patient without active infection.

ACTIONS BY THE CUSTOMER/DISTRIBUTOR:

- Before using Simplexa™ CMV lot 29529, run a new calibration curve with Simplexa™ CMV Quantitation Standards lot 30138 (or later).
- If establishing a new calibration curve with CMV Quantitation Standards lot 30138 (or later), use CMV lot 29529.
- 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.

See attached CMV labels and product information for ease in identifying the product. Please refer to the lot number adjacent to the lot symbol **LOT**.

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 the appropriate International Ministry of Health:

Sincerely,

Valerie Cimmarusti
Vice President, Quality, Regulatory and Clinical Affairs

Attachments: Acknowledgement Form
Simplexa™ CMV Kit Label
Simplexa™ CMV Quantitation Standards Label

CORRECTION RETURN RESPONSE
Acknowledgement and Receipt Form - Response required

Simplexa™ CMV
Simplexa™ CMV Quantitation Standards

I have read and understand the correction instructions dated February 17, 2016 Yes □ No □

Were there any adverse events associated with the product? Yes □ No □

If yes, please explain:

_____

_____

ACKNOWLEDGEMENT:

Signature of Recipient: _____ Date: _____

Name:	
Title	
Telephone	
Email address	

Please email the form to Technicalinfo@focusdx.com or fax back to Focus Diagnostics Technical Services at 562-240-6526 within 10 business days.