IMPORTANT: CORRECTION NOTICE

Direct Amplification Discs included with kits:
Simplexa™ HSV 1 & 2 Direct
Simplexa™ Flu A/B & RSV Direct
Simplexa™ Group A Strep Direct

August 21, 2015

Dear Customer/Distributor,

The purpose of this letter is to advise you that Focus Diagnostics is providing a correction notice for the Direct Amplification Discs supplied with the Simplexa HSV 1 & 2 Direct (MOL2150), Simplexa Flu A/B & RSV Direct (MOL2650) and Simplexa Group A Strep Direct kits (MOL2850).

ISSUE:
Focus Diagnostics has received some customer complaints of MOL2150, MOL2650 and MOL2850 kits with insufficient specimen volume errors in the sample wells of the Direct Amplification Discs (MOL1455, MOL1452, MOL1451) while performing the MOL2150, MOL2650, and MOL2850 testing. This error may result in higher invalid rates (Report Note Statement: "Insufficient Specimen Volume").

Focus has determined that potential insufficient specimen volume errors are lot specific and may be variable across the affected kits. The frequency of complaints for this issue is remote (0.24%). To date, we have received a total of 29 customer complaints including 85 disc issues out of a total of 34,809 distributed discs (4,587 discs with MOL2150 kits, 28,605 discs with MOL2650 kits, 105 discs with MOL2850 kits, 264 discs with MOL1455 and 1,248 discs with MOL1451). If you have kits that are not identified in this correction notice please continue to use as instructed in the labeling.

RECOMMENDATION:
Focus Diagnostics is not requesting removal of the kits or Direct Amplification Discs from the test facility. If an insufficient specimen volume error is obtained with any of the identified MOL1455, MOL1452, MOL1451 kits, Focus Diagnostics requests the customer to repeat any invalid results following the instructions stated in the package inserts for re-testing INVALID RESULTS. If upon re-test and the problem is unresolved or you experience an increase in invalid results, please contact our Technical Services department.

We are currently investigating this issue with our supplier (3M) and will provide further recommendations, if required.

MOL1455 is supplied with each MOL2150, MOL2650 and MOL2850 kit. Three discs of MOL1452 are packed in a box and labeled as MOL1455. Additionally, a box of 24 discs of MOL1452 is labeled as MOL1451. Affected disc numbers include manufacturing kits 1698910 through 2039469 with a manufacturing date of March 28, 2014 with a distribution date starting Dec 9, 2014, through mid-September 2015. Please evaluate your inventory to verify if you have an impacted DAD disc lot and re-test any invalid results as described above.

RISK– Potential for delayed result:

Simplexa HSV 1 & 2 Direct (MOL2150)
In spite of a delayed result, treatment for presumed HSV encephalitis should continue until a valid result is received. This could lead to a possible delay in alternative diagnosis.

In pregnant patients, if results are delayed substantially, the risk is a possible delay in therapy if the result is positive, and if the patient is not being treated empirically.

In routine genital HSV screening, a delayed result may lead to a delay in diagnosis, treatment and counseling. This may increase patient anxiety. If genital HSV is not diagnosed in timely fashion, the public health risk is of possible ongoing transmission to other partners.

Simplexa Flu A/B & RSV Direct (MOL2650)
An invalid or delayed result has little risk as illness is typically self-limited and treatment is essentially supportive. If a result were delayed, this may lead to delay of treatment but the health impact is typically not substantial.

Antiviral therapy can reduce complications and mortality in severe cases. Therefore, a delayed result may hinder timely administration of these medications, however, in critically ill patients antivirals will be empirically given to the patient, regardless of delay of testing results.

Simplexa Group A Strep Direct (MOL2850)
An invalid or delayed result has little risk as illness is typically self-limited, fever resolves in 3 to 5 days, and other signs and symptoms resolve within one week. If the delay is longer than nine days, and if GAS pharyngitis was not presumptively treated with antibiotics, there may be an increased risk of acute rheumatic fever, especially in developing countries.

Results from these kits must be considered in conjunction with the clinical history, epidemiological data and other laboratory information available to the clinician evaluating the patient.

ACTIONS BY THE CUSTOMER/DISTRIBUTOR:

- Check to see if you have any of the identified MOL1455, MOL1452 and MOL1451 kits.
- If upon re-test and the problem is unresolved or you experience an increase in invalid results, please contact Focus Technical Services department.
- Acknowledge that you have received this notification by signing the enclosed acknowledgement form and email the form to DxTS@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 Direct Amplification Disk 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 DxTS@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: Direct Amplification Disc Labels
Acknowledgement Form
Simplexa HSV 1 & 2 Direct Package Insert (PI.MOL2150 Rev. D)
Simplexa Flu A/B & RSV Direct Package Insert (PI.MOL2650 Rev. E)
Simplexa Group A Strep Direct Package Insert (PI.MOL2850 Rev. C)