IMPORTANT: CUSTOMER NOTIFICATION - Update

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

March 18, 2016

Dear Customer/Distributor,

The purpose of this letter is to provide an update to the Customer Correction Notice dated February 10, 2016. Focus Diagnostics and 3M (manufacturer of the Direct Amplification Discs [DAD]) identified the root cause for the early Ct threshold and Insufficient Specimen Volume Error to be related to a 3M manufacturing process. An adjustment was made to the equipment and Focus and 3M conducted several studies to ensure that the corrective actions taken to address the issues were effective.

Based on the data generated, we are confident that the changes we implemented to the corrected DAD will allow you to reuse the DAD as it was originally intended with our Simplexa HSV 1 & 2 Direct (MOL2150), Simplexa Flu A/B & RSV Direct (MOL2650), and Simplexa Group A Strep Direct (MOL2850) assays.

As a reminder, any DAD supplied to your facility previously identified in Amendment 3 dated February 26, 2016 is only intended for single use. Reusing any of these impacted DAD may continue to provide invalid and false results.

The DAD lots that have the implemented corrective action and can be <u>reused</u> are provided in the list below. We expect to ship these identified DAD lots beginning with orders shipped on and after Friday, March 18, 2016.

Corrected DAD **3M Manufacturing Lot # (Pouch and White Box of 24 DAD)**	Corrected DAD **Focus Lot #MOL 1455 Box of 3 DAD (3 MOL1452)**	Corrected DAD **Focus Lot # (green sticker on shipping box) MOL 1451 Box of 24 DAD (24 MOL1452)**
2315090	30781	160475
2315092	30782	160497
2319288	30875	160524
2320464	30876	160525

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 Focus, the 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