



Notice to Customers - July 3, 2018

Product Impacted: 400-002-C-MAX - Bordetella Speciation Plus Toxin - OSR for BD MAX™

Effective: Immediately for shipments prior to July 03, 2018

Summary:

- Discontinue use of UDP version: Bord 400-002-C-MAX_v1.osrxml UDP
- Replace with UDP version: Bord 400-002-C-MAX_v2.osrxml on all instruments.
- Review patient results for any runs using the Bord 400-002-C-MAX_v1.osrxml UDP to ensure that patient reporting was not impacted.

Issue: Result logic within the electronic user defined protocol (eUDP) for Bordetella Speciation Plus Toxin panel was incorrectly applied to the targets **IS481** and **hIS1001** resulting in potential false logic reporting of these targets. Reporting of pIS1001 and ptxS1 is correct. It should be noted that the incorrect result logic settings for IS481 and hIS1001 do not impact the PCR amplification curves.

Table 1. Result Logic Correction for UDP v1

Target and SPC amplification for impacted results	Reported Result with UDP v1	Correct Result
IS481 +, SPC -	IS481 negative	IS481 positive
IS481 -, SPC +	IS481 positive	IS481 negative
hIS1001 +, SPC -	hIS1001 negative	hIS1001 positive
hIS1001 -, SPC +	hIS1001 positive	hIS1001 negative

- + symbol denotes amplification curve crossing threshold
- symbol denotes no amplification curve crossing threshold

Recommendation: Immediately update any instruments with the version 1 eUDP (Bord-002-C-MAX_v1.osrxml) to the provided version 2 of the eUDP (Bord 400-002-C-MAX_v2.osrxml). Review run reports where patient reporting may have been impacted in order to determine if result correction is necessary.

If you have further questions please contact technical support at eu@biogx.com

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