



July XX, 2020

**URGENT: FIELD SAFETY NOTICE – IDS-20-3850**

**BD MAX™ SARS-CoV-2 Reagents**

**REFs: 445003 and 445003-01 (All LOT Numbers)**

**Type of Action: Advisory**

**Attention: Clinical Personnel, Risk Managers, Biomedical Personnel**

This letter contains important information which requires your **immediate** attention.

Dear valued Customer,

BD is issuing an advisory Field Safety Notice for the BD MAX™ SARS-CoV-2 Reagents (REFs: 445003 and 445003-01) to inform users of an update to the product Instructions for Use (IFU) following reports of false positive results. According to our distribution records your organisation may have received the impacted product.

**Description of the Problem**

Through customer feedback, BD has identified a potential for false positive results when using the BD SARS-CoV-2 Reagents for the BD MAX™ System. As a result, BD is instructing users, through this Field Safety Notice, that the User Defined Protocol (UDP) threshold for the N2 target in the IFU needs to be revised from 50 RFU to 80 RFU (per Figure 1 below).

The revised translated IFU will be made available for users to download from [www.BD.com/e-labeling](http://www.BD.com/e-labeling) by July 24<sup>th</sup>, 2020 (English is available now), which will include the specific update to the User Defined Protocol (UDP) threshold for the N2 target from 50 RFU to 80 RFU (per Figure 1).

A false positive SARS-CoV-2 test result could lead to a delay in diagnosis and potentially cause the patient to be exposed to COVID-19 if they are isolated with an infected individual.

Per the current product IFU, *“Positive results are indicative of the presence of SARS-CoV-2 RNA; clinical correlation with patient history and other diagnostic information is necessary to determine patient infection status. Positive results do not rule out bacterial infection or co-infection with other viruses. The agent detected may not be the definite cause of disease.”*

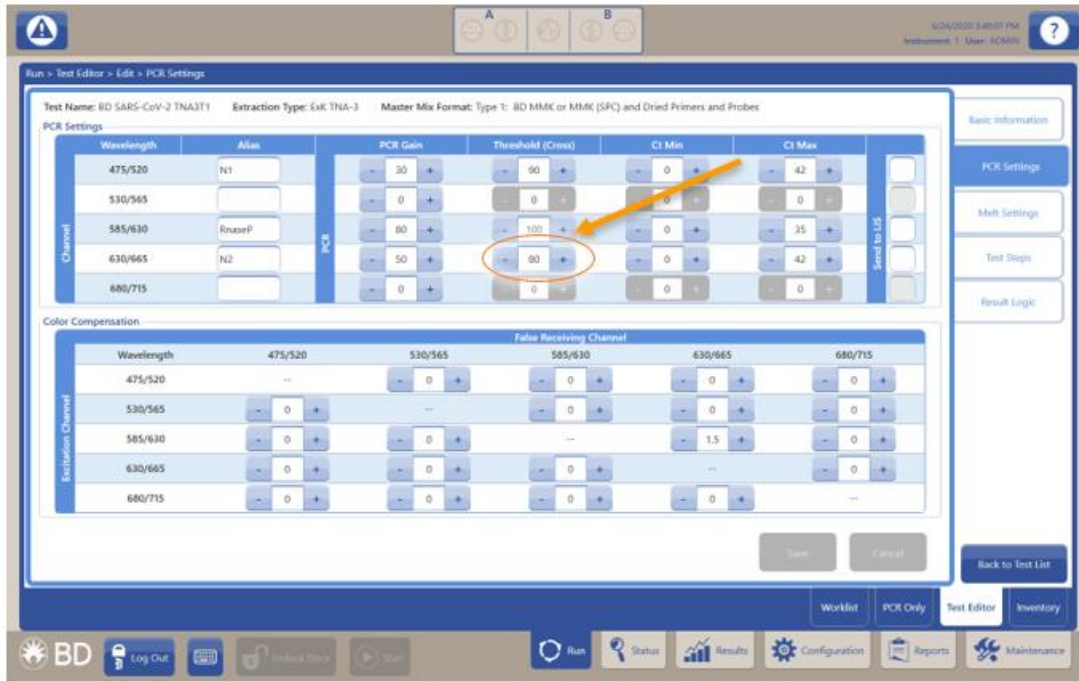


Figure 1: Screenshot of updated UDP PCR Settings.

**Actions for Customers to take:**

1. Circulate this Field Safety Notice to all those within your organisation that may use the BD MAX™ SARS-CoV-2 Reagents (REFs: 445003 and 445003-01).
2. If you have further distributed the product, please identify those organizations and notify them at once of this advisory Field Safety Notice.
3. Complete the customer response form on page 3 and return it to <<insert contact details here>> as soon as possible or no later than July XX, 2020.

**Contact Reference Person**

If you have any questions about this issue, please contact your local BD representative or the local BD office on <<insert telephone/email here>>.

We confirm that the appropriate regulatory agencies have been informed of these actions. BD is committed to advancing the world of health. Our primary objectives are patient safety and user safety and providing you with quality products. We apologise for the inconvenience this situation may cause you and thank you in advance for helping BD to resolve this matter as quickly and effectively as possible.

Sincerely,

xxx  
 EMEA Quality Compliance, BD Switzerland Sàrl



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## Customer Response Form - IDS-20-3850

### BD MAX™ SARS-CoV-2 Reagents

REFs: 445003 and 445003-01 (All LOT Numbers)

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Please read in conjunction with Field Safety Notice IDS-20-3850 and return the completed and signed form as soon as possible or **no later than the July XX, 2020** to <<insert fax/email address here>>.

**By signing below, you confirm this notice has been read, understood and that all recommended actions have been implemented as required.**

<b>Account/Organisation Name:</b>	
<b>Department (if applicable):</b>	
<b>Address:</b>	
<b>Postcode:</b>	<b>City:</b>
<b>Contact Name:</b>	
<b>Job Title:</b>	
<b>Contact Telephone Number:</b>	<b>Contact E-mail Address:</b>
<b>Signature:</b>	<b>Date:</b>

*This form must be returned to BD before this action can be considered closed for your account.*