

21.10.2016

Product Quality Notification 2016-02 UPDATE**PRODUCT DETAILS:**

Product Name	Catalog No	Test code (for instrument)
ID Anti-N	007111	PR44N
ID Anti-M/N	006011	MO45D

Dear valued customers,

We would like to share with you an update about this issue described in the **Product Quality Notification 2016-02** sent out on March 23, 2016

Since, in-depth investigations have been carried out in order to find out the root cause of this interference and to set the respective corrective / preventive actions.

Based on the investigation results, our manufacturing dept. has started producing the following new lots that have undergone additional production steps:

Product Name	Catalog No	Lot No
ID Anti-N	007111	From lot 50221.78.01 onwards
ID Anti-M/N	006011	From lot 51210.57.01 onwards

Extensive testing conducted on these new lots allow us to state that this interference is no longer detectable in manual testing or on our instruments except on the IH-500.

Therefore, it is no longer necessary to follow the instructions provided in the PQN 2016-02 except for the IH-500 where the recommendations must still be applied.

As the phenomenon appears occasionally (except on IH-500) and as there is no patient risk, customers should nonetheless finish their existing stock before re-ordering.

We are continuing with the investigations and we will keep you informed as soon as this issue is fully resolved.

Please inform your customers about this update.

For any further information, please refer to the **Product Quality Notification 2016-02**

We sincerely apologize for the inconvenience that this situation may cause and we remain at your disposal should you need any additional information

With best regards,

Bio-Rad

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