

30.11.2016.

Product Quality Notification 2016-06

PRODUCT DETAILS:

Product Name	Catalog No	Lot No	Expiry date
ID-DC Screening II	004831	50560.79.04	30.09.2017

Dear valued customers,

It has come to our notice that the box insert of the above-mentioned lot may not be the one corresponding to the product. Investigations are still ongoing to determine the reason for this; however, the current status of the investigation demonstrated that the cards are indeed ID-DC Screening II cards. There is no patient risk associated with this issue.

IMPLEMENTATION INSTRUCTIONS:

The cards of the above mentioned lot can be used but the box inserts must be thrown away. The correct box insert accompanies this notification, but can also be downloaded from the website.(http://www.diamed.com/BoxInserts.aspx?NavId=48)

If you have any additional questions on this matter, we kindly ask you to get in touch with our Complaint Handling department (email address: slabor_cressier@bio-rad.com) quoting this PQN reference.

With best regards,

Bio-Rad

Emilie Machold QA Customer Complaint officer Immunohematology Division

30 Jul 2016

Florian Lambercier
Division Product Support Manager
Immunohematology Division

30.11.2016