

FIELD ACTION INFORMATION – 26.07.2017

Indicate Field Action Type: PQA update II
Field Action Reference Number: 2016-02
Bio-Rad Division: Immunohematology

PRODUCT DETAILS:

Product Name	Mat. n°	Test code for instrument	Lot No IHD	Lot No SAP	Expiry Date
ID Anti-N	007111	PR44N	Currently in date until further notice		
ID Anti-M/N	006011	MO45D			

DESCRIPTION OF THE ISSUE:

We would like to share with you an update about this issue described in the **Product Quality Notification 2016-02** sent out on 21st of October 2016.

Issue description:

Following some customer feedbacks, we have been able to confirm that in specific conditions the anti-N (MNS2) of the above-mentioned lots of cards ID Anti-N (ref. 007111) and ID Anti-M/N (ref. 006011) may give an unexpected interference with N negative samples as described in IFU under the introduction chapter, paragraph 2.

This interference cannot be confused with a true positive reaction of the type expected with this reagent whereas they may be interpreted by our instruments as a positive result.

Current status:

Now the investigations regarding unexpected reactions are now completed. A limitation for the use of the above mentioned products will be inserted in the IFU under the chapter Limitations. The sentence is the following: "by testing under working conditions below 23°C, this may cause false positive reaction* with Anti-N". We cannot give you an exact timeline for the implementation of the new version of IFU, because it is dependent on the change notification approvals in some countries (rest of the world, Europe is not concerned).

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

*see related IFU, introduction chapter, paragraph 2.

IMPLEMENTATION INSTRUCTIONS:

We kindly ask you to carry out the following actions when you are working with these ID-cards on instruments:

If using the automatic validation function on the instruments, we recommend that it should be disabled specifically when you want to carry out these 2 tests (MO45D and PR44N) on the instrument as this interference may be interpreted as positive by the system. This implies that these tests should be carried out in a separate run as it is not possible to disable the automatic validation just for these two test codes.

Specific Conditions and Recommendations

Testing method	Specific conditions	Recommendations
IH-1000 Techno Twin Station ID GelStation	The amount of interference will depend on the temperature of the room and the temperature within the instrument. Once the instrument reaches an internal temperature approaching 25°C, it can be expected that the majority of the interference will disappear	For results that are not clearly positive or negative, repeat testing. If results do not become clearly negative, repeat using an alternative method (see below)
IH-500	Due to the controlled temperature system within this instrument, increased levels of interference can be expected	For results that are not clearly positive or negative, repeat using an alternative method (see below)
Any combination of Swing, Saxo, Banjo and manual pipetting/reading	The amount of interference will depend on the temperature of the room. Once the room temperature approaches 25°C, it can be expected that the majority of the interference will disappear	For results that are not clearly positive or negative, repeat testing. If results do not become clearly negative, repeat using an alternative method (see below)

Alternative Method

As an alternative method, we can provide upon request kits of ID-Antigen Profile III:

- Cards: ref. 008701 for 1 x 12 cards (12 tests)
- Antisera: ID-M, N, S, s, Fya, Fyb in the following format
 - 6 x 1.4ml – ref. 008711 - not suitable for automation OR
 - 6 x 5ml - ref. 008712 - ideal for automation
- The respective test code for our instruments is the PR43

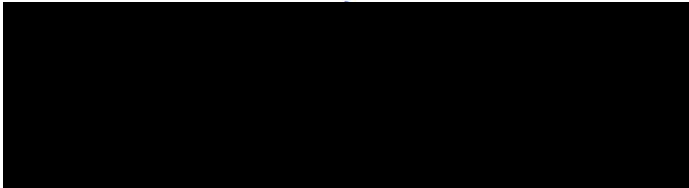
We have been able to demonstrate that the anti-N (MNS2) included in the ID-Antigen Profile III kit works as expected and does not show this interference.

DATE MANUFACTURER’S FINAL REPORT EXPECTED: As soon as the corrective action has been implemented.

Bio-Rad



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