

23.03.2016

Product Quality Notification 2016-02

PRODUCT DETAILS:

Product Name	Catalog No	Lot No	Test code (for instrument)
ID Anti-N	007111	From the lot 50221.73.01 and further*	PR44N
ID Anti-M/N	006011	From the lot 51210.52.01 and further*	MO45D

Dear valued customers,

Following some customer feedbacks, we have been able to confirm that in specific conditions described below (ref. to *Conditions required for getting this interference*), 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.

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

Hereunder, examples of interference (clear red) are compared with a true positive reaction and a standard negative result (clear blue):

Expected results		Unexpected interference		
Negative sample	Positive sample	Negative sample	Negative sample	Negative sample
Negative	+++ or ++++	?, wD, wR or +	+	++
Interpretation by the instruments				

* You will be notified once we will be able to provide products that do not show this phenomenon

Conditions required to see this interference

Our investigations have demonstrated that this phenomenon is temperature dependent, becoming stronger if the ambient temperature drops to the lower range of room temperature, 18-25°C and tending to disappear once the temperature reaches the upper limit of this range. Reagents and samples that are at the lower end of the room temperature range will also increase the interference.

In addition, it is important to note that some samples never show this phenomenon even in the worst conditions.

See also the table below, *Specific conditions and recommendations*

Patient risk

An in depth risk analysis has been conducted considering the different applications for these reagents and no unacceptable risk was identified. Indeed, either the result will be questioned at one point or the result will be without any clinical impact for the patient.

Results validation:

- We recommend you to **not** validate a positive result that gives a reaction strength lower than a 3 (ref. to images above). Negative results and positive results of 3+ to 4+ may be validated unconditionally.
- 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.

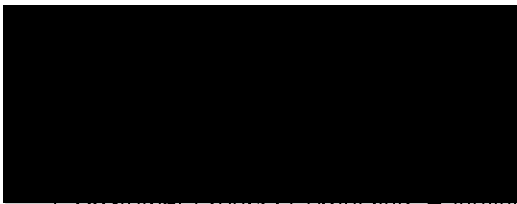
In case you require kits of ID-Antigen Profile III for this purpose, or additional kits of 007111 or 006011, or if you have any additional questions on this matter, we kindly ask you to get in touch with our Complaint Handling department (email address: slabor_cressier@bio-rad.com) quoting this PQN reference.

Please be aware that we are doing everything in our power to resolve this unsatisfactory situation as soon as possible, and you will be informed as soon as it is resolved.

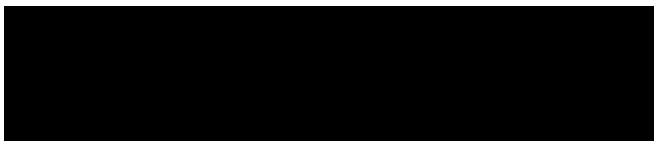
We sincerely apologize for the inconvenience that this situation may cause and we remain at your disposal should you need any additional information

With best regards,

Bio-Rad



Customer Product Complaints Handling Manager
Immunoematology Division



Regulatory Affairs Manager
Immunoematology Division

Jörg Scharrenberg
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