

PRODUCT QUALITY INFORMATION

This information is intended for the product end user. If you are not the end user, please forward this information to the appropriate laboratory person(s).

Ref. PQA 01-17 IDD

Platelia™ *Aspergillus* Ag assay-Ref. 62794/Evolis™ System-Ref.89601

OD R4(Cut-off Control Serum) validation criteria modification, using the assay with an automated method on Evolis™ System

Dear Valued Customer,

We would like to thank you for using Platelia™ *Aspergillus* Ag assay for years.

Some laboratories performing the assay using an automated method on Evolis™ System informed us recently that they were facing some issues when validating the OD R4(Cut-off Control Serum) criteria. For some runs, the OD R4 value being <0.600 , the current OD R4 validation criteria ($0.600 \leq OD R4 \leq 1.800$) were not met and the calculation of sample index was impossible:

- The OD R4 decrease was particularly visible between assay lots # 4E0027 and 4L0030.
- Run invalidations were observed only when performing the assay on Evolis™ System. No invalidation was observed on the same assay lots when using a manual procedure.

Taking your observations into consideration, we set up investigations to identify the source of the run invalidations:

- Since extensive internal studies demonstrated that no reagent of the Platelia™ *Aspergillus* Ag kit was responsible (following a deep analysis of the reagent raw materials, especially on the antibodies on the microplate and in the conjugate) and that the Evolis™ systems were meeting conformity standards (after a complete maintenance check-up procedure), we decided to set up modifications of OD R4 validation criteria for the use of the assay on Evolis™.
- To make sure that the criteria change would not lead to a decrease of the assay performance characteristics, numerous negative and positive serum samples were tested at Bio-Rad's R&D department, following an adequate experiment protocol. A deep analysis of the study results showed that implementing the new validation criteria, $0.300 \leq OD R4 \leq 1.200$, was not resulting in lowering the assay performances.

A "patch" (Evolis™ *Aspergillus* Patch CD Ref. 93486) containing the new Evolis™ APF will be used for implementing the new validation criteria in laboratories performing the assay on Evolis™ System. After contacting your Bio-Rad's Customer Technical Support, the new Evolis™ APF will be installed as soon as possible and at your convenience by remote control (equipped laboratories) or by a Bio-Rad FSE visiting your laboratory.

We apologize for the inconvenience caused by the run invalidations.

Best regards

PS: for a manual utilization of the assay, the validation criteria remain unchanged.

CUSTOMER FIELD ACTION RESPONSE FORM
Form to return to your local customer service

Field Action Type: PQA

Field Action Reference Number: 01-17

Bio-Rad Division: IDD

INVOLVED PRODUCT

Product Name : **Platelia™ Aspergillus Ag assay-Ref. 62794 / Evolis™ System-Ref.89601**

CUSTOMER INFORMATIONS

LABORATORY	
Undersigning Manager :	
Address :	
Telephone Number / Fax :	
Customer Account Number :	

ACTIONS :

- I have read information regarding the required implementation of new validation criteria for **Platelia™ Aspergillus Ag assay-Ref. 62794** on **Evolis™ System-Ref.89601** with new APF on Evolis™ Aspergillus Patch CD Ref. 93486.

Number of EVOLIS to update :

Date:

Laboratory Stamp and Signature

Please return this form to: [enter local details]

For any other further information or support, please contact your local customer service.

