



Infectious Disease Testing

PQA 04-17 IDD Salmonella antisera

Marnes La Coquette, September 25th, 2017

FIELD ACTION INFORMATION

Indicate Field Action Type: **PQA**
Field Action Reference Number: **PQA 04-17- IDD**
Bio-Rad Division: **Infectious Disease Division**

PRODUCT DETAILS:

Nom du produit	Antiserum Salmonella Monovalent H:z	Antiserum Salmonella Monovalent H:x	Antiserum Salmonella Polyvalent HMB (e,h+e,n,x+e,n,z 15+G)	Antiserum Salmonella Polyvalent HMC (k+y+z+L+Z4+r)
Code Produit	60221	61123	60461	60471
Numéro de Lot	5B2028, 6H2029	5M2033	5E2030, 6J2031	5F2030, 6E2031
Date d'expiration	28/02/2018 30/09/2019	15/12/2018	30/05/2018 15/09/2019	15/06/2018 15/06/2019

DESCRIPTION OF THE ISSUE :

- Anti-sera are used for serotyping which is a classical epidemiologic tool.
- We have observed that some cross agglutinations may happen between these antisera and Salmonella strains with an antigenic formula without the corresponding antigen H.
- The occurrence can be limited when customers follow the Kauffmann scheme, search for O antigen first and continue by testing with the H antisera corresponding to the most frequent serotypes. The agglutination time and the intensity may help to differentiate a true from a false positive agglutination.
- There is no risk for the patient health since the identification of Salmonella and antibiotic susceptibility testing will be performed before determining the serotype.

IMPLEMENTATION INSTRUCTIONS :

Inform customers with regular orders to make them aware about this risk (attached letters to translate at your convenience)



DATE MANUFACTURER'S FINAL REPORT EXPECTED :

This notification constitutes the final report. No further communication will be provided for this action.

ATTACHEMENTS :

- PQA 04-17- IDD memo
- Customer letters templates (EN –FR)
- Traceability to be consolidated by each region
- IFU available on website www.bio-rad.com