Bio-Rad Laboratories

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Ref. **PQA 04-17- IDD**

Marnes-la-Coquette, September 29th 2017

Objet : Salmonella Antiserum – Quality information

Dear Customer,

Alerted by the French Pasteur Institute – National Reference Center for Salmonella – we inform you about an anomaly on the following products:

Product Name	Antiserum Salmonella Monovalent **H:z**	Antiserum Salmonella Monovalent **H:x**	Antiserum Salmonella Polyvalent **HMB** **(e,h+e,n,x+e,n,z15+G)**	Antiserum Salmonella Polyvalent **HMC** **(k+y+z+L+Z4+r)**
Product Code	60221	61123	60461	60471
Lot Number	5B2028, 6H2029	5M2033	5E2030, 6J2031	5F2030, 6E2031
Expiration date	2018/02/28 2019/09/30	2018/12/15	2018/05/30 2019/09/15	2018/06/15/ 2019/06/15/

We observe a risk of nonspecific agglutination between 30 seconds and 1 minute when using the antisera mentioned above with Salmonella for which the antigenic formula does not include the corresponding flagellar H antigen. Performance degradation was verified on collection strains of known antigenic formula.

	Antiserum Salmonella Monovalent **H:z**	Antiserum Salmonella Monovalent **H:x**	Antiserum Salmonella Polyvalent **HMB** **(e,h+e,n,x+e,n,z15+G)**	Antiserum Salmonella Polyvalent **HMC** **(k+y+z+L+Z4+r)**
Possible cross reaction with Salmonella strains of antigenic formula content :	H : c H : z35	H : c H : e, n, z15	H : c	H : c H : z35

The initial investigations point to a defect in the manufacturing process (imperfect absorption).

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These Salmonella antisera are for the serological identification of Salmonella cultures by the slide agglutination method for epidemiological purposes and the identification of bacterial species must be carried out before the serotype is determined. Consequently, these possible cross-reactions should not affect the diagnosis and treatment of Salmonella infection but will potentially impact the final serotyping.

Therefore, we ask you to carefully analyze your results.

For further information, please contact your usual Bio-Rad representative.

We remind you that in case of sending strains for serotyping to the National Reference Center, you are asked to specify the reagents used in your possible determination of the serotype.

We thank you for your confidence and we apologize for any inconvenience caused by this situation.

Regards

Hélène ESVAN | Int. Product Support Manager
Infectious Disease Division