

## APPENDIX 6 CUSTOMER LETTER

For the attention of Laboratories Managers,  
For the attention of Healthcare Chairmen,  
For the attention of Local Reactovigilance Correspondent,

Address  
City, date

**IMPORTANT: LOT WITHDRAWAL**  
**TPHA 100 – REF. 72492**

**LOT 0908101600 EXPIRATION DATE 25/11/2010**  
**LOT 0910101894 EXPIRATION DATE 01/01/2011**

Dear Sir, dear Madam,

BioMérieux records indicate that you have received our TPHA 100 reagent (ref: 72492).

We would like to inform you that, further to the complaint of a French customer on the results obtained for an external quality control, our Quality Control Laboratory performed investigations which confirmed a problem of sensitivity with lots **0908101600** and **0910101894**. This phenomenon can be observed only on certain sera.

Investigations are in progress to define the root cause of this defect.

**The main risk is that certain sera of low titre could have given false negative results. However, as mentioned in the product instructions, the interpretation of the test has to be made by taking into account results of the other tests and clinical information relative to the patient. In these conditions, the risk to give a wrong diagnosis is limited.**

Consequently, we request you:

- To stop using TPHA 100 kits, reference 72492, lots **0908101600** and **0910101894** that you may still have in inventory.
- To destroy these kits and to return us the enclosed destruction certificate by fax XX XX XX XX.
- To retest with a new lot the samples found negative, if you only used the TPHA 100 test, reference 72492, lots **0908101600** and **0910101894**, to perform the serologic examination of the patients.

The French Competent Authority (AFPSSAPS) has been informed of this action.

Once the destruction certificate received, we will send you a new lot of TPHA 100.

Please find attached, a spreadsheet to help you in the follow-up of your potential retests. We ask you to sent back this document completed to our Customer Service.

We are aware of the inconvenience this situation may cause in the organisation of your laboratory. bioMérieux will take care of expenses bound to the carrying out of these new measurement series.

Should you need any additional information, please feel free to contact our Customer Relation Center.

☎ : xxxxxxxxxxxxxx

Yours sincerely,

Customer Service