SIEMENS

Urgent Field Corrective Action

BR-07317

September 2017

Enzygnost® HBsAg 6.0 -

Increased number of reactive results for plasma samples

Dear valued customer,

Our records indicate that your facility may have received the following product:

Table 1. Affected Product(s)

Assay	Catalog Number	Siemens Material Number (SMN)	Lot Number	Expiration Date	Manufacturing Date
Enzygnost HBsAg 6.0 Kit (10x96)	OPFM05	10446017	47023	2019-01-19	2017-04-03
			47119	2019-02-07	2017-05-11
			47352	2019-04-06	2017-07-10
Enzygnost HBsAg 6.0 Kit (2x96)	OPFM03	10446016	47118	2019-02-07	2017-06-13

Reason for Correction

Siemens Healthcare Diagnostics has confirmed that the above listed lots of Enzygnost® HBsAg 6.0 show an increased number of reactive results when testing plasma samples. We have no indication that sensitivity is also affected.

Based on our current knowledge serum samples are not affected by this issue.

Risk to Health

There is generally negligible health risk associated with false positive results with the HBsAg for diagnostic purposes as well as for recipients of blood donations. All reactive samples must be resolved according to an established confirmation method following lab internal policy or national/international guidelines.

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D – 35041 Marburg, Germany

Enzygnost® HBsAg 6.0 - Increased number of reactive results for plasma samples

Actions to be Taken by the Customer

Please do not use any kind of human plasma samples for the qualitative detection of hepatitis B (surface) antigen with the affected lots of Enzygnost® HBsAg 6.0 listed in Table1.

Please retain this letter with your laboratory records, and forward this letter to those who may have received this product.

We apologize for the inconvenience this situation may cause. If you have any questions, please contact your Siemens Customer Care Center or your local Siemens technical support representative.

Sincerely yours,

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Enzygnost is a trademark of Siemens Healthcare Diagnostics.

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