

[REDACTED]

[REDACTED]

07.11.2017

**Additional information to the important customer information about the
Measles IgM ELISA (Order number: EC105M00) dated 13.10.2017**

[REDACTED]

For the LOT 122 of the Measles IgM ELISA (EC105M00) unspecific reactions were observed for certain sera from pregnant women. In these cases there were pregnant women and women who want children who have received medication treatment to achieve pregnancy (fertility center). On basis of the results for the LOT 122 unspecific reaction in individual sera out of that collective can't be completely excluded.

For sera from "normal" pregnant women the test works perfectly.

Excerpt from the SK2-guidline (Germany) for pregnant women:

Measles IgM sometimes shows cross-reaction with other viruses or can be positive because of a polyclonal stimulation (for example by EBV). The Measles IgM test therefore could show false positive results in individual cases.

For 30% the IgM is only detectable 72 after symptoms occur. So you always have to check if the laboratory results fits to the clinical picture.

Recommendation:

We recommend that the customers only in these special cases have to double check the results for example by RT-PCR or an increase in the IgG.

We also recommend checking the country specific guidelines for pregnant women.

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Transmission of the described information:

Please ensure within your organization, that all users of the above mentioned products and other persons in charge are going to be informed about this **“Important customer information”**. In case you have provided the product to a third party, please make sure a copy of this information is forwarded or inform the below mentioned contact person about the fact immediately.

Please confirm the receipt of this important customer information using the FAX response in the appendix.

Contact Person: [REDACTED]

[REDACTED]

Kind Regards,

VIROTECH Diagnostics GmbH

[REDACTED]

Confirmation of the

Important customer information

about the Measles IgM ELISA (Order number: EC105M00)

Please return this confirmation as soon as possible via Fax or Email to VIROTECH
Diagnostics GmbH, Löwenplatz 5, 65428 Rüsselsheim

FAX: + 49 61 42 96 66 13



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Hereby we confirm the acknowledgment of the important customer information from
07.11.2017 on the Measles IgM ELISA (EC105M00).

Company stamp:

Company: _____

Contact Person: _____

Date & Signature: _____

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