

Please forward the letter to: VIDIA Customers and Distributors

In Vestec, 7.3. 2023

### **Urgent Field Safety Notice FSN2023-01DE**

For the product ELISA-VIDITEST anti-HHV-6 IgM Lot no. 010122, REF ODZ-345

Dear customers,

VIDIA spol. s.r.o. initiated the corrective action for the above-mentioned product. This letter contains important information for your immediate attention.

**Description of the problem including the determined cause:** Based on the customer's complaint, a decrease in the value of optical density (O.D.) of the calibrator was identified for the above-mentioned product. The ELISA tests performed using the calibrator from this lot. may cause false positive results. Internal tests revealed that the O.D. value of the calibrator is reduced, and it maintains a stable reduced level, so it was decided to recalculate the correction factor for this Lot. of the kit.

**Determined risk:** A decrease in the calibrator value may in some cases mean an increase the risk of false positive results. This risk does not affect the direct threat to patients, as it is a complementary examination, the result of which must be evaluated in the context of the patient's clinical condition and other tests.

**Action to be taken:**

1. If you have already used the kits and you have not observed an increased number of positive samples, there is no need to take any further measures, given the established risk
2. If during the test already performed the customer found a higher percentage of positive results than usual, and the value O.D. of calibrator CAL is  $\leq 0.800$ , recalculate the results obtained using the above noticed ELISA kit using the new correction factor. Part of the notification is the revised Quality Control Certificate with the newly stated correction factor.
3. If you will perform a new test with the above-mentioned lot of the kit, please use the newly recalculated correction factor.

**Information to be forwarded:** Please forward this information to all users of the above-mentioned product.

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Thanks for cooperation! We apologize for any inconvenience. For further information, do not hesitate to contact us, e-mail: [Kvalita@vidia.cz](mailto:Kvalita@vidia.cz)

Sincerely

Ing. Michaela Poláková  
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