QuidelOrtho™

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Month XX, 2024

URGENT FIELD SAFETY NOTICE

VITROS® Chemistry Products DGXN Slides May Generate Negatively Biased Results Due to Hemoglobin Interference

Dear Valued Customer,

The purpose of this notification is to inform you that QuidelOrtho has confirmed an issue involving VITROS Chemistry Products DGXN Slides which may generate negatively biased results due to hemoglobin interference at a concentration lower than what is currently listed in the Instructions For Use (IFU) at 300 mg/dL.

Affected Product Name	**Catalog Number** (Unique Device Identifier)	**Affected Coatings**
VITROS Chemistry Products DGXN Slides	834 3386 (10758750004782)	All current and expired coatings.
For *in vitro* diagnostic use only. VITROS Chemistry Products DGXN Slides quantitatively measure digoxin (DGXN) concentration in serum using VITROS 250/350/5,1 FS/4600/XT 3400 Chemistry Systems and the VITROS 5600/XT 7600 Integrated Systems.		

Summary
Currently the VITROS Chemistry Products DGXN Slides IFU (current version 12.0) lists the hemoglobin Interferent Concentration limit at 300 mg/dL for a digoxin concentration of 2.0 ng/mL (2.6 nmol/L). In our investigation of the issue, QuidelOrtho determined that hemoglobin interference may occur at concentrations lower than 300 mg/dL, and may cause negatively biased digoxin results, with a maximum observed bias of up to -0.37 ng/mL (-18% bias) at a hemoglobin concentration of 200 mg/dL. There was no evidence of significant hemoglobin interference at 100 mg/dL.

QuidelOrtho is currently performing testing to revise the Interferent Concentration limit at which hemoglobin interference may reach an unacceptable level. Until our investigation has completed, as a temporary mitigation, we are making the following changes:

- QuidelOrtho is lowering the hemoglobin Interferent Concentration limit from 300 mg/dL to 100 mg/dL at a digoxin concentration of 2.0 ng/mL (2.6 nmol/L).
- QuidelOrtho is also lowering the Sample Indices Threshold default hemolysis limit from 300 to 100 for the VITROS DGXN assay on VITROS® 5,1 FS/4600/XT 3400 Chemistry Systems and VITROS® 5600/XT 7600 Integrated Systems. No changes will be made to the VITROS DGXN assay on VITROS® 250/350 Chemistry Systems, as they do not have the capability to measure sample indices.

Summary (Cont.)
The Sample Indices Threshold default hemolysis limit will be updated in Assay Data Disk (ADD), Data Release Version (DRV) 6308 (and above) and customers are advised to load ADD DRV 6308 (or above) upon receipt. Upon loading ADD DRV 6308 (or above), the Sample Indices Threshold default hemolysis limit for DGXN will automatically be updated to 100. As the VITROS 250/350 Systems do not have the capability to measure sample indices, there will be no updates to the Calibration Diskette. Please note that, as lowering the limit to 100 is a temporary mitigation, the limit may be revised again after we have completed our investigation.

If you have programmed your Instrument Manager or Laboratory Information System to the default HEM Indices value of 300 instead of the sample integrity hemolysis 'H' flag, then this value will need to be updated to 100.

Impact to Results
A bias of up to -18% will result in a clinically significant negatively biased digoxin result. A negatively biased digoxin result may lead to erroneous dose adjustment, which could result in a higher-than-expected serum digoxin concentration. Due to digoxin's narrow therapeutic index, inappropriate dose adjustments may result in chronic digoxin toxicity. Clinical factors such as repeat digoxin monitoring, routine EKGs, and clinical assessment of early signs of toxicity increases the detectability of erroneous results and mitigates serious patient consequences. The likelihood of occurrence of severe medical harm is considered remote.

QuidelOrtho does not recommend a review of previous results due to the difficulty in identifying patient results which may have been affected by hemoglobin interference and assessing potential patient impact based solely on digoxin test results. Discuss any concerns regarding previously reported results with your Laboratory Medical Director to determine the appropriate course of action. The results from any diagnostic test should be evaluated in conjunction with a patient's history, risk factors, clinical presentations, signs, and symptoms as well as the results of other tests.

As of 05-Dec-2024, QuidelOrtho has received 1 customer complaint related to this issue, with no reports of adverse effects.

REQUIRED ACTIONS

- For customers who have VITROS 5,1 FS/4600/5600/XT 3400/XT 7600 Systems: Load ADD DRV 6308 upon receipt.
- For customers who have VITROS 250/350 Systems: Please be aware of the lowering of the Interferent Concentration limit from 300 mg/dL to 100 mg/dL at a digoxin concentration of 2.0 ng/mL (2.6 nmol/L).
- Complete and return the enclosed Confirmation of Receipt form no later than **Month DD, 2024**.
- Save this notification with your User Documentation or post this notification by each VITROS 250/350/5,1 FS/4600/5600/XT 3400/XT 7600 System in your laboratory until the issue has been resolved.
- Please forward this notification if the affected product was distributed outside of your facility.

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REQUIRED ACTIONS (Cont.)

- If your laboratory has experienced the issue with this product and you have not already done so, please report the occurrence to your local Global Services Organization.

Resolution

Our investigation to revise the limit at which hemoglobin interference may reach an unacceptable level is ongoing. In the interim we will be issuing a Technical Bulletin to implement the temporary changes to the Sample Indices Threshold default hemolysis limit on the ADD and the hemoglobin Interferent Concentration limit for digoxin listed in the IFU. We will communicate again after our investigation has completed. QuidelOrtho is targeting to have an update by Q1 2025.

Contact Information

We apologize for the inconvenience this may cause your laboratory. If you have further questions, please contact our Global Services Organization at [800 Number].

Insert signatory if applicable in your region.

Enclosure: Confirmation of Receipt form (Ref. CL2024-297_EU_CofR)