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Urgent Field Safety Notice:

Dimension Vista® System

Incorrect Default Hemolysis, Icterus or Lipemia (HIL) Index for Five Dimension Vista Assays

Dear Sirs,

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

Table 1. Dimension Vista® Systems

System	Siemens Material Number (SMN)	Global Trade Item Number (GTIN)[1]
Dimension Vista® 1500	10444802	00630414945460
Dimension Vista® 500	10488224	00630414989556

[1]GTIN + Instrument Serial Number = Unique Device Identification (UDI)

Reason for Urgent Field Safety Notice

The purpose of this communication is to inform you of an issue with the products indicated in Table 1 above with all versions of software prior to 3.10.2 and provide instructions on actions that your laboratory must take.

Siemens Healthineers has confirmed five Dimension Vista assays have incorrect Hemolysis, Icterus or Lipemia (HIL) indices defaulted in the Method Parameter screen of the software and must be manually updated once the HIL feature is activated. All Hemolysis, Icterus, and Lipemia information in the corresponding assay Instructions for Use (IFU) are correct. This communication is to ensure that the HIL indices within your Dimension Vista system software are aligned with the Hemolysis, Icterus, and Lipemia information in the respective Instructions For Use. The Dimension Vista software has been updated with the correct HIL index default settings recommended in this letter and included in software version 3.10.2.

Dimension Vista Folate (FOL)

The I index identifying icterus in the sample is defaulted at 8 (inactive) within the software Method Parameter screen and should be revised to a setting of 6 when activating the HIL feature to align the FOL I index with the Icterus information in the FOL IFU. If the Icterus index is allowed to remain at the default setting of 8, significant positive bias may be observed on grossly icteric samples.

Siemens investigation has found that Unconjugated Bilirubin has significant positive interference with Dimension Vista FOL above 20 mg/dL [342 µmol/L]. Siemens observed conjugated bilirubin at 60 mg/dL [1026 µmol/L] shows 37.1% interference with FOL and conjugated bilirubin at 40 mg/dL [684 µmol/L] shows 16.9% interference with FOL.

Dimension Vista Ammonia (AMM)

The L Index identifying lipemia in the sample is defaulted to a setting of 3 within the software Method Parameter screen and should be revised to a setting of 2 when activating the HIL feature to align the AMM L index with the Lipemia information in the AMM IFU. The AMM IFU states that Lipemia (Intralipid®) at 50mg/dL [50 g/L] increases AMM results by 13% at an ammonia concentration of 85 µg/dL [50 µmol/L]. At levels above 100 mg/dL [100 g/L] Intralipid may trip a test report message.

Dimension Vista Cardiac Troponin I (CTNI)

The I index identifying icterus in the sample is defaulted as 8 (inactive) within the software Method Parameter screen and should be revised to a setting of 7 when activating the HIL feature to align the CTNI I index with the information in the IFU. Siemens observed unconjugated bilirubin at 60 mg/dL [1026 µmol/L] shows less than 10% interference with CTNI.

Note: The Dimension Vista Cardiac Troponin I (CTNI) assay is currently in the end of life process and is being replaced by the Dimension Vista High Sensitivity Troponin I (TNIH) assay.

Dimension Vista Total Prostate Specific Antigen and Free Prostate Specific Antigen (TPSA/FPSA)

The H index identifying hemolysis in the sample and the I index identifying icterus in the sample are defaulted to the setting of 8 (inactive) in the Method Parameter screen of the software and should be revised to a Hemolysis Index setting of 7 and Icterus Index setting of 6, respectively, to align with the Hemoglobin and Icterus information in the TPSA and FPSA IFUs. Siemens observed Hemoglobin at 1000 mg/dL [0.62 mmol/L] shows less than 10% interference with both TPSA and FPSA. Relative to icterus, Siemens observed unconjugated bilirubin at 60 mg/dL [1026 µmol/L] shows less than 10% interference with both TPSA and FSPA.

Risk to Health

There is negligible risk to health associated with the incorrect HIL settings for the AMM, CTNI, TPSA, and FPSA assays.

In rare scenarios when conjugated bilirubin is ≥40 mg/dL [1026 µmol/L] the potential exists for misinterpretation of folate results, which may affect consideration for intervention. Clinical impact would be mitigated by correlation to other diagnostic laboratory testing (e.g. vitamin B12, complete blood count) and to the presence of symptomology such as yellow/pale skin, fatigue, rapid or irregular heartbeats, and/or variable neurologic abnormalities.

Siemens is not recommending a review of previously generated results.

Actions to be Taken by the Customer

For the products listed in Table 1, please perform the following steps if the HIL feature is activated on your Dimension Vista System. If your laboratory is not using the HIL feature and it is not activated on your system no action is required:

- If the HIL indices for Dimension Vista FOL are activated, be sure to set the I index (icterus) to 6 which is aligned with the information in the Dimension Vista FOL IFU.
- If the HIL indices for Dimension Vista AMM are activated, be sure to set the L index (lipemia) to 2 which is aligned with the information in the Dimension Vista AMM IFU.

  Note: Instructions for setting HIL indices can be found in the Dimension System Operator's Guide, in Section **Configuration, System Configuration**.

- If the HIL indices for Dimension Vista CTNI are activated, be sure to set the I index (icterus) to 7 which is aligned with the information in the Dimension Vista CTNI IFU.
- If the HIL indices for Dimension Vista TPSA and/or FPSA are activated, be sure to set the H index (hemolysis) to 7 and the I index (icterus) to 6 which is aligned with the information in the Dimension Vista TPSA and FPSA IFUs.
- Please review this letter with your Medical Director.
- Complete and return the Field Correction Effectiveness Check Form attached to this letter within 30 days to Siemens Healthineers for reporting to the Authorities.
- If you have received any complaints of illness or adverse events associated with the product listed in Table 1, immediately contact your local Siemens Healthineers Remote Services Center or your local Siemens Healthineers Technical Support Representative.

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 Healthineers Customer Care Center or your local Siemens Healthineers technical support representative.

Sincerely yours,

Siemens Healthcare Diagnostics GmbH

Signature: 

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