Urgent Field Safety Notice

ACHC20-18.A.OUS.CHC

September 2020

ADVIA® Chemistry 1800
ADVIA Chemistry 2400
ADVIA Chemistry XPT

Fructosamine Assay - Positive Bias with Quality Control and Patient Samples

Our records indicate that you may have received the following product:

Table 1. ADVIA® Chemistry Systems Affected Product:

Assay	Test Code	Reference Number	Siemens Material Number (SMN)	Lot Number
Fructosamine (FRUC)	115	04862501	10361941	All lots

Reason for Correction

The purpose of this communication is to inform you of a positive bias with Quality Control (QC) and patient samples when using the ADVIA Chemistry Fructosamine (FRUC) assay listed in Table 1.

An investigation performed by Siemens Healthcare Diagnostics Inc. has confirmed that the ADVIA Chemistry Fructosamine (FRUC) assay exhibits a 60 µmol/L positive bias for QC and patient samples across the analytical measuring range when compared to the predicate assay referenced in the method comparison section of the ADVIA Chemistry FRUC Instructions for Use (IFU).

Risk to Health

In this scenario, the potential exists for misinterpretation of fructosamine results, which may affect consideration of intervention. Clinical impact is extremely unlikely and would be mitigated by correlation to clinical history and presentation as well as to other laboratory testing (e.g. glucose) and serial testing. Siemens is not recommending a review of previously generated results.

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Additional Information

Siemens has determined that the application of a Real-time correction factor to the FRUC Analytical Parameters (Chemistry) is required to correct for this bias and restore alignment of assay correlation to the predicate assay. Instructions to configure the Real-time correction factor are provided in the Additional Instructions section below. The Real-time correction factor will only need to be configured once. The factor will automatically be applied to future versions of the FRUC test definition. The FRUC Analytical Parameters (Chemistry) will incorporate this correction factor in a future version.

Refer to Figure 1 for the ADVIA Chemistry FRUC method comparison to the predicate assay after the correction factor is applied.

After implementation of the Real-time correction factor, Siemens verified a new reference interval which is consistent with the reference interval of the predicate assay. The FRUC IFU will be updated with the new reference interval of 153-300 µmol/L. As stated in the IFU, “Siemens provides this information for reference. As with all *in vitro* diagnostic assays, each laboratory should determine its own reference ranges for the diagnostic evaluation of patient results. Consider this range as a guideline only. You can enter normal range values and abnormal range values at the Analytical Parameters (Chemistry) window.”

The information related to the FRUC reference range provided in this letter supersedes the information in the current ADVIA Chemistry FRUC IFU until it is updated. Once updated the revised IFU will be available in Document Library where all registered users who opt in to receive alerts will be notified of the updated IFU.

Adjust your QC mean and ranges to account for the Real-time correction. To adjust QC ranges, subtract 60 µmol/L from your current values. Refer to Table 2 for an example of QC targets and ranges with an adjusted target.

Actions to be taken by the Customer

- Perform the following actions on the ADVIA Chemistry System
    1. Enter the Real-time correction factor in the Analytical Parameters (Chemistry) window. Refer to the Additional Instructions section below
    2. Once the Real-time correction factor has been configured, update QC ranges as described above in the FRUC QC Definition following your laboratory procedures.
    3. Update the reference range following your laboratory procedures.
    4. Perform a FRUC calibration and process QC.
    5. Perform a system back-up.

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- Complete and return the Field Correction Effectiveness Check attached to this letter within 30 days.
- Review this letter with your Medical Director.
- If you have received any complaints of illness or adverse events associated with the products listed in Table 1, immediately contact your local Siemens Healthineers Customer Care Center or your local Siemens Healthineers technical support representative.

Table 2: Example Quality Control Recovery

Quality Control Material	Previous Target (µmol/L)	Previous Control Range (µmol/L)	Adjusted Target (µmol/L)	Adjusted Control Range (µmol/L)
RANDOX Fructosamine Control Level 1 Lot 538FR	258	206 – 310	198	146 - 250
RANDOX Fructosamine Control Level 3 Lot 539FR	939	751 – 1127	879	691 - 1067

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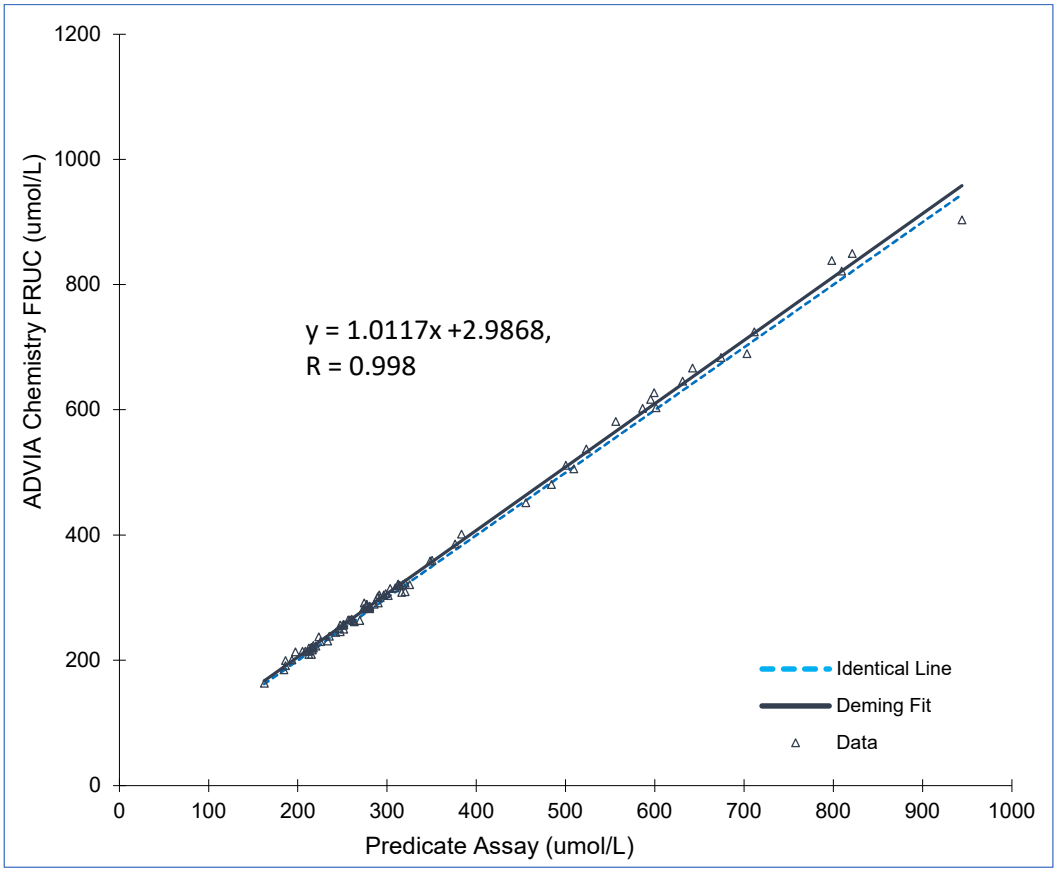
Figure 1: Method Comparison between ADVIA Chemistry FRUC Assay and the Predicate Assay with Correction Applied



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 or need assistance with making these updates, please contact your Siemens Healthineers Customer Care Center or your local Siemens Healthineers technical support representative.

ADVIA is a trademark of Siemens Healthcare Diagnostics.

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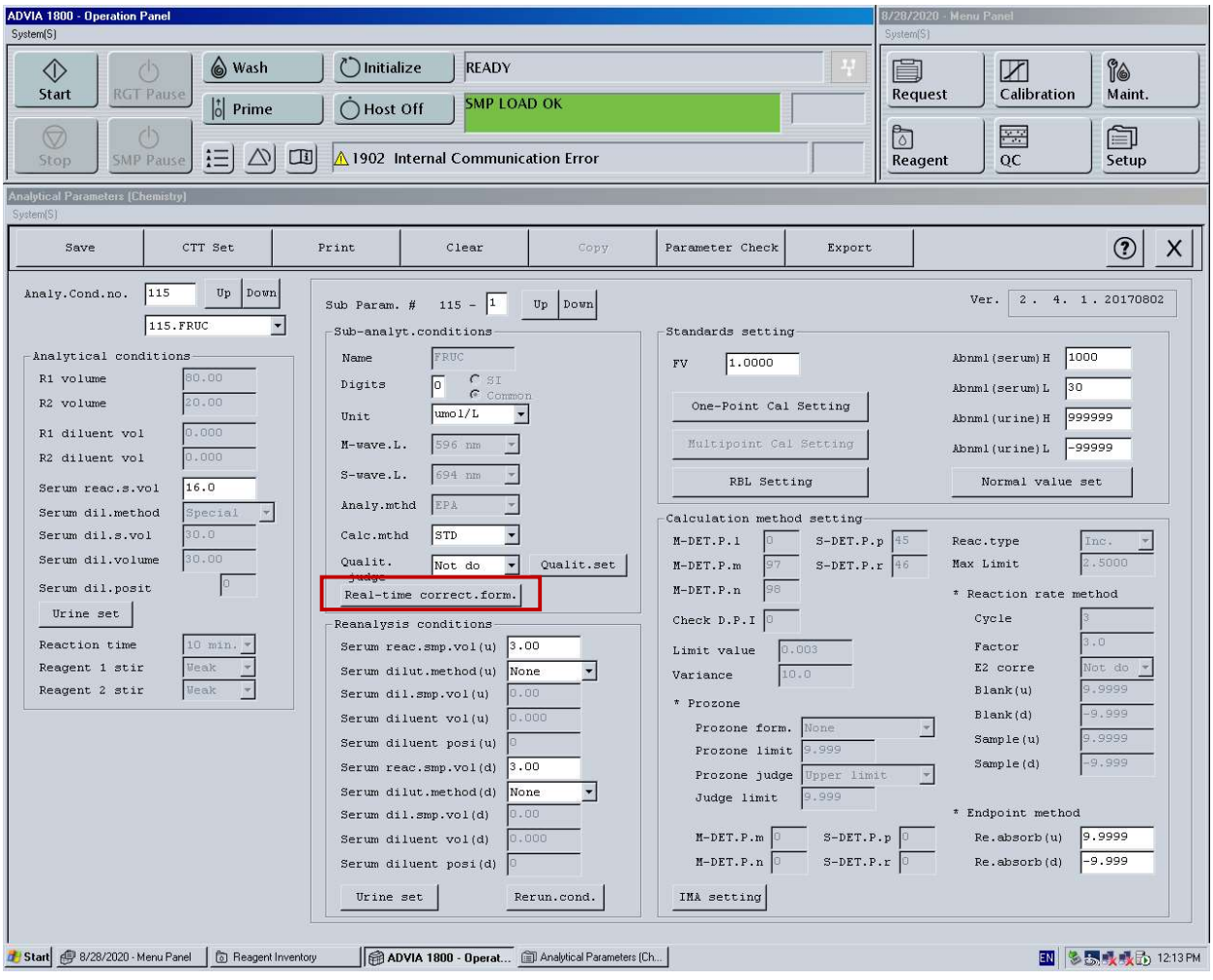
Additional Instructions:

Manual Configuration of the Real-Time Correction Factor in Analytical Parameters (Chemistry)

ADVIA 1800 and 2400:

1. Ensure system is in the Ready state.
2. On the Menu Panel, select Setup > Analytical Parameters (Chemistry).
3. Select the Fructosamine (FRUC) assay from the Analytical Condition Number. The Analytical Condition Number for FRUC is 115.

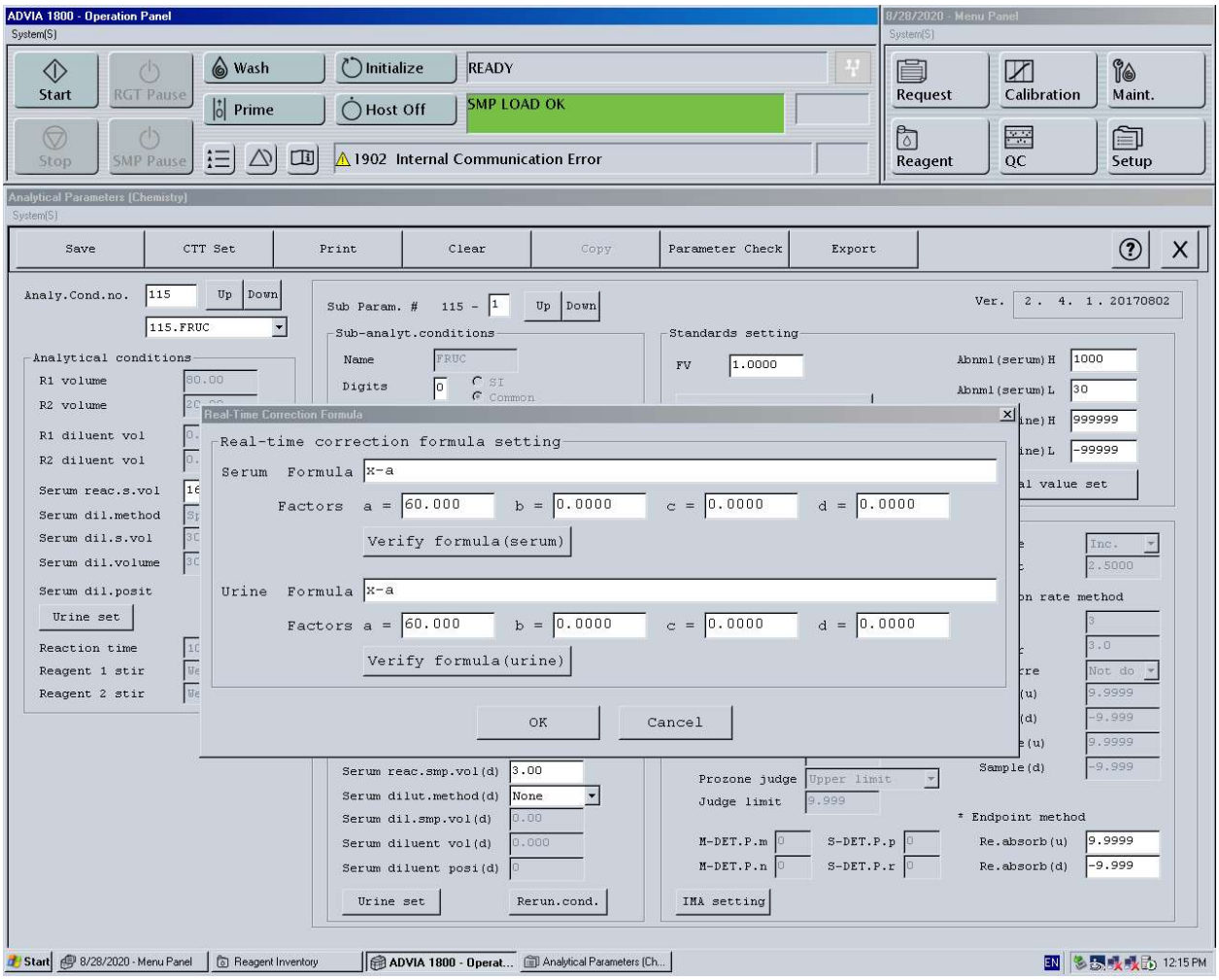


4. Select Real-time correction form.

5. In the FRUC Analytical Parameters (Chemistry) screen, select Real-Time Correction Formula button. Enter the following:

- In the Serum formula field enter “x-a”
- Factors a = 60

- In the Urine Formula field enter “x-a”
- Factors a = 60



6. Select OK.

7. Select Save.

8. Select Yes.

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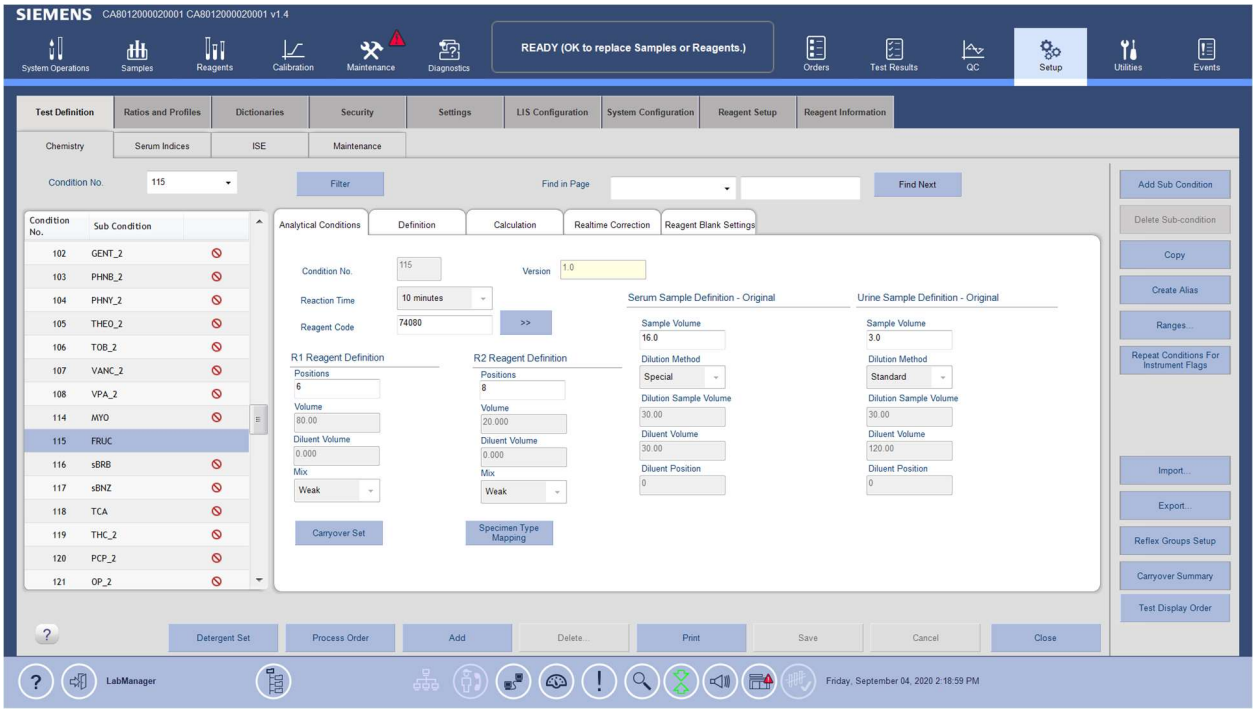
ADVIA Chemistry XPT:

1. Ensure system is in the Ready state.
2. On the Command bar, select Setup > Test Definition > CH Test Definition.
3. Select the Fructosamine (FRUC) assay from the list.
4. Select Real-time correction.



5. In the FRUC Analytical Parameters (Chemistry) screen, select Real Time Correction Formula button. Enter the following:

- In the Serum formula field enter “x-a”
- Factors a = 60

- In the Urine Formula field enter “x-a”
- Factors a = 60

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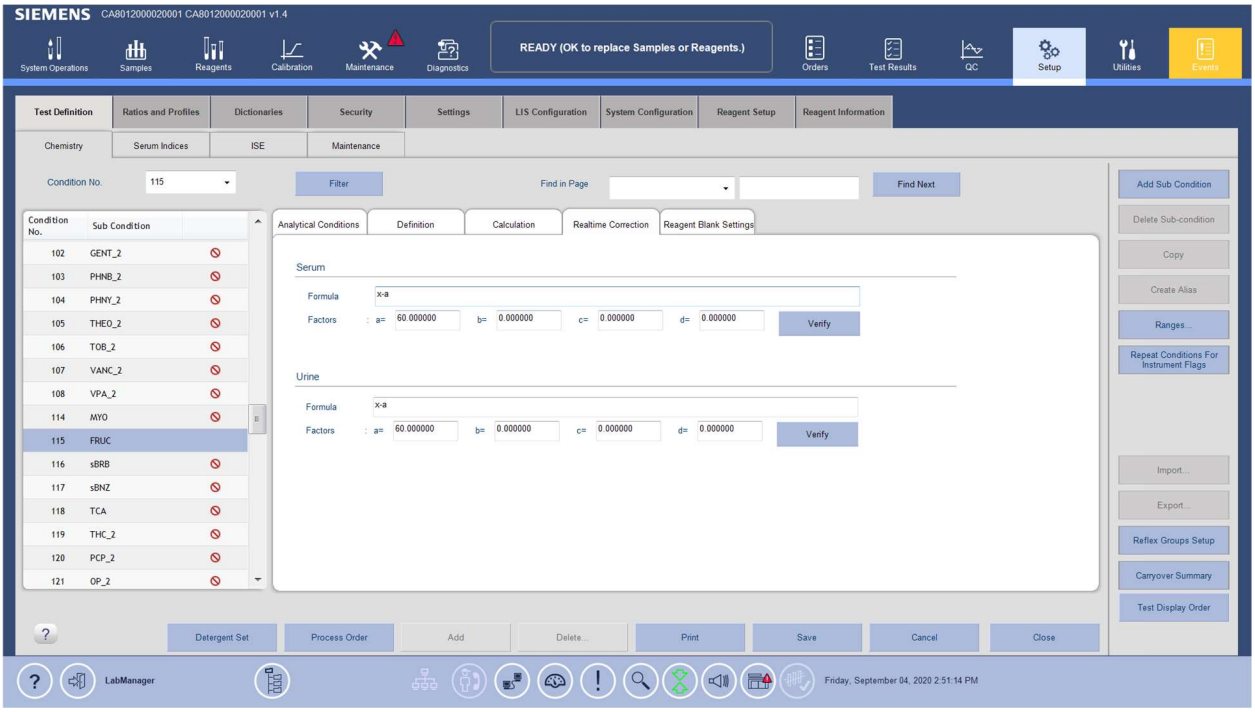

6. Select Save.
7. Select Close.
8. Select Yes at the prompt.

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