ADVIA® Chemistry 1800 Systems
ADVIA® Chemistry 2400 Systems
ADVIA® Chemistry XPT Systems

Multiple issues identified with Analytical Parameters (APTool) Disks and Test Definition (TDef) Disks

Our records indicate that your facility may have received one or more of the following products:

Table 1.   ADVIA® Chemistry Affected Product(s)

Assay	Siemens Material Number (SMN)
ADVIA Chemistry 1800 System	10315183
ADVIA Chemistry 2400 System	10315769
ADVIA Chemistry XPT System	10723034

Reason for Correction

Siemens Healthcare Diagnostics has identified the following issues with the ADVIA Chemistry products listed in Table 1 and is providing instructions on actions that your laboratory must take.

These issues will be corrected in APTool v1.10 and TDef v1.06 or higher, which will be available soon.

Description of Observed Behaviors

Issue Number and Assays	Issue Observed
1. Automated and Manual Enzymatic Hemoglobin A1c (A1c_E) Assay	APTool v1.09 and TDef v1.05 software incorrectly contains a total hemoglobin lower concentration limit of **74.74** µmol/L for the ADVIA Chemistry A1c_E and A1c_EM assays. This incorrect concentration limit does not impact Quality Control (QC) and patient results. Results are valid and acceptable for reporting. The correct lower total hemoglobin concentration limit is **88.98** µmol/L.
2. Urinary/ Cerebrospinal Fluid Protein (UCFP)	In APTool Disk v1.08 and v1.09 and TDef Disk v1.04 and v1.05, the Maximum Reagent Blank Deviation (Max RBL Dev) default analytical parameter was incorrectly set to **0.0037**, rather than the correct setting of **9.9999**. When using the incorrect default

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| | | parameter, some customers may intermittently observe a flag indicating the Max RBL Dev was exceeded resulting in a failed calibration.

When an invalid calibration is obtained, QC and patient sample testing cannot be performed. When a valid calibration is obtained and QC is in range, patient results are valid and acceptable for reporting. |
| --- | --- | --- |
| 3. | Urinary/ Cerebrospinal Fluid Protein (UCFP) | In APTool Disk v1.08 and v1.09 and TDef Disk v1.04 and v1.05, the International System (SI) units and the calibration criteria limits are incorrectly set to **mg/dL**, rather than **mg/L** for the ADVIA Chemistry UCFP assay. When calibrator SI values are used, Max Fit Dev is exceeded, calibration will not pass, and results cannot be generated. The lot specific ADVIA Chemistry UCFP Calibrator Instructions for Use (IFU) contain the correct SI units (mg/L) and values.

Customers using Common units (CU) are not impacted by this issue. |

Risk to Health

Issue 1	Enzymatic Hemoglobin A1c (A1c_E) Assay	The accuracy of patient samples is not impacted when the lower total hemoglobin value is used. The risk to health is negligible. Siemens is not recommending a review of previously generated results.
Issues 2 and 3	Urinary/Cerebrospinal Fluid Protein (UCFP) Assay	The issues described above for the UCFP assay would be considered clinically negligible as no erroneous patient results are generated or reported. Siemens is not recommending a review of previously generated results.

Actions to be Taken by the Customer

- Please review this letter with your Medical Director.

- Perform the instructions provided in the "Additional Information" section for issues 1 – 3.

    o Issue #1 applies to all laboratories utilizing A1c_E on their system.

    o Issue #2 applies to all laboratories utilizing UCFP on their system.

    o Issue #3 only applies to laboratories utilizing UCFP and reporting in SI units.

- Once all changes listed in the Additional Information for issues #2 and #3, are complete, perform a UCFP calibration and process Quality Control samples.

- A calibration is not required for Issue #1 related to A1c_E.

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- Perform a system back-up after all changes are complete.

- Complete and return the Field Correction Effectiveness Check Form attached to this letter within 30 days.

- 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.

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.

Additional Information:

Issue #1: ADVIA Chemistry Automated and Manual Enzymatic Hemoglobin A1c (A1c_E and A1c_EM) Assay Workaround

ADVIA Chemistry 1800/2400

1. Ensure system is in the Ready state.

2. Log in as tech_manager or supervisor for Setup to appear in the Menu Panel.

3. On the Menu Panel, select **Setup > Analytical Parameters (Chemistry)**

4. Select the A1c_E assay from the list. **(Analy. Cond. No. 6).**

5. In the Sub-parameter box, click Up to navigate to the **tHb_E Sub-analyt. Conditions 6 - 2.**

6. In the Standards Setting box, change the Abnml (Serum) L value from **74.74 to 88.98.**

7. Click Save and then Yes to save the changes to the Analytical Parameters (**Reference Figure 1**).

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Figure 1: Screen showing Abnml (serum) L value for tHb_E sub-parameter of the A1c_E assay on the ADVIA 1800/2400 Chemistry System
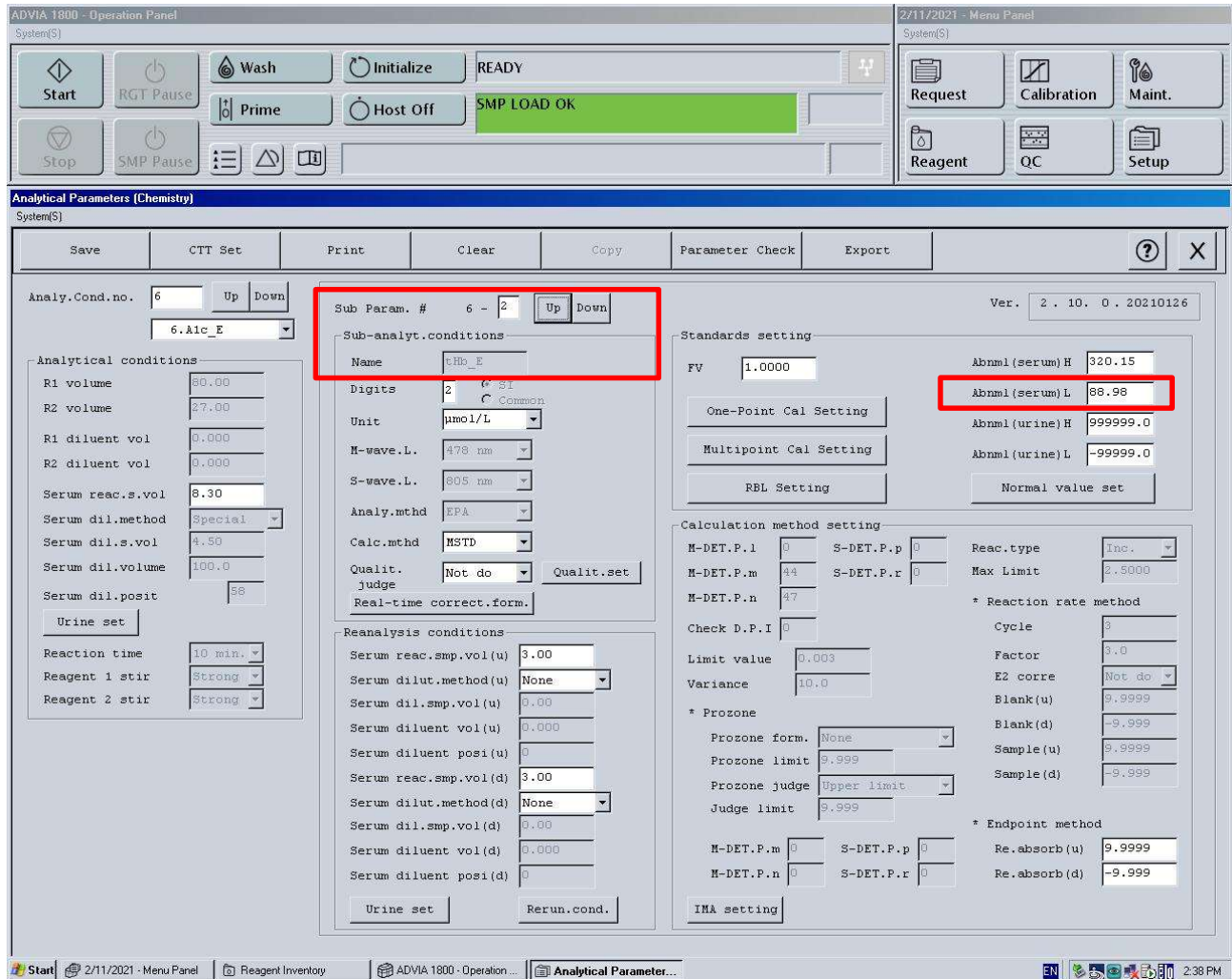
8. For **A1c_EM**, in the drop-down box, select **Analy. Cond. No. 19.**

9. In the Sub-parameter box, click Up to navigate to the tHb_EM **Sub-analytical Conditions 19 - 2**.

10. In the Standards Setting box, change the Abnml (Serum) L value from **74.74 to 88.98.**

11. Click Save and then Yes to save the changes to the Analytical Parameters **(Reference Figure 2)**.

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Figure 2: Screen showing Abnml (serum) L value for tHb_EM sub-parameter of the A1c_EM assay on the ADVIA 1800/2400 Chemistry System
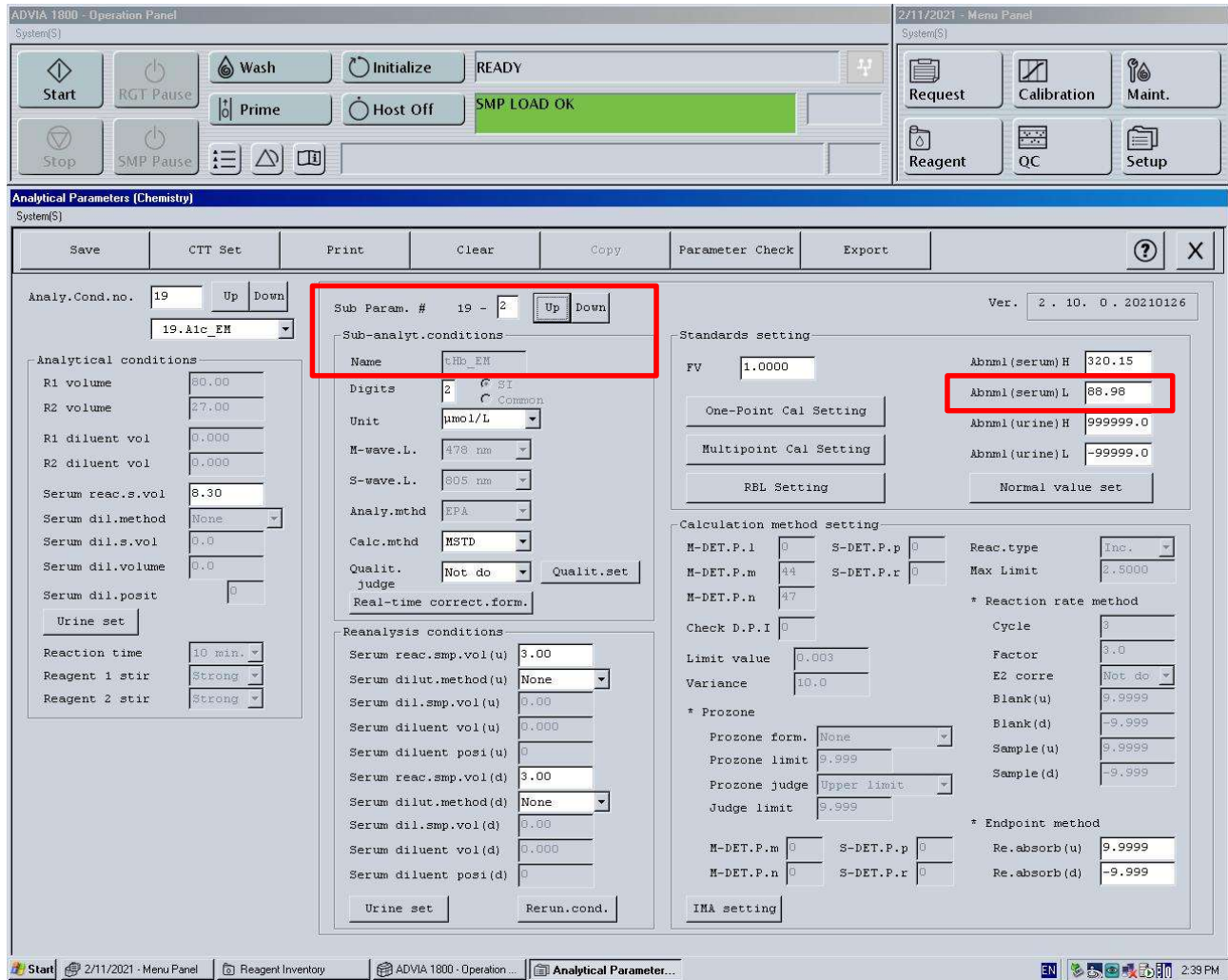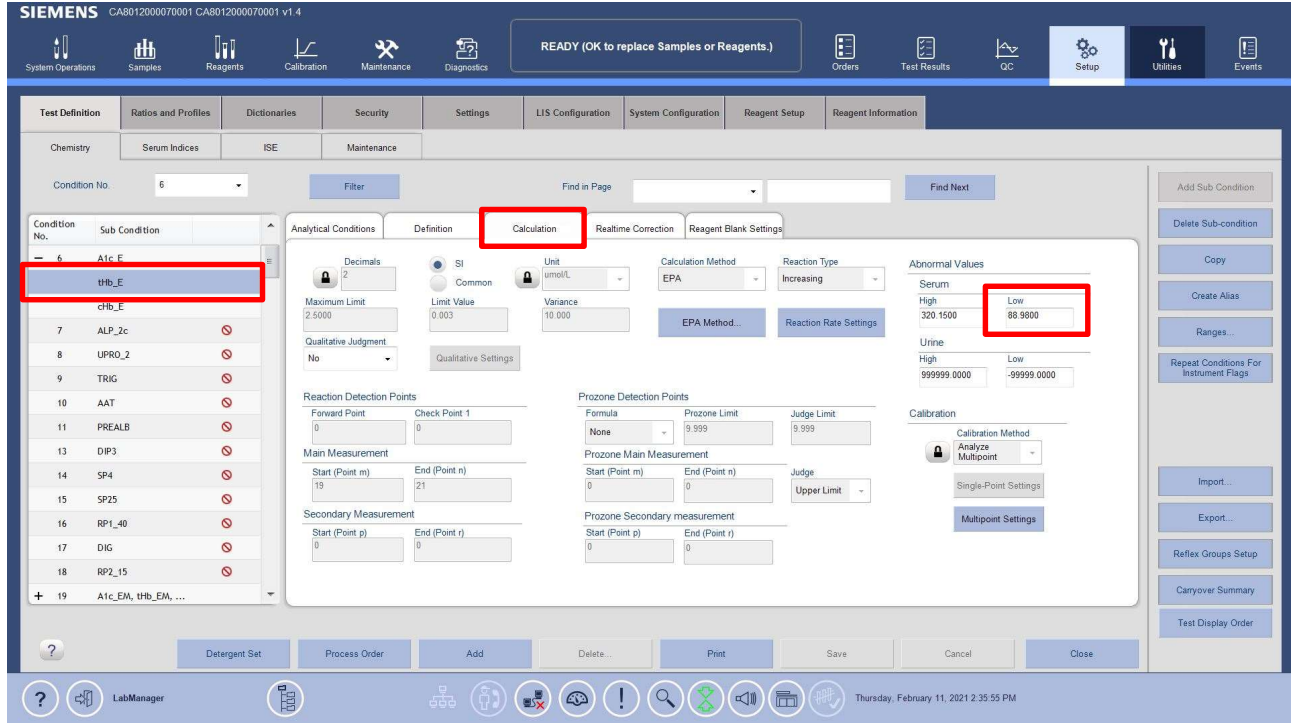

ADVIA Chemistry XPT

1. Ensure system is in the Ready state.

2. Log in as LabManager to make the changes.

3. Select **Setup > Test Definition Tab > Chemistry Tab.**

4. Select the A1c_E assay from the list. (Condition No. 6).

5. Select the + sign to expand the sub conditions. Select tHb_E and navigate to the Calculation Tab.

6. Change the Serum Abnormal Low Values from 74.74 to 88.98. Save changes (**Reference Figure 3**).

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7. For **A1c_EM** assay, select **Condition no. 19** and repeat steps 4 and 5. Save changes.

Figure 3: Screen showing Serum Abnormal Low value for tHb_E sub-parameter of the A1c_E assay on the ADVIA XPT Chemistry System


Issue #2: ADVIA Chemistry UCFP Assay, Max RBL Dev Exceeded Workaround

ADVIA Chemistry 1800/2400

1. Ensure system is in the Ready state.

2. Log in as tech_manager or supervisor for Setup to appear in the Menu Panel.

3. On the Menu Panel, select **Setup** > **Analytical Parameters (Chemistry)**

4. Select the **UCFP** assay from the list. (Analy.Cond.no 59)

5. Select **Reagent Blank Setting (RBL Setting)** under the Standard Setting section.

6. In Reagent Blank Setting subscreen, change **Max. RBL Deviat** value from 0.0037 to **9.9999**

7. Select OK, then click Save and Yes to save the changes to the Analytical Parameters (**Reference Figure 4**)

8. If using SI units proceed to the instructions for Issue #3. If using common units, return to Actions to be Taken.

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**Figure 4: ADVIA 1800/2400 Reagent Blank Setting Subscreen**
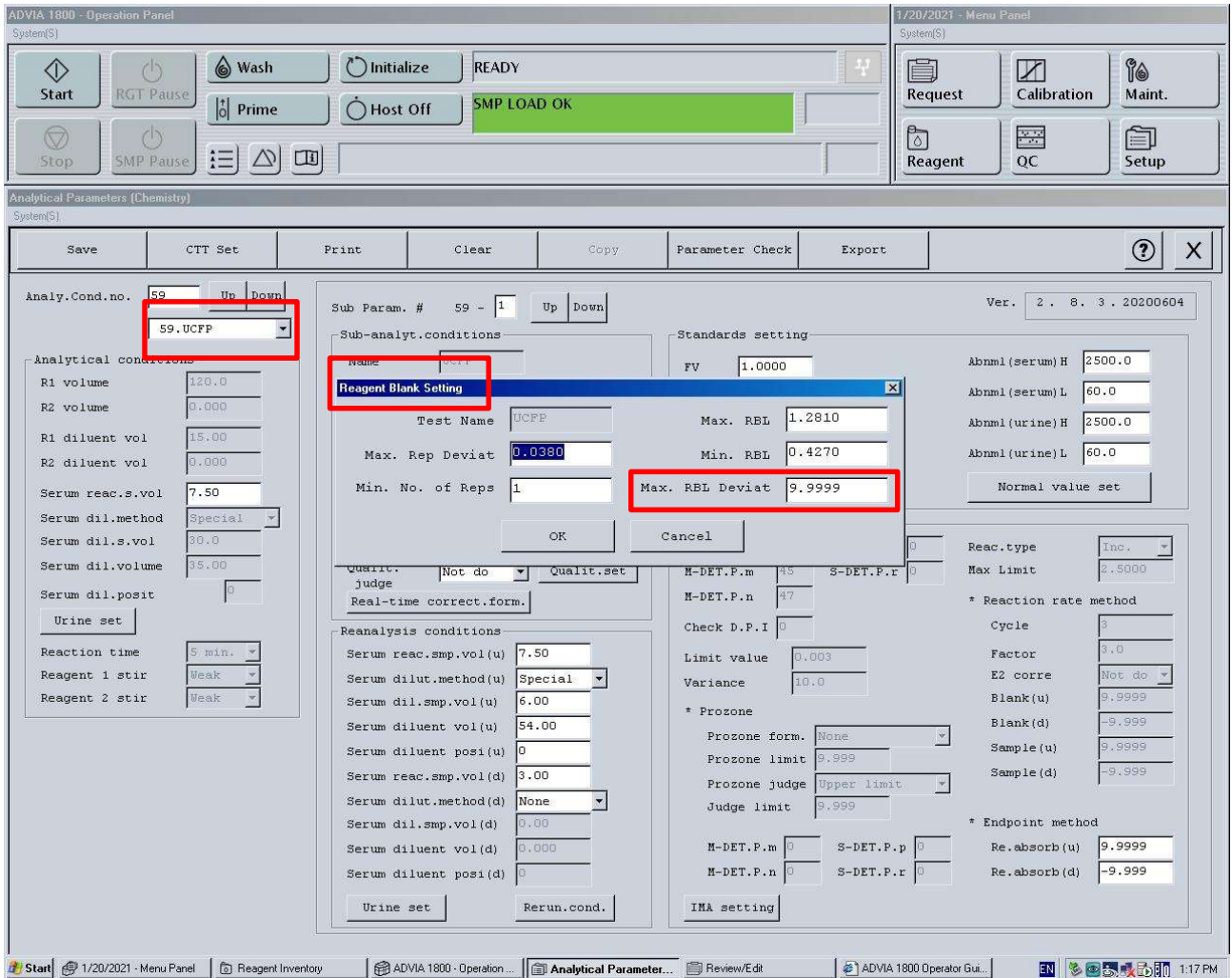
ADVIA Chemistry XPT

1. Ensure system is in the Ready state.

2. Log in as LabManager to make the changes.

3. On the Command bar, select **Setup** > **Test Definition Screen** > **Chemistry**

4. Select the **UCFP** assay from the list. (Analy.Cond.no 59)

5. In the UCFP Analytical Parameters (Chemistry) screen, select **Reagent Blank Settings**

6. In Reagent Blank Settings subscreen, change **Maximum Deviation** box under Values to **9.9999**

7. Select **Save**, then select **Close** (**Reference Figure 5**)

Multiple issues identified with Analytical Parameters (APTool) Disks and Test Definition (TDef) Disks on the ADVIA Chemistry Systems

8. If using SI units proceed to the instructions for Issue #3.   If using common units, return to Actions to be Taken.

Figure 5: ADVIA XPT Reagent Blank Settings Subscreen
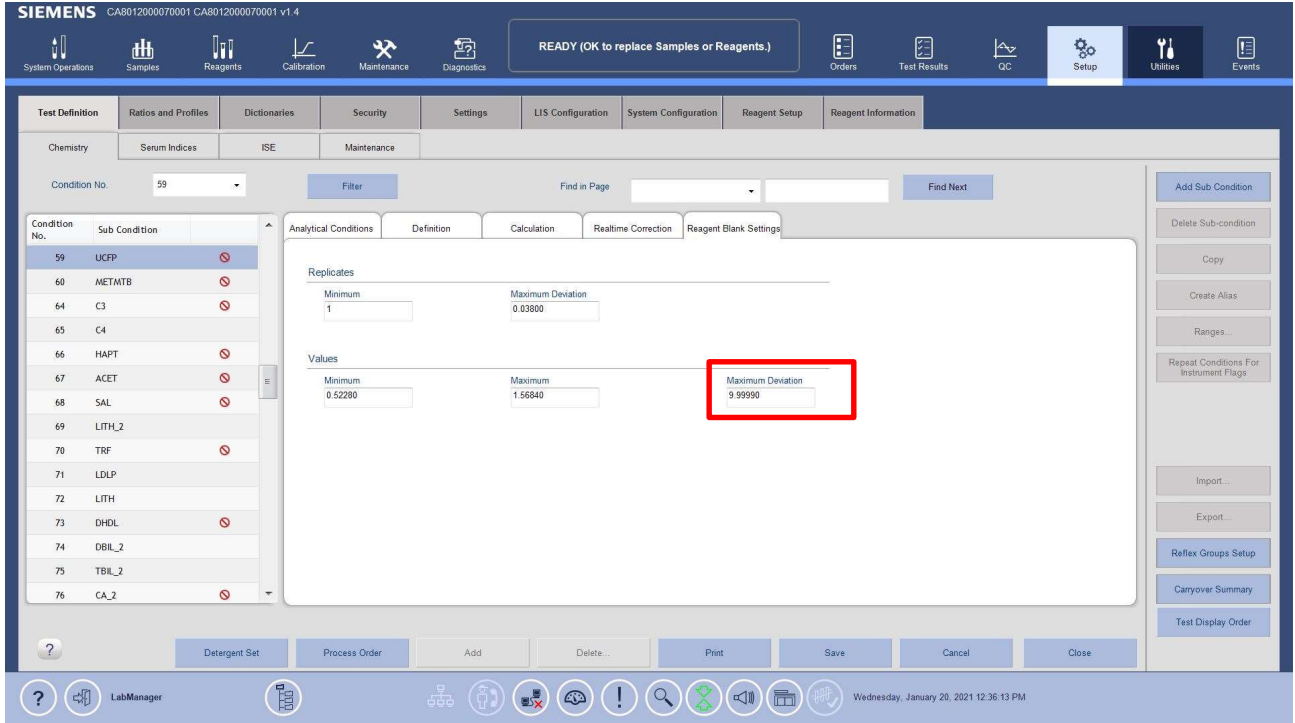
## Issue #3: ADVIA Chemistry UCFP Assay, International System (SI) units Workaround

ADVIA Chemistry 1800/2400

1. Ensure system is in the Ready state.

2. Log in as tech_manager or supervisor for Setup to appear in the Menu Panel.

3. On the Menu Panel, select Setup > Analytical Parameters (Chemistry)

4. Select the UCFP assay from the list. (Analy.Cond.no 59)

5. In that screen,
   a. Change *Unit* entry from mg/dL to **mg/L**
   b. Change *Abnml (serum) H* from 250.0 to **2500.0**
   c. Change *Abnml (serum) L* from 6.0 to **60.0**
   d. Change *Abnml (urine) H* from 250.0 to **2500.0**
   e. Change *Abnml (urine) L* from 6.0 to **60.0**
   f. Select **SAVE** (**Reference Figure 6**)

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Figure 6: ADVIA 1800/2400 UCFP Parameters Screen
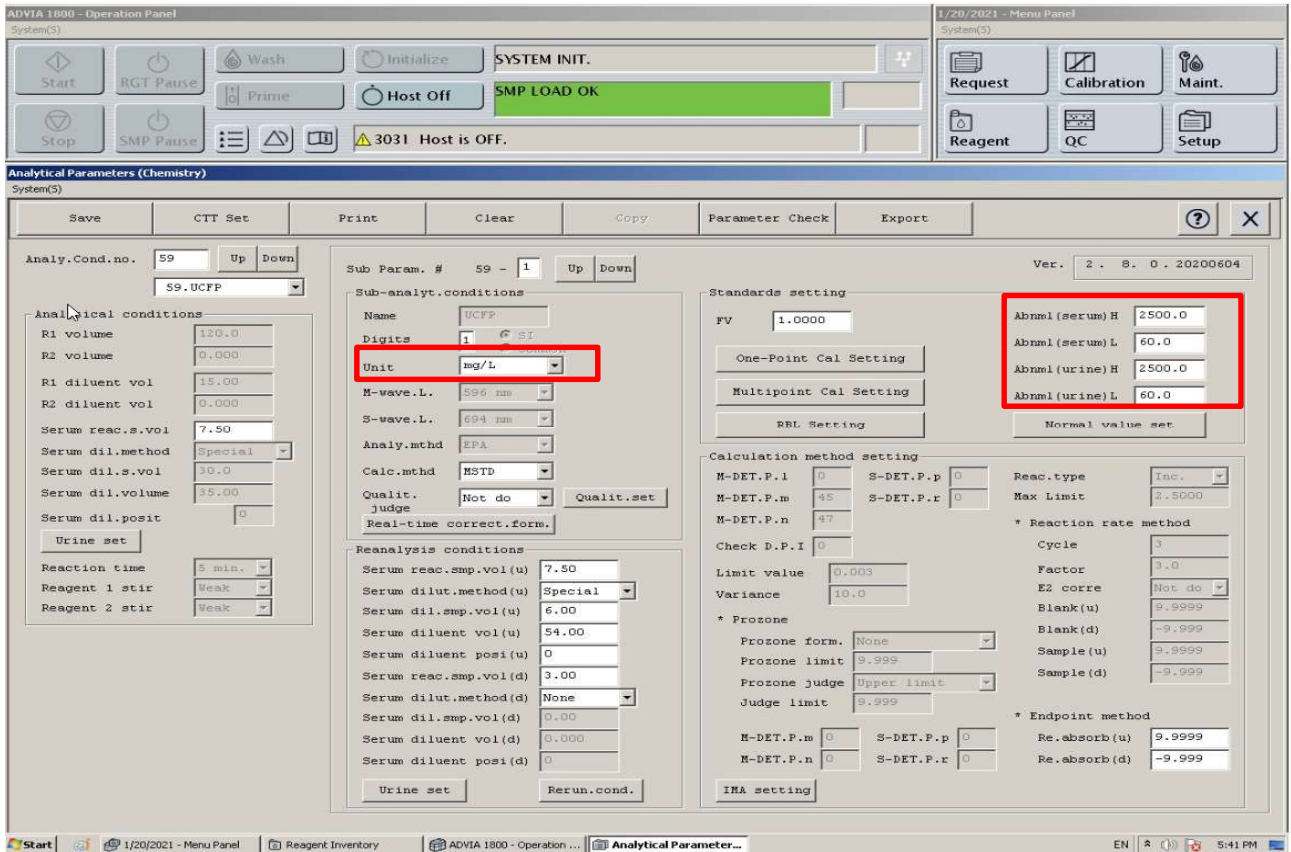
g. Open the Multipoint Cal Setting subparameters (**Reference Figure 7**)
h. Change the Max Fit Deviation entries for 1, 2, 3, 4, and 5 rows (Calibrators): row 1 from **3.80 to 38.00**, row 2 from **5.48 to 54.80**, row 3 from **7.22 to 72.20**, row 4 from **7.02 to 70.20**, and row 5 from **13.74 to 137.40**
i. Change the Max. RMS of Fit from **1.63 to 16.3**

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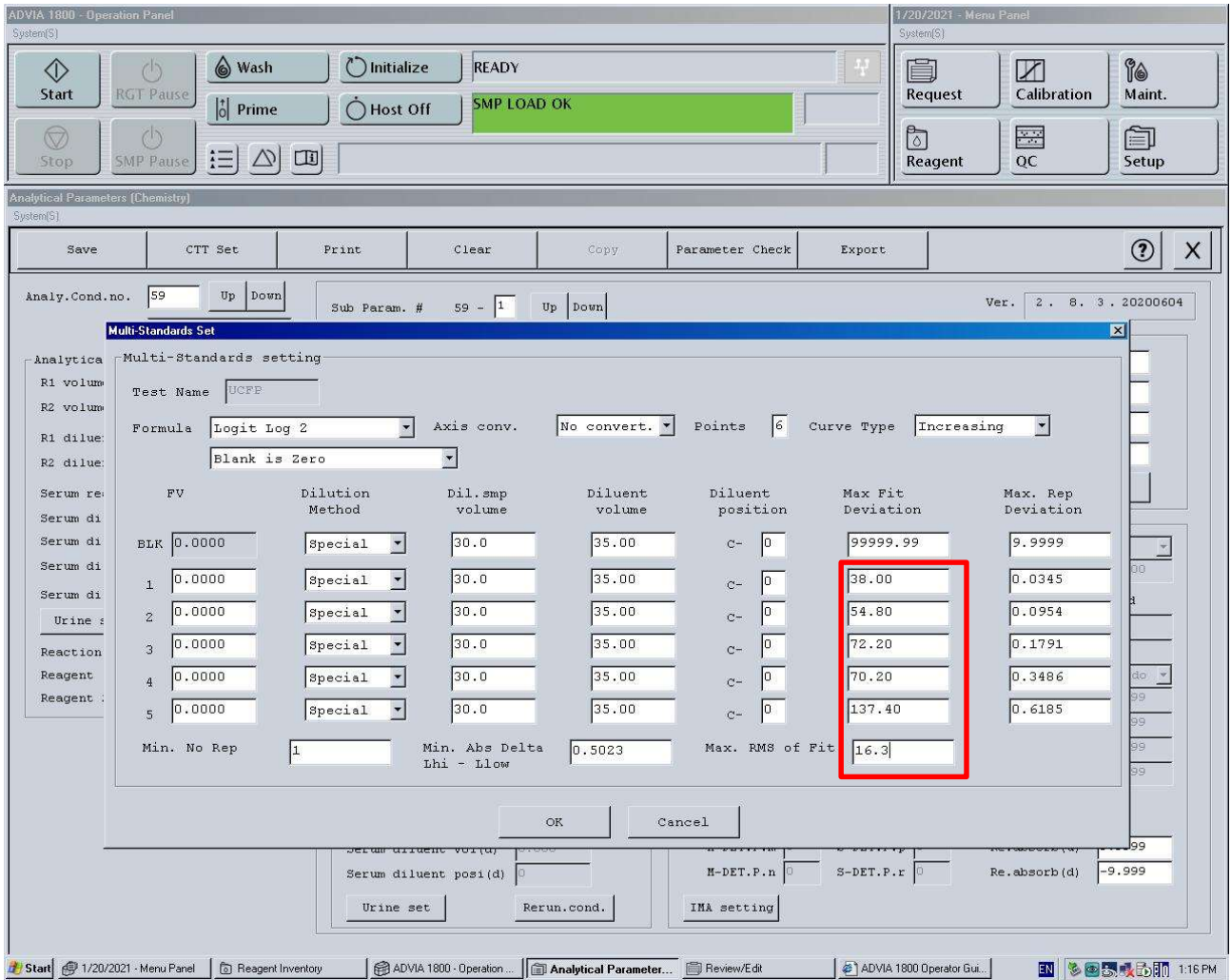**Figure 7: ADVIA 1800/2400 Multipoint Cal Setting subparameters screen**

ADVIA Chemistry XPT

1. Ensure system is in the Ready state.

2. Log in as LabManager to make the changes.

3. On the Command bar, select **Setup** > **Test Definition Screen** > **Chemistry**

4. Select the **UCFP** assay from the list. (Analy.Cond.no 59) Then click Calculation tab.

5. In that screen,

    a. Change the *SI Unit*s from mg/dL to **mg/L** (Reference Figure 5)

        a. See Additional Instructions below if icon is not on **Unlock**

    b. Change *Abnormal Values* for both Serum and Urine High from **250.0000** to **2500.0000** and Low from **6.0000** to **60.0000**.

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      c.   Select Save, then Close (**Reference Figure 8**)

Figure 8: ADVIA XPT UCFP Parameters Screen
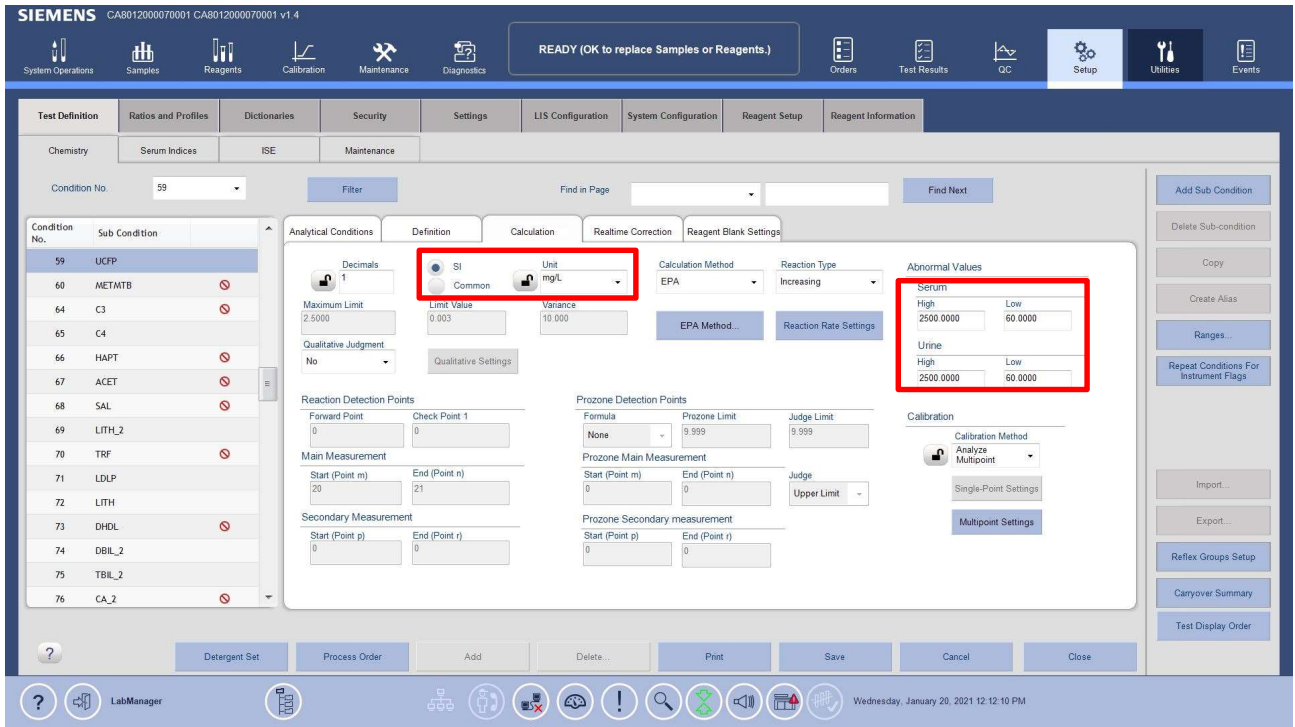
      d.   Select *Multipoint Settings* subscreen (**Reference Figure 9**) (Bottom right of calculation tab).

      e.   Change the *Maximum Fit Deviation* entries for 2, 3, 4, 5 and 6 rows (Calibrators): row 2 from 3.80 to 38.**00**, row 3 from **5.48 to 54.80**, row 4 from **7.22 to 72.20**, row 5 from **7.02 to 70.20**, and row 6 from **13.74 to 137.40**.

      f.   Change the *Max RMS of Fit* from **1.63 to 16.300**

      g.   Select Continue, then Save and Close

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Figure 9: ADVIA XPT Multipoint Setting Subscreen
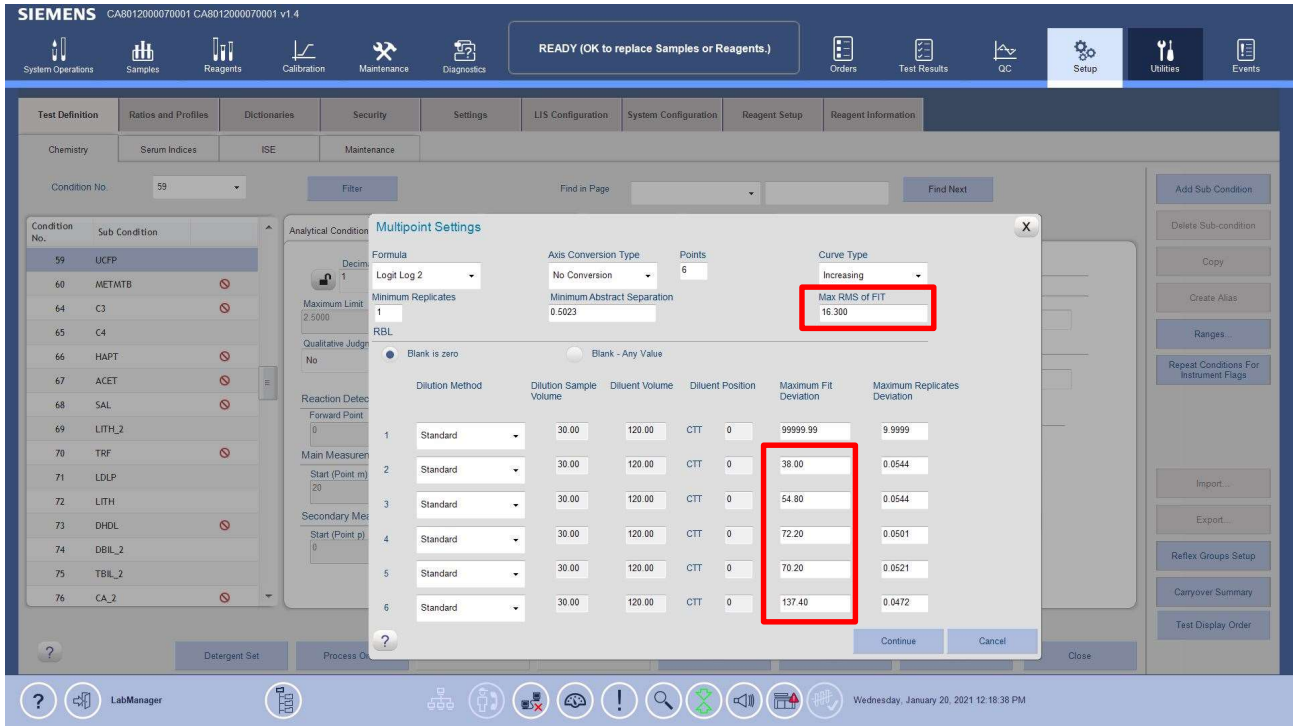
ADVIA Chemistry XPT Test Definition Editor

Once data has been generated on an assay, to edit Assay Calculation and Calibration the following steps must be followed for updates.

1. Select Setup > Test Definition **> Chemistry > Calculation**

2. Select the Lock icon next to the field to be edited

   Note: **Lock** Icon changes to **Unlock**

3. A system message displays if any of the following actions are necessary:

   a. Review and move to historical any Patient and QC records in the Orders and Test Results windows for the selected test definition

      • Select Test Results > Overview > Predefined Filters> No Filter

      • Click square to select all > Move to Historical

   b. Deselect the test from any QC Definitions

      • Select QC - go through predefined QC list and remove UCFP

   c. Deselect the test from any Calibrator Definitions

      •Select Calibration > Calibrator Definition

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  d. Select **Export & Delete button** in the Calibration >Chemistry window to remove any calibration data for the selected test

   i. Exporting and Deleting Calibration Chemistry Reports

1. Select **Calibration >Chemistry > Export and Delete**

2. Select a date filter option:

3. For all available data, select **All Dates**

4. For data from a range of dates, select **Date Range** and specify the range to be exported.

5. Select the assay to be exported from the drop-down menu.

6. Select file name and location

7. Select Ok

4. Make changes to the field(s) to be edited manually

5. Select Save

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FIELD CORRECTION EFFECTIVENESS CHECK

Multiple issues identified in Analytical Parameters (AP Tool) Disks and Test Definition (TDef) Disks

This response form is to confirm receipt of the enclosed Siemens Healthcare Diagnostics Urgent Field Safety Notice CHI21-01.A.OUS dated March 2021 regarding Multiple Issues identified in Analytical Parameters (AP Tool) Disks and Test Definition (TDef) Disks on the ADVIA Chemistry Systems. Please read each question and indicate the appropriate answer.

Return this completed form to Siemens Healthcare Diagnostics as per the instructions provided at the bottom of this page.

1. I have read and understood the Urgent Field Safety Notice instructions provided in this letter. Yes ☐   No ☐

Name of person completing questionnaire: _____

Title: _____

Institution: _____ Instrument Serial Number: _____

Street: _____

City: _____ State: _____

Phone: _____ Country: _____

Please send a scanned copy of the completed form via email to XXXX@XXXX

Or to fax this completed form to the Customer Care Center at XXXXXX

If you have any questions, contact your local Siemens Healthineers technical support representative.

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