SIEMENS

Urgent Field Safety Notice

4011

March 2014

IMMULITE®
IMMULITE® 1000
IMMULITE® 2000
IMMULITE® 2000 XPi

Dilution Protocol for Androstenedione Samples >5.5 ng/mL

Reason for Correction

In December 2013 Siemens Healthcare Diagnostics issued Urgent Field Safety Notice #4008 for IMMULITE®/IMMULITE® 1000 and IMMULITE® 2000/IMMULITE® 2000 XPi Androstenedione assays, advising customers to verify Androstenedione samples with values >5.5 ng/mL using an alternate method.

This communication provides supplementary information regarding the dilution of Androstenedione samples with values >5.5 ng/mL as an alternative to verifying samples with an alternate Androstenedione method. Table 3 provides confirmation of linearity up to 5.5 ng/mL as stated in UFSN #4008.

Table 1. IMMULITE Systems Affected Products

Assay	Test Code	Catalog Number	Siemens Material Number (SMN)	Lot Number
IMMULITE/IMMULITE 1000 Androstenedione	AND	LKAO1	10381158	409 and above
IMMULITE 2000/IMMULITE 2000 XPi Androstenedione	AND	L2KAO2	10381188	314 and above

Siemens has developed a temporary dilution protocol for Androstenedione samples with values exceeding the current upper limit of the reportable range of the assay (5.5 ng/mL). Refer to Table 2 for data demonstrating the percentage recovery to the original dose when using the dilution protocol. While the data provided in Table 2 was derived from testing with the IMMULITE 2000/IMMULITE 2000 XPi Androstenedione assay, the IMMULITE/IMMULITE 1000 Androstenedione assay has a similar performance.

The dilution protocol developed by Siemens uses a pooled sample of multiple normal male serum samples collected in Serum Separator Tubes (SST). Storage and handling of these samples was in accordance with the IMMULITE Systems Androstenedione Instructions for Use (IFU). Refer to Table 2 for data demonstrating the percentage recovery to the original dose when diluting samples with values > 5.5 ng/mL.

Table 2. IMMULITE 2000/IMMULITE 2000 XPi Androstenedione Recovery to Original Dose for Samples with Doses Greater Than 5.5 ng/mL Using a 1 in 4 Dilution

Sample	Expected Dose	Observed Mean Dose	Observed Mean Recovery
Sample 1	7.8	7.8	99%
Sample 2	9.5	9.1	96%
Sample 3	10.2	9.8	97%
Sample 4	6.6	7.1	107%
Sample 5	7.1	7.3	104%
Sample 6	13.5	13.6	101%
Sample 7	6.1	6.5	107%
Sample 8	10.0	11.2	112%

Androstenedione Patient Dilution Protocol

NOTE: This dilution protocol has only been validated for use with the IMMULITE Systems Androstenedione assays.

1. Pre-tested normal male serum samples that have an Androstenedione value from 0.5 to 1.5 ng/mL may be used with this protocol. Male serum samples should be collected and processed per the Sample Handling section of the IMMULITE Systems Androstenedione IFUs.
2. Prepare a manual 1 in 4 dilution of the patient sample using 1 part sample to 3 parts normal male serum.
3. Run the sample on the instrument to obtain a result. Do not enter a dilution factor into the instrument software.
4. Correct for the dilution factor and allow for any dose in the diluent by using the following equation:

   Calculated Original Sample Dose = (dose diluted patient sample) - (¾ dose normal male serum) * 4

   or alternatively

   Result = (X - 3/4Y) * 4 where X = dose of diluted sample reported by instrument and Y = dose normal male serum.

5. Report the calculated original sample dose.

Example of Calculation: Dose of diluted patient sample (X) = 2.52 ng/mL. Dose of normal male serum (Y) = 0.66ng/mL.

Calculated neat dose = (2.52 - (0.66 * ¾)) * 4
= (2.52-0.50) * 4
= 2.02 * 4
= 8.08 ng/mL

Refer to Table 3 for data demonstrating that the IMMULITE 2000/IMMULITE 2000 XPi Androstenedione assays are linear up to 5.5 ng/mL, as stated in UFSN #4008. While the data provided in Table 3 was derived from testing with the IMMULITE 2000/IMMULITE 2000 XPi Androstenedione assay, the IMMULITE/IMMULITE 1000 Androstenedione assay has a similar performance.

Table 3. Sample Linearity with IMMULITE 2000/IMMULITE 2000 XPi Androstenedione

Sample 1			
Dilution	**Observed Dose**	**Expected Dose**	**% Recovery**
9 in 10	5.76	5.76	100%
8 in 10	4.61	4.61	100%
7 in 10	3.98	4.03	99%
6 in 10	3.46	3.46	100%
5 in 10	2.72	2.88	94%
4 in 10	2.00	2.30	87%
3 in 10	1.65	1.73	96%
2 in 10	1.04	1.15	90%
1 in 10	0.53	0.58	93%
0.5 in 10	0.28	0.29	97%
Sample 2			
Dilution	**Observed Dose**	**Expected Dose**	**% Recovery**
5 in 10	6.07	6.07	100%
4 in 10	4.36	4.86	90%
3 in 10	3.57	3.64	98%
2 in 10	2.25	2.43	93%
1 in 10	1.16	1.21	96%
0.5 in 10	0.56	0.61	93%

Risk to Health

Siemens has determined that diluting specimens greater than 5.5 ng/mL, according to the provided protocol, poses no health risk.

Actions to be Taken by the Customer

Patient values >5.5 ng/mL must be verified using one of the options outlined below:

- Dilute patient samples with values >5.5 ng/mL using the Siemens-validated dilution protocol described in this letter.
- Alternatively report the patient value as >5.5 ng/mL.
- Verify patient values >5.5 ng/mL using an alternate method.

In addition, please perform the following:

- Please review this letter with your Medical Director.
- Complete and return the Field Correction Effectiveness Check attached to this letter within thirty (30) days.

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 has caused. If you have any questions, please contact your Siemens Customer Care Center or your local Siemens technical support representative.

Siemens Healthcare Diagnostics
511 Benedict Ave.
Tarrytown, NY 10591
www.siemens.com/diagnostics

FIELD CORRECTION EFFECTIVENESS CHECK

Dilution Protocol for Androstenedione Samples >5.5 ng/mL

This response form is to confirm receipt of the enclosed Siemens Healthcare Diagnostics Urgent Field Safety Notice # 4011 dated March 2014 regarding Dilution Protocol for Androstenedione Samples >5.5 ng/mL. Please read the question and indicate the appropriate answer. Fax this completed form to Siemens Healthcare Diagnostics at the fax number provided at the bottom of this page.

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 fax this completed form to the Customer Care Center at (###) ###-####. If you have any questions, contact your local Siemens technical support representative.