

IMMULITE[®]
IMMULITE[®] 1000
IMMULITE[®] 2000
IMMULITE[®] 2000 XPi

IMMULITE Calcitonin Control Module 0019 Incorrect Expiration Date in IFU

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

Table 1. IMMULITE Systems Affected Product

Product	Catalog Number	Siemens Material Number (SMN)	Lot Number	IFU Reference
Calcitonin Control Module	LCLCM	10385383	0019	PILCLCM-11 {24}, 2014-02-19 PINLCLCM-11{24}, 2014-02-19 PIELCLCM-9{24}, 2014-02-19

Reason for Correction

Siemens Healthcare Diagnostics has identified a typographical error in the IMMULITE[®] Calcitonin Control Module Instructions For Use (IFU) listed in Table 1. The published expiration date in the IFU is 2017-10. The correct expiration date for IMMULITE Calcitonin Control Module lot 0019 is 2017-01.

The control box, control vial, and control barcodes all contain the correct expiration date.

Risk to Health

The overall risk to health is negligible to nonexistent. Siemens is not recommending a laboratory look back as a result of this issue.

Actions to be Taken by the Customer

- Please review this letter with your Medical Director.
- Discard the IMMULITE Calcitonin Control Module IFU listed in Table 1. Refer to Table 2 for the list of revised IFU versions. Navigate to the Siemens Document Library for the current version of the IFU: <https://www.healthcare.siemens.com/doclib>.

Table 2. IMMULITE Systems Calcitonin Control Module Instructions For Use

Product	IFU Reference (Correct Expiration Date)
Calcitonin Control Module	PILCLCM-25, 2014-07-08 PINLCLCM-12{25}, 2014-07-08 PIELCLCM-10{25}, 2014-07-08

- Check the system for the expiration date. If the expiration date is correct, no further action is required.
- If the expiration date is incorrect, refer to the Additional Information section in this communication for instructions on how to change the expiration date.
- Complete and return the Field Correction Effectiveness Check attached to this letter within 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 may cause. If you have any questions, please contact your Siemens Customer Care Center or your local Siemens technical support representative.

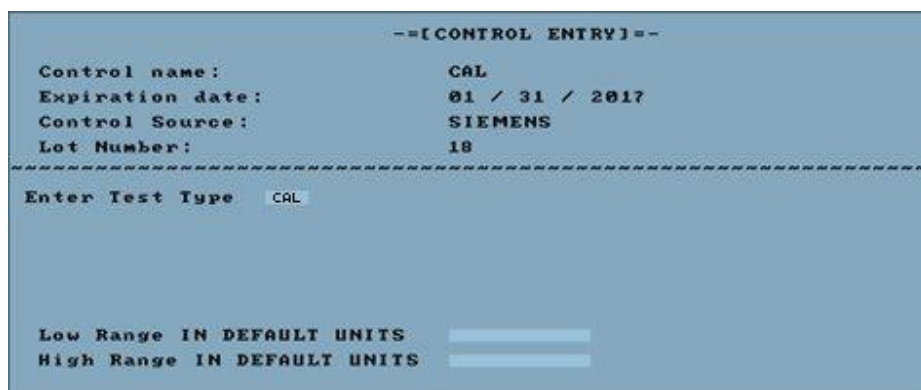
Additional Information

IMMULITE DOS Editing Control Information

Refer to the IMMULITE Operator's Guide for DOS (600882-0002 Rev. A) for more information.

1. Select Data Entry and Control Entry. The Control Entry screen will appear.
2. From the list of existing controls, select the Calcitonin control to edit.
3. To modify the current definitions, type the correct expiration date in the expiration date field, then press **Enter**. Refer to Figure 1.

Figure 1. Control Entry screen



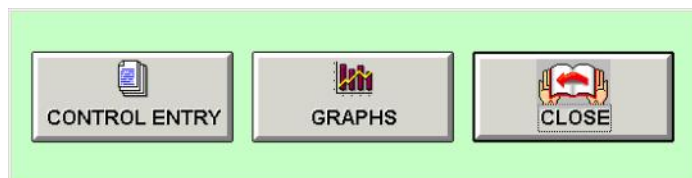
4. When complete, press **Enter** to save changes to the Control Information screen.

IMMULITE/IMMULITE 1000 Windows Editing Control Information

Refer to the IMMULITE Operator's Guide for Windows (600881-002 Rev. A) for more information.

1. Select the **QC** button located on the horizontal toolbar. Refer to Figure 2.

Figure 2. Control Entry



2. Select the **CONTROL ENTRY** button.
3. Select the desired control using the drop-down arrow in the **Control Name** field.
4. Select the lot number using the drop-down arrow in the **Control Lot #** field.
5. Select the **EDIT CONTROL** button.
6. Click in the **Expiration Date** field using the mouse. A pop-up calendar displays. Refer to Figure 3.

Figure 3. Pop-Up Expiration Date Calendar



7. Use the arrow keys to select the month and year.
8. Click on a date.
9. Select **OK**.
10. Select the **CANCEL CHANGES** button to cancel the information.
11. Select the **SAVE CONTROL** button to save the new information. Refer to Figure 4.

Figure 4. Control Saved Message



12. Select **OK**.

IMMULITE 2000/IMMULITE 2000 XPi Editing Control Information

Refer to the IMMULITE 2000/2000 XPi Operator's Guide (601005-0004 Rev. A) for more information.

1. Navigate to the Control Range Entry screen, and then select the QC, then **Data Entry** menu buttons.
2. Click in the **Expiration Date** field using the mouse. A pop-up calendar displays.
3. Select the expiration date from the calendar pop-up and select the **OK** button.
4. Edit the expiration date in the Accession Num field to match the month and year of the new expiration date. The accession number is in the following form.

~C identifier = 2 characters

Control Name = 6 characters for non Bio-Rad controls, 4 characters for Bio-Rad controls

Control Lot# = 3 characters for non Bio-Rad controls, 5 characters for Bio-Rad controls

Expiration date = 6 characters in the form YYYYMM

Control Level = 1 character

In the following sample accession number, the expiration date is 201710 or October, 2017:

~CCAL^^0192017102

To change the expiration date to 2017-01 or January, 2017:

~CCAL^^0192017012

5. If there are multiple levels for the control, the accession number must be changed for each level. Select the level and edit the accession number as described above.
6. Select the Save button to save the modified control. The message box will appear confirming that you want to change the expiration date to the new date. Select **Yes**. Another message box will appear confirming the change to the accession number.
7. Select **Yes** to save the modified control. An informational message will appear indicating the control was successfully saved.

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FIELD CORRECTION EFFECTIVENESS CHECK

IMMULITE Calcitonin Control Module 0019 Incorrect Expiration Date in IFU

This response form is to confirm receipt of the enclosed Siemens Healthcare Diagnostics Urgent Field Safety Notice #4011 dated October 2014 regarding IMMULITE Calcitonin Control Module 0019 Incorrect Expiration Date in IFU. 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.

Ref: IMC 14-12 [C/2955]

I have read and understood the Urgent Field Safety Notice instructions provided in this letter.	Yes <input type="checkbox"/>	No <input type="checkbox"/>
Signed:	Date:	

Name of person completing questionnaire: Block capitals	
Title:	
Institution:	Instrument Serial Number:
Street:	
City:	Post Code:
Phone:	Email:

It is important that your organisation takes the actions detailed in the FSN and replies immediately using the FIELD CORRECTION EFFECTIVENESS CHECK attached to this FSN. Your organisations reply is evidence which, Siemens Healthcare, and subsequently the MHRA, needs to monitor the progress of the FSN. Without your reply Siemens Healthcare cannot verify the completeness of the FSN and the MHRA may need to issue a Medical Device Alert.

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