

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

IMMULITE IGF-I Control Module Revised Control Targets and Ranges

Our records indicate that you have received the following:

Table 1.

Product	Catalog Number	Siemens Material Number (SMN)	Lot Number
IMMULITE IGF-I Control Module	LGCOCM	10385387	025L 0025 0026

Reason for Voluntary Correction

Siemens Healthcare Diagnostics confirmed a negative bias against the mean values obtained with the LGCOCM control lot 0026 level 2 when used with IMMULITE[®]/IMMULITE[®] 1000 (LKGF1, SMN 10381403) kit lots 322 and above. Siemens Healthcare Diagnostics also confirmed an increase of mean values obtained with the LGCOCM control lots 0025, 025L, and 0026 when used with IMMULITE[®] 2000/IMMULITE[®] 2000 XPi IGF-I (L2KGF2, SMN 10381448) kit lots 486 and 487.

Refer to Table 2 for revised IMMULITE/IMMULITE 1000 control targets and ranges (ng/mL) for LGCOCM lot 0026 level 2 only.

Table 2. IMMULITE/IMMULITE 1000 Revised Control Targets and Ranges (ng/mL) for LGCOCM lot 0026 Level 2 Only

Level	Previous	Revised for LKGF1 kit lots 322 and above		
	Mean	Mean	SD	2SD Range
LGCOC20026	252	237	23.7	190 – 284

Patient results remain unchanged.

Siemens Healthcare Diagnostics Inc.

511 Benedict Ave.
Tarrytown, NY 10591

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Refer to Table 3 for revised IMMULITE 2000/IMMULITE 2000 XPi control targets and ranges (ng/mL) for LGCOCM lots 0025, 025L, and 0026. The control values are the same for LGCOCM control lots 0025 and 025L.

Table 3. IMMULITE 2000/IMMULITE 2000 XPi Revised Control Targets and Ranges (ng/mL) for LGCOCM lots 0025, 025L, and 0026

Level	No Change for L2KGF2 kit lots 482-485, 488 and above			Revised for L2KGF2 kit lots 486 and 487		
	Mean	SD	2SD Range	Mean	SD	2SD Range
LGCO10025	51	5.1	41 – 46	68	6.8	54 – 82
LGCO20025	198	19.8	158 – 238	231	23.1	185 – 277
LGCO10026	58	5.8	46 – 70	70	7.0	56 – 84
LGCO20026	196	19.6	157 – 235	236	23.6	189 – 283

Patient results remain unchanged.

The control revision is limited to IMMULITE 2000/IMMULITE 2000 XPi IGF-I (L2KGF2) kit lots 486 and 487. Previously labeled control targets and ranges have been restored for IMMULITE 2000/IMMULITE 2000 XPi IGF-I (L2KGF2) kit lots 488 and above.

Risk to Health

If quality control results are within the established ranges, reported patient results are acceptable. This issue does not pose a risk to patient health and a review of the previously generated results is not necessary.

Actions to Be Taken by the Customer

Please refer to the revised control targets and ranges for LGCOCM lot 0026 level 2 listed above when using IMMULITE/IMMULITE 1000 IGF-I (L2KGF1) kit lots 322 and above.

Please also refer to the revised control targets and ranges for LGCOCM lots 0025, 025L, and 0026 listed above when using IMMULITE 2000/IMMULITE 2000 XPi IGF-I (L2KGF2) kit lots 486 and 487.

In addition, please perform the following:

- Complete and return the Field Correction Effectiveness Check form attached to this letter within 30 days.
- Keep this letter with your laboratory records.
- Forward this letter to whomever you may have distributed this product.

If you have any questions or need additional information, please contact your Siemens Technical Solutions Center or your local technical support representative.

We apologize for the inconvenience that this situation has caused. Siemens is committed to providing our customers the highest quality assays. Thank you for your patience and continued support.

Trademark Information

IMMULITE is a trademark of Siemens Healthcare Diagnostics.



FIELD CORRECTION EFFECTIVENESS CHECK

IMMULITE IGF-I Control Module Revised Targets and Ranges

This response form is to confirm receipt of the enclosed Siemens Healthcare Diagnostics Urgent Field Safety Notice # 4004 dated October 2012 regarding IMMULITE IGF-I Control Module Revised Targets and Ranges. Please read the question and indicate the appropriate answer. Fax this completed form to Siemens Healthcare Diagnostics at the fax number indicated at the bottom of this page.

I have read and understood the Urgent Field Safety Notice instructions provided in this letter for IMMULITE/IMMULITE 1000 and/or IMMULITE 2000/IMMULITE 2000 XPi. Yes No

Name of person completing questionnaire:

Title:

Institution:

Instrument Serial Number:

Street:

City:

State:

Phone:

PLEASE FAX THIS COMPLETED FORM TO THE TECHNICAL SOLUTIONS CENTER AT
(###) ###-####.

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Tarrytown, NY 10591

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