SIEMENS

Urgent Field Safety Notice

3022-OUS
February 2015

IMMULITE® 2000
IMMULITE® 2000 XPi

GI-MA (CA 19-9) Positive Bias

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

Table 1. IMMULITE 2000/IMMULITE 2000 XPi Affected Product(s)

Assay	Test Code	Catalog Number	Siemens Material Number (SMN)	Kit Lot Number
GI-MA (CA 19-9)	GIM	L2KGI2	10380988	312, 313

Reason for Correction

Siemens Healthcare Diagnostics has confirmed a positive bias with the Bio-Rad Lyphochek® Tumor Marker Plus Control and the Bio-Rad Liquichek™ Tumor Marker Control when used with IMMULITE® 2000/IMMULITE® 2000 XPi GI-MA (CA 19-9) assay kit lots 312 and 313.

The bias in quality control values is the result of the introduction of a new lot of the bead coat antibody (murine monoclonal anti-CA 19-9 antibody) in kit lot 312.

Refer to Tables 2 – 7 for Bio-Rad Lyphochek Tumor Marker Plus Control and Liquichek Tumor Marker Control lots that have been reassigned for IMMULITE 2000/IMMULITE 2000 XPi GI-MA (CA19-9) kit lots 312 and above.

In addition, a greater than expected change in patient sample recovery may be observed when moving from kit lot 311 to kit lots 312 and above. While recovery with patient samples for individual kit lots continues to meet Siemens quality control release specification, kit lot 311 was observed to perform at the lower end of the specification and kit lot 312 at the upper end of the specification, resulting in a greater than expected difference between these two kit lots.

When comparing kit lot 312 with kit lot 311, Siemens observed an average percent bias of 38% (ranging from 30% to 47%) for patient samples recovering from 29.6 to 44.4 U/mL and an average percent bias of 5% (ranging from 1% to 11%) for patient samples recovering from 540 to 660 U/mL. Refer to Figures 1 – 3.

Future kit lots are expected to recover quality control and patient samples similar to kit lot 312.

Risk to Health

The risk to health is related to a delay in testing if laboratories have chosen not to test for more than one month. It is limited to a potential delay in radiographic testing if biochemical testing has indicated a recurrence of disease. If laboratories have continued to test, there is the potential that additional radiographic testing took place. However, this should not pose a risk to health. Siemens does not recommend a look back.

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Actions to be Taken by the Customer

- Please review this letter with your Medical Director.
- If patients were baselined using kit lot 311, consider re-baselining patients with IMMULITE 2000/IMMULITE 2000 XPi GI-MA kit lots 312 and above.
- Refer to Tables 2 – 7 for the revised control targets and ranges for use with IMMULITE 2000/IMMULITE 2000 XPi GI-MA kit lots 312 and above.
- If you determine that a communication is required with your physicians, Siemens has provided an optional template for your use. You may adapt this to your needs or simply complete the highlighted sections.
- 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

Refer to Tables 2 – 7 for Bio-Rad Lyphochek Tumor Marker Plus Control and Liquichek Tumor Marker Control lots that have been reassigned for the IMMULITE 2000/IMMULITE 2000 XPi GI-MA (CA 19-9) assay. Bio-Rad lists assigned values as “Lots 312 and above” in the insert sheet and Unity reports.

Table 2. Revised Targets and Ranges for Bio-Rad Lyphochek Tumor Marker Plus Control Lot 54560 Applicable to IMMULITE 2000/IMMULITE 2000 XPi GI-MA Kit Lots 312 and Above

Original		Revised (Kit Lots 312 and Above)		
Level	**Target (U/mL)**	**Target (U/mL)**	**SD (U/mL)**	**3SD Range (U/mL)**
54561	21.8	26.0	2.11	19.7 – 32.3
54562	69.3	80.9	9.54	52.2 – 110
54563	216	234	22.7	166 – 302

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Table 3. Revised Targets and Ranges for Bio-Rad Lyphochek Tumor Marker Plus Control Lot 54580 Applicable to IMMULITE 2000/IMMULITE 2000 XPi GI-MA Kit Lots 312 and Above

Original		Revised (Kit Lots 312 and Above)		
Level	**Target (U/mL)**	**Target (U/mL)**	**SD (U/mL)**	**3SD Range (U/mL)**
54581	24.3	31.0	2.51	23.5 – 38.5
54582	77.5	114	13.5	73.7 – 154
54583	256	357	34.6	253 – 461

Table 4. Revised Targets and Ranges for Bio-Rad Lyphochek Tumor Marker Plus Control Lot 54590 Applicable to IMMULITE 2000/IMMULITE 2000 XPi GI-MA Kit Lots 312 and Above

Original		Revised (Kit Lots 312 and Above)		
Level	**Target (U/mL)**	**Target (U/mL)**	**SD (U/mL)**	**3SD Range (U/mL)**
54591	27.2	41.4	3.35	31.3 – 51.4
54592	84.2	122	14.4	78.7 – 165
54593	279	394	38.3	280 – 509

Table 5. Revised Targets and Ranges for Bio-Rad Liquichek Tumor Marker Control Lot 19960 Applicable to IMMULITE 2000/IMMULITE 2000 XPi GI-MA Kit Lots 312 and Above

Original		Revised (Kit Lots 312 and Above)		
Level	**Target (U/mL)**	**Target (U/mL)**	**SD (U/mL)**	**3SD Range (U/mL)**
19961	12.5	21.6	1.75	16.4 – 26.9
19962	65.9	114	13.4	73.4 – 154
19963	218	371	36.0	263 – 478

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Table 6. Revised Targets and Ranges for Bio-Rad Liquichek Tumor Marker Control Lot 19970 Applicable to IMMULITE 2000/IMMULITE 2000 XPi GI-MA Kit Lots 312 and Above

Original		Revised (Kit Lots 312 and Above)		
Level	**Target (U/mL)**	**Target (U/mL)**	**SD (U/mL)**	**3SD Range (U/mL)**
19971	11.0	18.0	1.45	13.6 – 22.3
19972	69.7	107	12.7	69.3 – 145
19973	224	339	32.9	241 – 438

Table 7. Revised Targets and Ranges for Bio-Rad Liquichek Tumor Marker Control Lot 19980 Applicable to IMMULITE 2000/IMMULITE 2000 XPi GI-MA Kit Lots 312 and Above

Original		Revised (Kit Lots 312 and Above)		
Level	**Target (U/mL)**	**Target (U/mL)**	**SD (U/mL)**	**3SD Range (U/mL)**
19981	12.0	21.0	1.70	15.9 – 26.2
19982	65.9	114	13.4	73.6 – 154
19983	198	314	30.5	223 – 405

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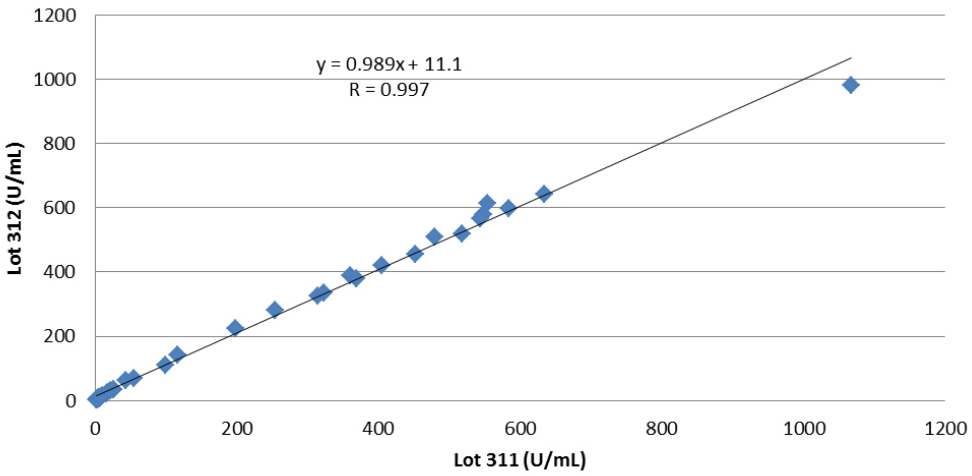
Comparison of Kit Lots 311 vs. 312

Refer to Figures 1 – 3 for correlation and bias plots of the IMMULITE 2000/IMMULITE 2000 XPi GI-MA (CA 19-9) kit lot 311 versus kit lot 312.

Figure 1. Correlation of IMMULITE 2000/IMMULITE 2000 GI-MA (CA 19-9) (U/mL) Kit Lot 311 vs. Kit lot 312



Lot 312 = 0.989 x Lot 311 + 11.1 U/mL
r = 0.997, n = 39

Figure 2. Bias Plot of IMMULITE 2000/IMMULITE 2000 GI-MA (CA 19-9) (U/mL) Kit Lot 311 vs. Kit lot 312

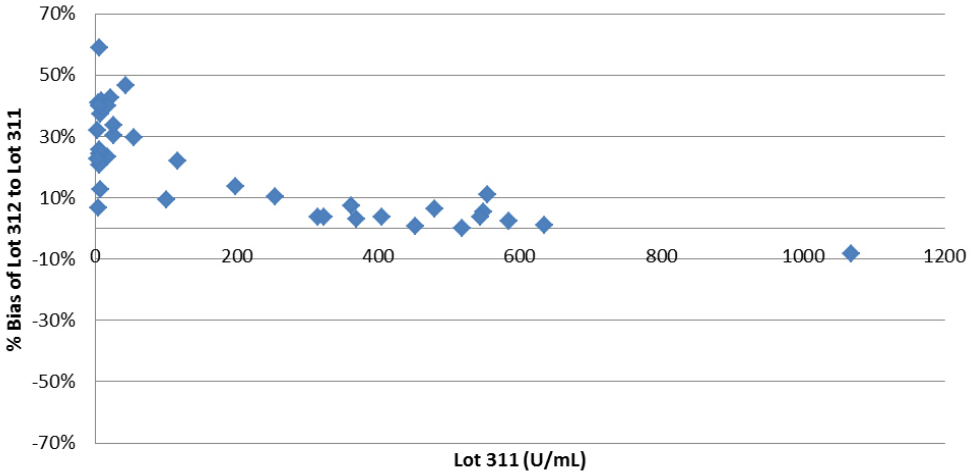


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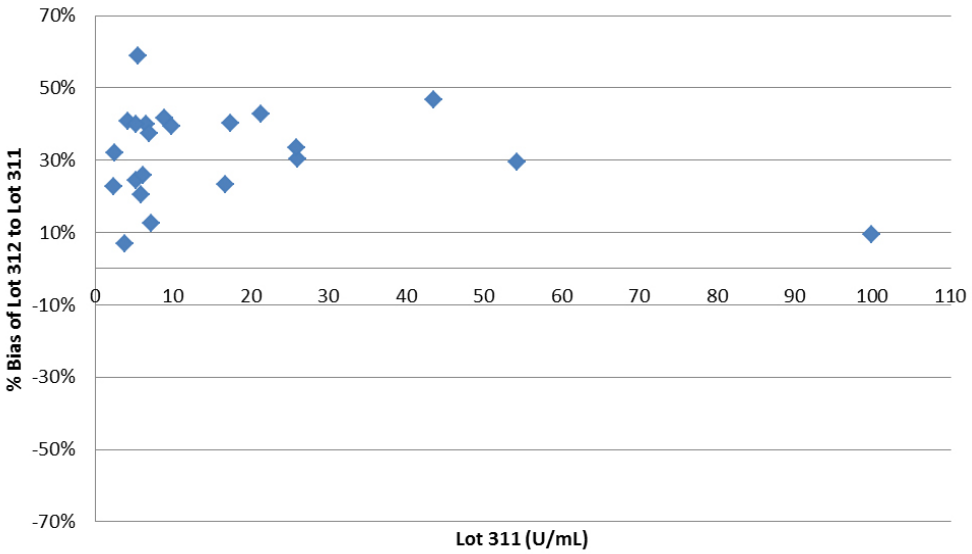
Figure 3. Bias Plot of IMMULITE 2000/IMMULITE 2000 GI-MA (CA 19-9) (U/mL) Kit Lot 311 vs. Kit lot 312 Looking at Samples From 0 – 100 U/mL



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FIELD CORRECTION EFFECTIVENESS CHECK

IMMULITE 2000/IMMULITE 2000 XPi GI-MA (CA 19-9) Positive Bias

This response form is to confirm receipt of the enclosed Siemens Healthcare Diagnostics Urgent Field Safety Notice # 3022-OUS dated February 2015 regarding IMMULITE 2000/IMMULITE 2000 XPi GI-MA (CA 19-9) Positive Bias. 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.

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[Laboratory Letterhead]

Informational Physician Letter

Date

Subject: GI-MA (CA 19-9)

Dear Dr. _____,

We are writing to inform you of an Urgent Field Safety Notice our laboratory has received from Siemens Healthcare Diagnostics regarding recent GI-MA (CA 19-9) results.

If you have ordered GI-MA (CA19-9) during dates when your laboratory began using the affected lot #, the GI-MA (CA 19-9) results for your patient(s) may have been higher than the expected GI-MA (CA 19-9) concentration. This may have been due to a reagent change in the Siemens assay and not reflective of a de novo change of GI-MA (CA 19-9) in your patient.

We ask that you consider re-baselining GI-MA (CA19-9) values for your patient(s) in cases where the following events have occurred:

1. You are monitoring GI-MA (CA 19-9) values in your patient(s) and have not yet ordered GI-MA (CA 19-9) during the dates listed above.
2. You have ordered GI-MA (CA 19-9) for your patient(s) during the dates listed above and have observed an increase not meeting overall clinical expectations.

We apologize for the inconvenience this has caused you and your patient(s), and are here to answer any questions or concerns you may have.

Sincerely,

Insert Laboratory Medical Director Info