SIEMENS

Urgent Field Safety Notice

4006

June 2013

PSA Assays for the Following Systems:

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

PSA Positive Bias to WHO 96/670

Reason for Recall

Siemens Healthcare Diagnostics has confirmed an overall average positive bias of approximately 20% – 23% across the assay range relative to WHO 96/670 with the IMMULITE Systems PSA assays. This positive bias is observed in patient values and the Siemens Tumor Marker controls (TMCO). Other commercially available controls may show this bias. Refer to Table 2 for approximate percent bias for specific concentrations.

Our records indicate that you have or may have received the following product:

Table 1. IMMULITE/IMMULITE 1000/IMMULITE 2000/IMMULITE 2000 XPi Affected Lots

Assay	Test Code	Catalog Number	Siemens Material Number (SMN)	Lot Number
IMMULITE/IMMULITE 1000 PSA	PSA	LKPS1	10380960	422, 423, 424, 425, 426
IMMULITE/IMMULITE 1000 PSA	PSA	LKPS5	10380949	
IMMULITE/IMMULITE 1000 PSA	PTS	LKPTS1(D)	10706279	D103, D104
IMMULITE 2000/IMMULITE 2000 XPi PSA	PSA	L2KPS2	10380986	377, 378, 379, 380, 381, 382, 383, 384
IMMULITE 2000/IMMULITE 2000 XPi PSA	PSA	L2KPS6	10380996	
IMMULITE 2000/IMMULITE 2000 XPi PSA	PTS	L2KPTS2(D)	10706281	D104, D106, D107, D108, D109
IMMULITE 2000/IMMULITE 2000 XPi PSA	PTS	L2KPTS6(D)	10706282	

Table 2. Approximate Percent Bias for Specific Concentrations

Expected Dose (ng/mL)	Mean Recovery	Mean % Bias	Lower 95th CI	Lower 95% Bias	Upper 95th CI	Upper 95% Bias
1.0	1.3	26%	1.2	19%	1.3	33%
2.0	2.5	23%	2.3	15%	2.6	30%
5.0	6.1	23%	5.7	13%	6.6	32%
10.0	13.0	30%	12.5	25%	13.6	36%
25.0	31.8	27%	30.2	21%	33.3	33%
50.0	57.0	14%	53.8	8%	60.3	20%
75.0	83.3	11%	78.2	4%	88.4	18%
150	152	1%	138	-8%	165	10%

The positive bias was determined to begin with kit lots released in February 2012:

- IMMULITE/IMMULITE 1000 kit LKPS lot 422 and LKPTS lot D103.
- IMMULITE 2000/IMMULITE 2000 XPi kit lots L2KPS 377 and L2KPTS lot D104.

The root cause of this bias is under investigation.

Risk to Health

A positive bias in PSA results may impact clinical interpretation of test results. In cases where the true values are near the cut off, the bias may increase the likelihood of a decision to initiate additional diagnostic tests (including prostatic biopsy). The risk of unnecessary biopsy is mitigated by the fact that the clinician/patient decision for prostatic biopsy is based on a number of factors in addition to a PSA result, including patient age, digital rectal exam findings, clinical signs or symptoms or co morbidities such as prostatic inflammation or infection.

Look Back

The decision to perform a biopsy is usually undertaken within a short period of time from the assay result. Therefore a conservative look back period can be limited to two months of test results. For results that were recorded as abnormal in your facility please notify your physicians of this communication. Actions by the clinician may be to reconsider a scheduled biopsy based on the test result taking into account the other factors that made biopsy a consideration.

Clinical decisions are the responsibility of the patient's caregiver. The positive bias does not negate the necessity of a biopsy if other findings support the decision.

Actions to be Taken by the Customer

Discontinue use of and discard the kits remaining in inventory. There are no replacement PSA kits available at this time. The projected date of availability is the week of July 8, 2013.

Please contact your local Siemens representative for assistance with determining appropriate PSA testing solutions for your laboratory.

In addition, please perform the following:

- Keep this letter with your laboratory records.
- Forward this letter to whomever you may have distributed these products.

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

IMMULITE is a trademark of Siemens Healthcare Diagnostics.