# Siemens Healthcare Diagnostics, Rapid Gram Negative Combo Panels - May Produce Incorrect Results

**Recall Class:** Class I

**Date Recall Initiated:** October 17, 2014

**Devices:**

- Rapid Neg BP Combo Panel Type 3 and Rapid Neg Urine Combo Panel Type 1

| Panel | Catalog Number | Siemens Material Number (SMN) | Lot Number |
|---|---|---|---|
| Rapid Neg BP Combo Panel Type 3 | B1017-117 | 10444632 | 2014-12-10<br>2015-02-27<br>2015-06-23 |
| Rapid Neg Urine Combo Panel Type 1 | B1017-167 | 10444652 | 2014-11-01<br>2015-01-03<br>2015-02-14<br>2015-03-21<br>2015-05-20<br>2015-06-18 |

| | | | |
|---|---|---|---|
| | | | 2015-07-18<br>2015-08-11 |

- Manufacturing dates: November 1, 2013 – August 11, 2014
- Distribution dates: December 2013 – September 2014

**Use:** These devices can identify certain gram negative bacteria and measure how these bacteria (*Enterobacteriaceae*, *Acinetobacter* species and *Pseudomonas aeruginosa*) respond to antibiotics such as Aztreonam, Cefotaxime, Ceftazidime, and Ceftriaxone in the laboratory. The results can help health care providers select the correct antibiotic treatment for a patient.

**Recalling Firm:**
Siemens Healthcare Diagnostics, Incorporated.
2040 Enterprise Boulevard
West Sacramento, California 95691

**Reason for Recall:** Incorrect test results may occur for the following antibiotics: Aztreonam, Cefotaxime, Ceftazidime, and Ceftriaxone. The test may report certain bacteria as sensitive to one of these antibiotics when the bacteria are actually resistant. Using these recalled devices may cause ineffective patient treatment, and in rare instances may contribute to death.

**Public Contact:** Customers who need additional assistance should contact the Siemens Customer Care Center at 1-800-988-2477 (24 hours a day, 7 days a week) or their local Siemens Technical Support Representative.

**FDA District:** San Francisco District Office

**More Information about this Recall:**
On October 17, 2014 and again on November 7, 2014 the firm sent Urgent Medical Device Recall letters to their customers stating the problem and the steps to be taken.
Customers who have these recalled devices in their inventory should:

- Stop using the recalled devices.
- Discard any remaining products in inventory.
- Complete and return the Field Correction Effectiveness Check that is attached to the Urgent Medical Device Recall letter.
- Forward the Urgent Medical Device Recall letters to others who may have received the recalled devices.

The firm’s second letter included the following information:

The firm is unsure when the increase in false test results for the Rapid Gram Negative Combo Panels may have occurred or what caused the false results.

- Combo Panel lots, distributed prior to those listed in the October 17, 2014 Urgent Medical Device Recall letter, may have produced incorrect readings.
- The firm will not replace Rapid Gram Negative Combo Panels because they are no longer being marketed.
- The identification of the gram negative bacterial species is not affected by the recall.
- The recall does not affect antimicrobial susceptible testing or identification on Dried Overnight Gram Negative panels.
- Customers should discuss this recall with their medical directors and the need to review previous test results, conduct patient follow-up, and/or repeat testing by another panel type if patient samples are still available.
- Customers do not have to complete a new Field Correction Effectiveness Check if previously submitted.

**About Class I Recalls**

Class I recalls are the most serious type of recall and involve situations in which there is a reasonable probability that use of these products will cause serious adverse health consequences or death.

Health care professionals and consumers may report adverse reactions or quality problems they experienced using these products to MedWatch: The FDA Safety Information and Adverse Event Reporting Program either online, by regular mail or by FAX.

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