

## Urgent Field Safety Notice

VC-15-11.A.OUS

September 2015

**Dimension Vista® Systems  
LOCI Progesterone (K6464 SMN 10461743)  
Lot 15163BA, E130 Math Errors**

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Our records indicate that your facility received the following product lot:

**Table 1. Dimension Vista® PROG**

Assay	Catalog Number	Siemens Material Number (SMN)	Lot Number
PROG	K6464	10461743	15163BA

### Reason for Field Action

Siemens Healthcare Diagnostics has determined that Dimension Vista® LOCI Progesterone (PROG) lot 15163BA produces E130 Math Errors on QC and patient sample results following calibration. Thus, all QC and patient sample results are suppressed. Siemens is recalling PROG lot 15163BA as a result of this issue.

### Risk to Health

Results are not generated when this issue occurs. The potential exists for a delay in testing. The overall risk to health of a possible delay in reporting progesterone values as a result of this issue is negligible to non-existent.

### Actions to be taken by Customer

Please do the following:

- Discontinue use and discard your remaining inventory of the reagent lot listed in Table 1.
- Indicate your replacement product needs on the attached Field Correction Effectiveness Check Form and fax the form to your local Siemens technical support representative within 30 days. Siemens will replace any unused inventory of the affected lot at no charge.

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 local Siemens technical support representative.

**FIELD CORRECTION EFFECTIVENESS CHECK**  
**Dimension Vista® Systems**  
**Progesterone (PROG) (K6464 SMN 10461743)**  
**Lot 15163BA, E130 Math Errors**

This response form is to confirm receipt of the enclosed Siemens Healthcare Diagnostics Urgent Field Safety Notice Letter Number VC-15-11.A.OUS dated September 2015 regarding PROG, E130 Math Errors. Please read each 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.

1. I have read and understood the Urgent Field Safety Notice instructions provided in this letter. Yes  No

2. Do you now have any of the noted product on hand? Please check inventories before answering. Yes  No

If the answer to the question above is yes, please complete the table below to indicate the quantity of affected product in your laboratory and replacement product required.

Dimension Vista® PROG (K6464, SMN 10461743)	Quantity of Affected Product in inventory that has been discarded	Replacement Quantity Required
Lot # 15163BA		

Name of person completing questionnaire: \_\_\_\_\_

Title: \_\_\_\_\_

Institution: \_\_\_\_\_

Instrument Serial Number: \_\_\_\_\_

Street: \_\_\_\_\_

City: \_\_\_\_\_

State: \_\_\_\_\_

Phone: \_\_\_\_\_

Country: \_\_\_\_\_

Customer Sold To #: \_\_\_\_\_

Customer Ship To #: \_\_\_\_\_

Please fax this completed form to your local Siemens technical support representative. If you have any questions, contact your local Siemens technical support representative.