SIEMENS

Urgent Field Safety Notice

November 25, 2008

Dimension® Clinical Chemistry System

HM Reaction Vessels (RXV1A) Physical Defect

Our records indicate that your laboratory uses HM Reaction Vessels (RXV1A) on the Dimension® clinical chemistry system. Siemens has confirmed a low frequency defect in the molding of the HM Reaction Vessels that may result in a hole in the bottom portion of the vessel (please refer to Figure 1 in the attachment). We have determined that the issue is related to a molding defect affecting a single cavity, 7G, of a multi-cavity mold. There are a total of 10 lots that have the potential to exhibit the defect: NC16-182-08, NC16-189-08, NC16-196-08, NC16-203-08, NC16-210-08, NC16-217-08, NC16-224-08, NC16-231-08, NC16-238-08, and NC16-245-08.

Use of the defective reactions vessels could result in leakage of the reagent with subsequent test report messages such as Abnormal Assay or Abnormal Reaction for HM methods (i.e., CCRP, CTNI, FERR, FT4, FPSA, HCG, LHCG, LMMB, LPBN, LTNI, MMB, MPO, MYO, PBNP, TPSA, and TSH) and Below Assay Range for ACMIA therapeutic drug monitoring (TDM) methods (i.e., CSA, CSAE, DGNA, DGTX, and TACR). Additionally, while extremely unlikely, it is possible to obtain a falsely depressed TDM result without generating a Below Assay Range test report message. Please review this situation with your laboratory director to determine the need to review previously reported TDM results. Delta checks in the laboratory and trending in the patient's medical record may be useful for evaluating prior patient TDM results.

Please immediately examine your inventory of HM Reaction Vessels to determine if you have any of the affected lots. Using the attached instructions, please examine at least one vessel from each bag of affected product to determine if the vessels were molded in the 7G cavity. If 7G is imprinted on the flange of the vessel, discard the entire bag. In addition, please empty the HM reaction vessel holder and track on all Dimension® systems in your laboratory and discard the vessels.

A no-charge order has already been placed so that you will receive one bag of replacement HM Reaction Vessels shortly. Please contact your Siemens Customer Service Center at 800-241-0420 to request additional no-charge replacement based on examination of your current inventory. If possible, please have the original purchase order number (PO) from your RXV1A order for the affected lot(s) to expedite processing of the product replacement.

We apologize for the inconvenience that this situation has caused. If you have any technical questions regarding this information, please contact the Siemens Technical Solution Center at 800-441-9250. Please forward this notification to anyone to whom you may have distributed this product.

Siemens Healthcare Diagnostics Inc.

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[800-441-9250]
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Attachment

1. Please immediately examine your inventory of HM Reaction Vessels to determine if you have any of the affected lots.

NC16-182-08	NC16-217-08
NC16-189-08	NC16-224-08
NC16-196-08	NC16-231-08
NC16-203-08	NC16-238-08
NC16-210-08	NC16-245-08

2. Examine at least one vessel from each bag of affected lot you have in inventory to determine if the vessels were molded in the affected cavity, 7G. The cavity marking is located on the inside of the vessel flange, as indicated the Figure 2 below. Discard any bags containing vessels from cavity 7G.

Figure 1: Location of HM Vessel Defect, if present

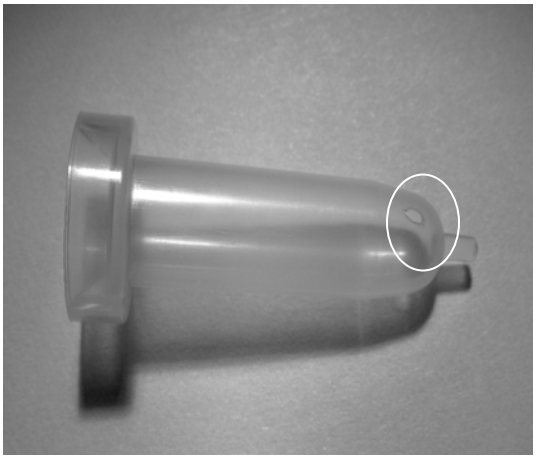

Figure 2: Cavity marking on flange of vessel