El INVIMA informa a los usuarios en general que el Grupo de Vigilancia Epidemiológica ha emitido una comunicación relacionada con un Informe de Seguridad asociado a:

NOMBRE DEL REACTIVO DE DIAGNOSTICO *IN VITRO*	IMMULITE PSA TERCERA GENERACION (sPS)
NO. IDENTIFICACIÓN	I-RD-02-09-13
LOTES DEL REACTIVO DE DIAGNOSTICO IN VITRO	320 y 321
REGISTRO SANITARIO	2007RD-0000412
INDICACIONES Y USO ESTABLECIDOS	Este producto es utilizado para realizara pruebas de inmunología.
NOMBRE DEL FABRICANTE	Siemens Healthcare Diagnostics INC.
DESCRIPCION DEL PROBLEMA	Problemas relacionados con los valores de control de calidad, ya que muestra rangos superiores a lo establecido.
FUENTE	Anexo 1
FECHA DE NOTIFICACION	6 de septiembre de 2013

RECOMENDACIÓN:

En caso de identificar la existencia del producto mencionado anteriormente comuníquese con su proveedor quien determinara las acciones que se llevaran a cabo.

Es importante mantener un estado de alerta, realizando un seguimiento permanente a los productos que se fabrican y/o comercializan en el país, divulgando la información de seguridad respectiva entre los profesionales de la salud que realizan uso de estos recursos tecnológicos.

Para mayor información comuníquese al teléfono 2948700 extensión 3946 en Bogotá, ó al correo electrónico Reactivovigilancia@invima.gov.co

A20838 - High Priority Medical Device Alert

Medical Device Ongoing Action
Updated: September 25, 2013

UMDNS Terms:
- IVD Test Reagent/Kits, Immunoassay, Tumor Marker, Enzyme, Prostate Specific Antigen [18127]

Suggested Distribution:
- Clinical Laboratory/Pathology
- Materials Management

Geographic Regions:
- Argentina
- Bosnia & Herzegovina
- Bulgaria
- Brazil
- Chile
- Colombia
- Costa Rica
- Croatia
- Cyprus
- Czech Republic
- Ecuador
- Egypt
- Germany
- Greece
- Guatemala
- Honduras
- Hungary
- India
- Italy
- Japan
- Lebanon
- Lithuania
- Latvia
- Malaysia
- Mexico
- Nicaragua
- Pakistan
- Panama
- Paraguay
- Philippines
- Portugal
- Russia
- Serbia
- Singapore
- Slovakia
- South Africa
- Spain
- Sri Lanka
- Switzerland
- Tunisia
- U.K.
- United Arab Emirates
- Uzbekistan
- Vietnam

Siemens—IMMULITE and IMMULITE 1000 Third Generation Prostate Specific Antigen Reagent Kits: May Fail Adjustments or Yield Out-of-Range Quality Control Results

Product Identifier:
Third-Generation Prostate Specific Antigen (PSA) Reagent Kits used with the following Immunoassay Systems: (1) IMMULITE, (2) IMMULITE 1000
[Consumable, Capital Equipment]
Kit Test No. sPS; Kit Catalog No. LKUP1; Siemens Material No. 10380956; Kit Lot Nos.: 320, 321

Manufacturer:
- Siemens Healthcare Diagnostics Inc511 Benedict Ave, Tarrytown, NY 10591, United States

Problem: In an August 2013 Urgent Field Safety Notice letter posted by the U.K. Medicines and Healthcare Products Regulatory Agency (MHRA), Siemens states that above kits may contain compromised vials of adjuster reagent (LUPL/H, lot number 0126), potentially leading to failed adjustments and/or quality control values exceeding the established ranges.

Action Needed:
Identify any affected product in your inventory. If you have affected product, verify that you have received the August 2013 Urgent Field Safety Notice and field correction effectiveness check form from Siemens. Siemens states that if the adjustment is successful and quality control results are within the established ranges, the above kits may be used to generate patient results and a review of previously generated results is not necessary. If the adjustment fails and quality control results are out of the established ranges, patient results are not reported and affected kits should be discarded. Contact your Siemens local representative to obtain replacement product. Complete the field correction effectiveness form, and return it to the Siemens technical solutions center using the information on the form. Keep a copy of the Urgent Field Safety Notice letter with your facility's laboratory records, and forward a copy of the letter to any facility to which you have further distributed affected product.

For Further Information:
Siemens Customer Care
Website: Click here

References:

- Great Britain. Medicines and Healthcare Products Regulatory Agency. Siemens Medical Solutions Diagnostics. IVDs, clinical chemistry instrumentation. Immulite & Immulite1000 third generation PSA [online]. London: Department of Health; 2013 Aug 27 [cited 2013 Aug 29]. 1 p. (Field safety notice; reference no. 2013/008/022/601/003). Available from Internet: Click here.

Comment:
- This alert is a living document and may be updated when ECRI Institute receives additional information. In circumstances in which we determine that it is appropriate for customers to repeat their review of an issue (e.g., when additional affected product has been identified), we will post a separate update alert. In other cases, we may add information, such as additional commentary, recommendations, and/or source documents, to the original alert. For additional information regarding the format of this alert, refer to our HDA Format Guide.

Source(s):

- 2013 Aug 29. MHRA FSN. 2013/008/022/601/003
- 2013 Aug 29. MHRA FSN. Reference No. 1109 (includes reply form)
- 2013 Sep 4. Manufacturer. Manufacturer confirmed information provided in source material.
- 2013 Sep 25. BfArM (Germany). 4801/13
- 2013 Sep 25. BfArM (Germany). Reference No. 1109 (includes reply form)