

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 <i>IN VITRO</i>	LPBN PRO-PEPTIDO CEREBRAL N- TERMINAL
NO. IDENTIFICACIÓN	I-RD-03-07-14
LOTE DEL REACTIVO DE DIAGNOSTICO <i>IN VITRO</i>	172
REGISTRO SANITARIO	2009RD-0001332
INDICACIONES Y USO ESTABLECIDOS	Determinación del analito relacionado en muestras procedentes del organismo humano.
NOMBRE DEL FABRICANTE	Siemens Healthcare Diagnostics INC
DESCRIPCION DEL PROBLEMA	Presenta problemas de calibración.
FUENTE	Anexo No 1
FECHA DE NOTIFICACION	21 de Julio de 2014

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

ANEXO 1

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A22705 - High Priority Medical Device Alert

Medical Device

Ongoing Action

Updated: July 21, 2014

UMDNS Terms:

- IVD Test Reagent/Kits, Immunoassay, Cardiac Marker, Protein, Brain Natriuretic Peptide [20692]

Suggested Distribution:

- Clinical Laboratory/Pathology
- Materials Management

Geographic Regions:

- Albania
- Argentina
- Australia
- Austria
- Bosnia Herzegovina
- Brazil
- Bulgaria
- Canada
- Chile
- China
- Colombia
- Croatia
- Cyprus
- Czech Republic
- Denmark
- Egypt
- Estonia
- Finland
- France
- Germany
- Georgia
- Greece
- Hong Kong
- Hungary
- Iceland
- India
- Indonesia
- Iran
- Iraq
- Ireland
- Israel
- Italy
- Japan
- Kazakhstan
- Latvia
- Lithuania
- Lebanon
- Malaysia
- New Caledonia
- The Netherlands
- Norway
- Oman
- Pakistan
- The Philippines
- Poland
- Portugal
- Qatar
- Republic of Yemen
- Republic of Korea

Siemens—BNP Reagents used with ADVIA Centaur CP Systems: Master Curve Card Error May Result in Failed Calibration

Product Identifier:

Brain Natriuretic Peptide (BNP) Reagents used with ADVIA Centaur CP Systems:	Catalog Nos.:	Siemens Material Nos.:	Kit Lots Ending In:
100 Tests	02B1613B	10309044	172
300 Tests	02B16634	10309043	

[Consumable]

Manufacturer:

- Siemens Healthcare 51 Valley Stream Pkwy, Mahwah, PA 19355, United States

Problem: In a June 2014 Urgent Field Safety Notice letter posted by the U.K. Medicines and Healthcare Products Regulatory Agency (MHRA), Siemens states that a master curve card error may occur while the above reagents are being used, potentially resulting in low calibration deviation outside the specified calibration evaluation range. This problem may prevent BNP results from being generated. Siemens states that the master curve card contained in kit lots ending in 172 for the ADVIA Centaur and ADVIA Centaur XP systems are not affected by this problem.

Action Needed:

Identify any affected product in your inventory. If you have affected product, verify that you have received the June 2014 Urgent Field Safety Notice letter and Field Correction Effectiveness Check from Siemens. If a successful calibration is achieved and quality control (QC) results are in range, you can continue to report patient results. However, if you are unable to obtain a successful calibration, Siemens recommends that you switch to an alternative lot of BNP reagent. Discuss the information in the letter with your medical director. Complete the Field Correction Effectiveness Check Form, and return it to Siemens using the instructions 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 center or technical support representative

Website: [click here](#)

References:

- Great Britain. Medicines and Healthcare Products Regulatory Agency. Siemens Healthcare Diagnostics. IVDs, clinical chemistry instrumentation. ADVIA Centaur CP, BNP master curve card error for reagent lot 038172 [online]. London: Department of Health; 2014 Jul 14 [cited 2014 Jul 16]. (Field safety notice; reference no. 2014/007/002/601/009). Available from Internet: [click here](#).

- Romania
- Russian Federation
- Saudi Arabia
- Serbia
- Singapore
- Slovakia
- Slovenia
- Spain
- South Africa
- Sweden
- Switzerland
- Taiwan
- Thailand
- Turkey
- U.K.
- Ukraine
- United Arab Emirates
- U.S.
- Venezuela
- Vietnam

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 [FDA Format Guide](#).

Source(s):

- 2014 Jul 16. MHRA FSN. 2014/007/002/601/009
- 2014 Jul 16. MHRA FSN. 10819217, Rev. A. (includes reply form)
- 2014 Jul 21. Manufacturer. The manufacturer confirmed the information in the source material.

