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*	LOCI TROPONIN I (TNI) CALIBRATOR
NO. IDENTIFICACIÓN	I-RD-03-09-13
LOTE DEL REACTIVO DE DIAGNOSTICO IN VITRO	3DD007
REGISTRO SANITARIO	2010RD-0001668
INDICACIONES Y USO ESTABLECIDOS	Determinación de analitos en muestras procedentes del organismo humano.
NOMBRE DEL FABRICANTE	Siemens Healthcare Diagnostics INC.
DESCRIPCION DEL PROBLEMA	Presenta variación en el control de calidad y en los resultados de los pacientes.
FUENTE	Anexo 1
FECHA DE NOTIFICACION	27 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

ANEXO1

A20974 - High Priority Medical Device Alert

Medical Device Ongoing Action
Updated: September 25, 2013

UMDNS Terms:
- IVD Test Reagent/Kits, Immunoassay, Cardiac Marker, Protein, Troponin I [19689]

Suggested Distribution:
- Clinical Laboratory/Pathology
- Materials Management

Geographic Regions:
- (Impact in specific regions has not been identified or ruled out at the time of this posting)
- Worldwide

Siemens—Dimension EXL Chemistry System LOCI Cardiac Troponin I Calibrator Reagents: May Exhibit Upward Shift

Product Identifier:

Dimension EXL Clinical Chemistry System LOCI Cardiac Troponin I Calibrator Reagents:	Catalog No.:	Siemens Material No.:	Lot No.:
TNI Cal	RC621	10464336	3DD007

[Consumable]

Manufacturer:
- Siemens Healthcare Diagnostics IncPO Box 6101, Newark, DE 19714-6101, United States

Problem:
In a September 2013 Urgent Field Safety Notice letter posted by the U.K. Medicines and Healthcare Products Regulatory Agency (MHRA), Siemens states that the above calibrator reagents may exhibit an average upward shift of 24% (range of 1 to 33%) in quality control (QC) and patient results, potentially causing samples to be read above the 99th percentile limit and leading to further observation and testing. Siemens also states that the risk is mitigated to an extent by a corresponding shift in QC values when processed immediately following calibration and before patient sample testing. The manufacturer has not confirmed the information provided in the source material.

Action Needed:
Identify, isolate, and discard any affected product in your inventory. If you have affected product, verify that you have received the September 2013 Urgent Field Safety Notice letter and recall effectiveness check form from Siemens. Siemens recommends that you discuss the contents of the Urgent Field Safety Notice letter with your facility's medical director regarding the need to review previous QC and patient samples tested within the past 24 hr. Complete the recall effectiveness check form, and return it to Siemens by fax using the number on the form. Contact Siemens if you experience an adverse event related to this problem. 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 local technical support representative
Website: Click here

References:

- Great Britain. Medicines and Healthcare Products Regulatory Agency. Siemens Healthcare Diagnostics. IVDs, clinical chemistry, calibrators. LOCI cardiac troponin I calibrator RC621—SMN 10464336—lot 3DD007 [online]. London: Department of Health; 2013 Sep 23 [cited 2013 Sep 24]. 3 p. (Field safety notice; reference no. 2013/009/018/601/001). 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 Sep 24. MHRA FSN. 2013/009/018/601/001
- 2013 Sep 24. MHRA FSN. Reference No. 13-71 (includes reply form)