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

NOMBRE DEL DISPOSITIVO MÉDICO	Analizador de Química Sanguínea ADVIA
NO. IDENTIFICACIÓN RISARH	I1402-55
REFERENCIAS DEL DISPOSITIVO MEDICO	ADVIA 1200, 1650, 1800 y 2400
REGISTRO SANITARIO	INVIMA 2008DM-0002852
INDICACIONES Y USO ESTABLECIDOS	Este equipo es un analizador automatizado para pruebas de química sanguínea por colorimetría, enzimáticas, punto final, cinéticas, ion selectivo para electrolitos de acceso aleatorio continuo. Utiliza muestras de orina, suero o plasma para ensayos de diagnóstico in vitro de enzimas, bioquímica, cardiovascular, oncología, anemia, electrolitos, etc. Es un sistema automatizado que reporta los valores de las pruebas y comunica los resultados clínicos del paciente.
NOMBRE DEL FABRICANTE	Siemens Healthcare Diagnostics Inc.
DESCRIPCION DEL PROBLEMA	Informa que el sistema puede superar incorrectamente la calibración y el control de calidad (QC) en las siguiente situaciones: • Autocalibración con los errores relacionados con el sistema (“s”, “t”, “S”, “R”, “F”, ”A”, “M”, “Q”, o “T”). • Autocalibración con cambio de lote • El sistema puede pasar del paquete de reactivos primarios al paquete reactivo de seguridad en medio de la ejecución de la calibración o del control de calidad. Conllevando a que se presenten errores en los resultados del diagnóstico y potencialmente eventos adversos sobre el paciente.
FUENTE	Anexo
FECHA DE NOTIFICACION	06 de Febrero 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 3880 en Bogotá, ó al correo electrónico tecnovigilancia@invima.gov.co

A21453 - Normal Priority Medical Device Alert

Medical Device Ongoing Action
Updated: February 11, 2014

UMDNS Terms:
- Analyzers, Laboratory, Clinical Chemistry [15551]

Suggested Distribution:
- Clinical Laboratory/Pathology
- Clinical/Biomedical Engineering
- Information Technology

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

Siemens—ADVIA Chemistry Systems: Electrodes May Incorrectly Pass Calibration and QC

Product Identifier:

ADVIA Chemistry Systems:	Software Versions:	Part Nos.:
1200	V2.00	10386841
	V2.01	10469445
1650	V3.52	10318424
	V4.01	10285281
1800	V2.01	10639244
2400	V4.01	10639265

[Capital Equipment, Consumable]

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

Problem:
In a November 2013 Field Safety Notice letter posted by the U.K. Medicines and Healthcare Products Regulatory Agency (MHRA), Siemens states that the above chemistry systems may incorrectly pass calibration and quality control (QC) in the following situations:
(1) Auto-calibration with system-related errors ("s", "t", "S", "r", "F", "A", "M", "Q", or "G"):
- The system is configured to perform an auto-calibration with blank [BLK] and standard [STD].
- The system will switch from the primary reagent pack to the backup reagent pack.
- The BLK that ran will become the BLK for the calibration of the backup reagent pack, but the STD values from the primary reagent pack will be used in place of the STD that generated the error.
- The system may also switch from the primary reagent pack to the backup reagent pack during regular calibrations initiated from the start screen. The new BLK will be used to calibrate the backup reagent pack, but the STD values from the primary reagent pack will be used in place of the STD that generated the error.

(2) Auto-calibration with lot change:
- The system is configured to perform an auto-calibration using the BLK only.
- The system will switch form the primary reagent pack (Lot A) to the backup reagent pack (Lot B).
- The system is programmed to run the BLK for Lot B, but uses the STD values from Lot A to generate the calibration instead of displaying an error message.

(3) Reagent pack switch mid-calibration or mid-QC:
- A calibration or QC run is ordered.
- Depending on reagent availability, the system may switch from the primary reagent pack to the backup reagent pack in the middle of the calibration or QC run.
- The system will generate a passing calibration curve or QC result, using a combination of the data from the primary and backup reagent packs.

FDA's Center for Devices and Radiological Health (CDRH) states that the manufacturer initiated a recall by Urgent Medical Device Correct letter dated November 6, 2013.The manufacturer has not confirmed the information provided in the source material.

Action Needed:
Identify any affected product in your inventory. If you have affected product, verify that you have received the November 2013 Field Safety Notice letter and field correction effectiveness check form from Siemens. Siemens recommends taking the following actions for each situation:
(1) If the system switches to a backup reagent pack and is scheduled to run a BLK and STD, but there is a system related error ("s", "t", "S", "r", "F", "A", "M", "Q", or "G") associated with the STD result, the new BLK and previous STD will be used to calculate the calibration curve. Siemens states that users should load adequate amounts of the BLK and STD materials in the positions defined in the calibration setup. If this situation occurs, resolve the system error and repeat the calibration.
(2) If the system switches to a backup reagent pack that is from a different lot, and is scheduled to run only a BLK, the system will use the BLK from the new lot and the STD value from the old lot to calculate the calibration curve. If auto-calibration with QC is enabled when placing a new lot of reagent on the system while the current lot is still in use, monitor the reagent inventory window and ensure that a new calibration and a QC run is performed on the new lot as soon as it becomes the primary pack. Alternatively, pre-calibration of a new lot can be performed before its first use. Review QC values for the new lot before reporting patient results. Repeat the calibration and/or QC as needed.
(3) If the system switches to a backup reagent pack in the middle of a calibration or QC run, the software will display a result for the calibration or QC. There is no flag to indicate a reagent pack switch; however, reagent inventory will indicate the use of a new primary reagent pack. If auto-calibration with QC is enabled, and a calibration and QC run is coming due, review reagent inventory before reporting patient results to determine whether a pack switch has occured. If a pack switch has occurred within the calibration, repeat the calibration and/or QC.
For additional information and instructions regarding configuration and system behavior, refer to the letter. Your Siemens representative will contact your facility to arrange for a software upgrade. Review the Urgent Field Safety Notice letter with your facility's laboratory medical director. Complete the field correction effectiveness check form, and return it to Siemens using the information on the form. Keep a copy of the Urgent Field Safety Notice letter with your laboratory records, and forward a copy of the letter to any facilities to which you have further distributed affected product.
For Further Information:
Siemens technical solutions center
Website: Click here

References:

- Great Britain. Medicines and Healthcare Products Regulatory Agency. Siemens Healthcare Diagnostics. IVDs, clinical chemistry, software. Clinical chemistry analyzers—ADVIA 1200 V2.00, V2.01; ADVIA 1650 V3.52, V4.01; ADVIA 1800 V2.01; ADVIA 2400 V4.01 [online]. London: Department of Health; 2014 Jan 27 [cited 2014 Feb 10]. (Field safety notice; reference no. 2013/011/007/601/007). Available from Internet: Click here.
- United States. Food and Drug Administration. Center for Devices and Radiological Health. Medical device recalls: Class 2 recall—Siemens ADVIA [online]. 2014 Feb 9 [cited 2014 Feb 10]. 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):

- 2014 Feb 10. MHRA FSN. 2013/011/007/601/007
- 2014 Feb 10. MHRA FSN. 10816443 Rev. A (includes reply form)
- 2014 Feb 10. FDA CDRH Database. Class II. Z-0940-2014