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	Sistema Integrado VITROS 5600
NO. IDENTIFICACIÓN RISARH	I1501-13
REFERENCIAS DEL DISPOSITIVO MEDICO	6802413, versión de software 3.1 y anteriores
REGISTRO SANITARIO	2009DM-0003172
INDICACIONES Y USO ESTABLECIDOS	Este equipo está indicado para uso en diagnóstico in vitro en la medición in vitro cuantitativa, semicuantitativa y cualitativa de diferentes analitos de interés clínico.
NOMBRE DEL FABRICANTE	Orthoclinical Diagnostics, Inc.
DESCRIPCION DEL PROBLEMA	El fabricante afirma que por causa de una anomalía de software los sistemas anteriores pueden no alertar al operador de la expiración de la calibración, generando resultados inesperados y provocando errores en los resultados del procesamiento de las muestras.
FUENTE	ANEXO 1
FECHA DE NOTIFICACION	09 de Enero de 2015

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

ANEXO 1

[High Priority] - A23627 : Ortho Clinical Diagnostics—Various VITROS Analyzer Systems: Software May Not Alert Operator to Calibration Expiration

Medical Device Ongoing Action

UMDNS Terms:

- Analyzers, Laboratory, Clinical Chemistry, Automated, Discrete [16299]
- Analyzers, Laboratory, Clinical Chemistry/Immunoassay [20821]
- Analyzers, Laboratory, Immunoassay, Chemiluminescent [17916]
- Analyzers, Laboratory, Immunoassay, Fluorimetric [16218]
- Analyzers, Laboratory, Immunoassay, Photometric, Enzyme (EIA) [16217]

Product Identifier:

VITROS Systems:	Product Codes:
3600 Immunodiagnostic	6802783
4600 Chemistry	6802445
5600 Integrated	6802413

[Capital Equipment]
Software Versions: 3.1 and below

Geographic Regions: Worldwide

Manufacturer(s): Ortho-Clinical Diagnostics Inc100 Indigo Creek Dr, Rochester, NY 14626, United States

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

Problem: In a November 19, 2014, Important Product Correction Notification letter submitted by an ECRI Institute member hospital, Ortho Clinical Diagnostics (OCD) states that a because of a software anomaly, the above systems may not alert the operator and may not flag results with a CE sample code (i.e., calibration expired) if a calibration expires. The system may unexpectedly generate results even though it is configured to not report results when a calibration has expired. OCD states that the reagent does not need to be on board the system for this to occur. OCD further states that the "Reagent Management - View by Assay" screen correctly displays the expiration status, but the "Opxions and Configuration - Review Calibrations" screen does not correctly display the calibration status. OCD also states that the anomaly may occur on any type of assay processed on the system.

Action Needed:
Identify any affected product in your inventory. If you have affected product, verify that you have received the November 19, 2014, Important Product Correction Notification and/or the December 19, 2014, Important Product Correction Notification (follow up) letter Receipx form from OCD. OCD states that a resolution for this anomaly will be contained in the next version of software. Until the software update is available, use the "All Assay Data" opxion instead of "Load New Lots" when installing assay data diskettes (ADDs) on your system. OCD states that you should immediately install the most recent ADD using the "All Assay Data" opxion. If any of your calibrations are expired, the system will post PZB-005 condition codes. Perform calibrations before using those reagents. As expected, calibrations that will expire within one hour will also be flagged. Continue to install the most recent ADD at least once each week using the "All Assay Data" load opxion so that the system properly flags expired calibrations. OCD states that if an expired calibration occurs for an assay and is not detected by the operator, samples may be processed without a valid calibration; however, quality control fluids would be processed at the next routinely scheduled time period. If quality control results were accepxable, patient results obtained before that time would not have been adversely affected. Discuss any concerns regarding previously reported results with your laboratory medical director to determine the appropriate course of action. Complete the Confirmation of Receipx Form, and return it to OCD using the instructions on the form. Post a copy of the letter by each affected system in your facility.

For Further Information:
OCD technical services department
Tel.: (800) 421-3311
Website: Click here

Comments:

- 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 Dec 29. Member Hospital. OCD letter submitted by ECRI Institute member hospital (includes reply form). OCD reference no. CL2014-296 Download
- 2014 Dec 31. Manufacturer. Manufacturer confirmed information

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