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	Equipo Automatizado para Análisis Inmunoquímicos
NO. IDENTIFICACIÓN RISARH	I1503-115
REFERENCIAS DEL DISPOSITIVO MEDICO	DxC 600i y Access 2
REGISTRO SANITARIO	2010DM-0005321
INDICACIONES Y USO ESTABLECIDOS	Equipo automatizado para hacer análisis Inmunoquímicos in vitro en laboratorio clínico.
NOMBRE DEL FABRICANTE	Beckman Coulter Inc.
DESCRIPCION DEL PROBLEMA	El fabricante que ha desarrollado las actualizaciones de software para los sistemas referenciados versiones 6.2.2 y 3.4.2 respectivamente, para controlar y detectar los paquetes de reactivo con volumen insuficiente, inadecuadamente cargado o faltante, evitando que se presentes retrasos en el procesamiento de las muestrass.
FUENTE	ANEXO 1
FECHA DE NOTIFICACION	13 de Marzo 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

[Normal Priority] - A14682 01 : *Beckman Coulter—Access 2 Immunoassay Systems and UniCel DxC 600i Synchron Access Clinical Systems: Manufacturer Notifies Customers of New Software Versions to Address Erroneous Results [Update]

Medical Device Ongoing Action

Published: Wednesday, March 11, 2015
Last Updated: Thursday, March 12, 2015

UMDNS Terms:

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

Product Identifier: Systems: (1) Access 2 Immunoassay, (2) UniCel DxC 600i Synchron Access Clinical *[Capital Equipment]*

Geographic Regions: Worldwide

Manufacturer(s): Beckman Coulter Inc Clinical Diagnostics Div250 S Kraemer Blvd, Brea, CA 92822-0550, United States

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

Summary:
This Alert provides new information based on source material posted by the German Federal Institute for Drugs and Medical Devices (BfArM) regarding Alert Accession No. A14682 . New information is provided in the following fields:

- Problem
- Action Needed

Problem:
[March 10, 2015]
In a February 9, 2015, Follow-up Urgent Field Safety Notice letter posted by BfArM, Beckman Coulter states that it is releasing Access 2 system software version 3.4.2 and Access 2i (for the above UniCel DxC 600i systems) software 6.2.2 to address the reagent pack volume problem described below. Beckman Coulter also states that the new Reagent Pack Monitoring feature of the new software versions enables the pressure monitoring hardware on the above systems to detect packs with insufficient volume, as well as packs that are improperly loaded or missing.
[September 30, 2010]
In an August 19, 2010, Urgent Field Safety Notice letter posted by the U.K. Medicines and Healthcare Products Regulatory Agency (MHRA), Beckman Coulter states that it has received reports of erroneous test results reported from the above systems because assay reagent packs had been transferred between systems. These systems maintain information regarding the currently loaded assay reagent packs and information for partially used reagent packs that have been unloaded from the system. This information, including the number of tests remaining in a specific reagent pack, is stored on the system and not on the reagent pack. If there is no record for a specific reagent pack, the system assumes that any introduced pack is new and contains 50 tests. Therefore, if you remove a partially used reagent pack from 1 of these systems and load it onto a different system, the second instrument will continue to draw tests from the reagent pack even when the reagents have been depleted. Additional reagent pack load errors include the following:

- Loading a reagent pack before the system positions the reagent carousel
- Scanning 1 reagent pack, then accidentally loading a different pack
- Forgetting to cancel the system load routine when you choose not to load a reagent pack during the load routine.

If any of these situations occur, there may be no available reagent, an incorrect amount of available reagent, or the incorrect assay reagent when the system samples the reagent pack. These problems may lead to dramatic effects on the signal generated for patient results. If the system attempts to pipette from an empty or partial reagent pack, the results for sandwich assays will typically report at or near 0, while competitive assays will report results at or above the highest calibrator. Beckman Coulter states that a chain of high or low results may indicate that reagent pack sharing has occurred and that a reagent pack is empty even though the system reports that sufficient tests remain in the pack. However, if the expected test results are near 0, the problem may not be evident from a routine review of results.

Beckman Coulter also states that while reagent packs should not be shared between independent systems, reagent packs can be shared between instruments in a single Access 2 workgroup, which consists of 2 to 4 interconnected Access 2 systems. 1 of the external Access 2 computers acts as a server and is linked to the other Access 2 systems in the workgroup. A variety of information, including the number of tests remaining in each reagent pack, is shared across each of the networked systems. Therefore, partially used reagent packs can be removed from 1 system within the workgroup and loaded onto another system in the workgroup without affecting test results.

Action Needed:
Identify any affected product in your inventory. If you have affected product, verify that you have received the software packet containing the newly released software and customer information and/or the February 9, 2015, Follow-up Urgent Field Safety Notice letter and Response Form from Beckman Coulter (only customers in European countries governed by the MEDDEV and in Australia are receiving the letter). Your Beckman Coulter service representative will contact your facility to schedule installation of the new software. Retain a copy of the Follow-up Urgent Field Safety Notice letter as part of your laboratory Quality System documentation. Notify all relevant personnel at your facility of the information in the letter, and forward a copy of the letter to any facility to which you have further distributed affected product. Complete the Response Form, and return it to Beckman Coulter using the instructions on the form.

For Further Information:
Beckman Coulter local representative

Website: Click here

References:

- Great Britain. Medicines and Healthcare Products Regulatory Agency. IVDs, clinical chemistry: instrumentation—Beckman Coulter UK Ltd—Access, UniCel, and SYNCHRON clinical systems [online]. London: Department of Health; 2010 Sep 23 [cited 2010 Sep 23]. 1 p. (Field safety notice; reference no. 2010/008/024/601/004). Available from Internet: Click here .
- Germany. Federal Institute for Drugs and Medical Devices. Safety notice for the Access 2 systems, Beckman Coulter [online]. 2015 Mar 2 [cited 2015 Mar 9]. Available from Internet: 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):

- 2015 Mar 9. BfArM (Germany). 0709/15 Download
- 2015 Mar 9. BfArM (Germany). February 9, 2015, Beckman Coulter letter posted by BfArM: FSN-14932-3 Download
- 2015 Mar 9. MHRA FSN. 2010/008/024/601/004 Download
- 2015 Mar 9. MHRA FSN. August 19, 2010, Beckman Coulter letter posted by MHRA: FSN 14932 (Access) Download
- 2015 Mar 9. FDA CDRH Database. Class II. Z-0607-2011 Download
- 2015 Mar 9. Health Canada Recall Listings. Type II. 56259 Download
- 2015 Mar 11. Manufacturer. Beckman Coulter confirmed the information provided in the source material.