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 Laboratorio VIDAS 3
NO. IDENTIFICACIÓN RISARH	I1411-475
REFERENCIAS DEL DISPOSITIVO MEDICO	VIDAS 3
REGISTRO SANITARIO	2014DM-0011236
INDICACIONES Y USO ESTABLECIDOS	El sistema autónomo de inmunodiagnostico VIDAS® 3 es un analizador automatizado multiparamétrico para pruebas de inmunoanálisis por quimiofluoresecencia (ELFA) de acceso aleatorio. Utiliza muestras de orina, suero o plasma y fluidos para ensayos de diagnóstico in-vitro en las áreas de serología, inmunología, química, microbiología y coagulación. Es en sistema automatizado que reporta los valores de las pruebas y comunica los resultados de clínicos del paciente.
NOMBRE DEL FABRICANTE	Biomerieux S.A. Biomerieux Italia Spa
DESCRIPCION DEL PROBLEMA	El fabricante afirma que las versiones de software anterior puede presentar anomalías claramente identificadas concernientes a la calibración del equipo, resultados de falsos negativos para las pruebas de CMVU y CMVA, así como falsos negativos producidos por la estabilidad del tampón de urea en pruebas de CMVU, conllevando a que se presenten potencialmente eventos adversos sobre el paciente por resultados de pruebas analíticas alteradas
FUENTE	ANEXO 1
FECHA DE NOTIFICACION	21 de Noviembre 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

A23255 01 - Normal Priority Medical Device Alert

Medical Device Ongoing Action

Updated: November 12, 2014

UMDNS Terms:
- Analyzers, Laboratory, Immunoassay, Fluorimetric [16218]

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

Geographic Regions:
- Algeria
- Australia
- Austria
- Belgium
- Brazil
- Chile
- Colombia
- France
- Germany
- Greece
- Hong Kong
- India
- Indonesia
- Iran
- Israel
- Italy
- Japan
- Libya
- Mexico
- Morocco
- Myanmar
- The Netherlands
- Poland
- Portugal
- Romania
- Saudi Arabia
- South Africa
- South Korea
- Spain
- Sweden
- Switzerland
- Thailand
- Tunisia
- Turkey
- U.K.

bioMerieux—VIDAS 3 Systems: May Exhibit Anomalies

Product Identifier:
VIDAS 3 Systems *[Capital Equipment]*
Product No. 412590
Software Versions: 1.1.0, 1.1.1, 1.1.2
All serial numbers

Manufacturer:
- bioMerieux SA 3 Chemin du Port Michaud, 38390, La Balm-les-Grottes, France

Summary:
This Alert provides additional information based on manufacturer correspondence regarding Alert Accession No. A23255. Additional information is provided in the Geographic Regions field (see bolded regions).

Problem:
[November 6, 2014]
In an October 17, 2014, Important Urgent Field Safety Notice letter posted by the U.K. Medicines and Healthcare Products Regulatory Agency (MHRA), bioMerieux states that the above software may exhibit the following 3 anomalies:

- The first anomaly occurs if the user launches a new calibration for a lot of a VIDAS test, for which an expired calibration already exists, and an instrument error occurs during the analytical phase (protocol) of the control. Under these specific conditions, the software calculates the sample results without flagging them with the message "incomplete calibration;" however, the overall calibration status is flagged as "incomplete" in the calibration screen. The problem could yield false results involving all VIDAS 3 reagent parameters.

The second anomaly concerns management of the analysis request of the test VIDAS CMV Avidity (CMVU) ref. 30203 and VIDAS CMV Avidity II (CMVA) ref. 413557. The anomaly occurs when the following conditions are met:
(1) The analysis is stopped (either by the user or because of a system inconsistency) during the pre-analytical phase (before the distribution of the first sample).
(2) The user unloads the analysis in the software (Loading Work Area) without physically unloading the strips from the instrument.
(3) The user recreates the same CMVU or CMVA analysis and adds another CMV IgG analysis ref. 30204 in the same section and physically loads new CMV IgG strips in the instrument.
Under these specific conditions, the strips previously prepared for the CMVU or CMVA analysis can be used to perform the CMV IgG tests ref. 30204 programmed in the same section. Because the strips to perform CMVU or CMVA are the same strips used for the tests CMV IgG, the system does not recognize the inversion of the strips. No error message will warn the user of this mix-up. This anomaly may yield a false-negative result for the CMV lgG test ref. 30204 and a false high result for the tests VIDAS CMVU ref. 30203 and VIDAS CMVA ref. 413557.
The third anomaly concerns the stability of urea buffer used for the test VIDAS CMVU ref. 30203 and VIDAS CMVA ref. 413557 when it is dispensed in the strip. The VIDAS 3 does not check the stability of the urea buffer once it is dispensed in the strip. An evaporation of urea occurs. After 2 hr on board, this evaporation may lead to a change of interpretation for the samples with "borderline" avidity. This anomaly may yield a false-negative result for the CMV lgG test ref. 30204 and a false-high result for the tests VIDAS CMVU ref. 30203 and VIDAS CMVA ref. 413557.
Please note that the two (2) anomalies associated with the VIDAS CMV IgG Avidity test will not occur if you program the analysis using the Manual Pipetting Mode (refer to the VIDAS 3 User Manual page 6-79).
In addition to the corrective actions, bioMerieux will also implement a software update to resolve the described anomalies and is targeted for implementation as a mandatory software update in Q2 2015. As part of the software update, the Automatic Pipetting Mode will be temporarily deactivated for the analysis of CMV IgG Avidity ref. 30203 and 413557.

Action Needed:
The following actions are those listed in Alert Accession No. A23255. bioMerieux

recommends the following actions:

- Forward a copy of the Important Urgent Field Safety Notice letter to all relevant personnel and to any facility to which you have further distributed affected product. Retain a copy of the letter for your records.

Perform a new kit control if the calibration status is "incomplete" in the calibration screen and a pictogram error is present in the strip used to perform the kit controls. The calibration status will be automatically updated to "complete" if the new control value is valid.
Program the test CMV Avidity (VIDAS CMVU ref. 30203 and VIDAS CMVA ref. 413557) using only the Manual Pipetting Mode.
Discuss any concerns regarding previously reported results with your facility's medical director to determine the appropriate course of action.
Complete the Acknowledgment Form, and return it to bioMerieux using the instructions on the form.

For Further Information:
bioMerieux
Website: Click here

References:

- Great Britain. Medicines and Healthcare Products Regulatory Agency. bioMerieux SA. IVDs, clinical chemistry software. VIDAS 3 system [online]. London: Department of Health; 2014 Oct 27 [cited 2014 Nov 3]. (Field safety notice; reference no. 2014/010/020/121/014). Available from Internet: Click here.
- Germany. Federal Institute for Drugs and Medical Devices. Corrective action for the VIDAS 3 system, bioMérieux SA [online]. 2014 Nov 10 [cited 2014 Nov 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 Nov 10. Manufacturer. Manufacturer confirmed information contained in source material
- 2014 Nov 10. MHRA FSN.
- 2014/010/020/121/014
- 2014 Nov 10. MHRA FSN.
- FSCA 2209 (includes reply form)
- 2014 Nov 10. BfArM (Germany). 7117/14
- 2014 Nov 10. (includes reply form)