INFORME DE SEGURIDAD

DIRECCIÓN DE DISPOSITIVOS MÉDICOS Y OTRAS TECNOLOGÍAS

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 para Química e Inmunoensayos COBAS ROCHE
NO. IDENTIFICACIÓN RISARH	I1805-365
REFERENCIAS DEL DISPOSITIVO MEDICO	E-801
REGISTRO SANITARIO	2011DM-0006900
INDICACIONES Y USO ESTABLECIDOS	Sistema íntegramente automatizado, de acceso aleatorio continuo y controlado por su software, para el diagnóstico in-vitro mediante el análisis fotométrico y de inmunoensayos cualitativos y cuantitativos de múltiples test de química sanguínea, inmunología y electrolitos. Utiliza la combinación de módulos con ion selectivo ISE para electrolitos (COBAS ISE), dos módulos fotométricos cobas c-701 y cobas c-502 para química y un módulo de inmunoensayos cobas e-602. Procesa muestras de orina, líquidos, suero o plasma para la totalidad de ensayos de diagnóstico in-vitro (IVD) en química, drogas, hormonas, inmunología etc. Viene con un DATA MANAGMENTE SYSTEM o software LIS para manejo automatizado delos resultados. Los reactivos que se utilizan con el sistema modular serie cobas 8000 roche cuentan con respectivo registro sanitario.
NOMBRE DEL FABRICANTE	Roche Diagnostics Gmbh Hitachi High Technologies Corporation Roche Diagnostics International Ltd. Roche Diagnostics Graz Gmbh
DESCRIPCION DEL PROBLEMA	El fabricante ha detectado que puede presentarse un problema con el émbolo de la jeringa en un conjunto de jeringa *PreWash (PW)* del módulo referenciado, donde el paso de prelavado requerido por la mayoría de los ensayos no se realizará y no se puede excluir un efecto sobre los resultados de la medición. Además, el problema también puede ocurrir en el conjunto de jeringa de reactivo del módulo cobas e 801 R1 o R2, ocasionando deficiencia en el pipeteado generando una alarma del sistema "*345-1 Advertencia señal anormal baja*" y una alarma de datos

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(<SigL), por lo que no se obtendrán resultados de medición, esta situación podría conllevar a que se presenten retrasos en el procesamiento de las muestras y en el proceso de atención de los pacientes.

FUENTE ANEXO

FECHA DE NOTIFICACION 29 de mayo de 2018

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

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ANEXO

[High Priority] - A30330 : Roche—cobas e 801 Module Plungers: Syringe Function May Be Impaire d
Medical Device Ongoing Action

Published: Thursday, May 24, 2018

UMDNS Terms:

- Analyzers, Laboratory, Clinical Chemistry/Immunoassay [20821]

Product Identifier:
[Capital Equipment]

Product	Hitachi High-Technologies Corp (Manufacturer) Model	Part No.	Serial No.	Item No.
Syringe Assembly Plungers	cobas e 801 Module PreWash (PW), cobas e 801 Module R1, cobas e 801 Module R2	798-3203	None listed	None listed
Modules	cobas e 801	None listed	1601-01 to 18E6-10	07682913001

Geographic Regions: Argentina, Australia, Brazil, Canada, Chile, Colombia, Europe, Hong Kong, Japan, Korea, Malaysia, Middle East, New Zealand, South Africa, Thailand, Turkey, U.K., U.S., Vietnam

Manufacturer(s): Hitachi High-Technologies Corp (Manufacturer)1-24-14 Nishi-Shinbashi, 105-8717 Minato-ku Tokyo, Japan
Roche Diagnostics GmbH (Authorized Representative)Sandhoferstrasse 116, Mannheim, D-68305, Germany

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

Problem: In a March 2018 Urgent Field Safety Notice letter posted by the U.K. Medicines and Healthcare Products Regulatory Agency (MHRA) and the German Federal Institute for Drugs and Medical Devices (BfArM), Roche states that it has received four complaints of a problem with the syringe plunger on a cobas e 801 module PreWash (PW) syringe assembly. The problem may also occur on the cobas e 801 module R1 or R2 reagent syringe assembly. Depending on the affected syringe, R1, R2, or prewash liquids will not be pipetted correctly, as follows:
(1) If the PreWash syringe plunger is broken, the cobas e 801 module cannot detect it and no alarm is issued. In this instance, the prewash step required by most assays will not be performed and an effect on measurement results cannot be excluded. The "Important Information" section in the letter outlines assays which are not affected by the problem. All other assays run on the cobas e 801 module may be affected.
(2) If the R1 or R2 syringe plunger is broken, a system alarm "345-1 Warning Abnormal Low Signal" is generated and data alarm (<SigL) is flagged; consequently, no measurement results will be generated.
Depending on how the seal pieces are assembled, the plunger may be mounted in a tilted position, which applies mechanical stress to the plunger. In the worst case scenario during the cobas e 801 initialization steps, when the largest strokes happen, the plunger may crack leading to an impaired syringe function.

Action Needed:
Identify any affected product in your inventory. If you have affected product, verify that you have received the March 2018 Urgent Field Safety Notice letter from Roche. As a final solution, a mandatory installation of a syringe plunger guide for the R1, R2, and PW syringes is required for cobas e 801 modules in the field, from serial numbers 1601-01 to 18E6-10. The hardware modification kit is already available in the warehouse. The installation of the kit requires a few minutes, if the instrument is available in [Standby] mode. The kit ensures the correct positioning and movement of the above syringe plungers and thus prevents the problem. Your Roche Diagnostics local representative will contact your facility to schedule the installation of the modification kit. The installation process is ongoing. If the described problem occurs with an R1 or R2 syringe plunger:
(1) A system alarm "345-1 Warning Abnormal Low Signal" is generated.
(2) A data alarm (<SigL) is flagged.
(3) No measurement results are generated.
(4) Contact Roche's customer support department.
If the described problem occurs with the PW syringe plunger:
(1) Refer to Table 1 in the letter for a list of cobas e 801 assays that are not affected because they do not require the prewash step.
(2) Refer to Table 2 in the letter for a list of cobas e 801 assays with controls within range and samples within control range. These assays require prewash steps. The effect on measurement results by omitting prewash steps is assay-dependent. Studies were performed to investigate the impact of a missing prewash step on controls and samples.
(3) Refer to Table 3 in the letter for a list of cobas e 801 prewash assays. These assays require prewash steps. The effect on measurement results by omitting prewash steps is assay-dependent. For these assays, the effect on measurement results cannot be excluded.
If it is not possible to have the above mentioned final solution (modification kit) in a timely manner, follow temporarily one of the below listed options (workarounds):
Option 1 (workaround):
This workaround (option 1) can be applied by the operators without support from a Roche field service representative.
Measure only assays that do not require prewash steps and assays which are not affected by the missing prewash step.
The lists are found under "Important Information", Table 1 and Table 2 in the letter.
The assays listed in Table 3 under "Important Information" must NOT be measured until installation of the modification kit has been completed. These assays have to be masked. The procedure for test masking is available in the cobas 8000 Operator's Manual, under Operation > Order and results > Processing samples > Masking tests.
Option 2 (workaround):
This workaround (option 2) requires intervention from your Roche local field service representative for the necessary configuration of the data manager. Consequences on the laboratory workflow will need to be considered.
Visually inspect the functionality of the PreWash syringe plunger before manually releasing results to Host/LIS, until the final solution is applied.
The automatic data transfer function of patient sample results on data manager needs to be disabled, so patient results measured on cobas e 801 module (prewash assays only) will not be automatically transferred to Host/LIS. Instead, these measurement results must be manually released to Host/LIS after visually checking the functionality of the PW syringe plunger.
Option 2 - Procedure:
(1) Define the time interval to visually inspect the PreWash syringe plunger and manually validate results (for prewash assays) on the data manager to be sent to Host/LIS.

(2) Start sample processing, and after the abovedefined time interval, stop the operation with the [S.Stop] button and waituntil the system goes to [Standby] mode.
(3) Visually check the PreWash syringe plunger movement, according to the attachment:
"Att. 01_FSN_PreWash Plunger check during System Prime"
(4) If the PreWash syringe plunger is visually working as expected, manually validate the transfer of patient results measured on cobas e 801 from data manager to Host/LIS. During the manual validation of patient results, it is recommended that the system is kept in [Standby] mode and no new samples are loaded.
(5) Repeat Step 2 through 4 until the end of routine operation.
If a damaged PreWash syringe plunger is identified (see the above procedure, step 3), stop using the cobas e 801 module and immediately contact Roche's customer support department. In addition, do not validate the measured results and repeat the measurement of concerned samples.
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.
For Further Information:
Roche
Website: Click here

References:

- Great Britain. Medicines and Healthcare Products Regulatory Agency. Hitachi: cobas 8000 modular analyzer cobas e801 module [online]. London: Department of Health; 2018 Apr 3 [cited 2018 May 22]. (Field safety notice; reference no. 2018/003/023/478/028). Available from Internet: Click here .
- Germany. Federal Institute for Drugs and Medical Devices. Urgent Field Safety Notice for cobas 8000 by Hitachi High-Technologies Corporation [online]. 2018 Apr 16 [cited 2018 May 22]. 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):

- 2018 May 22. MHRA FSN. 2018/003/023/478/028 Download
- 2018 May 22. MHRA FSN. SBN-CPS-2018-002 Download
- 2018 May 22. BfArM (Germany). 03589/18 Download
- 2018 May 22. BfArM (Germany). SBN-CPS-2018-002 Download
- 2018 May 22. Manufacturer. Manufacturer confirmed information contained in source material