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	Equipo Preanalítico para Manejo de Muestras ROCHE
NO. IDENTIFICACIÓN RISARH	I1703-86
REFERENCIAS DEL DISPOSITIVO MEDICO	P612, seriales 63001216 y superiores, versiones de software 2.0.0, 2.0.1, 2.0.2, 2.0.3.
REGISTRO SANITARIO	2015DM-0013314
INDICACIONES Y USO ESTABLECIDOS	El sistema Preanalítico cobas 8100 y los modelos P512 y P612 es un equipo modular interconectado entre sí, para el procesamiento y transporte de las muestras de los pacientes en el laboratorio clínico. El sistema ha sido diseñado para centrifugar las muestras de los pacientes, retirar e inserta los tapones, aplicar las etiquetas de código de barras y con el pipeteador preparar las alícuotas a partir de las muestras primarias. Puede clasificar las muestras en línea o fuera de ella y almacenar temporalmente las muestras. El sistema transporta las diferentes muestras individualizadas entre los módulos analíticos cobas para inmunología, química sanguínea, hematología, hormonas, drogas, orinas, coagulación y especiales para los respectivos análisis de laboratorio. El sistema no reporta valores de resultados de las muestras, no es un analizador de muestras.
NOMBRE DEL FABRICANTE	Roche Diagnostics Gmbh
DESCRIPCION DEL PROBLEMA	El fabricante informa que ha identificado que cuando en el sistema referenciado se usan puntas desechables sin filtro, el software puede calcular incorrectamente la profundidad de inmersión, ocasionando una aspiración de un mayor número de coágulos, lo cual podría conllevar a que se presenten retrasos en la obtención de resultados de los análisis realizados hasta la contaminación de las muestras.
FUENTE	ANEXO 1
FECHA DE NOTIFICACION	02 de Marzo de 2017

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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 1

[High Priority] - A27970 01 : Roche—cobas p 612 Preanalytical Systems: Manufacturer Revises Software to Correct Aspiration Process
Medical Device Ongoing Action

Published: Wednesday, February 22, 2017

UMDNS Terms:

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

Product Identifier: cobas p 612 Preanalytical Systems *[Capital Equipment]*
GMMI/Part No. 07563116001
Serial Nos.: 63001216 and higher
Software Versions: 2.0.0, 2.0.1, 2.0.2, 2.0.3

Geographic Regions: Asia, Australia, Brazil, Chile, Colombia, Cuba, Ecuador, Europe, Jamaica, Panama, Philippines, Tunisia, U.K., U.S.

Manufacturer(s): Roche Diagnostics GmbHSandhoferstrasse 116, D-68305 Mannheim, Germany

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

Summary:
This Alert provides new information based on manufacturer correspondence and a December 15, 2016, Urgent Field Safety Notice letter posted by the U.K. Medicines and Healthcare Products Regulatory Agency (MHRA) regarding Alert Accession No. A27970 . New information is provided in the following fields:

- Product Identifier (see bolded information)
- Geographic Distribution (see bolded regions)
- Problem
- Action Needed

Problem:
[February 22, 2017]
In a December 15, 2016, Urgent Field Safety Notice letter posted by MHRA, Roche states that when the above system is using disposable non-filter tips, the system software may incorrectly calculate the submersion depth. An incorrect submersion depth calculated by the software when non-filter tips are used may lead to the aspiration of an increased number of aspired clots, caused by the tip moving past the serum layer and entering the gel or blood cake layer. The clots are still being correctly detected, creating a system alarm. When a clot is detected, the pipettor may fail to stop the aspiration. This creates an underpressure in the pipettor tip, which may lead to liquid splashing up inside the pipettor tip when the blockage is removed, potentially resulting in a droplet forming at the pipettor nozzle. The firm received 1 report regarding an increased number of aspirated clots. While no reports of sample carryover have been received, the effect could not be excluded. The effect of cross-contamination on patient results depends on the assay (e.g., on the sensitivity of the assay) as well as the size of the droplet, the aspirated amount of sample, and the concentration of the primary sample from which the droplet originates. A medical risk cannot be excluded. The firm adds that all cobas p 612 (63x) systems that use disposable filter tips are not affected by a potential nozzle contamination or sample carryover. The submersion depth with filter tips is correct and, in addition, filter tips physically prevent liquid reaching and contaminating the nozzle.
[February 1, 2017]
FDA's Center for Devices and Radiological Health (CDRH) states that Roche is revising the software of the above systems to correct the aspiration process. FDA's CDRH also states that Roche initiated a product correction of the above systems by Urgent Medical Device Correction letter sent by fax or e-mail on December 27, 2016.

Action Needed: Identify any affected product in your inventory. If you have affected product, verify that you have received the December 15, 2016, Urgent Field Safety Notice letter from Roche. The manufacturer states that a new software version is available and that the upgrade of affected systems is planned for July 31, 2017. Until the new software version 2.0.4 is installed, stop aliquoting sample tubes if you are using affected systems for aliquoting in combination with non-filter tips. As a workaround, if sample aliquoting is required until the software version 2.0.4 is installed, systems using non-filters tips can be modified free of charge by your Roche local field service representative to use disposable filter tips. Inform 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 technical support hotline
Tel: (0808) 1001920 (U.K.), (1800) 409564 (Ireland)
Website: Click here

References:

- United States. Food and Drug Administration. Center for Devices and Radiological Health. Class 2 device recall cobas p 612 preanalytical system [online]. 2017 Jan 24 [cited 2017 Feb 1]. Available from Internet: Click here .
- Great Britain. Medicines and Healthcare Products Regulatory Agency. Roche: cobas p 612 pre-analytical system [online]. London: Department of Health; 2017 Feb 20 [cited 2017 Feb 22]. (Field safety notice; reference no. 2016/012/020/701/016). 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):

- 2017 Feb 22. FDA CDRH Database. Class II. Z-1090-2017 Download
- 2017 Feb 22. Manufacturer. Manufacturer confirmed information contained in source material