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 Fotométrico – HEMOCUE / Microcubetas
NO. IDENTIFICACIÓN RISARH	I1412-501
REFERENCIAS DEL DISPOSITIVO MEDICO	Glucose 201, referencia Microcubetas 110715, 110716, 110717, 110718, 110719 y 110720, lotes específicos
REGISTRO SANITARIO	2014DM-0012197
INDICACIONES Y USO ESTABLECIDOS	Los sistemas analizadores están indicados para la determinación cuantitativa de parámetros en muestras de sangre total capilar o venosa. Los sistemas están destinados únicamente para el diagnóstico in vitro.
NOMBRE DEL FABRICANTE	Hemocue Ab
DESCRIPCION DEL PROBLEMA	El fabricante afirma que las microcubetas referenciadas pueden producir mediciones de glucosa superiores a la real, conllevando a que se presenten posibles eventos adversos sobre los pacientes
FUENTE	ANEXO 1
FECHA DE NOTIFICACION	04 de Diciembre 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

A23364 - Normal Priority Medical Device Alert

Medical Device Ongoing Action

Updated: December 1, 2014

UMDNS Terms:
- Cuvettes, Clinical Chemistry Analyzer [17750]

Suggested Distribution:
- Clinical Laboratory/Pathology
- Materials Management

Geographic Regions:
- Worldwide

HemoCue—Glucose 201 Microcuvettes: May Yield Higher-than-Expected Results at End of Shelf Life

Product Identifier:
Glucose 201 Microcuvettes [Consumable]

Model Nos.: US	Lot Nos.:
110705	1310500, 131051, 1310502, 1310503, 1310518, 1310519, 1310520, 1310521, 1310767, 1310768, 1310769, 1310770, 1310771, 1310772, 1310779, 1310780, 1310781, 1310788, 1310789, 1310790, 1310799, 1311524, 1311525, 1311526, 1311527, 1311528, 1311529, 1311530, 1311531, 1311532, 1311533, 1311534, 1311535, 1311536, 1311537, 1311538, 1311539, 1311541, 1311542
110706	1310207, 1310208, 1310209, 1310210, 1310211, 1310212, 1310213, 1310214, 1310215, 1310216, 1310228, 1310231, 1310232, 1310234, 1310235, 1310238, 1310239, 1310247, 1310249, 1310250, 1310256, 1310257, 1310258, 1310259, 1310260, 1311270, 1311271, 1311272, 1311273, 1311274, 1311279, 1311280, 1311281, 1311282, 1311283, 1311284, 1311291, 1311296, 1311297, 1311314, 1311315, 1311316, 1311317, 1311318

International Product Nos.:	Lot Nos.:
110715	1310217, 1310218, 1310219, 1310221, 1310222, 1310229, 1310230, 1310237, 1310240, 1310241, 1310242, 1310251, 1310252, 1311267, 1311268, 1311269, 1311298, 1311301, 1311302, 1311303, 1311304, 1311321, 1311322, 1311323, 1311324
110716	1310202, 1310203, 1310204, 1310223, 1310224, 1310225, 1310227, 1310243, 1310244, 1310245, 1310246, 1310261, 1311263, 1311264, 1311265, 1311266, 1311277, 1311278, 11311305, 1311306, 1311307, 1311308, 1311309, 1311310, 1311311, 1311312, 1311313, 1311325

110717	1310504, 1310505, 1310506, 1310507, 1310508, 1310509, 1310510, 1310514, 1310515, 1310516, 1310517, 1310773, 1310774, 1310775, 1310776, 1310783, 1310784, 1310785, 1310791, 1310792, 1310794, 1310795, 1310796, 1311540, 1311543, 1311544, 1311545
110718	1310511, 1310512, 1310513, 1310777, 1310778, 1310786, 1310787, 1310797, 1310798
110719	1310236, 1310237, 1310248, 1311285, 1311286, 1311287, 1311288, 1311289, 1311290, 1311292, 1311293, 1311294, 1311295, 1311299, 1311300
110720	1310205, 1310206, 1310226, 1310253, 1310254, 1310255, 1311319, 1311320

Manufacturer:
- HemoCue ABKuvettgatan 1, Angelholm, SE-262 71, Sweden

Problem:
In a November 3, 2014, Urgent Field Safety Notice letter submitted by ECRI Institute member hospitals and posted by the U.K. Medicines and Healthcare Products Regulatory Agency (MHRA), HemoCue states that the above microcuvettes may yield glucose measurements higher than specified, which could result in unnecessary insulin treatment or a lack of glucose treatment. HemoCue also states that the affected lots are beyond their expiration date and should have been used or discarded.

Action Needed:
Identify any affected product in your inventory. If you have affected product, verify that you have received the November 3, 2014, Urgent Field Safety Notice letter and verification form from HemoCue. Complete the verification form, and return it to HemoCue using the instructions on the form. Inform all relevant personnel at your facility of the information in the Urgent Field Safety Notice letter.

For Further Information:
HemoCue
Website: Click here

References:

- Great Britain. Medicines and Healthcare Products Regulatory Agency. HemoCue. IVDs, extra laboratory testing, POC instrumentation—HemoCue glucose 201 microcuvettes (110705, 110706, 110715, 110716, 110717, 110718, 110719, 110720) [online]. London: Department of Health; 2014 Nov 14 [cited 2014 Nov 21]. (Field safety notice; reference no. 2014/011/007/701/006). 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 20. MHRA FSN. MHRA Reference No.: 2014/011/007/701/006
- 2014 Nov 20. Member Hospital. HemoCue letter submitted by member hospital

(includes reply form)
- 2014 Nov 20. MHRA FSN. HemoCue letter posted by MHRA (includes reply form)
- 2014 Dec 1. Manufacturer. Manufacturer confirmed information.