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Urgent Field Safety Notice

HBA Sperm-Hyaluronan Binding Assay

FSCA- 18 December 2014 – Reference # 1132-002-12014
Field Safety Corrective Action – Recall – 4.11 Indirect Harm, 4.19 Unanticipated

MHRA Incident Number - 2014/004/081/008

Date: 18 December 2014

Attention: MHRA via MIR Report

Details on affected devices:
The HBA Sperm Hyaluronan Binding Assay (Biocoat Catalogue #: 1132-002) is indicated for use as a component of:

1. The standard analysis of semen in suspected male infertility.
2. Analysis for determining the proper course of IVF treatment of infertility.

The HBA Sperm Assay is a dual chamber diagnostic laboratory slide. It is indicated as a component of the standard sperm analysis of semen in the diagnosis of suspected male infertility. As a component of analysis for determining the proper course of IVF treatment of infertility. The device is packaged in a White plastic Clam Shell package that is exclusively distributed by Origio Inc, The label (shown below) is affixed to the package. The affected Lot #'s for this action are:

Lot #	Manufacture Date
11028	2011-12-01
11073	2011-12-13
11088	2011-12-16
11110	2011-12-27
20064	2012-01-20
20116	2012-02-02
20157	2012-02-10
20189	2012-02-17
20529	2012-05-25
20555	2012-06-05
20581	2012-06-13
20594	2012-06-15
20603	2012-06-25
20682	2012-07-13
20698	2012-07-19
20809	2012-08-17
20846	2012-08-27
20856	2012-08-28
21100	2012-10-18
21289	2012-12-06
21302	2012-12-10
21315	2012-12-11
21339	2012-12-14
21341	2012-12-17
30029	2013-01-08
30161	2013-02-12
30163	2013-02-12
30515	2013-05-06

Lot #	Manufacture Date
30553	2013-05-14
30603	2013-05-29
30684	2013-06-18
30882	2013-08-06
30933	2013-08-14
31114	2013-09-18
31184	2013-10-01
31186	2013-10-01
31401	2013-11-14
31429	2013-11-19
31484	2013-12-02
31507	2013-12-05
40053	2014-01-15
40128	2014-01-28
40133	2014-01-29
40159	2014-02-05
40169	2014-02-06
40191	2014-02-10
40213	2014-02-18
40248	2014-02-25
40284	2014-02-26
40291	2014-02-27
40811	2014-05-28
40846	2014-06-03
40850	2014-06-04
40862	2014-06-05
40939	2014-06-18

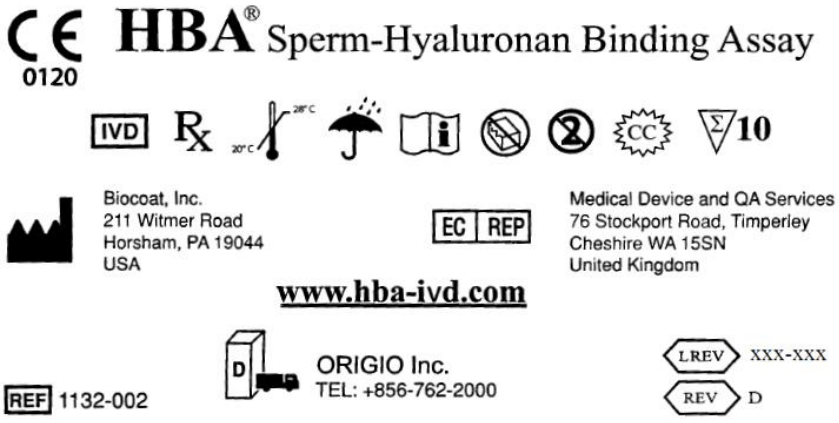

Figure 1 – HBA Assay Immediate Container Labeling

The units involved with this activity can be identified by the following Lot # and Expiration symbols:

LOT XXXXX 20XX-XX

Biocoat, Inc., (the manufacturer) and distributed by Origio, Inc. has initiated this voluntary recall to the user level due to labeling concerns involving the expiration date. The labeled expiration date may be longer than the known stability of the product.

Biocoat is not aware of any adverse patient events resulting from the use of this product. Biocoat has determined that this assay and the expiration dating poses zero risk to a patient.

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These assays were distributed from October 1, 2011 through October 1, 2014.

Customers are being notified by fax, email, FedEx, and/or certified mail that includes instructions for the disposition of the product. Customers have been instructed to examine their inventory immediately and to quarantine, discontinue use and return or destroy the identified lots of product. Customers who may have further distributed this product have been requested to identify their customers and notify them at once of this action.

Any questions about returning unused product should be directed to the original distributor. Customers may contact Biocoat directly at support@biocoat.com.

Description of the problem:
During a review of the Device History File (DHF) and Technical File (TF) it was determined that inadequate data existed to support the three (3) year shelf life, (Real time, controlled – as determined by Management following an independent review). A two (2) year shelf life claim is correct and supported by real time data. There is Zero potential hazard associated with this shortened shelf life assignment.
We are initiating this FSCA to recall the identified lot(s) from the field.

Advice on action to be taken by the user:

- Stop use of the product that falls within the identified Lot(s).
- End users and Distributor are requested to review inventory for any affected Lot(s) of the HBA device.
- Quarantine and segregate any impacted lot(s)
- Contact your Distributor or the Manufacturer for further instructions on the return of the affected product.
- The devices are requested to be returned to the Manufacturer. Contact the distributor for instruction on the return process.

Transmission of this Field Safety Notice:

This notice is to be forwarded to all parties who need to be aware within your organization or to any organization where the potentially affected devices have been transferred.

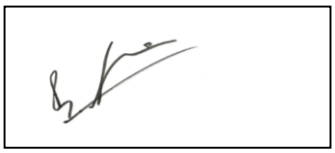
Please transfer this notice to other organizations on which this action has an impact.

Please maintain awareness on this notice and resulting action for an appropriate period to ensure effectiveness of the corrective action.

Contact reference person:

Greg Kleinert – Biocoat, Inc.
211 Witmer Road
Horsham, PA 19044
215 734 0888 – ext 117
gk@bicoat.com

The undersigned confirms that this notice has been presented to the appropriate Regulatory Agency.

Signature  AR to Biocoat.