



## **Urgent Field Safety Notice**

### **ACCURUN® 51 Multi-Marker Hepatitis Positive Control FSCA 27 JUN 2017 Notice to Distributors and Users**

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Date: 27 June 2017

Attention SeraCare Life Sciences Customer:

**Details on affected devices:** ACCURUN® 51 Multi-Marker Hepatitis Positive Control

Material Number	Catalog Number	Batch Number
2000-0040	A51-5001	10164524
2000-0040	A51-5001	10231486
2000-0041	A51-5005	10164525
2000-0041	A51-5005	10231487

Table 1. Affected Material Numbers/Batches

#### **Description of the problem:**

The batches in Table 1 meet all criteria related to the intended use as *in vitro* diagnostic controls reactive for HBeAg, HBc IgM, HAV IgM, and HBsAg. This letter is to inform you that we have discovered that these batches are positive for antibodies to HIV 1 and/or HIV 2, despite a claim on the package insert that the product is manufactured from serum or plasma that is negative for antibodies to HIV 1 and 2. There is no impact on the performance of the affected batches. In addition, the anti-HIV 1/2 positive stock used to manufacture the ACCURUN 51 products is treated with beta propiolactone and ultraviolet radiation to reduce virus activity, minimizing any safety risk.

#### **Advice on action to be taken by the user:**

The affected batches in Table 1 continue to meet their intended use, therefore customers may continue to use the products as intended.

#### **Communication of this Field Safety Notice:**

Please share this information with your laboratory staff and retain this notification as part of your Quality System documentation. If you have forwarded any of the affected products listed above to another laboratory, please provide them with a copy of this letter.

The national competent authority has been informed of this field safety corrective action.

**Please complete and return the enclosed response form within 10 business days so that we are assured you have received this important communication.**



Should you have any questions about this notice, please contact SeraCare Technical Support at 508-244-6400 or 508-634-3359, or email: [techsupport@seracare.com](mailto:techsupport@seracare.com)

or

Robert Brownlee

Technopath

1d, Fort Henry

Garrynatineel, Ballina

Co. Tipperary, V94W967

Ireland

Tel. + 44 (0)28 3083 3808

Email: [robert.brownlee@techno-path.com](mailto:robert.brownlee@techno-path.com)

We apologize for the inconvenience that this caused your laboratory.

Sincerely:

A handwritten signature in black ink that reads "Heather M. Buckley".

Heather M. Buckley

Vice President, Quality and Regulatory

SeraCare Life Sciences

37 Birch St.

Milford, MA 01757

U.S.A.

508-244-6400

Enclosed: Field Safety Notice Response Form



## Field Safety Notice Response Form

Please complete the appropriate sections below:

Customer Name: \_\_\_\_\_

ACCURUN 51 Batch Number(s) in use: \_\_\_\_\_

### URGENT FIELD SAFETY NOTICE – FSCN 22 JUN 2017

ACCURUN 51 Multi-Marker Hepatitis Positive Control

- The Notification has been actioned – I have read and understood the information within the accompanying SeraCare Life Sciences Notification. All relevant personnel have been informed of its contents, any recommended actions taken and records retained as part of our Quality System documentation.
- The Notification has not been actioned – We do not have this product.

Signed: \_\_\_\_\_

Date: \_\_\_\_\_

Name: \_\_\_\_\_

Tel: \_\_\_\_\_

(Please Print):

Email: \_\_\_\_\_

Please return this form within 10 business days by fax, post or email to:

Heather M. Buckley  
 Vice President, Quality and Regulatory  
 SeraCare Life Sciences  
 Milford, MA 01757 – U.S.A.  
 Phone: 508-244-6400  
 Fax: 508-244-6502  
 37 Birch St.  
 email: [hbuckley@seracare.com](mailto:hbuckley@seracare.com)

or

Robert Brownlee  
 Technopath  
 1d, Fort Henry  
 Garrynatineel, Ballina  
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 Tel. + 44 (0)28 3083 3808  
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