
Urgent Field Safety Notice
LBgard® Blood Collection Tube
FSCA-identifier (2019-001)

Date: [08-XX-2019]

Attention: [LBgard Blood Collection Tube Customer]

Details on affected devices:

LBgard® Blood Collection Tube (LBgard)

CE-71001-002

Lots impacted: A1710353, A18043A5, A1807398, A1811357, A190236R, A190337V, A190435Y, A1905385

Description of the problem:

A review of all data reports referenced in the Technical File for LBgard, along with data from additional studies performed after the CE Mark was attained, was performed as part of a post-acquisition integration. The following performance indicators were not supported by the data: Product shelf life at 14 months and sample stability at 14 days. As a result, the Instructions for Use (IFU) and the label claims for LBgard will be modified as noted in the chart below.

Specifications	Old	New
Product Shelf-Life	14 months	9 months
Sample Stability	14 days	7 days
Storage Temperature (post-blood draw)	4-37°C	4-25°C

Please note that neither the overall product design nor the respective manufacturing processes have changed.

A risk assessment was performed to evaluate the potential hazard to patients associated with the pre-collection and post-collection stability of the LBgard as it pertains to cell-free DNA. LBgard is designed to stabilize DNA in blood samples for downstream use in in vitro diagnostic (IVD) tests as validated by the test provider. LBgard is not designed or validated by Biomatrix to generate results from IVD tests. The product does not have any direct contact with patients, therefore, only indirect hazard was identified, and the greatest indirect hazard for LBgard is potential deterioration of product performance (including reduction in shelf life and sample stability).

BIOMATRICA, INC.
5627 Oberlin Drive, Suite 120
San Diego, California 92121 USA
Telephone: 858-550-0308
Fax: 858-678-0597

Confidential

Based on the new product specifications, the following is a list of lots that are expired.

Lot Number	Current Expiration Date (14-month shelf life)	Revised Expiration Date (9-month shelf life)
A1710353	Dec-18	NA – product is expired
A18043A5	Jun-19	Jan-19 – product is expired
A1807398	Nov-19	Jun-19 – product is expired
	Dec-19	July-19 – product is expired

The following is a list of lots that are within the 9-month shelf life, along with the new expiration date.

Lot Number	Current Expiration Date (14-month shelf life)	Revised Expiration Date (9-month shelf life)
A1807398	Jan-20	August-19
A1811357	Jan-20	August-19
A190236R	Apr-20	Nov-19
A190337V	May-20	Dec-19
A190435Y	Jun-20	Jan-20
A1905385	Jul-20	Feb-20

If product is within the supported shelf life of 9-months, please utilize internal processes to adjust the expiration date to reflect 9-month shelf life, as provided in the table above. Please complete the attached Customer Reply or Distributor/Importer Reply Form, as applicable, and mail or fax to:

Biomatrix, Inc.
5627 Oberlin Drive, Suite 120
San Diego, California 92121 USA
Attn: Bill Standwill
bstandwill@biomatrix.com
Fax: +1 858 678 0597

If product has exceeded the supported shelf life of 9-months, please dispose/destroy expired material. Please complete the attached Customer Reply or Distributor/Importer Reply Form, as applicable, and return to:

Biomatrix, Inc.
5627 Oberlin Drive, Suite 120
San Diego, California 92121 USA
Attn: Bill Standwill
bstandwill@biomatrix.com
Fax: +1 858 678 0597

For disposed/destroyed LBgard Blood Collection Tubes, credit/replacement will be provided based upon prior agreement between Biomatrix and company.

BIOMATRIX, INC.
5627 Oberlin Drive, Suite 120
San Diego, California 92121 USA
Telephone: 1-858-550-0308
Fax: 1-858-678-0597

Confidential

Please contact me with any questions or to discuss further. We appreciate your patience as we work through this situation.

Best Regards,



William R. Standwill
VP, Global Sales & Marketing

Transmission of this Field Safety Notice: (if appropriate)

This notice needs to be passed on all those who need to be aware within your organization or to any organization where the potentially affected devices have been transferred. (If appropriate)

Please transfer this notice to other organizations on which this action has an impact. (If appropriate)

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

Contact reference person:

Bill Standwill
Biomatrica, Inc.
5627 Oberlin Drive, Suite 120
San Diego, California 92121 USA
bstandwill@biomatrica.com
Fax: +1 858 678 0597

BIOMATRICA, INC.
5627 Oberlin Drive, Suite 120
San Diego, California 92121 USA
Telephone: 1-858-550-0308
Fax: 1-858-678-0597

Confidential

Customer Reply Form

1. Field Safety Notice (FSN) information	
FSN Reference number*	2019-001
FSN Date*	2019-001
Product/ Device name*	LBgard Blood Collection Tubes
Product Code(s)	1 2 3
Batch/Serial Number (s)	1 2 3

2. Customer Details	
Account Number	
Healthcare Organisation Name*	
Organisation Address*	
Department/Unit	
Shipping address if different to above	
Contact Name*	
Title or Function	
Telephone number*	
Email*	

3. Customer action undertaken on behalf of Healthcare Organisation			
<input type="checkbox"/>	I confirm receipt of the Field Safety Notice and that I read and understood its content.	Customer to complete or enter N/A	
<input type="checkbox"/>	I performed all actions requested by the FSN.	Customer to complete or enter N/A	
<input type="checkbox"/>	The information and required actions have been brought to the attention of all relevant users and executed.	Customer to complete or enter N/A	
		Qty:	Lot/Serial Number: Date Returned (DD/MM/YY):

BIOMATRICA, INC.
5627 Oberlin Drive, Suite 120,
San Diego, California 92121 USA
Tel: 858-550-0308
Fax: 858-678-0597

Confidential

<input type="checkbox"/>	I have returned affected devices - enter number of devices returned and date complete.	Qty:	Lot/Serial Number:	Date Returned(DD/MM/YY):
		N/A	Comments:	
<input type="checkbox"/>	I have destroyed affected devices – enter number destroyed and date complete.	Qty:	Lot/Serial Number:	
		Qty	Lot/Serial Number:	
		N/A	Comments:	
<input type="checkbox"/>	No affected devices are available for return/ destruction	Customer to complete or enter N/A		
<input type="checkbox"/>	Other Action (Define):			
<input type="checkbox"/>	I do not have any affected devices.	Customer to complete or enter N/A		
<input type="checkbox"/>	I have a query please contact me (e.g. need for replacement of the product).	Customer to enter contact details if different from above and brief description of query		
Print Name*		Customer print name here		
Signature*		Customer sign here		
Date*				

4. Return acknowledgement to sender	
Email	bstandwill@biomatrica.com
Customer Helpline	+1 858 550 0308
Postal Address	Biomatrica, Inc. 5627 Oberlin Drive, Suite 120 San Diego, California 92121 USA
Web Portal	Biomatrica.com
Fax	+1 858-678-0597
Deadline for returning the customer reply form*	30/09/2019

Mandatory fields are marked with *

BIOMATRICA, INC.
5627 Oberlin Drive, Suite 120,
San Diego, California 92121 USA
Tel: 858-550-0308
Fax: 858-678-0597

Confidential

It is important that your organization takes the actions detailed in the FSN and confirms that you have received the FSN.

Your organization's reply is the evidence we need to monitor the progress of the corrective actions.

BIOMATRICA, INC.
5627 Oberlin Drive, Suite 120,
San Diego, California 92121 USA
Tel: 858-550-0308
Fax: 858-678-0597

Confidential