



URGENT: DISTRIBUTOR NOTIFICATION

Date: January 2026

FA #: FA-WKS-26-001

Dear Distributor,

Our records indicate you have previously received the following LIFECODES LSA Class I lot:

Product Name	Product Number	UDI Number	Lot Number	Expiration Date
LIFECODES LSA Class I	265100	10888234400332	3015822	04 APR 2026

Manufacturer
Immucor GTI Diagnostics, Inc.
(A Werfen Company)
20925 Crossroads Cir
Waukesha, WI, 53186-4054
USA
+1 855.466.8267
www.werfen.com

Issue Details:

Due to a stability failure observed at the 9-month test interval, we have identified that LIFECODES LSA Class I lot 3015822 may not consistently achieve bead acquisition of 60 beads within 90 seconds for samples or controls during a run. Previous stability assessments met all acceptance criteria.

Product Impact:

Patient Risk is low as bead count failures are not reportable. Results from valid assays are not impacted and have been determined to be accurate.

Actions Taken:

Immucor GTI Diagnostics, Inc. has stopped distribution of the impacted lots.

Requested Customer Actions

Please take the following actions:

- 1) Please provide a copy of this communication to your customers
- 2) Inform them that they may continue to use the affected kit lot number using the acceptance criteria as labeled in the IFU for LIFECODES LSA Class I. Assay results generating passing bead counts are considered valid.
- 3) There is no requirement to return any kits.


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- 4) **Please complete and sign** the Mandatory Response Form on page 3 of this communication and return it to the email below within 10 days of receipt to acknowledge this notification.

E-mail: kyoung1@werfen.com

We apologize for any inconvenience this issue has caused. We appreciate the trust and confidence you place in our products. If you need additional information, please contact Technical Support for the US, Canada, and LATAM by phone at +1.800.678.0710, or by email at lifecodestechsupport@werfen.com. For International Technical Support, please reach out via email at tech.support.int.transplant@werfen.com, or contact your local Technical Sales Specialist.

Sincerely,

Signed by Leon Lambry
 I am the author of this document
29-Jan-2026 | 4:59:23 PM EST
Leon Lambry
Senior Director, Quality and Regulatory Affairs

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Mandatory Response Form

I verify that our facility was provided with this notification document for LIFECODES LSA Class I lot listed in this notification.	
Printed Name: Chow Li Yin	
Signature: Li Yin	Date: 05-Feb-2026
Title: Regulatory Specialist	
Facility / Institution Name: BMS Diagnostics (M) Sdn Bhd	
Regulatory Agency Notification Required? <input checked="" type="checkbox"/> Yes <input type="checkbox"/> No	
If yes, Name and Country of Agency Notified: Medical Device Authority	Date Notified: 05-Feb-2026