

Date 09 APRIL 2026


MEDICAL DEVICE MARKET WITHDRAWAL

FA #: FA-WAR-26-01

Dear Customer:

Our records indicate that your site has purchased the below listed product(s).

Exposure Test Carrier (ETC)

REF Kit: 800-20301	REF Slide: 830-00063		
LOT	LOT		UDI
24-104-V	24-102	2026-05-31	(10)-24-104-V(17)260531
25-159-V	25-158	2027-08-31	(10)-25-159-V(17)270831

Issue Details: BioArray Solutions Ltd. has received several complaints of low signal results in our BeadChip™ assays. The investigation has indicated that the above lots of the Exposure Test Carrier (ETC) used to calibrate the Array Imaging System™ (AIS 400) have target intensities that were within specification, but lower than previously released lots.

Product Impact: Running the exposure test on the Array Imaging Systems (AIS) with the impacted ETC lots may still yield a 'passed' result, indicating no intervention is required to adjust the assay auto-exposure multiplier prior to processing BeachChip™ Carriers. Depending on your AIS set up and your settings for the auto-exposure multiplier, you may observe an increased frequency of no-result conditions flagged as low signal when running BeachChip™ assays.

Manufacturer Actions Taken: Our investigation identified that malfunction of equipment used to assign the ETC target intensity as the root cause. The impacted equipment has been taken out of service, and we have implemented additional quality checks to prevent recurrence. In addition, we have scanned remaining inventory of ML 25-159-V and have reassigned a corrected intensity to these ETCs. ETCs with the corrected intensity will be released with the lot number designation of ML 25-159-V-R. A limited quantity is available for replacement with a new lot of ETC will be available in mid APR 2026. Werfen is facilitating no-charge shipments of the replacement lots.



Customer Actions to Be Taken: Please stop using the above listed lots.

From our investigation, the increase in low signal results is attributed to the lower than expected ETC target intensities. For previous runs where quality control passed, genotype assignments are considered valid.

If your site has been experiencing an increased rate of low signal results, please also contact technical support to report the details.

Please complete the attached customer response acknowledging that this notification was received and indicate how many ETC slides the site will discard and their lot number.

We apologize for any inconvenience this issue has caused.

If you have questions or require additional information, please contact Technical Support at 855-466-8267, option 2 and then option 7 or BASTechSupport@werfen.com.

Sincerely,

Signed by Sarah Rickert
 Sarah Rickert | I am the author of this document
09-Apr-2026 | 12:12:28 PM EDT
6327999863504B69ADE514325C5EC0BF

Sarah Rickert

Director of Quality and Regulatory Affairs
BioArray Solutions, dba Werfen
Warren, NJ USA



MEDICAL DEVICE MARKET WITHDRAWAL

CUSTOMER RESPONSE FORM


FA-WAR-26-01

I verify that our facility was made aware of the voluntary field action of Exposure Test Carrier (ETC) PN 800-20301 Lot 24-104-V and 25-159-V	
Printed Name:	
Signature:	Date:
Position:	
Facility / Institution :	

Exposure Test Carrier (ETC):

Please record the number of slides the site has in inventory and/or use and will discard.

REF 800-20301 (Kit)

LOT		Number of Slides
ML 24-104-V	2026-05-31	
ML 25-159-V	2027-08-31	

Please return this completed form by 30 April 2026 via e-mail to BAS-Regulatory@werfen.com or srickert@werfen.com