

#### Bio-Rad Laboratories

Clinical Diagnostics Group 9500 Jeronimo Road Irvine, California 92618-2017 Tel: (949) 598-1200 www.bio-rad.com/qualitycontrol

 Please complete and return the attached response form as soon as possible so that we are assured you have received this important communication.

# Resolution by Bio-Rad:

We are working to resolve the issue and apologize for any inconvenience.

#### **Contact Information:**

Please contact your local Bio-Rad Technical Support if you have any questions regarding this communication. USA contact information is provided below.

 Technical Support Department (USA) at 1-800-854-6737, option #2, or by email at qsd.techservice@bio-rad.com if you have technical questions regarding this notice.

Bio-Rad is committed to ensuring the highest levels of safety and quality. We sincerely apologize for any inconvenience this issue may have caused

Mario Wijker Bio-Rad SVP, RAQA

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# IMPORTANT PRODUCT INFORMATION

Liquichek Unassayed Chemistry Control - Level 2

Important information in Liquichek Unassayed Chemistry Control - Level 2 of lot 92982

For the attention of: Clinical Laboratory Director, Manager or Supervisor /Laboratory Professional Users /Channel Partner

Please retain this letter for your records

Date: January 10, 2025

Bio-Rad Reference: FAR 2024-04A

Dear Valued Customer / Channel Partner,

The purpose of this letter is to inform you that you may observe lower calcium recovery in Level 2 of Liquichek Unassayed Chemistry Control, Lot 92982, when the product is initially thawed.

### Reason for the Action:

Lower calcium recovery is observed when the product is initially thawed, followed with recovery increasing to the expected values within several hours after thaw.

### Affected Product Identification:

Product Name		Liquichek Unassayed Chemistry Control - Level 2		
Level	Catalog	Lot Number	Lot Number	UDI NUMBER
Control of the Contro	Number	NAME OF TAXABLE PARTY.	Expiration Date	
Level 2	692	92982	2025-08-31	00847661000013
MiniPak	690X	92980		00847661002161

# Action(s) to be taken by the Customer:

For optimal performance and to minimize the impact of the initial low calcium recovery, the product requires an additional hold time of at least 24-48 hours in the refrigerator (2-8 °C) after the product is thawed and unopened, prior to use.

Bio-Rad is requesting that customers affected by this notice take the following action:

- Hold Lot 92982 (Level 2) for at least 24-48 hours in the refrigerator (2-8 °C) after the product is thawed and unopened prior to use.
- Ensure this notice is provided to all those who need to be aware within your organization or to any organization where the impacted devices have been transferred.