



EKF Diagnostics Inc.

1261 North Main Street
Boerne, Texas 78006
USA

Phone: 1.830.249.0772

Email: stanbio@stanbio.com

Web: www.stanbio.com

PRODUCT CORRECTION NOTIFICATION

July 12, 2021

Dear Valued Customer,

Product quality is Stanbio Laboratory's main priority, so we have initiated a voluntary recall involving:

β-Hydroxybutyrate LiquiColor®

Catalog #	Lot #	Expiry
2440-058	164312	2022-09-30
2440-058	161081	2022-09-30
2440-058	161039	2022-06-30
2440-058	161031	2022-06-30
2440-058	158972	2022-09-30

Our records indicate that you purchased one or more of the β-Hydroxybutyrate LiquiColor® kits listed above.

We have observed in the affected lots above, deterioration in the stability of the liquid reagents which has resulted in lower than expected or out of range Quality Control values. This situation is not likely to cause any adverse health consequences to patients and none have been reported.

Please discontinue use of and quarantine any affected product. Please complete the attached Verification Form and fax it to Stanbio Laboratory at (830) 249-0851 or email at productsafety@ekfdiagnostics.com. Your cooperation is appreciated. We will send replacement kits, free of charge.

If you are a distributor, please forward this letter on to your β-Hydroxybutyrate LiquiColor® kit customers. Complete and fax or email the enclosed Verification Form within 10 days to confirm your receipt of this notice.

Please retain this letter for your records as documentation that you received this information.

STANBIO®

Stanbio is part of the EKF Diagnostics Holdings plc group of companies



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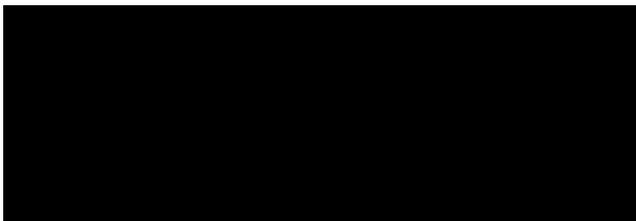
CUSTOMER REQUIRED ACTION

- **Please discontinue use of and quarantine any affected product.**
- **Only lots listed in the table above are affected and you may continue to use any other lots you may have in your possession.**
- **Please share this information with your laboratory staff and retain this notification as part of your laboratory Quality System documentation.**
- **If you have forwarded the product to another laboratory, please provide a copy of this letter to them. Please provide the name, address and a contact for the laboratory on the Verification Form.**
- **Complete and fax or email the enclosed Verification Form within 10 days to confirm your receipt of this notice.**

If you have further questions, please contact Technical Support at 1-800-531-5535 ext. 128.

We sincerely apologize for any inconvenience this issue may have caused.

Thank you.



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To satisfy global requirements for regulatory reporting, please complete and return this form within 10 business days of receipt even if you do not have any involved product and email to productsafety@ekfdiagnostics.com or fax to (830)-249-0851.

**Customer Verification Form
 PRODUCT CORRECTION NOTIFICATION**

1. We acknowledge receipt of the Stanbio Laboratory PRODUCT CORRECTION NOTIFICATION dated, July 12, 2021 for the following product:

β-Hydroxybutyrate LiquiColor®
2. We confirm that all areas where the product could be located have been checked.
3. The following has been verified (SELECT ALL THAT APPLY):
 - We have read and understand the contents of this letter.
 - We do have affected product and have quarantined the product.
 - Product was redistributed to another facility; notice was forwarded.
 - We do not have any affected product.

Catalog #	Lot #	Expiry	Quantity on hand
2440-058	164312	2022-09-30	
2440-058	161081	2022-09-30	
2440-058	161039	2022-06-30	
2440-058	161031	2022-06-30	
2440-058	158972	2022-09-30	

Date: _____ Signature: _____

Print Name: _____

Title: _____ Department: _____

Institution: _____

Address: _____

City: _____ State: _____ Postal Code: _____

Country: _____ Phone: _____

Email: _____