Bio-Rad Laboratories

Clinical Diagnostics Group
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Important Product Field Action Notification
Notice of Correction

Lyphochek Coagulation Control

Level	Catalog Number	Lot Number Expiration: 2023-04-30	Lot Number Expiration: 2023-11-30	Lot Number Expiration: 2024-03-31	Lot Number Expiration: 2024-09-30	Lot Number Expiration: 2025-01-31	Lot Number Expiration: 2025-04-30	Lot Number Expiration: 2025-08-31	UDI
1	744	84641	84651	84661	84671	84681	84691	84701	00847661000778
2	745	84642	84652	84662	84672	84682	84692	84702	00847661000785
3	746	84643	84653	84663	84673	84683	84693	84703	00847661000792
MiniPak	745X	84640	84650	84660	84670	84680	84690	84700	00847661001959

This Notice is intended for the end-users of this product.
If you are not the end-user, please forward this Notice to the appropriate laboratory personnel.

Date January 31, 2023

To Clinical Laboratory Director, Manager or Supervisor

From Bio-Rad Laboratories QSD Regulatory Affairs

Product Lyphochek Coagulation Control

Issue

We have received intermittent complaints about flakes/clots in Lyphochek Coagulation Control. This product is prepared from non-defibrinated plasma; sporadic flakes/clots can form when the reconstituted product is frozen. We are, therefore, removing the reconstituted frozen and freeze-thaw cycles claims and are revising the LIMITATIONS section to instruct customers to discard the vials if they find evidence of fibrin clots.

The STORAGE AND STABILITY and LIMITATIONS sections in the Instructions for Use (IFU) have been revised as shown below. (This is a permanent change and will also be reflected in the IFU of all future lots).

All other claims for Lyphochek Coagulation Control remain unchanged.

Revised Claims

Significant changes are highlighted!

STORAGE AND STABILITY

After reconstituting and storing tightly capped at 2 to 25°C, this product will be stable as follows:
- All analytes: 48 hours

LIMITATIONS

If there is evidence of microbial contamination, excessive turbidity, or **fibrin clots** in the reconstituted product, discard the vial.

Actions Required

- Please obtain the revised (Rev. 1) IFU through the Internet at http://myeinserts.qcnet.com. Discard all previous versions that you may have at your location.
- Contact Bio-Rad Laboratories 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.

We appreciate your patience and apologize for any inconvenience this may have caused.