

Tuesday, February 21, 2017

IMPORTANT PRODUCT INFORMATION COMMUNIQUE

Dear RNA Medical Customer,

Our records indicate that your site has ordered RNA Medical[®] Brand QC HGB Hemoglobin Control QCHGB2 Lot 67320 EXP: 2018-09-30 or QCHGB Lot 672009 EXP: 2018-08-31. This letter contains important information regarding these lots of controls. Please review the information below as the level 2 Normal daily quality control recovery may fall outside of the expected values range as published on the lot specific insert.

NOTICE:

RNA Medical has determined that the assaying of level 2 Normal Lot 67320 which is also included in Multi-level Lot 672009 is not representative of the full production lot and as a result, segments of the lot have shown to recover outside of the published expected values range. The entire lot targets a *normal* hemoglobin level however a segment of the lot recovers outside the expected value range provided on the product insert. Refer to your specific laboratory Quality Assurance instruction if an out of range result presents when testing level 2 Normal.

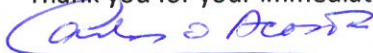
The expected values ranges for the Levels 1 Low Lot 67220 and 3 High Lot 67419 contained within the Multi-level Lot 672009 perform as expected and recover within the published ranges, only the Level 2 Normal Lot 67320 may be impacted. If you have already used the level 2 Normal control and recovered within the published range your test results are valid and no action is required.

RECOMMENDED ACTIONS:

- Destroy remaining inventory of Level 2 Normal Lot 67320. Disposal of this product should be according to the practices of your institution for infectious medical waste. Discard all materials in a safe and acceptable manner and in compliance with all federal, state and local requirements. NOTE: If your Level 2 Normal recovered values have been within the insert range and if you wish to continue using the lot 67320 you may do so at your discretion. RNA Medical will still issue credit upon completion of the RESPONSE FORM.
- Complete the attached RESPONSE FORM and forward a copy to customerservice@RNAMedical.com or fax it to 978-598-7918. RNA Medical will issue a full credit for the QCHGB2 and a partial credit for the QCHGB Multi-level material upon receipt of the RESPONSE FORM.

If you have any questions regarding this information, please contact RNA Medical Technical Support at 978-772-7070 or contact us directly at customerservice@RNAMedical.com.

Thank you for your immediate attention to this matter.



Carlos O. Acosta

Director of Quality Assurance & Regulatory Affairs

RESPONSE FORM
QC HGB LEVEL 2 NORMAL LOT 67320

| | |
|---|--|
| Hospital/Clinic Name | |
| Address | |
| Phone | |
| Contact Name and Title | |
| Email | |
| Quantity of QCHGB boxes Lot 672009 Purchase Order or Invoice Number(s) | |
| Quantity of QCHGB2 boxes Lot 67320 Purchase Order or Invoice Number(s) | |

All materials have been disposed of in accordance with practices for infectious medical waste.

Signature and Date

Email completed form to customerservice@RNAMedical.com
FAX: 978-598-7918