



March 15, 2016

Field Corrective Action 16-001, Customer Notification Letter

PTS Panels® CHOL+HDL+GLU Test Strips, Catalog #2412 Lot #I502
Date of Manufacture: 2015 02 11
Expiration Date: 2016 05 18

An integral part of our quality system is continuous product performance surveillance. Recently, we have discovered during this process that the above identified lot of PTS Panels CHOL+HDL+GLU test strips, lot number I502, is showing an under-recovery when tested against a reference method. Based on the available data and the observed low frequency of under-recovery, we have determined that the degree of glucose under-recovery does not present a health risk. However, we are taking action to remove this product from the field.

We have identified that you have received some of this product. **Customers with any of this product remaining in their possession must immediately discontinue use and dispose of their remaining inventory of PTS Panels CHOL+HDL+GLU test strips, lot number I502. No other lots of this product or other PTS Diagnostics products are impacted by this action. PTS Diagnostics will provide appropriate replacement product for any product properly identified on the attached Customer Acknowledgement and Confirmation Form.**

Please immediately identify the number of remaining PTS Panels CHOL+HDL+GLU test strip vials you currently have remaining in inventory of lot I502 on the attached form. We will supply you with replacement product for any unused inventory you have of this product and lot. Please return your completed form to PTS Diagnostics via fax at +1-317-870-5608 or via email at customerservice@ptsdiagnostics.com.

We appreciate your assistance and understanding as we take this action to ensure that our products always continue to meet the high quality standards you have come to expect from PTS Diagnostics. We are committed to continuing to ensure customer satisfaction, and look forward to serving you in the future. Please save this information and make appropriate changes to your records. If you have any questions, please contact PTS Diagnostics Customer Service toll-free at 877-870-5610 or direct at +1-317-870-5610.

Sincerely,

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