

To: Clients of URMC Labs

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Re: Low fasting insulin results

Date: Feb 2, 2011

We have just recently received a customer notification bulletin from our insulin assay manufacturer (Siemens Healthcare Diagnostics) about the observed downward shift of results from a reference population using reagent kit lots which have been in use in our laboratory since April 2010. As stated in the notification, use of these lots "may result in a higher frequency of fasting patient samples showing values below the assay limit of 2 μ IU/mL" (Reference range 6-27 μ IU/ml)

Upon receiving the notice, we validated the statement with 21 normal samples and found there were 11 results (52%) with values less than 2 μ IU/ml. We also found that there has been a significant increase of insulin results at the level of < 2 μ IU/ml in Dec. 2010 (25.6% of total performed) compared to the number obtained in Dec. 2009 (12.5% of total performed).

Siemens Healthcare Diagnostics will "continue to investigate this issue", and we will update you when we have further information. We have also begun to investigate an alternative method for the assay. We apologize for the inconvenience this problem may cause you. If you have any questions, please contact Dr. Chen via the contact information listed above or the Automated Lab Chief Supervisor Barbara A. Meiklejohn @ x5-2435 or via e mail to: Barbara_Meiklejohn@URMC.Rochester.edu