Device Correction

ABBOTT LABORATORIES
100 Abbott Park Road
Abbott Park, IL 60064-6081

ARCHITECT® Folate Reagent
List Number 6C12-20, 6C12-25, 6C12-30

March 11, 2005

Dear Abbott ARCHITECT Folate Customer:

This letter contains important information regarding the ARCHITECT Folate Reagent. Please review the information carefully and follow the instructions below.

BACKGROUND

Abbott Diagnostics Division has recently noted an increase in customer complaints for a downward shift in control and/or patient results when using the ARCHITECT Folate assay. An investigation of these complaints has determined that the folate concentrations for normal samples generated with current reagent lots of the ARCHITECT Folate assay are lower than data generated for the package insert.

- The median ARCHITECT Folate concentration from the serum population was 23% lower (10.0 ng/mL) when compared to the median value in the package insert (12.9 ng/mL).
- The median ARCHITECT Folate RBC concentration from the whole blood population was 32% lower (209.4 ng/mL) when compared to the median value in the package insert (306.6 ng/mL).

The investigation has not yet identified the time the shift occurred. However, it has been determined that all reagent lots currently within expiration are performing consistently and show this downward shift. Control values may be similarly affected and produce values that are out of range low.

Patient management decisions may be impacted near the concentration your laboratory uses to distinguish between a normal and a deficient folate level. For example, based on the percent shift identified in the internal studies and using established package insert ranges, samples with serum folate values between 2.7 - 3.0 ng/mL, which are considered normal, would now be classified as deficient (</= 2.3 ng/mL).

NECESSARY ACTIONS

It is important that the following actions are taken:

- Assess your normal and deficient ranges for your specific population.
- Assess your quality control ranges.
- Follow your laboratory procedures for reviewing patient results and notifying Health Care Providers that you serve.

If you have forwarded any ARCHITECT Folate Reagent to another laboratory, please provide a copy of this letter to them. Retain this letter for your laboratory records.

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ADDITIONAL INFORMATION

An investigation is being conducted into the cause of the shift in folate values. Until the investigation is completed, actions will be taken to ensure future reagent lots continue to perform consistently with current product.

If you or any of the health care providers you serve have any questions regarding this information, please contact your local customer service.

Abbott Diagnostics Division considers you a valuable customer and sincerely regrets the inconvenience this has caused you and your laboratory. Thank you for your patience and cooperation.

Sincerely,

[redacted]
Medical Director, On Market Product Safety
Abbott Laboratories
Abbott Diagnostics Division

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