

Date: 4/6/2009

To: Marquette General Staff Physicians, Physician Assistants, Ordering Physicians

From: John Rhoades – Director – Marquette General Health Systems Laboratory
Dale Hamari – Supervisor Special Chemistry
George Krzymowski M.D. Pathologist – Marquette General Hospital laboratory

Re: **Positive bias for PTH test results** and notification of physicians

Siemens Diagnostics, the test vendor for MGH's PTH test, has notified all users of their PTH reagents of a positive bias affecting PTH test results. The time interval of affected samples is from October 2008 until mid March 2009. The positive bias affected samples with reported concentrations of 150 pg per milliliter or less. Positive bias observed averaged 20-25 %.

Siemens has now corrected the positive bias in their reagents.

We have reviewed all patient results from the affected kits for the relevant time range. After consultation with select medical staff, we have decided to individually notify the ordering physician of all patients with results within the range of 65-100 pg per milliliter. PTH reference range is 12-65 pg/ml. Please find attached a list of your patients potentially affected by the positive bias of the PTH test. (This notification is also being distributed to all staff physicians. You may receive a duplicate and attachment list will only be included with individual ordering physician copy for patients who met notification criteria).

The MGH laboratory will offer repeat testing (at no charge) of PTH levels from now until July 30, 2009 for any affected patient at the patient or clinician's request. Please order as "no charge repeat PTH" in order to facilitate no charge testing. Contact Dale Hamari (225-3050; ext 7374; dhamari@mgh.org) if any assistance is needed.

The MGH laboratory and the manufacturer are reassessing current practices in an attempt to preclude similar systematic errors in the future.

We apologize for any inconvenience for you or your patients.

Any questions or concerns can be directed to Dale Hamari or Dr. Krzymowski (gkrzymowski@mgh.org; 225-3050).