

Memorandum

To: Spectrum Health Medical Staff

From: Richard A. Horvitz MD, Clinical Pathologist

Date: February 1, 2011

Re: Thyroglobulin antibody

The manufacturer of the Thyroglobulin Antibody test used in the Spectrum Health Laboratory has notified us that the current lot of reagent for this test has been recalled and no replacement reagent is presently available.

The most common use of thyroid antibody tests (Thyroglobulin antibody, SH#8523 and Thyroid Peroxidase antibody (TPO antibody), SH#8524) is for the evaluation of patients with suspected Hashimoto's or other autoimmune mediated thyroid disorders. It is well established in the literature, and in professional guidelines in this field (references available from the Laboratory upon request), that **TPO antibody is the most useful test for these disorders** and that Thyroglobulin antibody is of only marginal, if any, additional diagnostic value in such patients.

Effective immediately, **the Spectrum Health Laboratory will therefore, on specimens where both Thyroglobulin antibody and TPO antibody tests are ordered, perform and report only the TPO antibody.** The Thyroglobulin antibody test will be cancelled with a notation that reagent is not available.

Specimens where the Thyroglobulin antibody test is ordered will be held frozen for 30 days in case this test is specifically required. If such testing is required, the test will be reordered and the specimen will be held until reagent is again available or sent to a reference laboratory where this test is available by a different method. Any requests for this test must be directed to Dr. Richard Horvitz in the Pathology Department at 616-391-1848 for review and approval before this test will be reordered.

It should also be noted that the Thyroglobulin antibody reagent manufacturer has notified us that the recalled reagent had the potential to produce erroneous patient results. This reagent was used in our laboratory from September 10 through September 24, 2010, and again from January 3 through January 28, 2011. Any Thyroglobulin antibody results during this period should be interpreted with caution, and the test repeated if clinically indicated.