Effective May 4, 2010, there is a new TSH reference range for adults:

**Current Reference Range:** 0.34 – 2.50 µU/mL  
**New Reference Range:** 0.30 – 5.00 µU/mL

**Has the TSH test method changed?**  
There has been no change in methodology. Only the reference range has been changed. The most significant change is that the upper limit of normal has been raised from 2.50 µU/mL to 5.00 µU/mL.

**Why was the upper limit for TSH set at 2.5 µU/mL in the first place?**  
A national guideline published in 2003 recommended lowering the upper limit of TSH to 2.5 µU/mL (NACB in Thyroid. 2003 Jan;13(1):3-126). Based on a population study, this was felt to be the true upper limit for euthyroid individuals after rigorous exclusion of all patients with possible thyroid dysfunction.

**Why is the laboratory now raising the upper limit of normal for TSH to 5.0 µU/mL?**  
More recent studies indicate that an upper limit of 2.5 µU/mL for TSH is too low. Kratzsch et al (Clin Chem. 2005 Aug;51(8):1480-6) showed that after rigorously excluding all patients with possible thyroid dysfunction, a normal range for TSH was 0.12-5.29 µU/mL. Massachusetts General Hospital uses a range of 0.5-4.7 µU/mL (New England Journal of Medicine 2004;351:1548-63) and Mayo Clinic uses a range of 0.3-5.0 µU/mL. Parallel tests of patient specimens at Allina and Mayo Clinic show the same TSH results and a recent reference range validation performed at AML indicates that the normal range for our population is consistent with the one used at Mayo Clinic.

**What is the clinical impact of this change?**  
Fewer patients will be flagged as having an elevated TSH. This will avoid overdiagnosis of hypothyroidism and provides more accurate detection of patients with true early thyroid dysfunction (TSH between 5-10 µU/mL).

**What follow-up testing is recommended for patients with abnormal TSH results?**  
TSH, although an adequate screening assay for thyroid disorders, is always evaluated with fT4 when TSH concentration is increased or decreased, as the diagnostic value lies in the dynamic changes of both markers. It should also be noted that normal ranges, although useful as a guideline for clinicians, should not be used as absolute indicators of health and disease.

**Questions:**  
Refer to Dr. Brenda Katz (612-863-4708) or Dr. Lauren Anthony (612-262-5013).