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Data reaffirms test's ability to identify benign thyroid nodules

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Aurora, CO (Oct. 23, 2013) The latest study co-led by a CU School of Medicine researcher has confirmed that a Gene Expression Classifier (GEC) test can drastically reduce the problem of unnecessary surgeries in thyroid nodule assessment. These indeterminate nodules are being evaluated with a new molecular diagnostic test that measures the expression levels of 142 genes. This test is able to identify which initially indeterminate nodules are highly likely to be benign, and thus allows patients to avoid unnecessary diagnostic surgery.

This multi-site study co-led by Bryan R. Haugen, MD, professor of medicine and pathology at the University of Colorado School of Medicine provides the first long-term look at how these patients fared, and its findings reaffirm the performance of the Afirma Gene Expression Classifier (GEC). Haugen said "Each year, tens of thousands of patients with thyroid nodules have surgery to remove all or part of their thyroids. This is due to fine needle aspiration (FNA) cell test results that are indeterminate or inconclusive yet raise suspicions for thyroid cancer. Often times, most of these nodules prove to be benign. Our findings suggest that when the GEC identifies an otherwise indeterminate thyroid nodule as benign – which it does about 50% of the time – it is comparable in accuracy to a benign diagnosis by cytopathology, This fact and the degree to which physicians and patients in the study opted against surgery when the molecular test result was benign underscore the test's potential to drastically reduce the problem of unnecessary surgeries in thyroid nodule assessment."

Researchers analyzed all patients who had received Afirma GEC testing following indeterminate FNA biopsy results at five academic medical centers between 2010 and 2013. The GEC identified 174 of 339 (51%) indeterminate nodules as benign and, among these, 71 had documented clinical follow-up for an average of 9 months. Of these, only one nodule proved cancerous, demonstrating a very high negative predictive value (NPV) for the GEC. This finding is consistent with results from an earlier prospective, multicenter clinical study. Additionally, in the new study only 6% of patients with nodules identified as benign by the GEC test underwent surgery. This is a substantial reduction compared to traditional surgical rates for patients with cytologically indeterminate thyroid nodules.

Thyroid nodules are common, but only approximately 5-15% prove malignant. Most nodules are evaluated using FNA, with approximately 525,000 thyroid nodule FNAs performed in the U.S. in 2011 to rule out cancer. In most cases, the results are benign, yet in approximately 15-30% of cases the results are indeterminate – not clearly benign or malignant. Because of the risk of thyroid cancer, most of these patients have historically been recommended for surgery to remove all or part of the thyroid to obtain a final diagnosis. However, such indeterminate nodules prove ultimately benign in 70-80% of cases. For these patients, the surgery was not needed and they were unnecessarily exposed to the cost, risk and morbidity of this intervention. Additionally, most patients subsequently require lifelong thyroid hormone therapy.

The study is published online in the *Journal of Clinical Endocrinology & Metabolism* and its findings were presented recently at the 83rd Annual Meeting of the American Thyroid Association, held in Puerto Rico.

The long-term findings built on the previous study which demonstrates the Afirma Gene Expression Classifier's accuracy was published in the *New England Journal of Medicine*.