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New Article in PLOS Currents: Evidence on Genomic Tests Supports Use of Veracyte's Afirma® Gene Expression Classifier to Resolve Ambiguous Thyroid Nodule Biopsies

South San Francisco, Calif. --- February 15, 2013 --- [Veracyte, Inc.](#) today announced that a new review article published in [PLOS Currents: Evidence on Genomic Tests](#) concludes that published studies and independent assessments and reviews of the Afirma Gene Expression Classifier support the test's use to help resolve inconclusive results on thyroid nodule fine needle aspiration (FNA) samples, and thus help patients avoid unnecessary surgery as part of thyroid cancer diagnosis. The findings also reinforce recent guidelines from the National Comprehensive Cancer Network (NCCN) recommending that physicians consider using molecular testing in lieu of diagnostic surgery for patients with ambiguous thyroid nodule FNA results – provided the test's performance is similar in accuracy to a benign diagnosis by cytopathology.

The authors determined that the clinical and analytical validation studies used to evaluate the Afirma Gene Expression Classifier were consistent with the stringent, Level 1 evidence criteria for study design and implementation standards established by the Evaluation of Genomic Applications in Practice and Prevention (EGAPP), an initiative of the U.S. Centers for Disease Control's Office of Public Health Genomics. The second and larger prospective clinical validation study involved 49 academic and community sites and found that when the genomic test reclassified indeterminate-cytology thyroid nodule FNA samples as benign – which it did more than half of the time – its accuracy was similar to a benign diagnosis using cytopathology. The new review article also evaluated the published literature regarding the test's clinical utility, as well as technology assessments/guidelines by independent parties and professional groups, such as the national contractor that administers Medicare benefits and the NCCN.

"This new review paper helps to further establish the Afirma Gene Expression classifier as a valuable tool for helping thyroid nodule patients avoid unnecessary surgery, while also removing costs from the healthcare system," said Bonnie Anderson, cofounder and chief executive officer of Veracyte. "It also supports the growing use of the test among community-based endocrinologists and leading academic institutions around the country."

Thyroid cancer is the fastest-increasing cancer in the United States, with 60,220 new cases expected in 2013, according to the American Cancer Society. Approximately 450,000 thyroid nodule FNAs – a minimally invasive procedure to extract cells for examination under the microscope – are performed each year in the U.S. to rule out cancer. However, in 15% to 30% of cases, the results are inconclusive, and current protocols typically recommend thyroid surgery for final diagnosis. Following surgery, however, 70-80% of patients turn out to have benign nodules.

About the Afirma® Gene Expression Classifier

The Afirma Gene Expression Classifier measures the expression of 142 genes to reclassify ambiguous thyroid FNA samples as either benign or suspicious for cancer. The test is offered as part of Veracyte's comprehensive Afirma Thyroid FNA Analysis, which combines specialized cytopathology assessment for initial review of thyroid nodule FNAs, with the gene expression test used to clarify inconclusive results. The test is covered for Medicare patients nationwide and is available throughout the U.S. through a global co-promotion partnership with Genzyme, a Sanofi company.

About Veracyte

Veracyte, Inc., based in South San Francisco, Calif., is a privately held molecular diagnostics company pioneering the emerging field of molecular cytology. The company discovers, develops and commercializes molecular diagnostic solutions that enable physicians to make more informed treatment decisions early, thus helping patients avoid unnecessary invasive procedures while reducing healthcare costs. Veracyte's first product – the Afirma® Thyroid FNA Analysis – combines specialized cytopathology assessment with the Afirma Gene Expression Classifier, a genomic test that clarifies inconclusive thyroid nodule results as benign or suspicious for cancer. The company has formed a global co-promotion partnership with Genzyme, a Sanofi company, to make the Afirma Thyroid FNA Analysis available throughout the U.S. and, subsequently, globally. Veracyte is currently in the early biomarker discovery phase for lung cancer and interstitial lung diseases. Veracyte is privately held and funded by Domain Associates, Kleiner Perkins Caufield & Byers, TPG Biotech and Versant Ventures. For more information, visit www.veracyte.com.

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