



New Publication Reinforces Clinical Utility of Afirma Genomic Sequencing Classifier in Thyroid Cancer Diagnosis

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SOUTH SAN FRANCISCO, Calif.--(BUSINESS WIRE)--Nov. 3, 2021-- [Veracyte, Inc.](#) (Nasdaq: VCYT) announced today the publication of new long-term clinical utility data showing that the company's Afirma Genomic Sequencing Classifier (GSC) helped reduce unnecessary surgeries in patients with indeterminate thyroid nodule cytology, as compared to the use of no molecular testing. The peer-reviewed paper appears online in [The Journal of the Endocrine Society](#).

Veracyte estimates that each year approximately 565,000 people with thyroid nodules undergo fine-needle aspiration (FNA) biopsies to assess potentially cancerous nodules. Up to 30 percent of these patients receive indeterminate results – meaning their nodules are not clearly benign or malignant based on traditional cytopathology evaluation. Historically, most of these patients were directed to diagnostic surgery, even though 70 percent to 80 percent of the time the nodules proved to be benign.¹

The Afirma GSC helps physicians identify patients with benign thyroid nodules from among those with indeterminate FNA results, so that they may avoid unnecessary thyroid surgery. Current American Thyroid Association guidelines include molecular testing as a recommended option to achieve definitive diagnosis for nodules classified as indeterminate following FNA biopsy.¹

In the current study, researchers at the University of Nebraska Medical Center (UNMC) and the VA Nebraska-Western Iowa Health System retrospectively analyzed 468 cytologically indeterminate thyroid nodules from January 2013 to December 2019 to assess and compare how use of the Afirma GSC (n=124) and the original Afirma Gene Expression Classifier (GEC; n=71) impacted patient care. Use of these tests was also compared to nodules that did not undergo molecular testing (n=273). They found that the Afirma GSC identified 30 percent more nodules as benign, compared to the GEC (60 percent vs. 46 percent, respectively) and that use of the Afirma GSC resulted in 41 percent fewer surgeries, compared to patients with no molecular testing (40 percent vs. 68 percent, respectively). Additionally, when surgery was performed, patients deemed “suspicious for cancer” by the Afirma GSC were 95 percent more likely to have cancer compared to those who had no molecular testing (39 percent vs. 20 percent, respectively).

“Our analysis showed a significant improvement in the benign call rate with the Afirma GSC as compared to no molecular testing, as well as a significant increase in confirmed malignancies among those patients who did go to surgery when utilizing the test,” said Whitney Goldner, M.D., professor, Department of Internal Medicine, Division of Diabetes, Endocrinology, and Metabolism, University of Nebraska Medical Center. “Additionally, the test demonstrated high sensitivity and NPV, and we saw enhanced specificity and PPV with the GSC test as compared to the Afirma GEC, which is all consistent with prior studies. Overall, these results demonstrate the value and accuracy of Afirma GSC testing in the diagnostic management of cytologically indeterminate thyroid nodules.”

“The Afirma GSC continues to usher in a paradigm shift in the management of patients with indeterminate thyroid nodules,” said Joshua Klopper, M.D., Veracyte's medical director, Endocrinology. “More patients are avoiding unnecessary surgery and more patients have a confirmed indication for surgery when it is performed. These new findings underscore the value that Afirma testing delivers to patients, physicians and the overall healthcare system.”

About Veracyte

Veracyte (Nasdaq: VCYT) is a global diagnostics company that improves patient care by providing answers to clinical questions, informing diagnosis and treatment decisions throughout the patient journey in cancer and other diseases. The company's growing menu of diagnostic tests leverages advances in genomic science and technology, enabling patients to avoid risky, costly diagnostic procedures and quicken time to appropriate treatment. The company's tests in lung cancer, prostate cancer, breast cancer, thyroid cancer, bladder cancer, colon cancer, and idiopathic pulmonary fibrosis are available to patients and its renal cancer and lymphoma subtyping tests are in development, the latter as a companion diagnostic. With Veracyte's exclusive global license to a best-in-class diagnostics instrument platform, the company is positioned to deliver its genomic tests to patients worldwide. Veracyte is based in South San Francisco, California. For more information, please visit www.veracyte.com and follow the company on Twitter (@veracyte).

Cautionary Note Regarding Forward-Looking Statements

This press release contains forward-looking statements, including, but not limited to, our statements related to our plans, objectives, expectations (financial and otherwise) or intentions with respect to the Afirma Genomic Sequencing Classifier. Forward-looking statements can be identified by words such as: “anticipate,” “intend,” “plan,” “expect,” “believe,” “should,” “suggest,” “may,” “will” “prospective” and similar references to future periods. Actual results may differ materially from those projected or suggested in any forward-looking statements. Examples of forward-looking statements include, among others, statements regarding Veracyte's belief that its Afirma Genomic Sequencing Classifier can help reduce unnecessary thyroid nodule surgeries. Additional factors that may impact these forward-looking statements can be found under the caption “Risk Factors” in our Annual Report on Form 10-K filed with the SEC on February 22, 2021 and our subsequent quarterly reports on Form 10-Q. A copy of these documents can be found at the Investors section of our website at www.veracyte.com. These forward-looking statements speak only as of the date hereof and, except as required by law, Veracyte specifically disclaims any obligation to update these forward-looking statements or reasons why actual results might differ, whether as a result of new information, future events or otherwise.

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¹ Haugen BR, Alexander EK, Bible KC, et al. 2015 American Thyroid Association Management Guidelines for Adult Patients with Thyroid Nodules and Differentiated Thyroid Cancer: The American Thyroid Association Guidelines Task Force on Thyroid Nodules and Differentiated Thyroid Cancer. *Thyroid* 2016;26(1):1-133.

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