

Afirma® Thyroid FNA Analysis

An Overview for Patients



The Afirma® Thyroid FNA Analysis, offered by Veracyte, is used to assess whether a lump (nodule) in your thyroid gland is likely to be benign or malignant (cancerous). Although most thyroid nodules are benign, the only way to be sure is to look closely at the cells that make up your nodule.

FNA: A simple way to examine nodule cells

First, your physician will perform a Fine Needle Aspiration (FNA). The FNA is a simple procedure in which your physician uses a very thin needle (smaller than one used to draw blood) to extract nodule cells. While most patients need to have an FNA performed on only one nodule, some need to have several nodules assessed. Your physician will collect nodule cells via FNA for both cytopathology assessment and molecular analysis. The entire procedure should take only a few minutes and is usually no more painful than a pinch.

Cytopathology: Expert assessment sufficient most of the time

The next step is for the FNA sample to be sent to a cytopathologist to determine whether the nodule is benign or malignant. (A cytopathologist is a physician who specializes in diagnosing diseases by the examination of cells.) If the cytopathologist determines that your nodule is likely benign or malignant, the Afirma Thyroid FNA Analysis is complete. In this case, your doctor will contact you with your final Afirma Thyroid FNA Analysis results and a recommended treatment plan.

The Gene Expression Classifier: An answer for inconclusive cytopathology results

Sometimes, the cytopathologist is not able to make a definitive benign or malignant diagnosis. Before the Afirma Thyroid FNA Analysis, the majority of patients with indeterminate* results were recommended to have surgery even though only a fraction of those patients' nodules would ultimately be deemed malignant.

Now, by requesting an Afirma Thyroid FNA Analysis, your physician has a new tool to assess these previously ambiguous cases. If the cytopathologist makes an indeterminate diagnosis, the Gene Expression Classifier is performed on the samples submitted for molecular analysis. The Gene Expression Classifier, available only through Veracyte as part of the Afirma Thyroid FNA Analysis, measures the activity level of many genes within each nodule and then classifies the nodule as either benign (risk of cancer less than 5%) or suspicious for cancer.¹⁻³ The results, which are incorporated into the final Afirma Thyroid FNA Analysis Patient Report, enable your physician to provide you with more informed recommendations about your care.

Veracyte Customer Care: Available to answer your questions about Afirma

Veracyte Patient Advocates are pleased to assist you with any questions you may have regarding the Afirma Thyroid FNA Analysis, including billing. You may contact us Monday through Friday 5:30am – 5:00pm (Pacific) at **1.888.9AFIRMA (888.923.4762)** or at support@veracyte.com. You may also visit www.veracyte.com to learn more about the Afirma Thyroid FNA Analysis.

Billing, Insurance and Financial Assistance

Veracyte's priority is to ensure that you have access to the Afirma Thyroid FNA Analysis regardless of insurance coverage or income. Even though the Afirma Thyroid FNA Analysis has been found to be cost effective for health plans, as a new medical technology, several insurance companies have not yet included the Afirma Thyroid FNA Analysis as a covered benefit.⁴ This means that your health insurance company may deny the claim or process it as out of network. In either case, Veracyte will appeal it and bill you once the claim has been completely settled, which can often take several months.

Further, Veracyte has an Afirma Access program which limits how much a patient has to pay; and for a majority of patients reduces the out-of-pocket expense to zero. The Afirma Access Information and Application Brochure will be sent to you after your testing is complete.

Maximum Patient Payment Amount

(your out-of-pocket expense will be less if you qualify for financial assistance)

If you are covered by Private Insurance, the out-of-pocket maximum is:

- \$20 for cytopathology (per nodule)
- \$300 for the Afirma Gene Expression Classifier (per patient), if necessary

Your out-of-pocket expense will be significantly less or completely forgiven if you qualify for financial assistance through the Afirma Access Program.

If you Do Not Have Insurance or Choose to Pay Cash, the out-of-pocket maximum is:

- \$300 for cytopathology (per nodule)
- \$3,350 for the Afirma Gene Expression Classifier (per patient), if necessary

Your out-of-pocket expense will be significantly less or completely forgiven if you qualify for financial assistance through the Afirma Access Program.

If you are covered by Medicare, the maximum you may pay will be \$35.45 per nodule for cytopathology (20% copay). There is no charge for the Gene Expression Classifier, if necessary. Veracyte accepts Medicare assignment in full.

Your out-of-pocket expense may be less if covered by a Medicare Advantage health plan

What to expect from your Health Insurance Company

After Veracyte performs the Afirma Thyroid FNA Analysis, your insurance company will send you an Explanation of Benefits (EOB) letter. This is not a bill from Veracyte. It is simply an acknowledgement that Veracyte has billed your insurance company. Please direct any questions regarding the EOB or any other billing or insurance questions Veracyte.

In some cases you may also receive a check from your insurance company with payment for the Afirma Thyroid FNA Analysis. If you receive a check, please endorse it and send it to Veracyte to:

Veracyte: Patient Billing 7000 Shoreline Court, Suite 250 South San Francisco, CA 94080

1. Chudova D, et al. 2010 *J Clin Endocrinol Metab* 95(12):5301-5309.
2. Haugen BR, et al. Abstract #LB137, ITC, Paris, France, 2010 [oral abstract].
3. Data on File.
4. Li H, et al. *J Clin Endocrinol Metab* 96(11):E1719-E1726.

Afirma Thyroid FNA Analysis Description

The Afirma Thyroid FNA Analysis is a diagnostic service provided by Veracyte, Inc. for the assessment of thyroid nodules. Patient samples obtained through fine needle aspirate (FNA) biopsies are collected for both cytopathology assessment and the Gene Expression Classifier. Initially, cytopathology assessment is conducted. If the cytopathology diagnosis is benign, suspicious for malignancy, malignant or nondiagnostic, the Afirma Thyroid FNA Analysis is complete. If the cytopathology diagnosis is indeterminate (includes Follicular Lesion of Undetermined Significance (FLUS)/Atypia of Undetermined Significance (AUS) and (suspicious for) Hürthle/Follicular Neoplasm), the thyroid nodule is greater than or equal to 1 cm and the patient is 21 years or older, the Gene Expression Classifier is performed. The Gene Expression Classifier determines the expression profile of RNA isolated from the nodule to be benign or suspicious for malignancy. Clinical correlation of the Afirma Thyroid FNA Analysis result is recommended. The Afirma Gene Expression Classifier and its performance characteristics were determined by Veracyte. Afirma Thyroid FNA Analysis is used for clinical purposes.

The Veracyte laboratory is regulated under the Clinical Laboratory Improvement Amendments of 1988 (CLIA) as qualified to perform high-complexity clinical testing.

*Indeterminate includes Follicular Lesion of Undetermined Significance (FLUS)/Atypia of Undetermined Significance (AUS) and (suspicious for) Hürthle/Follicular Neoplasm.

Veracyte is committed to patient health information privacy. It will be used and disclosed only for treatment, payment, healthcare operations and other purposes permissible by law.

Veracyte reserves the right to modify or discontinue the Afirma Access Program with respect to any patient or its entirety at any time and without notice.