The Indeterminate Thyroid Nodule, Fine-Needle Aspiration Biopsy and the Afirma Gene Expression Test

If you were just diagnosed with a thyroid lump, thyroid nodule or thyroid mass, you may be recommended for a fine needle aspiration biopsy (FNA).

How do I know if I need fine needle aspiration (FNA) biopsy?
Your doctor will help determine if a thyroid nodule is worrisome based on its size and appearance on ultrasound imaging.

What is a fine needle aspiration biopsy?
An FNA is a quick, safe, and reliable method of evaluating thyroid nodules. The procedure is usually less painful than a bee-sting and is performed with very thin needles. A needle is inserted into the nodule (usually with the assistance of an ultrasound), and cells are extracted (aspirated) into the needle. Slides are made from the material collected in the needle, and a cytopathologist (a physician who is trained to diagnose thyroid diseases by the examination of cells) will determine the nature of your nodule by looking closely at these cells under the microscope. Typically several needle sticks are required to collect enough cells for diagnosis.

The results of the biopsy will be one of the following:

- Benign or noncancerous: These nodules can be monitored over time.
- Malignant or cancerous: You will need thyroid surgery and potentially treatment with radioactive iodine. Most patients with thyroid cancer have an excellent prognosis.
- Non-diagnostic or insufficient: The aspirated thyroid cells were too few to make a diagnosis, so you may need a repeat FNA.
- Indeterminate (ambiguous): Three subtypes are summarized as “indeterminate”:
  - Follicular neoplasm (FN)
  - Follicular lesion or atypia of undetermined significance (FLUS or AUS)
  - Suspicious for malignancy
The indeterminate result occurs in about 10-15% of cases. In the past, surgery (removal of part of your thyroid gland or your whole thyroid gland) was recommended to make a definitive diagnosis. The majority of follicular neoplasms and FLUS/AUS lesions are found to be benign after surgery.

The optimal treatment of “indeterminate” nodules depends on patient factors, size, subtype, and other features of the nodule. Your physician may also request an Afirma test (see below) which may involve a second FNA. This can sometimes be performed with the first FNA, but requires additional samples and special processing.

What is the Afirma Gene Expression Classifier test?
The Afirma test is a new tool to assess indeterminate nodules. A separate FNA sample is submitted for molecular analysis and a so-called Gene Expression Classifier is performed. The Gene Expression Classifier measures the activity level of more than 100 genes within the nodule. Based on which genes are expressed, the nodule is classified as either “Benign” (risk of cancer < 5%) or “Suspicious” (40-60% risk of cancer). The additional information enables you and your physician to come up with an optimal treatment plan for your thyroid nodule.

To find more about the Afirma Gene Expression Classifier, talk to your physician. More information, particularly on billing, insurance and financial assistance can also be found at www.veracyte.com.