ThyroSeq®
Thyroid Genomic Classifier

SONIC HEALTHCARE USA
A Division of Sonic Healthcare

TSQ Req

ThyroSeq® GC Requisition

TSQ Req

Patient Information (Please print legibly, fill in ALL information)

Last Name | First Name | M.I. | Gender ☐ M ☐ F

Date of Birth (MM/DD/YYYY)

Address

City/State

Phone #

Client Case # | Patient Chart / MRN

☐ Hospital Inpatient ☐ Hospital Outpatient ☐ Non-Hospital Patient

Billing Information (Please attach secondary insurance information)

☐ Self-Pay ☐ Client ☐ Insurance Attach copy of front and back of insurance card ☐

Insurance Name

Subscriber Name | ID #

Group # | Prior-Authorization #

ICD Code

Prior-Authorization approval may be required for the patient if a ThyroSeq test is requested.

Account Information

Physician Signature (if required)

Submitting Physician (First & Last)

Referring Physician (First & Last)

Referring Physician Fax #

Referring Physician Phone #

Statement of Medical Necessity: When ordering tests for which reimbursement will be sought, physicians (or other individuals authorized by law to order tests) should only order tests that are medically necessary for the diagnosis or treatment of a patient rather than for screening purposes.

Clinical Information (Please provide clinical data relevant to specimen interpretation)

Previous "Indeterminate" FNA Result: ☐ No ☐ Yes, specify: _____ ☐ Other: _____

Collection Details

Collection Date: _____/_____/_____ # of Containers: _____

CYTOLOGY SITES

Nodule Site #1

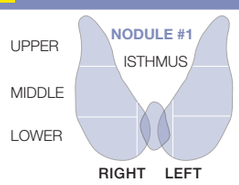
PLEASE ATTACH CYTOPATHOLOGY REPORT TO SPECIMEN

Thyroid: ☐ Right Lobe ☐ Left Lobe ☐ Upper pole ☐ Mid ☐ Lower Pole ☐ Isthmus ☐ Other:_____

Nodule Size: _____

Bethesda Category: ☐ I ☐ II ☐ III ☐ IV ☐ V ☐ VI

MARK ON DIAGRAM



Specimen Type

☐ FNA Sample, ThyroSeq®*Preserve* Solution
☐ FNA Sample, Fixed Cell Block Sections
☐ FNA Sample, Direct Smears (Pap or Diff-Quik™)
☐ Tissue, Paraffin sections (FFPE)

Nodule Site #2

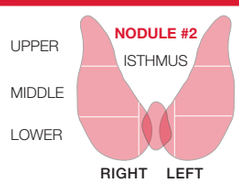
PLEASE ATTACH CYTOPATHOLOGY REPORT TO SPECIMEN

Thyroid: ☐ Right Lobe ☐ Left Lobe ☐ Upper pole ☐ Mid ☐ Lower Pole ☐ Isthmus ☐ Other:_____

Nodule Size: _____

Bethesda Category: ☐ I ☐ II ☐ III ☐ IV ☐ V ☐ VI

MARK ON DIAGRAM



Specimen Type

☐ FNA Sample, ThyroSeq®*Preserve* Solution
☐ FNA Sample, Fixed Cell Block Sections
☐ FNA Sample, Direct Smears (Pap or Diff-Quik)
☐ Tissue, Paraffin sections (FFPE)

Nodule Site #3

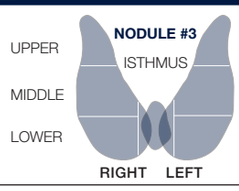
PLEASE ATTACH CYTOPATHOLOGY REPORT TO SPECIMEN

Thyroid: ☐ Right Lobe ☐ Left Lobe ☐ Upper pole ☐ Mid ☐ Lower Pole ☐ Isthmus ☐ Other:_____

Nodule Size: _____

Bethesda Category: ☐ I ☐ II ☐ III ☐ IV ☐ V ☐ VI

MARK ON DIAGRAM



Specimen Type

☐ FNA Sample, ThyroSeq®*Preserve* Solution
☐ FNA Sample, Fixed Cell Block Sections
☐ FNA Sample, Direct Smears (Pap or Diff-Quik)
☐ Tissue, Paraffin sections (FFPE)

Diff-Quik is a trademark of BAXTER DIAGNOSTICS INC.

Pap-stained smears are preferred. Only Pap and Diff-Quik smears are acceptable.

SPECIMEN NUMBER ON STICKER MUST MATCH SPECIMEN SITE NUMBER ON REQUISITION

15625

Site 1 | ThyroSeq | Patient: | Specimen Site: | DOB: | Date:

Site 1 | ThyroSeq | Patient: | Specimen Site: | DOB: | Date:

Site 1 | ThyroSeq | Patient: | Specimen Site: | DOB: | Date:

Site 2 | ThyroSeq | Patient: | Specimen Site: | DOB: | Date:

Site 2 | ThyroSeq | Patient: | Specimen Site: | DOB: | Date:

Site 2 | ThyroSeq | Patient: | Specimen Site: | DOB: | Date:

Site 3 | ThyroSeq | Patient: | Specimen Site: | DOB: | Date:

Site 3 | ThyroSeq | Patient: | Specimen Site: | DOB: | Date:

Site 3 | ThyroSeq | Patient: | Specimen Site: | DOB: | Date:

Site: | Patient: | Specimen Site: | DOB: | Date:

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PATIENT INFORMATION

Enter patient name, gender, date of birth, and patient address information as it is necessary for billing purposes. You may choose to enter Patient Chart or Medical Record Number for the patient. If you are providing patient information with a copy of a face sheet, you must still enter patient name, gender, and date of birth. If the patient is registered as a Hospital Inpatient or Outpatient, or Non-Hospital, check the box.

BILLING INFORMATION

Check the box indicating the party responsible for payment. Self-Pay, Client or Insurance: Provide a clear copy of the front and back of the patient's primary insurance/ Medicaid/ other payor card. If the patient a has secondary insurance, please provide a clear copy of the front and back of the secondary insurance card.

- **Client:** Check box if Lab is to bill the clinic, laboratory or affiliated institution.
- **Patient Self-Pay (no insurance):** Patients may be contacted for payment information such as credit card or bank wire.
  Note: *that payment may be required prior to ThyroSeq GC Testing.*

PHYSICIAN INFORMATION (or authorized healthcare provider)

Select or write the name of submitting and referring/ treating physician. In addition, please verify submitting physician address information. If you would like a copy of the report sent to the referring physician, please provide that fax number. Patient report will be delivered to submitting and referring/ treating physician.

MEDICAL NECESSITY AND PATIENT CONSENT

If required by law, regulation or commercial payors, the submitting physician should sign the requisition indicating the test meets applicable medical necessity and/ or state law requirements regarding patient consent.

The referring/ treating physician has obtained the patient's consent, where required for Laboratory to submit and, if necessary appeal claims on the patient's behalf to seek reimbursement for ThyroSeq GC.

ICD DIAGNOSIS CODES

The ICD Diagnosis code(s) must be defined by the most detailed level of specificity available and should always be based on what has been documented in the patient's medical record. If a diagnosis code cannot be supported by the patient's medical record, then the code should not be used for ordering laboratory services.

CLINICAL HISTORY

Provide relevant clinical history for this patient. When describing ultrasound characteristics, please do so on a per nodule basis. Please provide relevant medical records when requested by patient's insurance carrier for reimbursement.

COLLECTION INSTRUCTIONS

Instructions for storage of ThyroSeq*Preserve* vials prior to specimen collection:

ThyroSeq*Preserve* solution is light sensitive, always store vials in dark place (inside the collection kit transport box or dark bag) and at room temperature (+15 to +25°C) until expiration date.

Instructions for storage of ThyroSeq*Preserve* vials after specimen collection:

- No longer than 3 hours at room temperature (+15 to 25°C)
- No longer than 24 hours at +2 to +8°C, i.e. in a refrigerator
- Up to 12 months at -15 to -25°C, i.e. in a freezer

Note: *if any crystallization forms inside the ThyroSeq vial or if the ThyroSeqPreserve solution turns yellow, appropriately discard the tube and collect the specimen using another ThyroSeq tube.*

Instructions for collecting an FNA Sample for ThyroSeq testing:

1. Label the ThyroSeq vial with the patient's name and specimen site using labels from the test requisition form.
2. Place a **full SECOND FNA pass** into the ThyroSeq*Preserve* solution vial.
3. In addition, for better representation of large-size nodules, **wash the needle** from all other passes taken from the nodule and express them into the SAME ThyroSeq vial. However, be sure that the solution is not retained in the needle or the syringe and the final volume in the vial remains the same.
4. After collection, secure the tube cap and invert several times to mix the collected sample then place the ThyroSeq tube into the dark bag along with a flat frozen ice pack.
5. Specimens collected into the ThyroSeq*Preserve* vial can be kept:
   a. No longer than 3 hours at room temperature (+15 to +25°C)
   b. No longer than 24 hours at +2 to +8°C, i.e. in a refrigerator
   c. Up to 12 months at -15 to -25°C, i.e. in a freezer
6. When collection of a fresh FNA sample into the ThyroSeq*Preserve* is not possible, the following are acceptable specimen types:
   a. FNA Sample, Fixed Cell Block Sections
   b. FNA Sample, Direct Smears (Pap or Diff-Quick)
   c. Tissue, Paraffin sections (FFPE)

Instructions for shipping a collected FNA Sample and ThyroSeq specimen:

1. Ensure that all vials, tubes and slides are labeled with at least two unique patient identifiers.
2. Place the ThyroSeq specimen vial(s) that are inside the dark bag in the bio-hazard bag along with a flat frozen cold pack then place the specimen inside the foam insert in the transport kit along with all other tubes and slides used for specimen collection.
3. Include a completed test requisition
4. Call for courier/ carrier pick-up.

CYTOPATHOLOGY RESULTS:

Please attach cytopathology report to specimen and identify cytopathology results as the following:

- Bethesda Category I, II, III, IV, V or VI

Further classification of indeterminate results:

- Atypia of undetermined significance (**Bethesda Category III**)
- Follicular lesion of undetermined significance (**Bethesda Category III**)
- Hurthle cell nodule (**Bethesda Category III**: Hurthle cell lesion of undetermined significance)
- Follicular neoplasm (**Bethesda Category IV**: Follicular neoplasm or suspicious for follicular neoplasm)
- Follicular Neoplasm, Hurthle Cell (Oncocytic Type) (**Bethesda Category IV**: Follicular Neoplasm, Hurthle Cell (Oncocytic Type) / Suspicious for Follicular Neoplasm, Hurthle Cell (Oncocytic Type).
- Suspicious for malignancy (**Bethesda Category V**: Suspicious for malignancy)

ThyroSeq Genomic Classifier DESCRIPTION:

ThyroSeq Genomic Classifier (GC) is a test for the pre-operative assessment of thyroid nodules with indeterminate cytology, which offers accurate assessment of cancer probability in a given nodule and additionally provides information on cancer prognostication, helping to select the most optimal patient management.