Bassett Healthcare Network

Thyroid Fine Needle Aspirations with Molecular Cotesting v4.0
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Copy of version 4.0 (approved and current)

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Comments for version 4.0
Managing laboratory for NYS is now LabCorp. Procedure updated to reflect this change

Approval and Periodic Review Signatures

Type	Description	Date	Version	Performed By	Notes
Approval	Lab Director	3/28/2023	4.0	Samantha Davenport MD Service Line Chief (M03764)	
Approval	Lab Director	3/27/2023	4.0	John Fisk MD Clinical Laboratory Director (M08480)	
Approval	Lab Director	3/20/2023	4.0	Timothy Chapman MD Clinical Laboratory Director (M11669)	
Approval	Lab Director	3/20/2023	4.0	Ghazala Nathu MD Clinical Laboratory Director (S00134)	
Approval	Lab Director	3/20/2023	4.0	Valerie Bush PhD Clinical Laboratory Director (M05512)	
Approval	Lab Director	9/16/2022	3.0	John Fisk MD Clinical Laboratory Director (M08480)	
Approval	Lab Director	9/6/2022	3.0	Ghazala Nathu MD Clinical Laboratory Director (S00134)	
Approval	Lab Director	8/29/2022	3.0	Valerie Bush PhD Clinical Laboratory Director (M05512)	
Approval	Lab Director	8/29/2022	3.0	Samantha Davenport MD Service Line Chief (M03764)	
Approval	Lab Director	8/26/2022	3.0	Timothy Chapman MD Clinical Laboratory Director (M11669)	
Approval	Lab Director	4/6/2022	2.6	Simha Sastry MD Clinical Laboratory Director (M06625)	
Approval	Lab Director	4/6/2022	2.6	Ghazala Nathu MD Clinical Laboratory Director (S00134)	
Approval	Lab Director	4/4/2022	2.6	John Fisk MD Clinical Laboratory Director (M08480)	
Approval	Lab Director	4/1/2022	2.6	Valerie Bush PhD Clinical Laboratory Director (M05512)	
Approval	Lab Director	3/31/2022	2.6	Timothy Chapman MD Clinical Laboratory Director (M11669)	

Version History

Version	Status	Type	Date Added	Date Effective	Date Retired
4.0	Approved and Current	Major revision	3/20/2023	3/28/2023	Indefinite
3.0	Retired	Major revision	8/26/2022	9/16/2022	3/28/2023

2.6	Retired	Initial version	3/16/2022	4/14/2022	9/16/2022

THYROID FINE NEEDLE ASPIRATIONS WITH MOLECULAR CO-TESTING

I. Principle:

Molecular testing on thyroid samples that have a diagnosis of AUS or a follicular lesion of undetermined significance, follicular neoplasm or suspicious for a follicular neoplasm can guide treatment decisions and help avoid unnecessary surgery.

II. Ordering and labeling:

1. Order the test in EPIC using test code LAB13 for Non-Gyn cytology.
2. Enter the Specimen Source. Enter the source description in the box on the same line at the far right of the screen.
3. When the Specimen Source is entered, another box opens below it for an additional specimen.
4. Complete for as many specimens as needed.
5. An order question appears "Perform molecular testing if diagnosis is AUS/FLUS/suspicious for neoplasm or malignancy (Bethesda category 3, 4 or 5)" Check yes if a specimen is collected for molecular testing. An order question appear "which source"- check the thyroid source for the molecular testing.
6. An order statement appears "Call the laboratory if molecular testing is needed on non-diagnosis/benign/malignant (Bethesda category 1, 2 or 6)." No reflex test will trigger. A phone call is required to request this test.
7. Sign the order.
8. Go to the Collection activity.
9. Select Print label.
10. Label the specimen container using the Epic generated label.
11. Scan the label to document the electronic collection.
12. Select Finish or Accept.
13. If microscopic slides are prepared, label the slides with the patient's name and medical record number using a pencil. Label the Microscopic slide container and the molecular test vial with the footie label.
    Proper patient history is essential to the successful interpretation of a cytological specimen and is required by regulations. Any evaluation and report is, at best, incomplete without correlating the cytological studies with a complete patient history. Improper labeling may cause the specimen to be returned for proper labeling, a delay while waiting for proper labeling or the specimen to be rejected and discarded.

    If molecular testing is ordered and no vial is received – the molecular testing will be performed on the cell block material if available.

III. Collection of the molecular test:

1. Complete the LabCorp Diagnostics requisition form by affixing a patient label.
2. After completing FNA passes for cytology, perform 1 additional pass for ThyGeNEXT genomic testing.
3. Rinse needle after the pass in the ThyGeNEXT vial.

4. Invert vial 3 times to mix material properly.
5. Record sample collection date and time on the LabCorp Requisition.
6. Apply a patient specimen label onto the vial

IV. Laboratory Processing the molecular Specimen:

1. Write the cytology case number on top of the requisition
2. Log the specimen on the Thyroid Collection Tube tracking log.
3. Prior to sending the vial out, confirm that the Requisition Form number and the Nodule ID number are selected for the correct patient, then:
4. Place the vial in the LabCorp specimen bag. (one patient per bag)
5. If a vial was not submitted and a cell block is available, the cell block will be sent. The cell block should be packaged in a small manila envelope, placed in the bubble padded pouch and inserted into the LabCorp Specimen bag.
6. If neither a vial or cell block is available, pathologist permission is required to send slides. Note the number of slides and the case number on the requisition. Slides are sent using the plastic slide holder, securely snap the lid shut and place into bubble padded pouch.
7. Remove the last copy of the requisition and store in the binder.
8. Print the patient's insurance information (face sheet) and cytology report.
9. Fold and insert the required documents (LabCorp requisition, cytology report and insurance face sheet) in the outer pouch of the LabCorp specimen bag.
10. Take the specimen bag to CLP for LabCorp courier pickup.
11. The vials are stored at room temperature for up to 6 weeks
12. Slides are digitally imaged and returned. Cells will be scraped off original slide. If there is insufficient cellular material present, (at least 60 follicular cells), the patient will not be billed and test not performed.

V. Laboratory documentation of Molecular Order

Follow Up Worklist

1. When an order exists for thyroid molecular testing, a cytology sendout follow up task automatically triggers and appears in the Cytology QC Follow UP Worklist.
2. Category I, II, and VI (unsatisfactory, benign, or malignant) require a letter of medical necessity written. The requesting provider is responsible for completing the letter of medical necessity.
3. The cytotech reviews the work list daily. If a sendout test is on the list- verify the molecular test was collected on the appropriate nodule.
4. If no vial was received – make a notation and test will be performed on a cell block or stained slide
5. Completing the Pathology Addon.
   a. Go to the AP Cyto QC follow up work list – In the event details box to the right enter Molecular thyroid testing and click Add Event. Click Complete.