Interpace Diagnostics®

Directory of Lab Services

Diagnostic Tests Currently Available

	Indication	Diagnostic Test	Diagnostic Report
ThyGeNEXT® THYROID ONCOGENE PANEL	Thyroid Cancer	NGS Panel for Thyroid Cancer	Rules In Thyroid Cancer
ThyraMIR®v2 THYROID miRNA RISK CLASSIFIER	Thyroid Cancer	microRNA Risk Classifier for Thyroid Cancer	Rules Out Thyroid Cancer

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Contact Info

Client Services Department

- Phone: 412-224-6900, or toll-free 800-495-9885
- Fax: 412-224-6425, or toll-free 888-674-6894
- Email: clientservices@interpace.com
- Hours of Support Services:
  - Monday to Friday, 8 AM - 8 PM EST
  - Closed Saturday, Sunday, and all major holidays

Billing and Reimbursement

- Phone: 888-963-6621
- Fax: 888-963-6627
- Email: reimbursement@interpace.com
- Hours of Support Service:
  - Monday to Friday, 9 AM - 5 PM EST
  - Closed Saturday, Sunday and all major holidays

Navigator Patient Support Team

- Phone: 866-316-0020
- Email: navigator@interpace.com
- Hours of Support
  - Monday to Friday, 9 AM - 5 PM EST
  - Closed Saturday, Sunday, and all major holidays

Laboratory Hours of Operation

- Monday to Friday, 8 AM - 4:30 PM EST (open through the lunch hour)
- Closed Saturday, Sunday, and all major holidays

Website

Visit Interpace Diagnostics on the web for more information.

www.interpace.com

Accreditations and Licensure

Copies of our licenses are available on our website.
https://www.interpace.com/labs

Pittsburgh, PA Laboratory Location

- College of American Pathologists.....#7186526
- CLIA.....#39D1024654
- New York.....#8306
- California.....#CDS00800224
- Maryland.....#1423
- Pennsylvania.....#29043A
- Rhode Island.....#LCO00913

List of Testing Services and Expected Turnaround Time (TAT)

Test(s)	Specimen Type(s) Accepted	Turnaround Time (business days, from time of accessioning)
Cytology (Thyroid)	Thyroid FNA	3 to 5
ThyGeNEXT®/ ThyraMIR®v2	FNA in provided collection buffer vial	10 to 14
	Cytology Slide (PAP, DiffQuik®, Giemsa)	Less than 18
	FFPE Tissue *Presurgical specimens only*	Less than 18

Specimen Collection Requirements

Please see each specific test type for more detailed collection requirements.

Patient Preparation: No special preparation or timing is required for collection of specimens.

If there are any questions regarding specimen collection, handling, or shipping, contact Interpace Diagnostics Client Services at 800-495-9885 or clientservices@interpace.com.

Specimen Labeling Requirements

Complete and correct labeling of specimens ensures proper identification and integrity of patient samples and accurate test reporting.

- All specimen containers must be labeled with at least 2 patient identifiers. One must be the patient's name as it appears on the test requisition, and the other identifier may be the date of birth and biological sex, social security number, medical record number, or specimen accession number (Pathology Department)
- Microscope slides must be labeled with the submitting Pathology Department's accession number. A copy of the pathology or cytology report must be provided for cross-checking the Test Requisition with patient name, date of collection, and Pathology Department's accession number

Failure to label specimens properly will result in delayed testing or specimen rejection.

Volume/Specimen Requirements For All Specimen Types

Test Requested	Sample Volume/Requirement
ThyGeNEXT®/ThyraMIR®v2	1 dedicated FNA pass in provided collection buffer vial or cytology slides with at least 80-100 follicular cells (PAP, DiffQuik®, Geimsa), or 1 FFPE block, or 1 H&E and 8 unstained recuts (presurgical specimens only) Please refer to the ThyGeNEXT section for **Important Information** including details regarding cytology slide submission
Thyroid Cytology	1 IDX Specimen Cytology Collection Kit

Specimen Collection/Transport Kits

Interpace Diagnostics Specimen Collection/Transport Kits are provided free of charge for your convenience and to ensure appropriate materials are used for specimen collection and shipping. **These are to be used only for submitting specimens to Interpace Diagnostics.**

To request an initial or replacement order for supply of Interpace Diagnostics Specimen Collection/Transport Kits, contact Client Services at 800-495-9885 or clientservices@interpace.com. Orders are filled and shipped via FedEx Ground (2 to 3 business days) within 1 business day of request. Overnight delivery shipping is provided upon request.

Test Ordering and Shipping Process

Physicians may order a test by completing the appropriate Interpace Diagnostics requisition form. The physician must sign and date the appropriate requisition and it must be included in the specimen shipment to Interpace Diagnostics. Incomplete information on the form may cause a testing delay. Interpace Diagnostics does not accept standing orders. If you have questions regarding any test ordering, please contact Client Services at 800-495-9885 or clientservices@interpace.com.

Test Requisition Forms

Test Requisition Forms are available and can be customized to an account, as possible, by contacting Client Services at 800-495-9885 or clientservices@interpace.com. Test Requisition Forms are also available on the Interpace Diagnostics website at www.interpace.com. **Completion of all fields is required**. Please be sure all fields have been completed prior to submitting to Interpace Diagnostics. Please complete and submit a separate Test Requisition Form for each patient. Refer to "How to Complete a Test Requisition" on page 12 if you have any questions.

Required Documents and Reports to be Shipped with the Specimen

(Failure to submit required documentation may lead to testing delays)

- Completed Test Requisition Form
- Patient billing information (full patient address, phone number, insurance information)
- Ultrasound report (if available)
- Cytology/Pathology report (if available)
  - If Ultrasound and/or Cytology/Pathology report are not available at time of submission, please send as soon as available

Packaging for Specimens

Use Interpace Specimen Collection Kit and contents for packaging and shipment (for instructions on how to request supplies, please refer to "Interpace Diagnostics Specimen Collection/Transport Kits" on page 9).

Once specimens are in a biohazard bag:

- Arrange the biohazard bag with specimen(s) material at the bottom of the kit box
- Insert a completed Test Requisition Form, billing information, face sheet, and any additional medical records in kit box on top of samples
- Please ensure to review and follow the test-specific collection requirements found within each test section
- Close the kit by tucking flaps into outer cardboard box
- Put collection kit in the FedEx® Clinical Pak, remove adhesive strip protector, and seal tightly. Affix pre-labeled FedEx Airbill to outside of FedEx Clinical Pak

Shipping

Call FedEx at (800) 463-3339 or visit https://www.fedex.com/en-us/shipping/schedule-manage-pickups.html to schedule specimen pickup. Requests for pickup made before 1 PM should be picked up on the same business day.

Specimens should be shipped via FedEx® Priority Overnight delivery to Interpace Diagnostics using pre-paid, pre-addressed labels provided by Interpace Diagnostics.

Ship To:	Or:
Interpace Diagnostics 2515 Liberty Avenue Pittsburgh, PA 15222 Ph: 412-224-6100	Hold At FedEx Interpace Diagnostics International Dr, Cargo 2 Coraopolis, PA 15108 Ph: 412-224-6100

We accept specimens for testing Monday through Friday from 8:00 AM to 5:00 PM EST. **Specimens sent by FedEx on Fridays with 'Saturday Delivery' selected on the FedEx Airbill** are received on Saturdays for testing on the next business day. The client is responsible for contacting FedEx to ship the specimens.

Interpace Diagnostics Specimen Collection/Transport Kits

Interpace Diagnostics Specimen Collection/Transport Kits are provided free of charge for your convenience and to ensure appropriate materials are used for specimen collection and shipping. **These are to be used only for submitting specimens to Interpace Diagnostics.**

To request an initial or replacement order for supply of Interpace Diagnostics Specimen Collection/Transport Kits, contact Client Services at 800-495-9885 or clientservices@interpace.com. Orders are filled and shipped via FedEx Ground (2 to 3 business days) within 1 business day of request. Overnight delivery shipping is provided upon request.

ThyGeNEXT® THYROID ONCOGENE PANEL ThyraMIR®v2 THYROID miRNA RISK CLASSIFIER

Cytology with Reflex to ThyGeNEXT®/ThyraMIR®v2

ThyGeNEXT: PLA 0245U
ThyraMIRv2: PLA 0018U

Cytology is used to evaluate thyroid fine needle aspirates and categorize into 1 of 6 Bethesda categories, each with implied risk of malignancy. Cytology is ordered, with reflex to ThyGeNEXT and/or ThyraMIRv2 in such cases when cytologic diagnosis is not clearly benign or malignant, but is indeterminate (Bethesda III, IV, or V). When all 3 tests are ordered, this is a full rule-in and rule-out test order. You can find additional information on our website, www.interpace.com.

Accepted Specimens

- Thyroid FNA in provided collection buffer vial
  - FNA specimens cannot exceed 6 weeks (42 days) from date of collection
- 1-2 Thyroid cytology smears, non-frosted slides
  - DiffQuik® (preferred slide sample type)
  - PAP stained
- 1-2 ThinPrep, or cytospin slides
  - Slide specimens cannot exceed 6 months from date of collection (See additional **Important Information** regarding cytology slide submission on the next page)
- Formalin-Fixed Paraffin-Embedded Tissue/Cell Block (FFPE)
  Presurgical specimens only (up to 6 months from collection)
  - 8 unstained non-frosted, recut slides (4 micron), plus 1 H & E slide (preferred FFPE sample type)
  - Whole block that will be recut for testing (increases TAT)

Turnaround Time

- 10-14 business days for FNA samples from time of accessioning
- Less than 18 business days for slides or FFPE samples from time of accessioning

Methodology

- Cytology staining
- Next-Generation Sequencing (NGS)

Specimen Requirements

Collection requirements using Interpace Diagnostics Specimen Collection Kit:
Note: When more than 1 nodule is present, use separate collection vials.

- Label each vial with 2 unique patient identifiers (full name, DOB, MRN), collection date, and nodule location
- Collect and express 2-4 FNA passes into the provided CytoLyt™ vial. Be sure to also rinse any residual material in the needle from each pass into the vial
- Obtain a single dedicated pass to express and rinse in provided collection buffer vial

Specimen Requirements (continued)

- Invert the collection buffer vial 2-3 times
- Securely tighten all caps and seal all containers to prevent leakage
- Place CytoLyt™ or provided collection buffer vial back into the biohazard bag with absorbent pad
- No special preparation or timing is required for collection of specimens
- Sample does not need to be refrigerated

Control Prep

A control sample is not required for ThyGeNEXT®/ThyraMIR®v2 testing.

IMPORTANT Information Regarding Cytology Slides Submitted for Molecular Analysis with ThyGeNEXT and ThyraMIRv2

- A high-resolution digital image of each slide will be captured prior to the testing process
- The slide(s) used for testing will not be returned since the material will be extracted for testing
  - Should the creation of a digital image not be possible for any reason, Interpace will immediately halt testing and notify the client, providing options for next steps. These may include requesting additional scannable material or canceling testing
- Ensure that the slide:
  - Aligns to standard measurements of 75mm by 25mm (3” by 1”) and be ~1mm thick
  - Has a coverslip that is properly fixed to the slide and is not loose (plastic or glass coverslips are both acceptable)
  - Has no overhanging coverslips or stickers
  - Has no glue residue
  - Is not cracked

Specimen Rejection Criteria

- Specimen not originating from thyroid
- Frozen specimen
- Co-mingled specimen (ex: mixing 2 different nodules in 1 vial)
- Unlabeled or mislabeled specimen

- Empty, leaking, or broken specimen vials
- FNA specimens submitted within an expired collection buffer vial
- FNA specimens older than 14 days when ordering cytology
- FNA specimens older than 42 days for molecular testing
- Slide specimens that do not align to the listed criteria above and are older than 6 months for molecular testing
- Any media other than the provided collection buffer (for molecular testing)
- FFPE specimens that do not align to the listed criteria above and are older than 6 months (for molecular testing)

Specimen Storage for Viability

- Store at room temp
- Do not freeze
- FNA specimens viable up to 42 days (6 weeks)

Related Test Orders

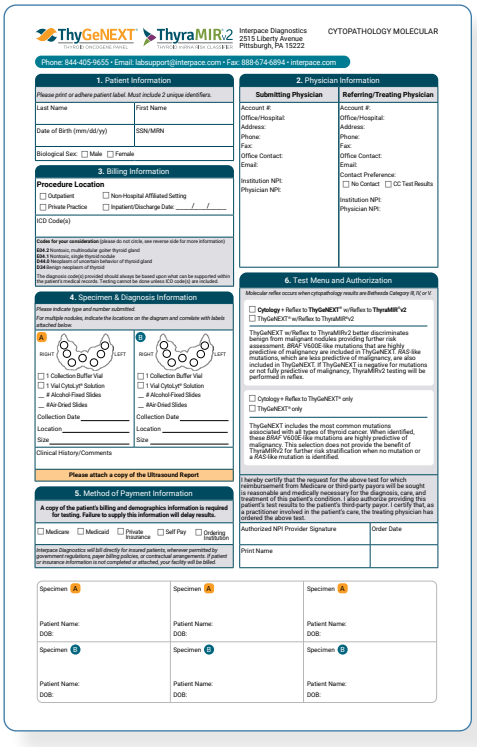
- ThyraMIR®v2
- ThyGeNEXT®

Ordering and Shipping Process

For instructions on how to order this test, see the Interpace Diagnostics "Test Ordering and Shipping Process" on page 8 of this document.

How to Complete a Test Requisition

Testing requisitions can vary. The following are general guidelines to assist in completing the Interpace Diagnostics Testing Requisition to ensure timely and correct handling of submitted specimens to our laboratory. Please refer to the examples below to help answer questions you may have about completing the testing requisition. If at any point you have additional questions or need a requisition for specimen submission, please contact Client Services at 800-495-9885 or clientservices@interpace.com. Additionally, blank requisitions can be found on our website, www.interpace.com.


ThyGeNEXT® ThyraMIR®v2
Interpace Diagnostics
2515 Liberty Avenue
Pittsburgh, PA 15222
CYTOPATHOLOGY MOLECULAR
Phone: 844-405-9655 • Email: labsupport@interpace.com • Fax: 888-674-6894 • interpace.com
1. Patient Information
Please print or adhere patient label. Must include 2 unique identifiers.
Last Name
First Name
Date of Birth (mm/dd/yy)
SSN/MRN
Biological Sex: ☐ Male ☐ Female
2. Physician Information
Submitting Physician
Referring/Treating Physician
Account #:
Office/Hospital:
Address:
Phone:
Fax:
Office Contact:
Email:
Institution NPI:
Physician NPI:
Contact Preference:
☐ No Contact ☐ CC Test Results
3. Billing Information
Procedure Location
☐ Outpatient ☐ Non-Hospital Affiliated Setting
☐ Private Practice ☐ Inpatient/Discharge Date: ___/___/___
ICD Code(s)
Codes for your consideration (please do not circle, see reverse side for more information)
E04.2 Nontoxic, multinodular goiter thyroid gland
E04.1 Nontoxic, single thyroid nodule
C73 Malignant neoplasm of thyroid gland
D34 Benign neoplasm of thyroid
The diagnosis code(s) provided should always be based upon what can be supported within the patient's medical records. Testing cannot be done unless ICD code(s) are included.
4. Specimen & Diagnosis Information
Please indicate type and number submitted.
For multiple nodules, indicate the locations on the diagram and correlate with labels attached below.
A
B
C
RIGHT
LEFT
☐ 1 Collection Buffer Vial
☐ 1 Vial CytoLyt® Solution
__ # Alcohol-Fixed Slides
__ #Air-Dried Slides
Collection Date
Location
Size
Clinical History/Comments
Please attach a copy of the Ultrasound Report
6. Test Menu and Authorization
Molecular reflex occurs when cytopathology results are Bethesda Category III, IV or V.
☐ Cytology + Reflex to ThyGeNEXT® w/Reflex to ThyraMIR®v2
☐ ThyGeNEXT® w/Reflex to ThyraMIR®v2
ThyGeNEXT w/Reflex to ThyraMIRv2 better discriminates benign from malignant nodules providing further risk assessment. BRAF V600E-like mutations that are highly predictive of malignancy are included in ThyGeNEXT. RAS-like mutations, which are less predictive of malignancy, are also included in ThyGeNEXT. If ThyGeNEXT is negative for mutations or not fully predictive of malignancy, ThyraMIRv2 testing will be performed in reflex.
☐ Cytology + Reflex to ThyGeNEXT® only
☐ ThyGeNEXT® only
ThyGeNEXT includes the most common mutations associated with all types of thyroid cancer. When identified, these BRAF V600E-like mutations are highly predictive of malignancy. This selection does not provide the benefit of ThyraMIRv2 for further risk stratification when no mutation or a RAS-like mutation is identified.
5. Method of Payment Information
A copy of the patient's billing and demographics information is required for testing. Failure to supply this information will delay results.
☐ Medicare ☐ Medicaid ☐ Private Insurance ☐ Self Pay ☐ Ordering Institution
Interpace Diagnostics will bill directly for insured patients, wherever permitted by government regulations, payer billing policies, or contractual arrangements. If patient or insurance information is not completed or attached, your facility will be billed.
I hereby certify that the request for the above test for which reimbursement is sought from the Third Party Payors was ordered or is reasonable and medically necessary for the diagnosis, care, and treatment of this patient's condition. I also authorize providing this patient's test results to the patient's third-party payor. I certify that, as a practitioner involved in the patient's care, the treating physician has ordered the above test.
Authorized NPI Provider Signature
Order Date
Print Name
Specimen A
Patient Name:
DOB:
Specimen A
Patient Name:
DOB:
Specimen A
Patient Name:
DOB:
Specimen B
Patient Name:
DOB:
Specimen C
Patient Name:
DOB:
Specimen B
Patient Name:
DOB:

Section 1. Patient Information

All fields are required. Include patient first and last name, date of birth, SSN/MRN code, and biological sex. A complete patient

label can be adhered in this field as long as the patient information is complete and includes 2 unique identifiers.

Incomplete information will result in testing delays.

Section 2. Physician Information

This section may be pre-filled if an account has been set up with Interpace Diagnostics. If blank, complete each field. Account Number should match your Interpace Diagnostics account number (leave blank if unknown). Complete the physician institution contact information. Please avoid Office/ Hospital acronyms or abbreviations and spell out the institution name.

Referring/Treating Physician:

Please provide full name and phone/fax number for the referring/treating physician, if applicable. Check the box to indicate if you would like the referring/treating physician to receive a copy of the results.

Leaving contact information incomplete will result in processing delays.

Section 3. Billing Information

Check the box to indicate where procedure was performed (Non-hospital affiliated setting, Private Practice, Outpatient, or Inpatient with discharge date).

Testing cannot be performed unless ICD-10 code(s) are included.

Write in the appropriate ICD-10 code based on the patient's medical records. The ICD diagnosis code must be defined by the most detailed level of specificity available. If a diagnosis code cannot be supported by the patient's medical record, then the code should not be used for ordering laboratory services. The list of common ICD diagnosis codes for the characterization of thyroid nodules shown below is not complete. Please refer to the ICD manual for a complete listing.

Common ICD-10 Diagnosis Codes:

- D34-Benign neoplasm of thyroid gland
- D44.0-Neoplasm of uncertain behavior of thyroid gland
- D44.9-Neoplasm of uncertain behavior of unspecified endocrine gland
- E01.0-Iodine-deficiency related diffuse (endemic) goiter
- E01.1-Iodine-deficiency related multinodular (endemic) goiter
- E01.2-Iodine-deficiency related (endemic) goiter, unspecified
- E04.0-Nontoxic diffuse goiter
- E04.1-Nontoxic single thyroid nodule
- E04.2-Nontoxic multinodular goiter
- E04.8-Other, specified nontoxic goiter
- E04.9-Nontoxic goiter, unspecified

Section 4. Specimen & Diagnosis Information

Submitted Specimen(s)

Check the box to indicate the type of specimen being sent for testing OR indicate the number of slides being sent (REQUIRED). If submitting multiple nodules, indicate type and quantity separately.

Specimen Collection Date

Enter the date of the procedure when the specimen was collected. Mark the circle on the thyroid diagram to indicate location of the nodule. The requisition can be used to submit specimens for up to 2 locations. Use letter A for the first specimen and letter B for the second specimen. Provide a descriptive name for each location on the line provided, along with the size of each nodule.

Ultrasound Characteristics

Attach a copy of the ultrasound report and provide relevant clinical history for the patient. Please provide relevant medical records at no cost when requested by the patient's insurance carrier for reimbursement.

Section 5. Method of Payment Information

Check the box indicating how the testing should be billed. Interpace Diagnostics will submit claims to all private insurance, Medicare, and other government plans for insured patients.

Patient Contact Information

Please provide a copy of the patient's face sheet or demographics page to include the patient's full name, biological sex, date of birth, address, and phone number.

A copy of the patient's billing information MUST be submitted with the specimen.

Medicare/Medicaid/Private Insurance

Provide a clear copy of the front and back of the patient's primary insurance/Medicaid/other payer card. If the patient has a secondary insurance please provide a clear copy of the front and back of the secondary insurance card.

Ordering Institution

Check this box if Interpace Diagnostics is to bill the ordering institution for the ordered testing.

Patient Self-Pay (no insurance)

Check this box if the patient has no insurance.

Section 6. Test Menu and Authorization

Specimen processing cannot begin until there is a clear indication of the type of testing to be performed (check box). Please indicate the tests requested for the patient's specimen. Details of each test can be found on our website and in test details from our Directory of Laboratory Services. Only 1 test should be selected (duplicate test selections within a Test Requisition Form cannot be processed and can delay testing).

The ordering physician is required to sign and date the requisition as authorization for Interpace Diagnostics to perform testing. Stamped signatures or physician initials cannot be accepted. An incomplete signature will result in testing delays. Order date cannot precede Collection Date of the specimen.

Post-dated requisitions are not accepted.

ThyGeNEXT®
THYROID ONCOGENE PANEL

ThyGeNEXT®

PLA 0245U

ThyGeNEXT is a rule-in test for malignancy. ThyGeNEXT is often ordered in conjunction with ThyraMIR®v2, and is available for indeterminate cytology results to provide additional risk assessment for clinical management decisions. You can find additional information on our website, www.interpace.com.

Accepted Specimens

- Thyroid FNA in provided collection buffer vial
  - FNA specimens cannot exceed 6 weeks (42 days) from date of collection
- 1-2 Thyroid cytology smears, non-frosted slides
  - DiffQuik® (preferred slide sample type)
  - PAP stained
- 1-2 ThinPrep, or cytospin slides
  - Slide specimens cannot exceed 6 months from date of collection
    (See additional **Important Information** regarding cytology slide submission on the next page)
- Formalin-Fixed Paraffin-Embedded Tissue/Cell Block (FFPE)
  Presurgical specimens only (up to 6 months from collection)
  - 8 unstained non-frosted, recut slides (4 micron), plus 1 H & E slide (preferred FFPE sample type)
  - Whole block that will be recut for testing (increases TAT)

Turnaround Time

- 10-14 business days for FNA samples from time of accessioning
- Less than 18 business days for slides or FFPE samples from time of accessioning

Methodology

Next-Generation Sequencing (NGS)

Specimen Requirements

FNA Collection Requirements

- Label vial with 2 unique patient identifiers (full name, DOB, MRN), collection date, and nodule location
- Obtain a single dedicated pass to express and rinse in provided collection buffer vial
- Invert the collection buffer vial 2-3 times

- Securely tighten all caps and seal all containers to prevent leakage
- Place collection buffer vial back into the biohazard bag with absorbent pad
- No special preparation or timing is required for collection of specimens
- Sample does not need to be refrigerated

Thyroid cytology smear, ThinPrep, Cytospin or FFPE Block Collection Instructions

- Slides must be labeled with the submitting Pathology Department's accession number. A copy of the pathology or cytology report must be provided for cross-checking the Test Requisition with patient name, date of collection, and with the Pathology Department's accession number
- On the test requisition, be sure to indicate the slide(s) accession number and appropriate amount of slide(s) being sent for testing
- Insert slide(s) into provided plastic slide holder, securely snap lid shut
- Place slide holder with glass slide into padded pouch
- No special preparation or timing is required for collection of specimens
- Sample does not need to be refrigerated

Control Prep

A control sample is not required for ThyGeNEXT®/ThyraMIR®v2 testing.

IMPORTANT Information Regarding Cytology Slides Submitted for Molecular Analysis with ThyGeNEXT and ThyraMIRv2

- A high-resolution digital image of each slide will be captured prior to the testing process
- The slide(s) used for testing will not be returned since the material will be extracted for testing
  - Should the creation of a digital image not be possible for any reason, Interpace will immediately halt testing and notify the client, providing options for next steps. These may include requesting additional scannable material or canceling testing
- Ensure that the slide:
  - Aligns to standard measurements of 75mm by 25mm (3" by 1") and be ~1mm thick
  - Has a coverslip that is properly fixed to the slide and is not loose (plastic or glass coverslips are both acceptable)
  - Has no overhanging coverslips or stickers
  - Has no glue residue
  - Is not cracked

Specimen Rejection Criteria

- Specimen not originating from thyroid
- Frozen specimen
- Slides that are non-diagnostic (lacking cellular material sufficient for diagnosis)
- Co-mingled specimen (ie, mixing 2 different nodules in 1 vial)
- Unlabeled or mislabeled specimen

- Specimens submitted on frosted slides
- Empty, leaking, or broken specimen vials

Specimen Rejection Criteria (continued)

- FNA specimens submitted within an expired collection buffer vial
- FNA specimens older than 14 days when ordering cytology
- FNA specimens older than 42 days for molecular testing
- Slide specimens that do not align to the listed criteria above and are older than 6 months for molecular testing
- Any media other than the provided collection buffer (for molecular testing)
- FFPE specimens that do not align to the listed criteria above and are older than 6 months (for molecular testing)

Specimen Storage for Viability

- Store at room temp
- Do not freeze
- FNA specimens viable up to 42 days (6 weeks)

Related Test Orders

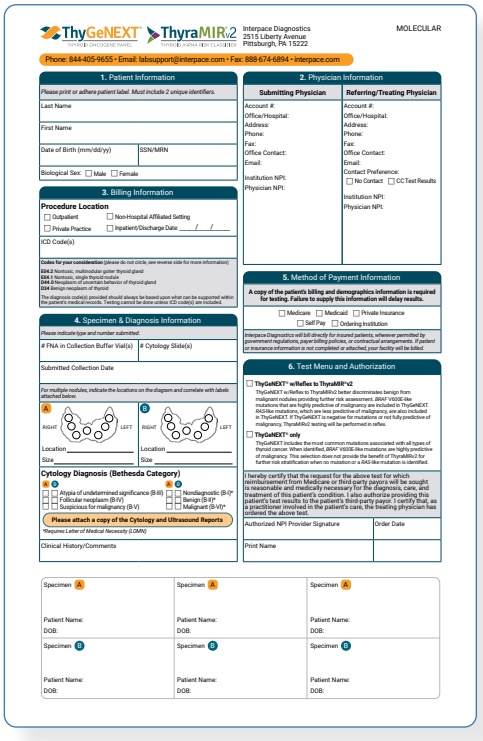
- Cytology
- ThyraMIRv2

Ordering and Shipping Process

For instructions on how to order this test, see the Interpace Diagnostics "Test Ordering and Shipping Process" on page 8 of this document.

How to Complete a Test Requisition

Testing requisitions can vary. The following are general guidelines to assist in completing the Interpace Diagnostics Testing Requisition to ensure timely and correct handling of submitted specimens to our laboratory. Please refer to the examples below to help answer questions you may have about completing the testing requisition. If at any point you have additional questions or need a requisition for specimen submission, please contact Client Services at 800-495-9885 or clientservices@interpace.com. Additionally, blank requisitions can be found on our website, www.interpace.com.


ThyGeNEXT ThyraMIRv2
Interpace Diagnostics
2515 Liberty Avenue
Pittsburgh, PA 15222
MOLECULAR
Phone: 844-405-9655 • Email: labsupport@interpace.com • Fax: 888-674-6894 • interpace.com
1. Patient Information
2. Physician Information
Submitting Physician
Referring/Treating Physician
3. Billing Information
4. Specimen & Diagnosis Information
5. Method of Payment Information
6. Test Menu and Authorization
Cytology Diagnosis (Bethesda Category)
Please attach a copy of the Cytology and Ultrasound Reports
Clinical History/Comments

Section 1. Patient Information

All fields are required. Include patient first and last name, date of birth, SSN/MRN code, and biological sex. A complete patient

label can be adhered in this field as long as the patient information is complete and includes 2 unique identifiers.

Incomplete information will result in testing delays.

Section 2. Physician Information

This section may be pre-filled if an account has been set up with Interpace Diagnostics. If blank, complete each field. Account Number should match your Interpace Diagnostics account number (leave blank if unknown). Complete the physician institution contact information. Please avoid Office/ Hospital acronyms or abbreviations and spell out the institution name.

Referring/Treating Physician:

Please provide full name and phone/fax number for the referring/treating physician, if applicable. Check the box to indicate if you would like the referring/treating physician to receive a copy of the results.

Leaving contact information incomplete will result in processing delays.

Section 3. Billing Information

Check the box to indicate where procedure was performed (Non-hospital affiliated setting, Private Practice, Outpatient, or Inpatient with discharge date).

Testing cannot be performed unless ICD-10 code(s) are included.

Write in the appropriate ICD-10 code based on the patient's medical records. The ICD diagnosis code must be defined by the most detailed level of specificity available. If a diagnosis code cannot be supported by the patient's medical record, then the code should not be used for ordering laboratory services. The list of common ICD diagnosis codes for the characterization of thyroid nodules shown below is not complete. Please refer to the ICD manual for a complete listing.

Common ICD-10 Diagnosis Codes:

- D34-Benign neoplasm of thyroid gland
- D44.0-Neoplasm of uncertain behavior of thyroid gland
- D44.9-Neoplasm of uncertain behavior of unspecified endocrine gland
- E01.0-Iodine-deficiency related diffuse (endemic) goiter
- E01.1-Iodine-deficiency related multinodular (endemic) goiter
- E01.2-Iodine-deficiency related (endemic) goiter, unspecified
- E04.0-Nontoxic diffuse goiter
- E04.1-Nontoxic single thyroid nodule
- E04.2-Nontoxic multinodular goiter
- E04.8-Other, specified nontoxic goiter
- E04.9-Nontoxic goiter, unspecified

Section 4. Specimen & Diagnosis Information

Submitted Specimen(s)

Check the box to indicate the type of specimen being sent for testing OR indicate the number of slides being sent (REQUIRED). If submitting multiple nodules, indicate type and quantity separately.

Specimen Collection Date

Enter the date of the procedure when the specimen was collected. Mark the circle on the thyroid diagram to indicate location of the nodule. The requisition can be used to submit specimens for up to 2 locations. Use letter A for the first specimen and letter B for the second specimen. Provide a descriptive name for each location on the line provided, along with the size of each nodule.

Cytology Diagnosis (Bethesda Category)

Check the box that corresponds with the patient's medical records to indicate the cytology diagnosis. A copy of the corresponding cytology report is requested to be sent with this specimen, as available. If these reports are not available at the time of specimen submission, please forward to Client Services (fax: 1-888-674-6894 or 412-224-6425) when received.

Please note that for Bethesda I, II, and VI categories a Letter of Medical Necessity is required to start testing.

Ultrasound Characteristics

Attach a copy of the ultrasound report and provide relevant clinical history for the patient. Please provide relevant medical records at no cost when requested by the patient's insurance carrier for reimbursement.

Section 5. Method of Payment Information

Check the box indicating how the testing should be billed. Interpace Diagnostics will submit claims to all private insurance, Medicare, and other government plans for insured patients.

Patient Contact Information

Please provide a copy of the patient's face sheet or demographics page to include the patient's full name, biological sex, date of birth, address, and phone number.

A copy of the patient's billing information MUST be submitted with the specimen.

Medicare/Medicaid/Private Insurance

Provide a clear copy of the front and back of the patient's primary insurance/Medicaid/other payer card. If the patient has a secondary insurance please provide a clear copy of the front and back of the secondary insurance card.

Ordering Institution

Check this box if Interpace Diagnostics is to bill the ordering institution for the ordered testing.

Patient Self-Pay (no insurance)

Check this box if the patient has no insurance.

Section 6. Test Menu and Authorization

Specimen processing cannot begin until there is a clear indication of the type of testing to be performed (check box). Please indicate the tests requested for the patient's specimen. Details of each test can be found on our website and in test details from our Directory of Laboratory Services. Only 1 test should be selected (duplicate test selections within a Test Requisition Form cannot be processed and can delay testing).

The ordering physician is required to sign and date the requisition as authorization for Interpace Diagnostics to perform testing. Stamped signatures or physician initials cannot be accepted. An incomplete signature will result in testing delays. Order date cannot precede Collection Date of the specimen.

Post-dated requisitions are not accepted.

ThyraMIR®v2
THYROID miRNA RISK CLASSIFIER

ThyraMIR®v2 (Ordered as a Reflex Test with ThyGeNEXT®)

PLA 0018U

ThyraMIR®v2 is a rule-out test for malignancy. ThyraMIRv2 is available to order in conjunction with ThyGeNEXT® and cannot be ordered as a stand-alone test. Like ThyGeNEXT, this test is available for indeterminate thyroid nodules to provide additional risk assessment for optimum clinical management decisions. You can find additional information on our website, www.interpace.com.

Accepted Specimens

- Thyroid FNA in provided collection buffer (FNA specimens submitted within an expired collection buffer vial will be rejected)
- Thyroid cytology smear, ThinPrep, or cytospin
  (Please refer to the ThyGeNEXT section for **Important Information** regarding cytology slide submission)
- Formalin-Fixed Paraffin-Embedded Tissue/Cell Block (FFPE) (8 recut slides plus 1 H&E slide)
  Presurgical specimens only (up to 6 months from collection)

Turnaround Time

- 10-14 business days for FNA samples from time of accessioning
- Less than 18 business days for cytology or FFPE samples from time of accessioning

Methodology

- MicroRNA Testing
- **Specimen Requirements and Collection requirements are the same as ThyGeNEXT testing. Please refer to the ThyGeNEXT section for additional details**

Related Test Orders:

- Cytology
- ThyGeNEXT

Ordering and Shipping Process

For instructions on how to order this test, see the Interpace Diagnostics "Test Ordering and Shipping Process" on page 8 of this document.

How to Complete a Test Requisition

ThyraMIRv2 is ordered as a reflex test with ThyGeNEXT. To ensure timely and correct handling of submitted specimens to our laboratory, please refer to the requisition completion guidance found on page 17.

Interpace Diagnostics®, LLC is a subsidiary of Interpace Biosciences, Inc.
www.interpace.com | 800.495.9885
IDX-007-11-0926-v19

Interpace Diagnostics®