A. SCOPE
RRMC Laboratory: Cytology

B. PURPOSE
The purpose of this policy is to define the workflow and process involved with the procurement of Fine Needle Aspirations.

C. POLICY
Pathologists may perform and/or assist on selected fine needle aspirate (FNA) procedures to insure optimal specimen preparation and, if assisting, to give a preliminary reading of adequacy and rapid interpretation to the radiologist or provider obtaining the sample.

Fine needle aspiration is an invasive procedure performed to obtain cytologic samples from suspected tumor masses located in various parts of the body. Most commonly the needle is inserted and guided by radiological images (CT scan, ultrasound and fluoroscopy) or the FNA may be guided by direct palpation into the suspected tumor. When a Chiba or straight needle is used, the needle tip is inserted into the mass and negative pressure is applied to draw up a cytologic sample. Rotex needles are threaded at the end and the needle is screwed into the mass, covered by a needle sheath and removed from the lesion. If the slides are deemed adequate for diagnostic interpretation, the aspirate is concluded. If deemed inadequate, additional needle passes are generally made to obtain adequate cytologic material.

Fine needle aspiration procedures may be performed by Radiologists, Pathologists and other physicians/providers trained in FNA collection procedures.

All assisted needle aspirations that need an attending pathologist or a cytotechnologist must be scheduled with the Anatomic Pathology administrative assistant by calling 802.747.1786. The following is required information for scheduling a FNA:

- Name
- Address
- Date of Birth or MRN
- Provider
- Site of aspiration
- Pertinent Insurance information

The Administrative assistant will then verify the availability with the pathologist and an Outlook calendar event is created and sent to all pathologist and cytotechnologists. The event is sent and tracked in the AP Outlook Calendar. Needle aspirations may be performed in the following locations: 3rd floor Laboratory, provider offices, Diagnostic Imaging, Foley Cancer Center, Endoscopy suite or patient's room.

Aspirations performed in Diagnostic Imaging are scheduled there first and then the Diagnostic Imaging assistant notifies the anatomic pathology administrative assistant who follows the outline above for scheduling with

Cytology staff. Endoscopy and Endocrinology procedures are scheduled in the same manner with respective office staff contacting the anatomical pathology dept.

All materials needed for FNA are kept in a tote stored in cytology and must be stocked with the materials listed in this procedure. A movable cart is available and maintained by the cytotechnologist with a microscope, toluidine blue stain and 3 Step staining set-up. One cart is located in Diagnostic Imaging. A second cart is located in the endoscopy suite and is utilized in other FNA locations as needed. The endocrinology clinic maintains a stock of supplies as outlined in this procedure. It is the responsibility of the cytotechnologist to ensure the FNA materials are stocked in all locations.

A surgical pathology, Non-GYN/FNA Cytology requisition form #4565 must be completed by the provider or pathologist and must accompany all specimens. RRMC Form #3, "Informed Request for Operation and Other Procedures" must be completed for all FNA procedures performed by a pathologist. See Appendix A for examples of the surgical pathology, Non-GYN/FNA Cytology requisition form #4565 and RRMC Form #3. Electronic orders are placed by the requesting provider using the Pathology FNA Request orderable in Cerner.

D. DEFINITIONS

FNA: Fine Needle Aspiration
ETOH: Ethyl Alcohol
DI: Diagnostic Imaging
HIM: Health Information Management

E. PROCEDURE

Sample Information

A specimen may be from an FNA procedure where a Pathologist's or cytotechnologist assistance is requested to help determine specimen adequacy and/or provide a rapid interpretation. The latter is only provided by an attending pathologist. If a statement of adequacy, preliminary diagnosis, or recommendations for additional studies is provided at the time of the cytology sample collection, documentation of that statement is maintained on Form #4565 by the pathologist involved under the Rapid Interpretation section of the form. These statements are entered into the final report under the 'Rapid Interpretation' heading. Additionally, Form #4565 is sent to the Health Information Management department to be scanned into the patient's medical record. The cytologic sample may consist of air dried and ETOH fixed slides or fluid, as well as, a needle rinse in saline or CytoLyt©. Occasionally a core biopsy technique may also be performed to obtain actual histologic tissue for evaluation.

Materials/Reagents/Media/Supplies:

Supplies –

- 1 Box Microscope Slides
- Cameco syringe pistol holder
- 12cc disposable syringe
- 4 CytoLyt© tubes
- Requisition Forms #4565
- Informed Request for Operation and Other Procedures Form #3
- Gauze
- Toluidine Blue stain
- Plastic Slide Tray
- Assorted gauge needles (10 each)
  - 25 to 18 gauge
- Alcohol Prep pads
- Disposable gloves
- 3 Step Criterion Stain
- Blotting paper towels
- 3 Coplin Jars with 95% ETOH
- Bandages
- 1 RPMI tube
- 1 Micro anaerobic culture tube
- 1 box Cover Glass
- 2 Formalin specimen containers

Method

Technique: FNA Performed by Pathologist

1. Using RRMC "Informed Request for Operation and Other Procedures" Form #3, the pathologist will discuss with the patient the procedure planned, the alternatives (if any) to be considered, the reasonable risks involved and obtain written consent before the procedure begins.
2. The following statements will be included with the current FNA statement:
    a. The procedure and possible complications were explained and written consent was obtained.
    b. (#) passes were performed with no complications on (Date and Time)
    c. Dr. _ identified the patient _; he/she confirms his/her understanding that a FNA (Fine Needle Aspiration) procedure will be performed on his/her _ (Right Neck, Left Breast, etc.).
        i. Example: The procedure and possible complications were explained and written consent was obtained. On 12/01/10 at 10:15am, Dr. Jones identified the patient, Mary North; she confirms her understanding that a FNA (Fine Needle Aspiration) will be performed on her Right Neck. 3 passes were performed with no complications.
3. The original signed written authorization form along with the FNA requisition form #4565 is delivered to the HIM Dept to be scanned into the patient's medical record.
4. Label microscope slides with Patient's Name and Date of Birth or MRN.
    a. Note: All specimens must be labeled at the time of collection to provide unique identification.
5. Each prepared slide must be labeled separately and any specimen container with collected material (e.g., fluid from aspiration) must also be labeled with both the patient's name and Date of Birth or MRN
6. EACH pass should be labeled on the slides.
7. Once the sample is aspirated, the Radiologist, Endocrinologist or Pulmonologist will give the needle to the Pathologist or Cytotechnologist, who will make smears from the aspirated material
8. Gloves must be worn when a sample is being obtained and slides are being prepared.
9. Protective eyewear is optional, but recommended.

For Chiba Needles (Aspiration with Negative Pressure):

Using the One-Step Method:

1. Place the slide with the harvest in the non dominant hand and hold firmly (Figure 28-10A)
2. Rest the edge of a clean, spreader slide on the stationary slide (Figure 28-10B)
3. Tilt spreader slide until the aspirated material is beginning to spread (Figure 28-10C)
4. Move top, spreader slide toward you, applying slight pressure to slide and aspirated material. (Figure 28-10D)
5. Do not lift either end of spreader slide until smear is complete.
6. End result of smear should appear like that shown in Figure 28-10D below.
7. Fix stationary slide in 95% ETOH and allow spreader slide to air dry.

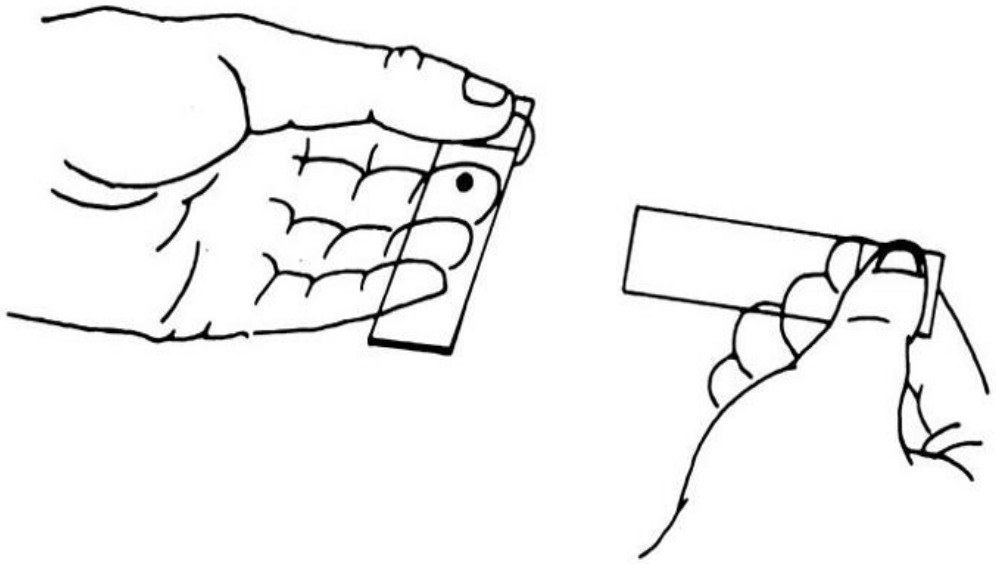

Figure 28-10A Basic smear preparation technique (one-step technique). Place the slide with the harvest in the nondominant hand.

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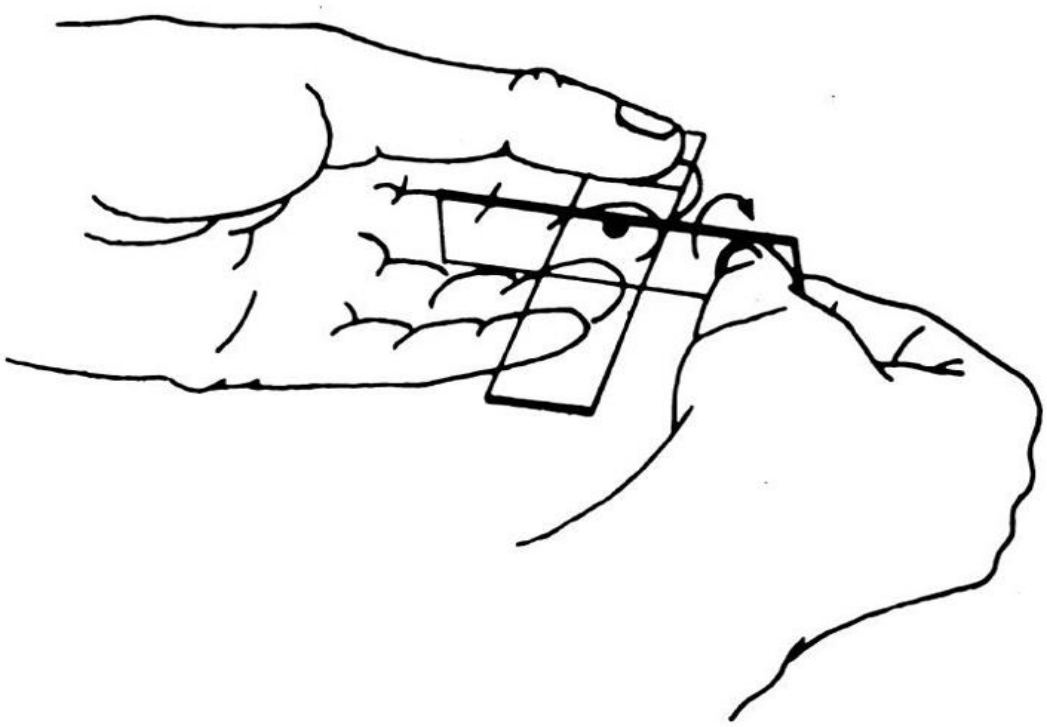

Figure 28-10B Basic smear preparation technique (one-step technique). Place a clean slide at an angle, resting on the bottom slide.

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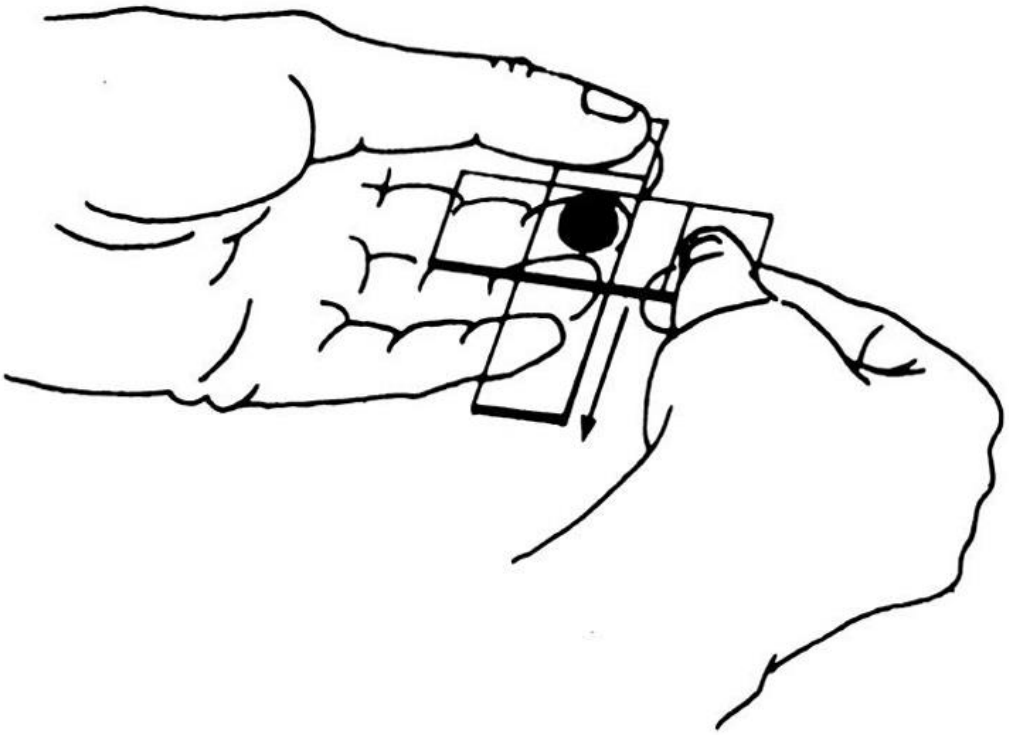

Figure 28-10C Basic smear preparation technique (one-step technique). Rotate the top slide until the two slides are flush.

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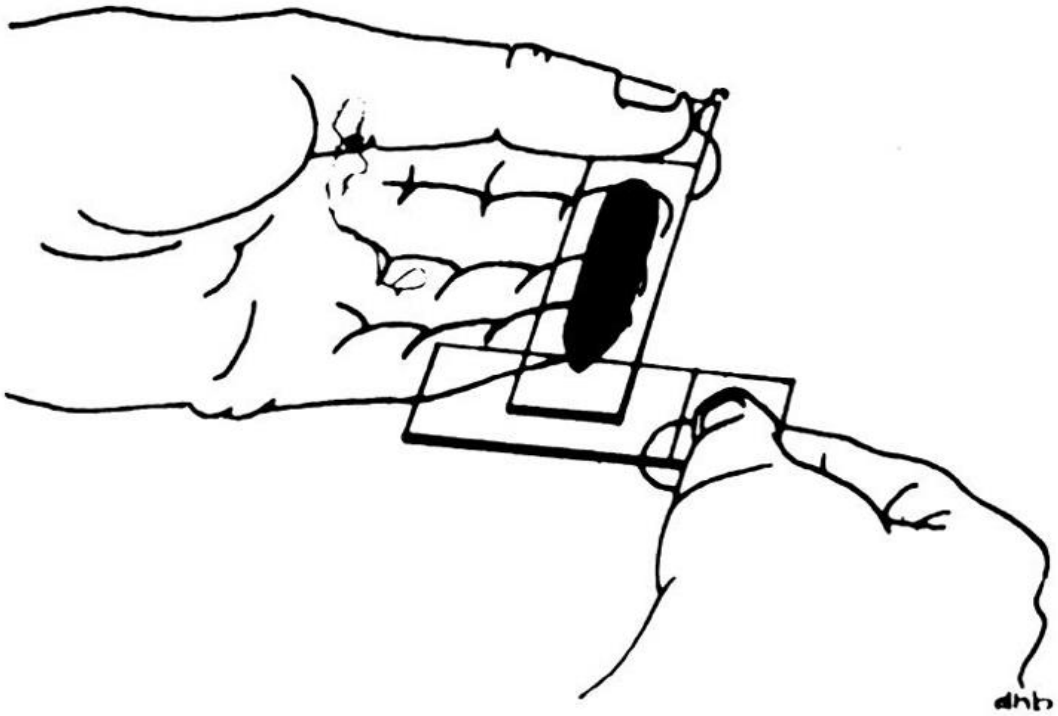

Figure 28-10D Basic smear preparation technique (one-step technique). Spread the material by sliding the top slide.

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8. Rinse Needle in CytoLyt© solution, sterile saline, RPMI or Afirma® FNAprotect Collection Tube as indicated.

8.1. If rinsed in CytoLyt© or Afirma® FNAprotect Collection solution do NOT re-use needle for additional passes
8.2. CytoLyt© tube, sterile saline containers, RPMI, or Afirma® FNAprotect Collection Tube must be labeled with appropriate patient identifiers

For Rotex needles:

1. Hold out one slide flat with the frosted end facing up.
2. Needle tip will be rolled or brushed on slide surface.
   2.1. Important: Cells air dry quickly with this procedure. Time spent rolling or brushing should be limited.
3. Place slide immediately into a Coplin jar of 95% ETOH.
4. Rinse needle in CytoLyt© solution, sterile saline or RPMI as indicated
   4.1. If rinsed in CytoLyt© do NOT re-use needle for additional passes
   4.2. CytoLyt© tube, sterile saline containers or RPMI must be labeled with appropriate patient identifiers

Rapid Assessment of Adequacy:

Using the Toluidine Blue method:

1. Allow slide to fix for 20 to 30 seconds in 95% ETOH
2. Remove slide from 95% ETOH
3. Add 2-4 drops of Toluidine Blue to slide
4. Apply cover slip
5. Allow sample to stain for 20 to 30 seconds
6. Inverted slide on paper towel
7. Apply gentle pressure to slide to expel excess stain and blot all edges dry
8. Evaluate Toluidine Blue slide(s) (see Procedure Note)
9. Once slides have been evaluated, the Toluidine Blue slides can be placed back into the original Coplin jar of alcohol.
   9.1. Upon returning to Cytology lab, the cytotechnologist must ensure that the cover glass has been removed from the slides to ensure proper fixation.

Using Criterion 3-Step stain method:

1. Allow slides to completely air dry
2. Dip slide 10 times into Fixative
3. Dip slide 10 times in Solution A
4. Dip slide 10 times in Solution B
5. Dip slide 10 times in water
6. Blot back of slide
7. Evaluate the Criterion stained slide(s) (see Procedure Note)

Specimen Delivery:

In pathologist-performed aspirations or assisted aspirations in DI, endoscopy or endocrinology, the cytotechnologist or pathologist will bring the FNA material back to the cytology department at the end of the procedure. The electronic order will be placed by the provider who obtained the FNA. FNA's from providers' offices are delivered to Central Accessioning where the order will be placed via the information on the 4565 requisition form or through electronic transfer of orders.

Sample Preparation:

1. Air-dried slides are stained with the 3 Step Criterion stain per the "Stain Three Step" procedure outlined separately.

2. 95% ETOH fixed slides are Pap stained per the "Stain Pap for NonGYN Specimens" procedure outlined separately.
3. CytoLyt© needle rinses are prepared per the "ThinPrep Processing Non-GYN Specimens procedure outlined separately using sequence 2 and are Pap stained.

Veracyte® Afirma® Thyroid FNA Analysis

1. Thyroid fine needle aspirate samples performed through the Endocrinology office may require collection of a Veracyte® Afirma® FNAprotect Collection Tube. The office will have the tubes in stock (more can be ordered through the lab) and available for the cytotechnologist attending the procedure.
2. Each aspirate should be expressed and made into smears as per protocol above. The needle should be carefully rinsed into a patient-labeled Afirma® FNAprotect tube before disposal of the needle.
3. The Afirma® FNAprotect tube will be transported back to the lab along with the direct smears and Cytolyt vial if also collected.
4. The specimen-containing Afirma® FNAprotect tube is stored at -15ºC in the freezer located in Chemistry department until it is either sent out for testing per Pathologist request or disposed. Tubes are disposed after 30 days in a red biohazard bag.

F. RELATED POLICIES AND FORMS

1. Surgical Pathology, Non-GYN/FNA Cytology Form #4565
2. RRMC Form #3

CAP Question:	CYP.03333, CYP.03366, ANP.12092
Supersedes Document Entitled:	Fine Needle Aspirations 3_26_2015: added Afirma testing and appendix images
Document locations:	Cytology Procedure Manual, t:\lab\anatomic pathology\cytology\procedure manual\fine needle aspirations 2016-05-27.docx

G. REFERENCES AND BIBLIOGRAPHY

1. Koss' Diagnostic Cytology and Its Histopathologic Bases, 5th Edition. Philadelphia; Lippincott, Williams & Wilkins, 2006, Vol. II, p. 1056-1080

H. APPENDICES

Appendix A: Surgical Pathology, Non-GYN/FNA Cytology Form #4565

Laboratory Services
A Department of Rutland Regional Medical Center
160 ALLEN ST.
RUTLAND, VERMONT 05701
802.747.1786

REQUISITION

SURGICAL PATHOLOGY
FNA / NON-GYN CYTOLOGY

NAME (LAST, FIRST, MI):	DOB:	SEX: ☐M ☐F	SOCIAL SECURITY NO.:
ORDERING PROVIDER (PRINT NAME):	COPY TO:		
ORDERING PROVIDER SIGNATURE (REQUIRED):	MRN:		FIN NO:

PLEASE FILL OUT BILLING INFORMATION BELOW OR ATTACH SEPARATE SHEET ☐ *NO INSURANCE* (FILL OUT INFORMATION BELOW)

BILLING INFORMATION

RESPONSIBLE PARTY NAME	PHONE NO.
ADDRESS (STREET, STATE, ZIP CODE)	
MEDICARE NO. / MEDICAID NO. / STATE	
INSURANCE COMPANY NAME / CERT. NO. / GROUP NO.	
SUBSCRIBER NAME	RELATIONSHIP
EMPLOYER NAME	
EMPLOYER ADDRESS	

BENEFICIARY AGREEMENT:
I have been notified by my provider that he or she believes that, in my case, Medicare is likely to deny payment for the services identified. If Medicare denies payment, I agree to be personally and fully responsible for payment.

Signed (beneficiary signature, date)

NOTICE TO PROVIDER: FOR MEDICARE PATIENTS, YOU SHOULD ONLY ORDER THOSE TESTS YOU BELIEVE ARE MEDICALLY NECESSARY FOR THE DIAGNOSIS AND TREATMENT OF YOUR PATIENT. MEDICARE MAY DENY PAYMENT FOR A TEST YOU BELIEVE IS APPROPRIATE, SUCH AS SCREENING TEST, BUT WHICH DOES NOT MEET THE MEDICARE DEFINITION OF MEDICAL NECESSITY.

SPECIMEN COLLECTION

COLLECTION DATE	COLLECTION TIME:	SPECIMEN RECEIVED DATE:	LAB ACCESSION NO.:
CLINICAL DIAGNOSIS/PERTINENT HISTORY	DIAGNOSIS CODE (ICD10)		

If you wish to decline reflex indicate here:

☐ Do not perform HER2 Assay
HER2 testing is performed on Core Biopsies unless specifically requested.

☐ Do not perform Estrogen and Progesterone receptor testing on breast biopsies with only ductal carcinoma in situ (DCIS)

SURGICAL PATHOLOGY TESTING (Tissue Samples)

List each specimen source separately:

1. _____
2. _____
3. _____
4. _____

SEE BACK OF THIS FORM FOR ANATOMIC PATHOLOGY REFLEX TESTING CRITERIA

NON-GYN CYTOLOGY TESTING (Cells/Fluid)

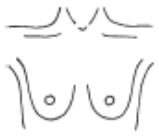
☐ Anal Pap		**Specimen Site:**
☐ CSF		☐ Brushing
☐ Nipple Discharge	☐L ☐R	☐ Washing
☐ Peritoneal Fluid/Ascites		☐ Skin Scraping (Tzanck Prep)
☐ Peritoneal Wash		
☐ Pleural Fluid	☐L ☐R	☐ Other:
☐ Sputum, Expectorated		
☐ Sputum, Induced		
☐ Urine, Catheterized		
☐ Urine, Voided		
☐ Ureteral Washing	☐L ☐R	
☐ Ureteral Brushing	☐L ☐R	

FINE NEEDLE ASPIRATE (FNA)

☐ FNA Palpation
☐ FNA Radiology Guided
Site of aspiration

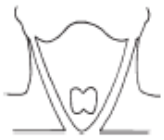
AIR DRIED SLIDES _____
FIXED SLIDES _____
NEEDLE RINSE _____

BREAST



Distance from Nipple _____
Lump size _____

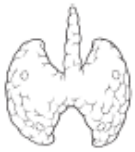
NECK



Lump size _____

Lump size _____

THYROID



ASSIGNMENT OF INSURANCE BENEFITS, RELEASE OF INFORMATION AND CONSENT FOR TREATMENT (see back of form)

WITNESS _____ DATE _____ PATIENT (PARENT OR GUARDIAN IF MINOR) _____

1405

FORM NO. 4565 (3/15) Copy 1 - PATHOLOGY DEPT. Copy 2 - PROVIDER

Place Patient Label Here

Appendix B: RRMC Form #3

INFORMED REQUEST FOR OPERATION AND OTHER PROCEDURES

I request the following operation or procedure: _____

_____

_____

Upon: _____

By _____ ☐ MD ☐ DO ☐ PA ☐ NP and his/her assistants. He/she has explained to my understanding the proposed procedure/treatment, the potential benefits, risks and side effects; reasonable alternatives; the risks related to not having the proposed procedure/treatment; the likelihood of the procedure/treatment achieving my goals; and potential problems that might occur during my recovery. I have had the opportunity to ask questions about this procedure/treatment, and my questions have been answered to my satisfaction.

I also understand that anesthesia (including moderate sedation/analgesia) may be needed in order to perform this procedure. This has been explained to me, and I authorize its use for this procedure

Additions (if none, so state): _____

_____

_____

Date: _____ **Time:** _____ **Patient:** _____

Witness to Signature: _____

If patient is unable to sign:

Date: _____ **Time:** _____ **Patient Representative:** _____

I have explained the proposed procedure, the potential benefits, reasonable alternative treatments (if any), the reasonable risks involved, and the risks of not having the procedure/treatment. The patient/parent/guardian appears to understand. The patient/parent/guardian has had the opportunity to ask me questions about the proposed procedure.

Date: _____ **Time:** _____ **Provider Signature:** _____

Form #3 Rev. 3/11, 2/13, 7/13, 2/14

Rutland Regional Medical Center
An Affiliate of Rutland Regional Health Services
160 Allen Street, Rutland, VT 05701 • 802.775.7111 • www.rrmc.org

* 1 2 3 0 *

Patient Label