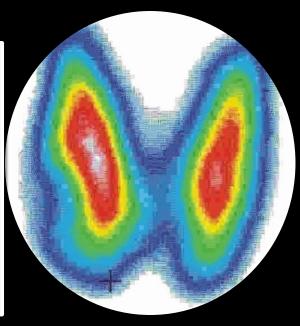
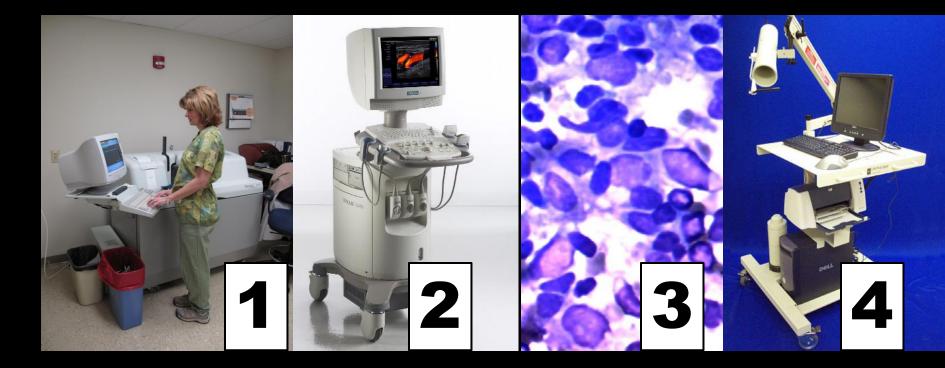
# Thyroid practice Enhancements ATA- 2013.



### J. Woody Sistrunk, MD

Jackson Thyroid & Endocrine Clinic, PLLC Jackson, Mississippi



#### KEEP THIS IN MIND!!!

THYROIDOLOGY PRACTICE ENHANCEMENTS In the order of importance.

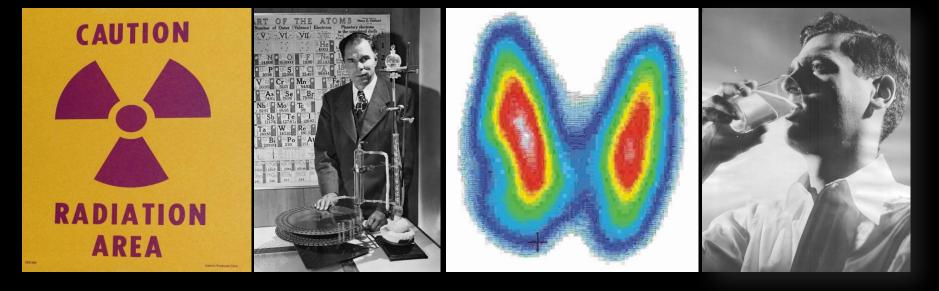
#### 2 sections:

- 1. An Introduction to Outpatient Nuclear Medicine
- 2. An Overview of Starting a Clinical Laboratory



#### J. Woody Sistrunk, MD

St. Dominic West Tower 971 Lakeland Drive, Suite 353 Jackson, Mississippi 39216 Phone: (601) 949-6990 FAX: (601) 949-6105



AN *INTRODUCTION* TO NUCLEAR THYROIDOLOGY IN THE OUTPATIENT PRACTICE OF ENDOCRINOLOGY

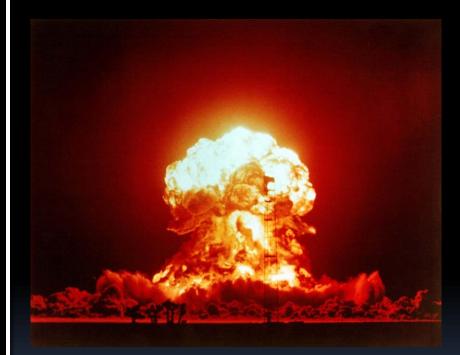


J. Woody Sistrunk, MD, FACE, ECNU •Radiation Safety Officer



### Why *Nuclear Medicine* in Endocrinology?

- Who knows more about the thyroid than an endocrinologist ?
- Proper safety instructions and reassurance to YOUR patients.
- Making sure YOUR patients are treated appropriately.
- SAFTEY INSTRUCTIONS FROM Hospital NUCLEAR MEDICINE:
  - "In that room you will find a metal box.
  - In that box you will find a lead container.
  - In that container is a pill.
  - Take it and leave."

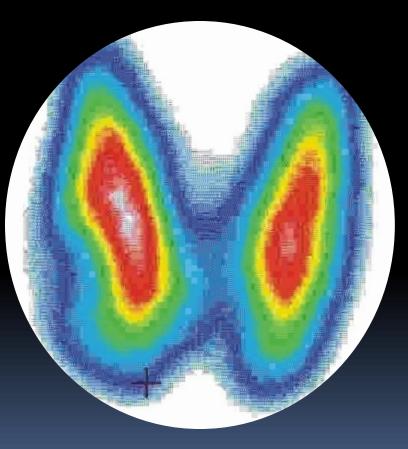






- Can have a Nuclear Medicine Hot lab in the office.
  - Thyroid Uptakes
  - Radioactive iodine therapy for hyperthyroidism.
  - Radioactive iodine therapy for thyroid cancer.
- With these procedures, you become the nuclear medicine physician/technologist.
  - Maintaining complete control of quality and decisions of your patients outcomes.
  - Ensuring correct instructions given to patients and safety measures followed.
  - Verifying all questions are answered.

#### NUCLEAR MEDICINE IN THE OUTPATIENT PRACTICE OF ENDOCRINOLOGY



### OUTLINE

- Licensure
  - AACE Course-
- Equipment

#### <u>History of 131 Therapy</u>

#### It is OUR heritage and OUR History!!

- 1946-1970
   Endocrinology
- 1970-1993
  Nuclear Medicine
- 1993-Present
  - American
     <u>Association of</u>
     <u>Clinical</u>
     <u>Endocrinologists</u>
     (AACE )Initiative.

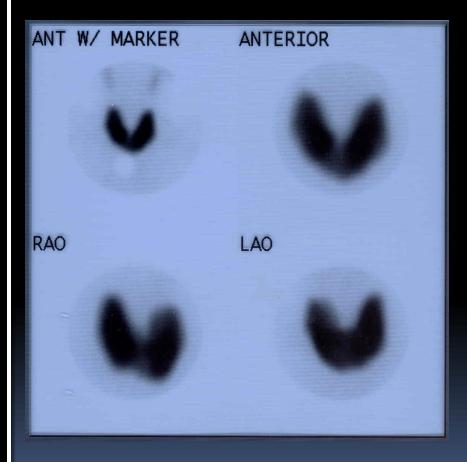


Figure 21. Positioning of scintillation counter tube for I<sup>131</sup> uptake test.

e 21. Positioning of scintillation counter tube for 1131 uptake test.

### History— *Nuclear Medicine* Era

- Missed diagnosis
- Failure to discuss other treatments
- Failure to discuss non-thyroid problems
- Misadministration
- Loss to follow-up
- "Thyroid uptake is low consistent with hypothyroidism."
- "Thyroid uptake is low, r/o paraneoplastic process."



# LICENSURE/DEFINITIONS

# NUCLEAR ENDOCRINOLOGY

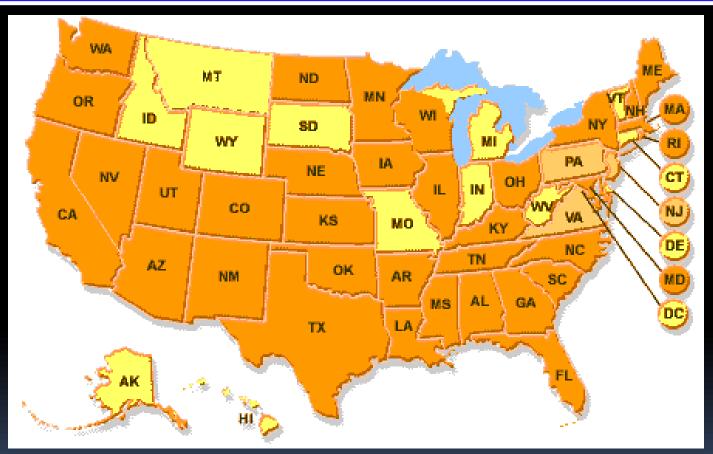
### Agreement State vs. Non-Agreement State

#### Agreement State

- A state that has signed an agreement with the Nuclear Regulatory Commission under which the state regulates the use of byproduct, source, and small quantities of special nuclear material in that state.
- Non-Agreement State

 The state is governed by the applicable laws of the Nuclear Regulatory Commission (NRC).

### **Agreement States**



Agreement State Non-Agreement State

Source: www.nrc.gov

#### What is a Radioactive Materials (RAM) License?

Issued to your clinic, or the hospital where you have privileges, by the NRC or Agreement State. Allows the facility to: order receive possess use radioactive materials.



**Authorized Users** are physicians listed on the radioactive materials license who are authorized to prescribe and administer particular radiopharmaceuticals for specific diagnostic or therapeutic procedures.

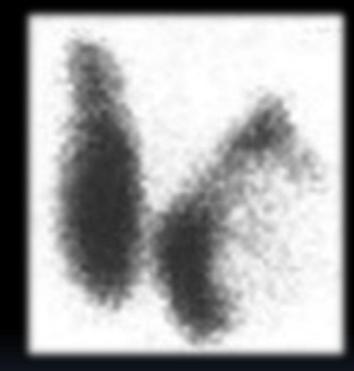
#### What will I be able to do as an Authorized User of Radioactive iodine?



 Thyroid Uptakes (1<sup>131</sup>, 1<sup>123</sup>)

2. Radioactive Iodine (I<sup>131</sup>)treatment for Hyperthyroidism.

3. Radioactive Iodine (I<sup>131</sup>)treatment for thyroid cancer / remnant ablation.



NOTE: YOU WILL NOT HAVE THE ABILITYTO PERFORMTHYROID SCANS. \*\*\*\*\*\*

# What Do I Have To Do To Become An <u>Authorized User</u>?

*8o hours* of classroom instruction with an emphasis on radiation safety, physics and math.

• AACE 80 HOUR COURSE.

Board certification by a medical specialty board.

Supervised treatment of 3 patients with less than 33 mCi. (Hyperthyroidism)

Supervised treatment of 3 patients with more than 33 mCi. (Thyroid cancer).





### AACE NUCLEAR MEDICINE COURSE Kansas City, Missouri Fall 2013 Go to aace.com for details.

HC. CENTY

RINO

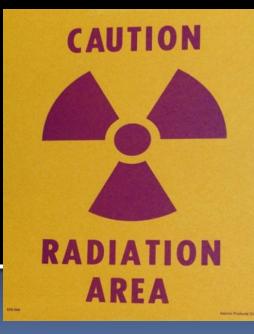
### How to Get Started

### What to Know?

- License requirements in your state.
- Equipment required.
- Layout of nuclear medicine hot lab.

### Who to contact?

- State nuclear regulatory agency
- Physicist
- Nuclear Pharmacy



### SIMPLE "HOT LAB" LAYOUT



- Essentials include a sink and a few electrical outlets.
- This can be the same room used for ultrasound exams.
- The same stretcher can even be used.

### Nothing this Fancy, Nothing this complicated.

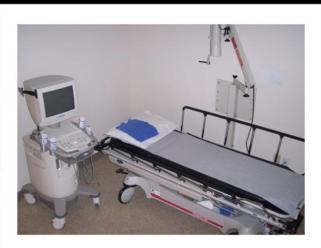
•No special leadlined room. No special facilities needed. •But this is impressive!!!!!!!!!



### SIMPLE PROCEDURE ROOM LAYOUT

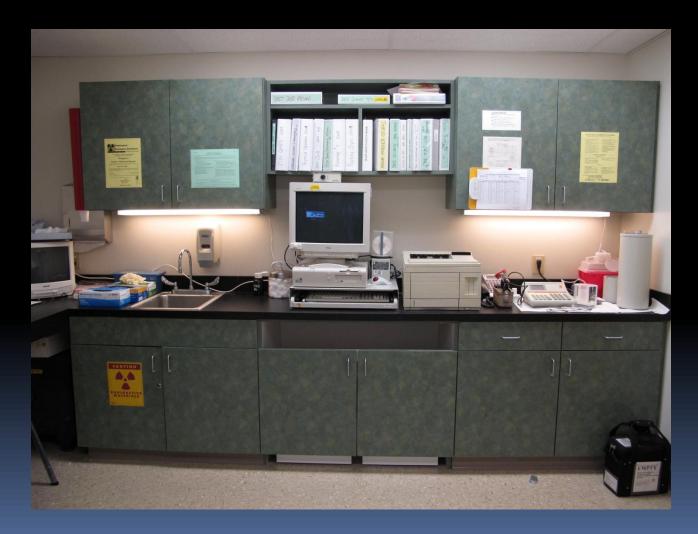
- Essentials include a sink and a few electrical outlets.
- This can be the same room used for nuclear medicine and ultrasound exams.
- The same stretcher can even be used.

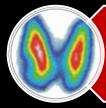






#### SIMPLE PROCEDURE ROOM LAYOUT





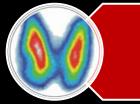
#### SIMPLE PROCEDURE ROOM LAYOUT





#### SIMPLE PROCEDURE ROOM LAYOUT





#### PROCEDURE ROOM MICROSCOPE LAYOUT



### EQUIPMENT OVERVIEW

- So now it's time to set up a HOT LAB!
- WHAT WILL I NEED TO PURCHASE??
  - Uptake System
  - Dose Calibrator
  - Geiger Counter

### HOW MUCH WILL ALL OF THIS COST??



- Uptake System--\$10,000-\$14,000
- Dose Calibrator--\$6000-\$8000
- Neck Phantom-- \$275
- Geiger Counter --\$1000
- Total Hot Lab Setup \$20,000- \$24,000

### HOW MUCH EXPOSURE WILL I RECEIVE??-



### Minimal !!! If any.

- No liquid!!!!!, all capsules arrive as pre-ordered unit doses.
- VERY SAFE A
- HOW DO YOU KNOW IF YOU ARE EXPOSED??
- Film Badges.
- WEEKLY Bioassay- which is simply placing the uptake probe over the neck will be performed weekly to confirm that radioactive iodine is not absorbed.

### YES, it will pay for itself!!!!!!!!!!



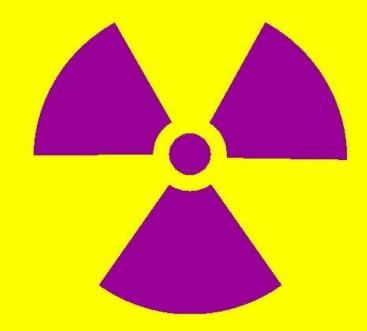
- US guidance with FNA 305
  FNA- 305
- Uptakes- 54
  Therapies- 45

HENCE, Thyroid Ultrasound is critical first. A

### **Fellows:** *WHILE INTRAINING*

# CAUTION

- Pursue all of the requirements needed for licensure.
- Review this talk with more detail at aace.com.
- Get to know the radiation safety officer at your institution (who often times is not a radiologist) and try to be put on the institution license as an "official USER".



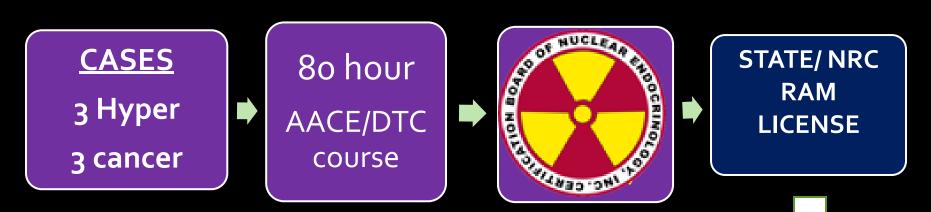
RADIOACTIVE MATERIALS



- Ask about the possibility of you having a "hot lab" and doing your own nuclear medicine procedures.
- Make sure you have access to a good ultrasound machine.
- Be specific with monetary figures, space requirement and the long term moneymaking potential.



### PATHWAY TO LICENSURE Certification, Licensure, then Accreditation.



#### ICANL

Intersocietal Commission for the Accreditation of Nuclear Medicine Laboratories ICANL LAB Accreditation

### Getting cases: A PROBLEM ATTIMES

- While you are still in fellowship, if you have any desire to become licensed in this, pursue the required cases (3 hyperthyroidism, 3 cancer.)
- Assist with dose decisions, safety instructions administration.

 Have a preceptor sign the appropriate NRC preceptor attestation form.

### **CONCLUSIONS:**

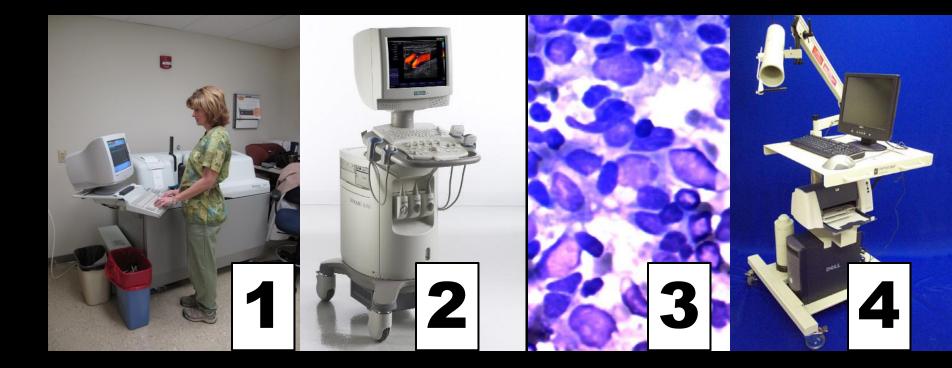
- Thyroid Doctors treating Thyroid Disease.
- A thyroid practice is a reality if you are willing to pursue it.



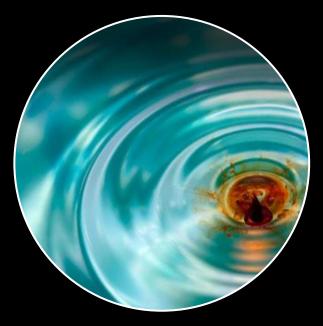
AACE NUCLEAR MEDICINE COURSE Kansas City, Missouri Fall 2013 www.aace.com



"Yes, my goitre is gone and now I am well and happy."



## THYROIDOLOGY PRACTICE ENHANCEMENTS In the order of importance.



### IN-OFFICE POINT OF CARE LABORATORY



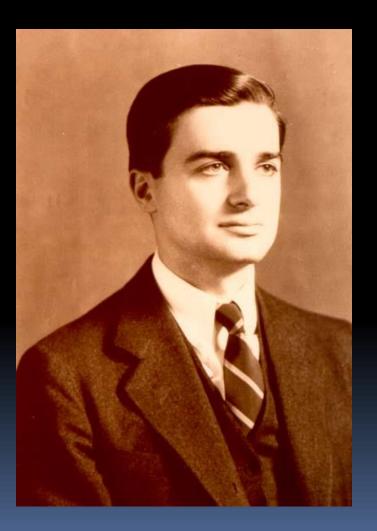
LAB OUTLINE

# Licensure Equipment



Never enough equipment in the practice of Thyroidology

### WHO IS THIS MAN???



# HINTs:

# Invented the radiation film badge

Invented polarized lenses

Had a role in changing our lives forever.

### Edwin H. Land



### Inventor of :

- The Polaroid Land Camera
- Polarized lenses.
- The radiation film badge.
- But what does he have to do with the practice of medicine?

### The Polaroid Camera changed the world.

- Pictures were available immediately.
- Good, bad, or ugly results were available immediately.
- No one was able wait for results anymore.
- Land was responsible for the expectation of the results in clinical medicine anticipated immediately by the patient (and Physician/ Endocrinologist.)



Why Laboratory Medicine??

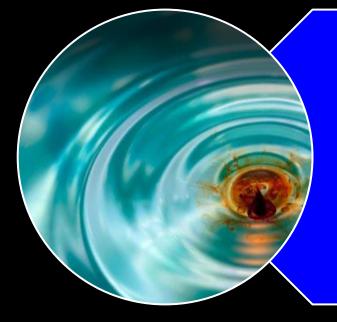
 Laboratory Medicine is essential is the heart of endocrinology.

 Without lab, we are doomed merely to watch and guess. Why Laboratory Medicine in Thyroidolgy?

## BUTIAMSOOBESE AND TIRED, IT MUST **BE MY** THYROID!!!!! The decisive "NO"= PRICELESS!!!!!!!!

# CLIA CERTIFICATION

# LABORATORY MEDICINE



LABORATORY MEDICINE IN THE CLINICAL PRACTICE OF ENDOCRINOLOGY

CLIA CERTIFICATION

### What is an OFFICE-BASED LABORATORY?

- Office-Based Laboratory
  - Defined as a clinical laboratory used by a fully licensed physician to test specimens collected primarily from patients of the practice.
  - It is usually located at the physicians principal sight of care.



### LABORATORY DIRECTOR-

 Responsible for the overall operation of the laboratory and the competency for all laboratory personnel.



#### HOW DO I BECOME A LABORATORY DIRECTOR?

- Certification in anatomic or clinical pathology.
- One year of laboratory training in residency.
- There's still time for this.
- OR
- 20 hours of CME credits of training on the responsibilities of the laboratory director. – http://www.cola.org/

### http://www.cola.org



This is the location for the Laboratory Directors Online Course.



WHAT CAN I DO IN AN OFFICE LAB?

50

### LABORATORY MAKE-UP

#### LABORATORY DIRECTOR-YOU

- Responsible for the overall operation of the laboratory and the competency for all laboratory personnel.
- The first step of getting this designation is to finish the on-line portion of the laboratory course.

#### TECHNICAL CONSULTANT-YOU

 Responsible for technical and scientific oversight of the laboratory.

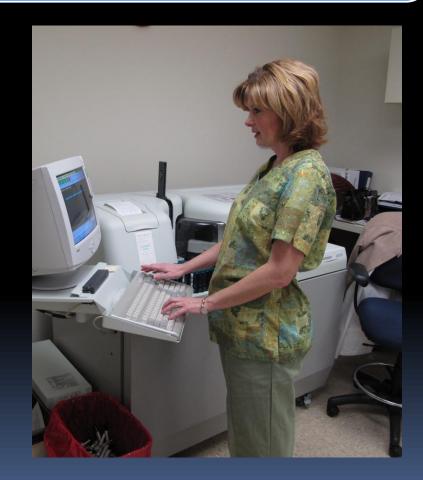
### CLINICAL CONSULTANT-YOU

- The physician that orders the appropriate tests.
- TESTING PERSONEL-Hopefully someone else.
  - GED/High School diploma and documented training appropriate to the test being performed.
  - www.cola.org

### THYROIDOLOGY WITHOUT LAB IS LIKE FISHING WITHOUT WORMS.

#### LAB is critical

- But the TSH/Free T4 is the essential part of the enterprise.
- From vein to results on paper in 20 minutes.
- Face to face decision making.
  - Are you taking your medicine.
  - I will write your 90 day RX now.
  - A note to PCP, recommending planned follow-up.



### A VAST MENU OF TESTS ARE AVAILABLE FOR THE OFFICE-BASED LAB



- TSH/ Free T4
- Simple Chemistry
- CBC
- COMPLEX LABS:
  - TSH/FT<sub>4</sub>
  - HgbA1c
  - MANY OTHERS.
- Clia-Waved Tests.
- NOTE: CLIA NOT REQUIRED FOR FNA ADEQUACY!!!!!!!!!!

#### LABORATORY IMPROVES CLINICAL OUTCOMES

- I. FASTER DIAGNOSIS AND TREATMENT.
- IMPROVED PATIENT COMPLIANCE.
- **3. LABORATORY CAN MODEL THE NATURE OF YOUR PRACTICE.**

### "TSH and FREE T<sub>4</sub> in < 30 minutes" "You're ONE-STOP THYROID SHOP"

#### What are the advantages of having an in office laboratory??

#### <u>CLINICAL RESEARCH</u>

- Phase 3 and Phase 4 drug studies are quickly becoming a big part of the private practice of Endocrinology.
- Having a laboratory makes your office a valuable site for data collection in these studies.
- Sites with laboratories are considered "more desirable."
- MAKE YOUR LAB WORK FOR YOU!!!!!!!

### DISADVANTAGES OF AN OFFICE LABORATORY.

- Costs.
- Regulations.
- Personnel.
  - Technologist
  - Phlebotomist
  - Laboratory Director (MD)

# My Current Practice With POINT OF CARE LAB



- Lab Drawn
- Patient Seen
- Lab Available
- LAB IMPORTED INTO EMR
- EMR Note sent to referring physicians.
- RX written/ wired.
- Disposition MADE!
- Follow-up scheduled.

 All inside of 30 minutes.

### **RESULTS TO PATIENTS**

- Patients want results.
- Face to face results cut down on questions and confusion.
- If you see 25 patients a day, you either have to pay the salary of the lab tech who processes the labs or ANOTHER nurse that will spend tomorrow tracking down the patient, verifying results, calling the pharmacy, and rearranging follow-up.
- In the end, make it a timesaving, money making proposition.
- Set the standard!!!!!!!!!



#### To Recap–

### The Advantages of Having an in office laboratory.

- PATIENT SATISFACTION
- CONVENIENCE
- Changes to treatment regimen can be made FACE TO FACE.
- <u>Patient understanding</u> is clearly better when communicated directly by the physician.
- FEWER PHONE CALLS or MAILING prescriptions.
- FASTER DIAGNOSIS AND TREATMENT.
- LESS ANXIETY WAITING FOR RESULTS.
- Ability to send Obese and Tired to an Internist!

#### RECAP- Many Reasons to have a lab in the office.

### It's good for the patient.

- Convenient, faster diagnosis and treatment.
- It's good for the practice.
  - Improved efficiency, Patient Satisfaction.
- It's good for revenue.
  - It keeps the bills paid.
- It's good for the physician.

  - IT MAKES YOU A VALUABLE COMMODITY.

#### HOW PROFITABLE IS HAVING AN *IN-HOUSE LAB?*

2008 FIGURES. – Jackson Thyroid & Endocrine Clinic, PLLC

LABTEST	#PERFORMED	YOUR COST	REIMB.
TSH	3217 @ \$1.40	\$4,503.80	\$152,775.
FREET4	3216@ \$2.25	\$7, 236.00	\$98,455.
Calcium	761@ \$.17	\$129.00	\$8,302.
HCG(Kit)	86@ \$1.19	\$102.30	\$1,892.

### HOW PROFITABLE IS IT FOR YOU TO BILL FOR YOUR SENDOUT LABS??

#### 2008 FIGURES. Jackson Thyroid & Endocrine Clinic, PLLC

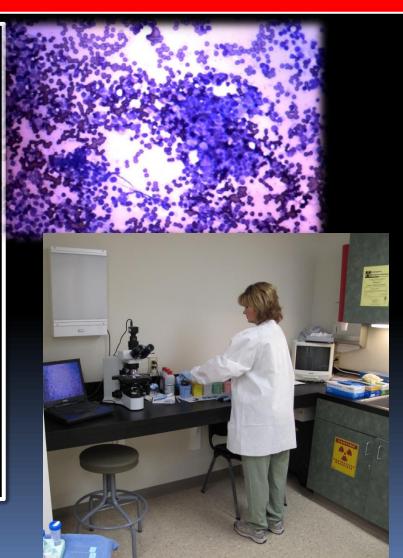
LABTEST	#PERFORMED	FEE	REIMB.
ТРО	601@	\$7212.00	\$22,838.00
TG	382@	\$8404.00	\$35,908.00
TSI	162@	\$9290.00	\$23,166.00
TSHRab	164@	\$8175.40	\$6,396.00
СВС	254@	\$825.00	\$5,334.00
COMP	200@	\$800	\$9,400.00

### SO WHY DOESN'T EVERYONE HAVE A LAB????

OTHER COSTS ARE SIGNIFICANT!!!!		
Lab Supplies	\$45,537.34	
Service Agreement	\$15,000.00	
CLIA	\$188.00	
<ul> <li>MLE Surveys</li> </ul>	\$363.00	
<ul> <li>Calibration of Equipment</li> </ul>	\$176.55	
<ul> <li>Validation standards</li> </ul>	\$946.52	
SALARIES	\$73,320.00	
REFERENCE LAB	\$95,880.91	
TOTAL COSTS	\$246,383.45	

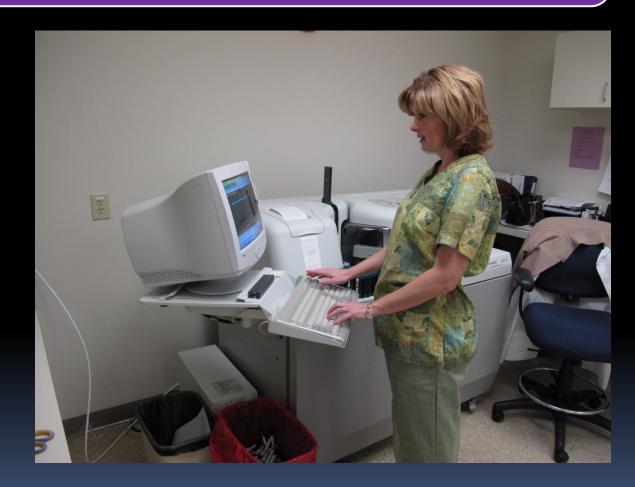
On site Microscopy– FNA Adequacy Another vital laboratory function.

- FNA adequacy does make a difference in the "point of care" results.
- Follicular cells seen in node, then STOP STICKING.



# A GOOD MEDICAL TECHNOLOGIST IS KEY TO THE WHOLE OPERATION.

FORGET THE MONEY MADE ON LABS, I COULD PAY HER SALARY WITH FNA ADEQUACY BILLING ALONE!!!

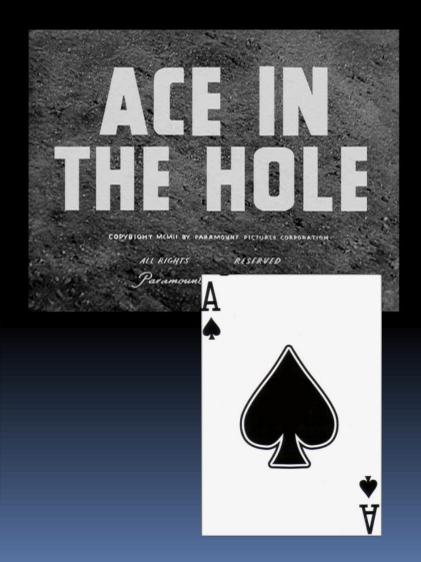


### WHAT SHOULD YOU NAME YOUR CLINIC?

Let them know what you do. Have THYROID in your clinic Jackson THYROID & name. If you have DIABETES in your clinic name, you will continue to be a diabetes doctor.

# Set yourself apart.

- WHAT MAKES YOU DIFFERENT FROM THE OTHER ENDOCRINOLOGISTS IN YOUR TOWN??
- Be the point person.
- Be visionary, not reactionary.
- You may not be able to start off with all of these things, but have a defined plan.



### \*DO SOMETHING YOU LOVE AND YOU WILL NEVER WORK A DAY IN YOUR LIFE."

Confucius

# "Do the work you love, and you will find joy in it"

### •Lawrence Welk

