

# *Security Concerns of the Medical Laboratory*

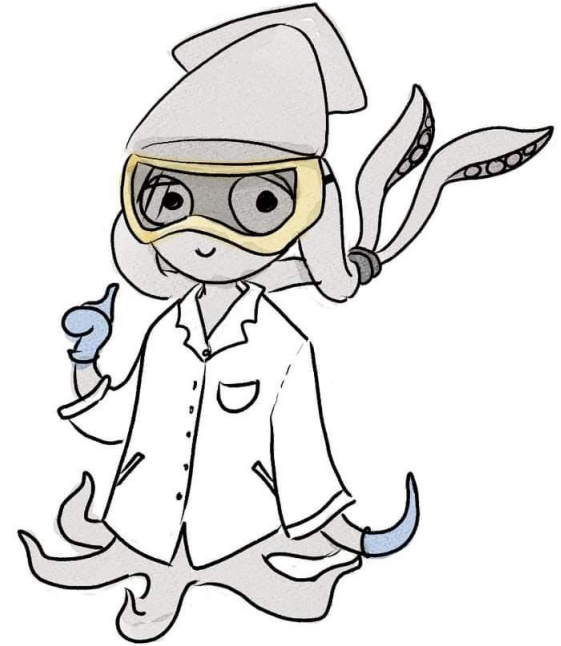
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Squiddy, 2022  
<https://squiddle.io/>  
email: teuthidae@proton.me

Blood Bank

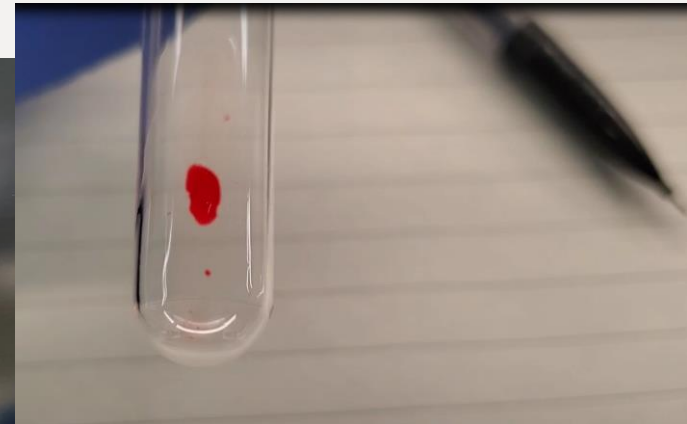
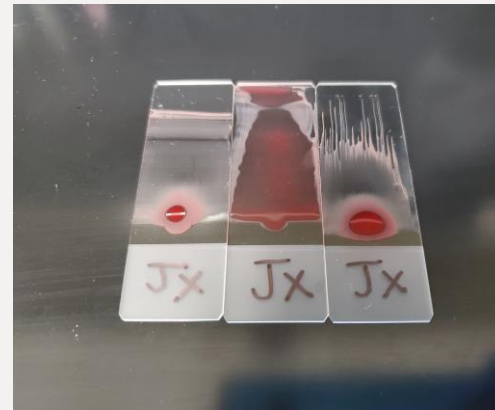
NO CRYING IN BLOOD  
BANK, ONLY USE  
APPROVED SALINE.

HA HA  
HA HA  
HA HA

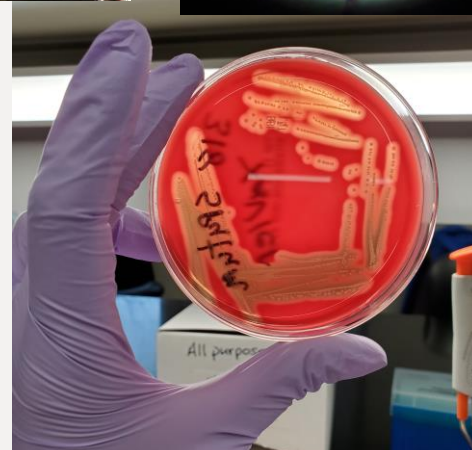
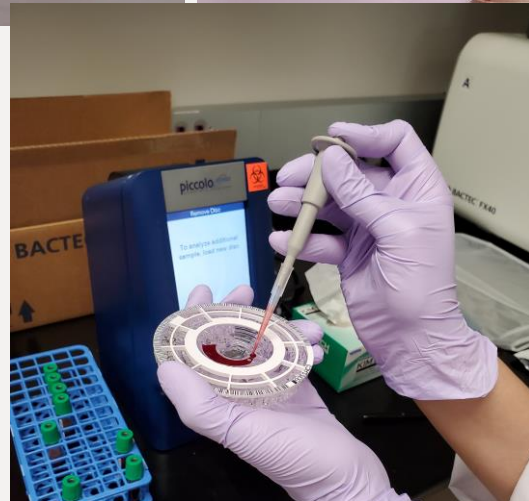
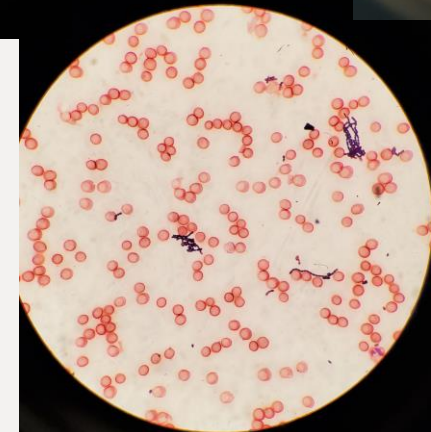
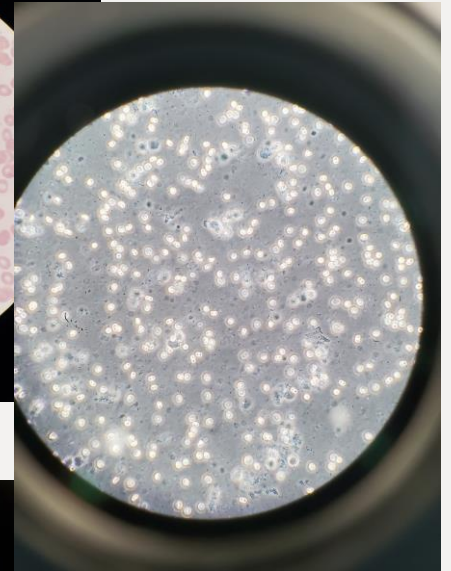
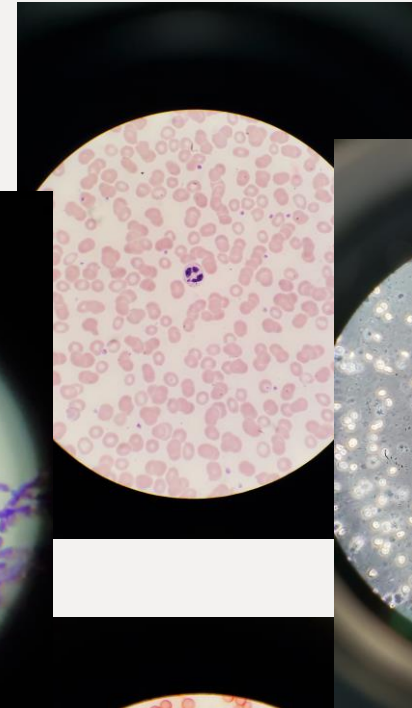
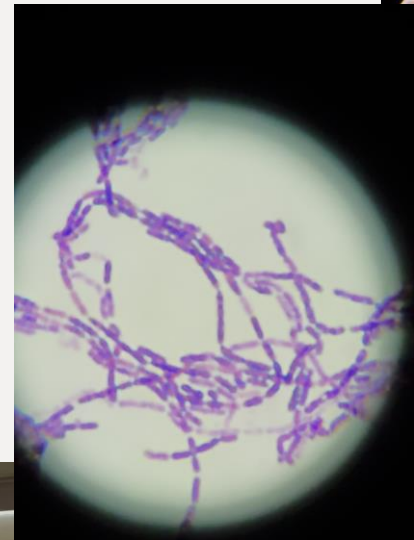
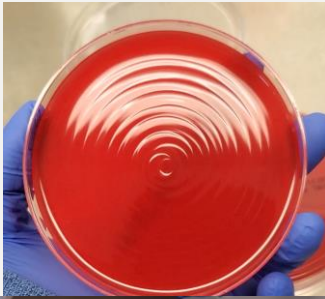
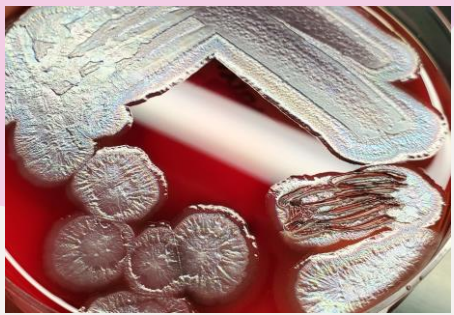


## *Who is Squiddy?*

- Graduate Student @ Indiana University  
M.S. Health Informatics  
Health Information Security & Medical Device Security
- Medical Laboratory Scientist (MLS)
- LIS Technical Specialist / Laboratory Informaticist



# *What is a Medical Laboratory Scientist?*



# *How are we regulated?*

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“The Clinical Laboratory Improvement Amendments (CLIA) regulate laboratory testing and require clinical laboratories to be certified by the Center for Medicare and Medicaid Services (CMS) before they can accept human samples for diagnostic testing.” – U.S. Food and Drug Administration, 2022

Three federal agencies are responsible for CLIA

- The Food and Drug Administration (FDA)
- Center for Medicaid Services (CMS)
- Centers for Disease Control and Prevention (CDC)

Each agency has a unique role in assuring quality laboratory testing.

# *The Laboratory*

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Multiple departments make up the medical laboratory including:

- **Chemistry** (thyroid + hormone tests, liver and heart enzymes, potassium levels, cholesterol)
- **Immunology** (study of immune products such as antibodies produced by the body in response to foreign material )
- **Hematology** (study of blood, blood morphology and blood diseases - think complete blood counts, and white blood cell count)
- **Microbiology** (where we culture samples for things like E.Coli, Salmonella, Staph Aureus, and Pseudomonas).
- **Blood Bank** (where we type your blood, blood products, and issue blood products for transfusion)



# *Medical Laboratory Members*



Vera Z. Dwyer College of Health Sciences: Indiana University South Bend

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- **Medical/Clinical Laboratory Scientists**

AKA:

Medical/Clinical Laboratory Technologists,

Medical Laboratory Professionals

Medical laboratorians

- **Laboratory Technicians**

- **Laboratory Assistants**

- **Phlebotomists**

- **Senior Techs (heads of departments)**

- **Laboratory Director**

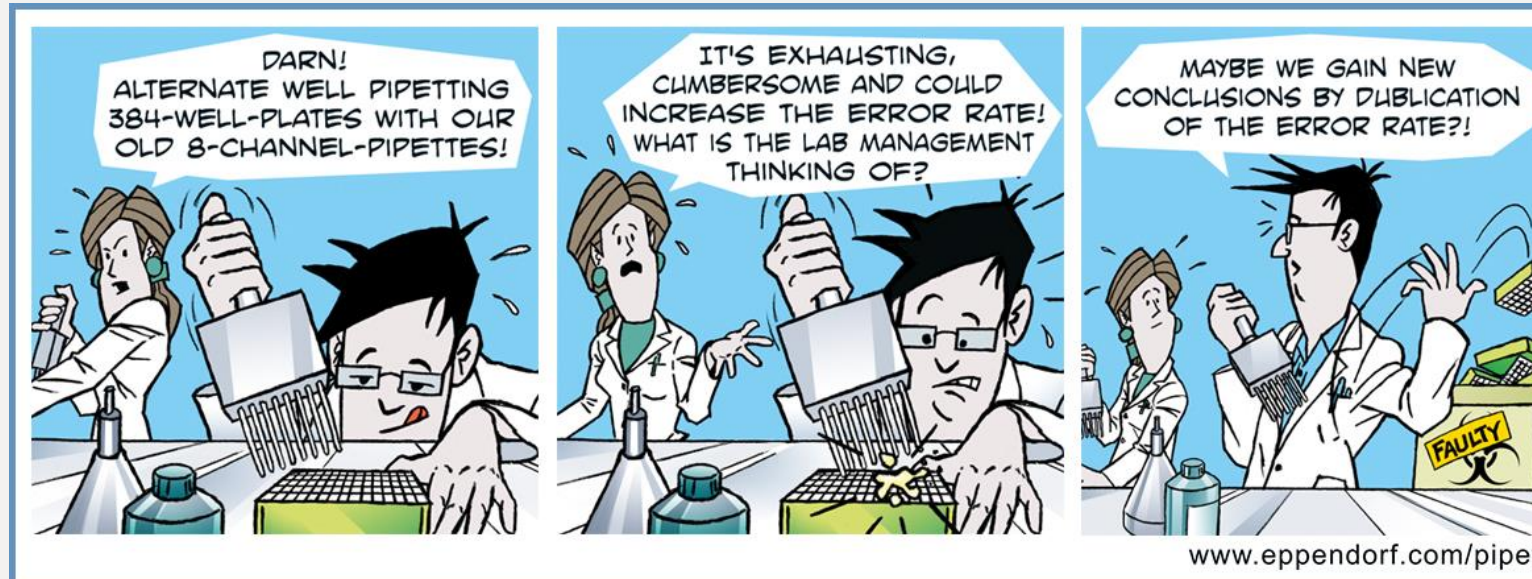
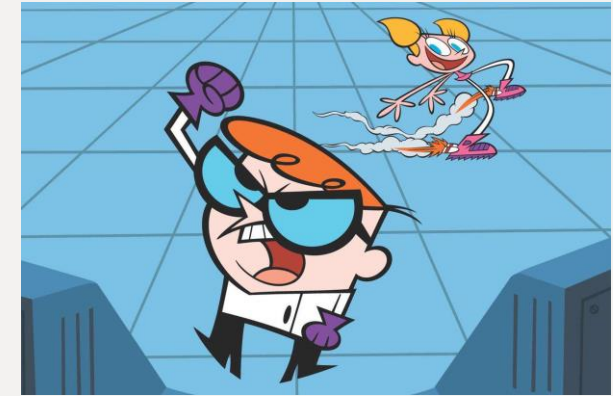
Other departments also reside in or near the lab in their own areas: such as Cytology, Histology, and Pathology.

# *Workflow of The Medical Laboratory*

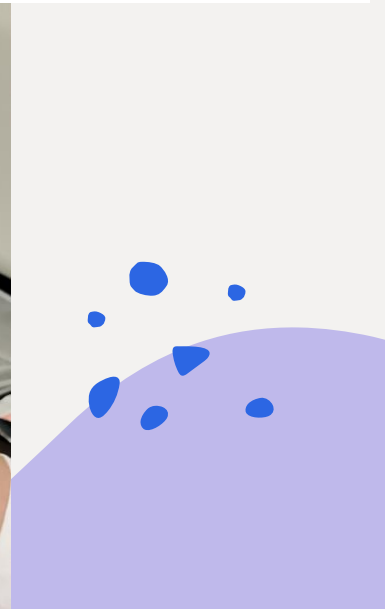
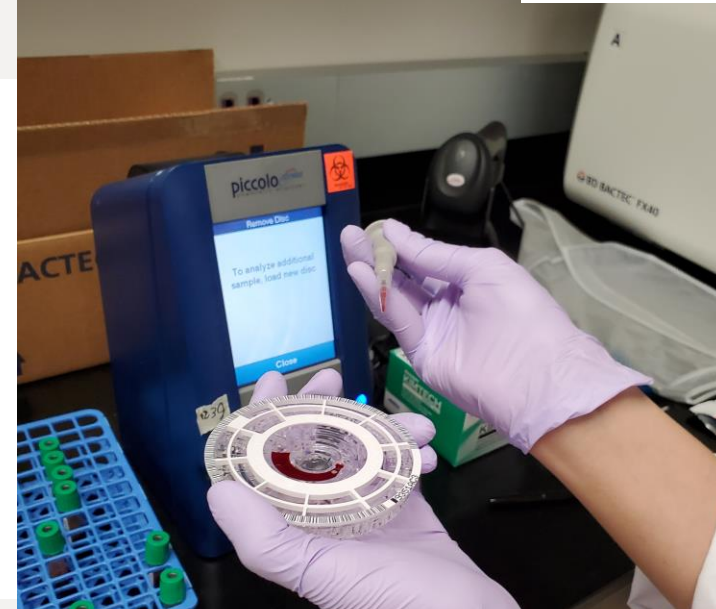
Constantly navigating between multiple departments and performing complex testing that varies per department.

We must be able to start a test, move to another department or area to complete a test that may be STAT, and come back and finish the test we started without error.

**It's busy, it's stressful, and it requires a lot of focus!!**



# *Instrumentation*





# *Laboratory Information System (LIS) vs LMS*

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Sometimes used interchangeably; the two overlap but were designed to support different laboratory types and functionality.

## **Laboratory Information System (LIS):**

Patient-based; for processing and reporting data for individual patients in a clinical setting

## **Laboratory Management System (LMS):**

Sample-based process; report data related to batches of samples

LIS and LIMS overlap such that distinctions have become harder to make, but their overall initial purpose for development remains the same.

# *Instrument Communication and Data Transmission*

## ASTM vs HL7 vs FHIR

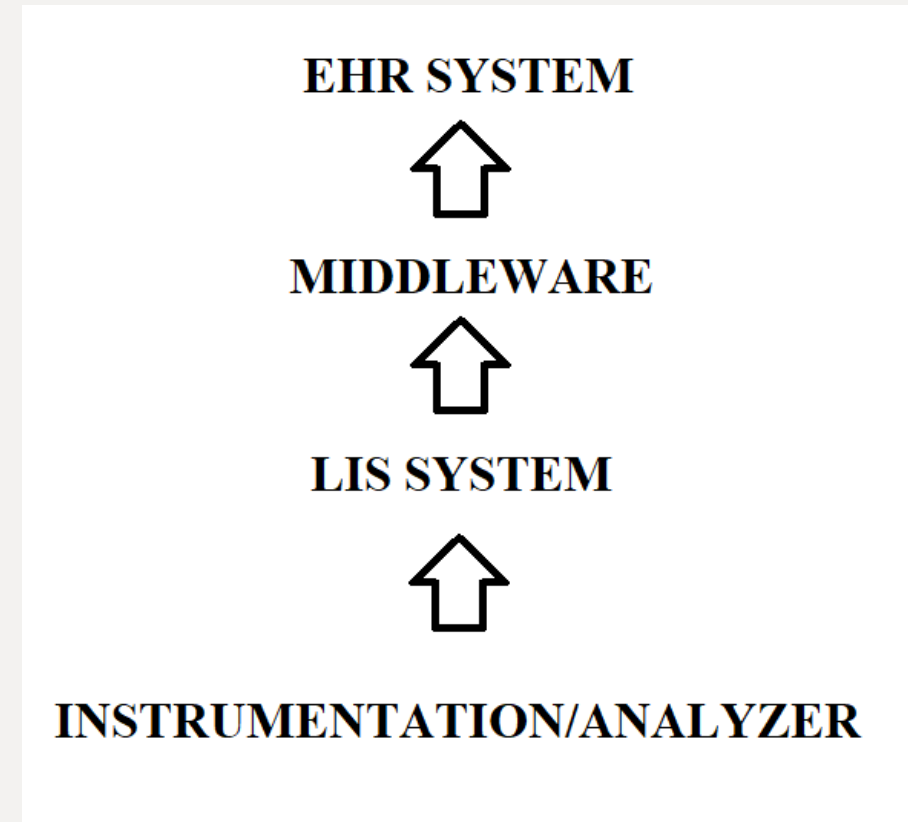
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MYSTREET AVE^^MYTOWN^OH^44123^USA|| (216) 123-4567||M|NON|400003403~1129086|
NK1||ROE^MARIE^^^^|SPO|| (216) 123-4567||EC||||||||||||||||||||
PV1||O|168 ~219~C~PMA^^^^^^^^^|||277^ALLEN MYLASTNAME^BONNIE^^^^|
||2688684||||||||||||||||||||199912271408||||002376853
```

Examples:

LIS (Cerner, Softlab, EPIC Beaker, Meditech)

Middleware (CLOVERLEAF, RALS)

EHR System (EPIC, CareCloud, AllScripts)



# *Vulnerabilities of the Medical Laboratory*

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- 1.** Physical access to the laboratory computers or instrumentation.
- 2.** The variation in instrumentation and how they each handle transferring patient data.
- 3.** Simple Human error.

# *Physical Security Aspects*

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Badge required for access, and a password required to access the computer terminals in the lab, but..

The same password used between computer and network login, and between the LIS and EHR systems.

The constant workflow and movement of techs between computers and the flow of works in and out of the laboratory.

Physical access to computers with USB ports.

Ability to plug in devices that you bring from home without having the devices screened.

No camera surveillance (surveillance can itself result in a HIPAA violation)

# *The biggest concern is...*

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Surprise! It's human error.



# *Patient Perspective: Why should I care?*

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THAT'S YOUR DATA!

That is your SSN! Your date of birth! Your address! Your test results saying you are positive or negative for something and **sometimes that information is a test result for HIV or a positive cancer diagnosis.**

That is your medical history sometimes spanning throughout your entire life and is all the personal data that can be held about you in your medical record.

# *What can I do?*

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Come join the lab! We need more security-oriented minds, we need more lab techs, and we need security warriors willing to protect patient data. We need more people who care enough **and** who possess the **background** to understand our workflow.

If you work in cybersecurity at a facility with a medical laboratory - get to know us!

We want your data to be safe, too.

# *Citations*

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Centers for Disease control and Prevention (2018, November 15). Strengthening clinical laboratories. <https://www.cdc.gov/csels/dls/strengthening-clinical-labs.html>

Centers for Medicare & Medicaid Services (2022, August 2). Clinical laboratory improvement amendments (CLIA). <https://www.cms.gov/Regulations-and-Guidance/Legislation/CLIA>

U.S. Food & Drug Administration (2021, September 13). Clinical laboratory improvement Amendments. <https://www.fda.gov/medical-devices/ivd-regulatory-assistance/clinical-laboratory-improvement-amendments-clia#:~:text=The%20Clinical%20Laboratory%20Improvement%20Amendments,human%20samples%20for%20diagnostic%20testing.>

Orchard Software (2021, November 2). What is the difference between an LIS & a LIMS? <https://www.orchardsoft.com/blog/what-is-the-difference-between-an-lis-a-lims/#:~:text=The%20Main%20Difference%20Between%20the%20LIS%20%26%20LIMS&text=The%20biggest%20distinction%20is%20that,individual%20patient%20identities%20are%20unimportant.>



*Thank You =]*

Come find me for a Sqoodle badge, or DM me on Twitter @teuthidae\_

