The Bureau of Clinical Laboratories:

Under the Microscope
Alabama Department of Public Health
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Bureau of Clinical Laboratories

Sharon P. Massingale, Ph.D., HCLD/CC(ABB)
Laboratory Director
Mobile Regional Laboratory
Background

• Operational in 1908
• Our Mission:
  – To give laboratory support for public health programs and policy decisions that protect and promote the health of the citizens of Alabama.
• 2015 specimens/samples
  – Clinical specimens
    ▪ Central Lab = 376,643
    ▪ Mobile Lab = 124,375
  – Environmental samples
    ▪ Central Lab = 9,866
    ▪ Mobile Lab Lab = 6,457
BCL Divisions

Testing Areas
• Montgomery
  – Chemistry
  – Microbiology
  – Newborn Screening
  – Quality Management
    ▪ STD Processing
  – Sanitary Bacteriology
    ▪ Milk & Water
  – STD
• Mobile
  – Drinking Water
  – Environmental Waters
  – Rabies
  – Shellfish
  – STD
  – Urine Culture

Support Areas
• Administration/Clerical/Human Resources
• Business Facilities Operations
  – Building Maintenance
  – Purchasing/Finance
  – Stockroom
• Quality Management
  – Assessment Teams
  – IT/LIMS
• Sanitary Bacteriology
  – Decontamination
  – Media
Mobile Laboratory

Curtis Andrews, B.S.
Division Manager
Clinical

- Urine Culture & Sensitivity
  - Identify & quantify bacteria
  - Determine antibiotic resistance

- STD
  - *Chlamydia trachomatis*
  - *Neisseria gonorrhoeae*
  - *Trichomonas vaginalis*
  - *Treponema pallidum*
Shellfish

• Partner with ADPH Seafood Branch
  – Growing waters (fecal coliform, Vibrio, phytoplankton & cyanobacteria)
  – Oysters (fecal coliform, Vibrio & E. coli)
  – Crabmeats (fecal coliform & E. coli)
BEACH, Drinking Water & Rabies

- Beaches Environmental Assessment & Coastal Health (BEACH) Act
  - Beach water tested for *Enterococci*
- Drinking/well water
  - *E. coli* & coliform
- Rabies
STD Division

Traci Dailey, MT (ASCP) Division Manager
Human Immunodeficiency Virus

- Process & test serum samples
- Use Bio Rad Ag/Ab Combo – 4th generation screening assay
  - Non-reactive specimens - results are reported to provider
  - Reactive specimens
    - Repeated in duplicate using Multispot
    - Specimens which are reactive at least 2 out of 3 times must be confirmed
- Bio Rad Multispot - HIV-1/HIV-2 differentiation assay to confirm presence of antibodies
  - Reactive specimens - reported to the provider
  - Non-reactive or indeterminate specimens - tested using a final confirmation assay [HIV-1 rRNA nucleic acid amplification test (NAAT)]
- NAAT
  - Non-reactive specimens - reported as not confirmed for HIV
  - Reactive specimens - reported as confirmed for HIV-1
**Human Immunodeficiency Virus**

- **HIV-1/2 antigen/antibody combination immunoassay**
  - (+): Negative for HIV-1 and HIV-2 antibodies and p24 Ag
  - (-): HIV-1/HIV-2 antibody differentiation immunoassay

- **HIV-1/HIV-2 antibody differentiation immunoassay**
  - HIV-1 (+), HIV-2 (-): HIV-1 antibodies detected
  - HIV-1 (-), HIV-2 (+): HIV-2 antibodies detected
  - HIV-1 (+), HIV-2 (+): HIV antibodies detected
  - HIV-1 (-) or indeterminate
    - HIV-2 (-): HIV-1 NAT
      - HIV-1 NAT (+): Acute HIV-1 infection
      - HIV-1 NAT (-): Negative for HIV-1

(+) indicates reactive test result
(-) indicates nonreactive test result
NAT: nucleic acid test
Syphilis Testing

- **Syphilis-EIA (IgG & IgM)**
  - Non-Reactive: Report: Non-Reactive
  - Indeterminate: Repeat
  - Reactive: RPR Confirmation
  - Reactive with dilution: Report: EIA, RPR & dilution

- **Non-Reactive** Preliminary report: EIA & RPR
  - Non-Reactive: TP-PA Confirmation (IgG only) TP-PA
  - Reactive: Report: EIA-Reactive, RPR-Non-Reactive, TP-PA-Non-Reactive
  - Reactive with dilution: Report: EIA-Reactive, RPR-Non-Reactive, TP-PA-Non-Reactive
**Clinical Chemistry**

- **Hematology**
  - Complete blood count
- **CD4/CD8 T-Cell Counts**
  - Track HIV progression
- **HIV Viral Loads**
  - Measure virus in blood & monitors treatment effectiveness
- **HIV Genotyping**
  - Detect mutations for drug resistance
- **General Chemistries**
  - Complete metabolic panel, renal panel, hepatic panel, etc.
Lead Screening

• Childhood Blood Lead Screening
• Adult Blood Lead Screening
• Environmental Lead Testing
  – Testing performed as needed
    ▪ Paint
    ▪ Water
    ▪ Soil
    ▪ Dust Wipes
    ▪ Other potential lead sources
Chemical Terrorism/Biomonitoring

- Cyanide
- Volatile organic compounds
- Organophosphate nerve agent metabolites
- Abrine/ricinine
- Metabolic toxins
- Tetramine
- Blood metals (Hg, Pb, Cd)
- Toxic elements screen in urine
- As/Se in urine
- Sulfur mustard metabolites
- Tetranitromethane
NEWBORN SCREENING (NBS)

Danita Rollin, MT (ASCP)
Division Manager
WHY DO WE SCREEN?

- Public Health Laws of Alabama state that each infant, 28 days or less of age, will be tested for inheritable diseases and conditions as designated by the State Board of Health.

- The State Board of Health shall put law into effect to provide for the care and treatment of those newborn infants whose tests are determined positive.

  - Taken from Public Health Laws of Alabama 22-20-3
NBS SPECIMENS

Filter Paper Forms  Dried Blood Spots
Timing of collection, submission, testing & reporting is critical.

Assist in diagnosis of 30 core disorders & 20 secondary disorders.

Recommendations for test implementation originate from American College of Medical Geneticists & March of Dimes.

Perform tests on a 1\textsuperscript{st} sample (mandated) & a 2\textsuperscript{nd} sample (recommended).

- Approximately 60,000 1\textsuperscript{st} test samples & 60,000 2\textsuperscript{nd} test samples analyzed yearly.

Diagnosis is urgent for treatment of affected infants.
**NBS DISORDER PANEL**

- Tandem Mass Spectrometry
  - Amino Acid Disorders
  - Fatty Acid Disorders
  - Organic Acid Disorders
- Hemoglobin (HPLC)/Biotinidase (colorimetric)
  - Sickle Cell Disease
  - Biotinidase deficiency
- Genetic screening processors (GSP)/DNA
  - Galactosemia
  - Congenital Adrenal Hyperplasia
  - Hypothyroidism
  - Cystic fibrosis
  - Coming soon – SCID (severe combined immunodeficiency)
Media

• The Media Branch prepares biochemicals, agar & solutions for the Montgomery & Mobile Laboratories.
Dairy

• Test raw & pasteurized dairy samples.
  – Milk (sheep, goat, cow) & creams are tested for antibiotics.
  – Test flavored milk, cottage cheese, yogurt, buttermilk, ice cream, popsicles, egg nog, pasteurized creams for coliform.

• Dairy products must meet the minimum Grade A pasteurized milk ordinance to ensure products are acceptable within limits established by Food & Drug Administration (FDA).
Fluoride & Water

- Test for fluoride in water as directed by Centers for Disease Control & Prevention (CDC).

- Test drinking & private well water for *E. coli* & coliform according to Environmental Protection Agency (EPA) guidelines.
Microbiology Division
Nancy Robinson, MPH, M(ASCP)
Division Manager
Conventional Microbiology

• Comprised of 4 sections:
  - Enterics
    ▪ Isolate, identify, serotype *Salmonella*, *Shigella*, & shiga-toxin producing *E.coli* via biochemicals, antisera & molecular methods.
  - Reference
    ▪ Isolate & identify pathogens from clinical specimens using biochemicals & staining techniques.
Conventional Microbiology

- Foods
  - Partner with ID&O & environmentalists during outbreaks to analyze food & environmental specimens.
  - All reportable foodborne bacterial isolates (Listeria, Campylobacter, Salmonella, Shigella, Vibrio sp., & shiga-toxin producing organisms) are reported to ID&O & CDC.

- Parasitology
  - Process stools by concentration wet mount & stains.
  - Examine pinworm preparations for eggs.
  - Identify blood parasites by stained smears & microscopy.
  - Identify arthropods.
Emerging Infectious Diseases

- Polymerase Chain Reaction (PCR)
  - *Bordetella*
  - Chikungunya
  - Dengue
  - Ebola
  - Influenza
  - *Haemophilus influenzae*
  - Malaria
  - *Neisseria meningitidis*
  - Norovirus
  - Zika

- ELISA
  - Lyme
  - West Nile Virus
Emerging Infectious Diseases

- Pulsed Field Gel Electrophoresis (PFGE)
  - Specimens received from Reference Bacteriology.
  - Member of PulseNet - international organization of labs that utilize PFGE to fingerprint DNA.
  - Images are compared to a database housed at CDC & reported.
  - Testing allows ADPH to identify if patient samples are part of a national foodborne outbreak.

- *Salmonella*
- *Shigella*
- *E. coli*
- *Campylobacter*
- *Vibrio*
- *Listeria*
- *MRSA*
- *Serratia*
Bioterrorism

• **Clinical Specimens**
  – Blood
  – Scabs
  – Wound/throat swabs
  – Sputum
  – Stool
  – Serum

• **Environmental**
  – Suspicious letters with white powder
  – Swabs
  – Air filters
  – US. Postal Service cartridges
  – Food

• **Collaborators**
  – Communicable Diseases
  – Center for Emergency Preparedness
  – Civil Support Team
  – Federal Bureau of Investigations
Tuberculosis

- Acid Fast Bacilli (AFB) Staining
- Cultures
- Drug Susceptibilities (new TB patients)
- PCR (TB/rifampin resistance)
- Genotyping (TB Control compare genotypes & # of patients in genotype clusters)
• Mycology
  - Dermatophytes
  - Yeasts
  - Systemic fungi such as Histoplasmosis, Coccidioides, & Blastomyces
  - 6,000 specimens/year
Rabies

- Detect presence of Rabies virus in animal brains by direct fluorescent antibody testing.
QUALITY MANAGEMENT

CHARLENE THOMAS, B.S., MT(ASCP) DIVISION MANAGER
Regulatory Agencies

• The Quality Management (QM) Division ensures testing quality:
  – CLIA (Clinical Laboratory Improvement Amendments)
  – FDA (Food & Drug Administration)
  – EPA (Environmental Protection Agency)
  –APHIS (Animal & Plant Health Inspection Services)
  – DOT (Dept. of Transportation)
  – Seeking ISO 17025 accreditation
Regulatory Agencies

- CLIA
  - Certified Labs:
    - Mobile
    - Montgomery
    - County Health Departments (CHHDs)
  - Dr. Sharon Massingale is the director for all 3 CLIA certificates.
Regulatory Agencies

- **FDA**
  - Montgomery Laboratory is certified to perform certain testing.

- **EPA**
  - Mobile & Montgomery shares certifications with AL Dept. of Environmental Management.

- **APHIS**
  - Select Agent Program certified by CDC.

- **DOT**
  - Regulate transport of hazardous waste.
QM Responsibilities

- Review:
  - Safety
  - Personnel records
  - Trainings
  - Procedure manuals
  - Instrument maintenance
  - Quality control
  - Quality assurance
  - Graded proficiency test results
QM Responsibilities

- Patient test management
- STD specimen processing
- Management of Laboratory Information Management System (LIMS)
- Development/presentation of CHD trainings
- CHD team travels to CHDs to perform assessments
- Internal audit team assesses the Montgomery & Mobile labs
Questions?