

Updating Sample Submission Guidelines

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Wyoming
Department
of Health



PUBLIC
HEALTH
DIVISION



WYOMING
PUBLIC HEALTH
LABORATORY

Wyoming

Highlights about our laboratory system and context

Quality Improvement

Quality Improvement: The Sample Submission Guide

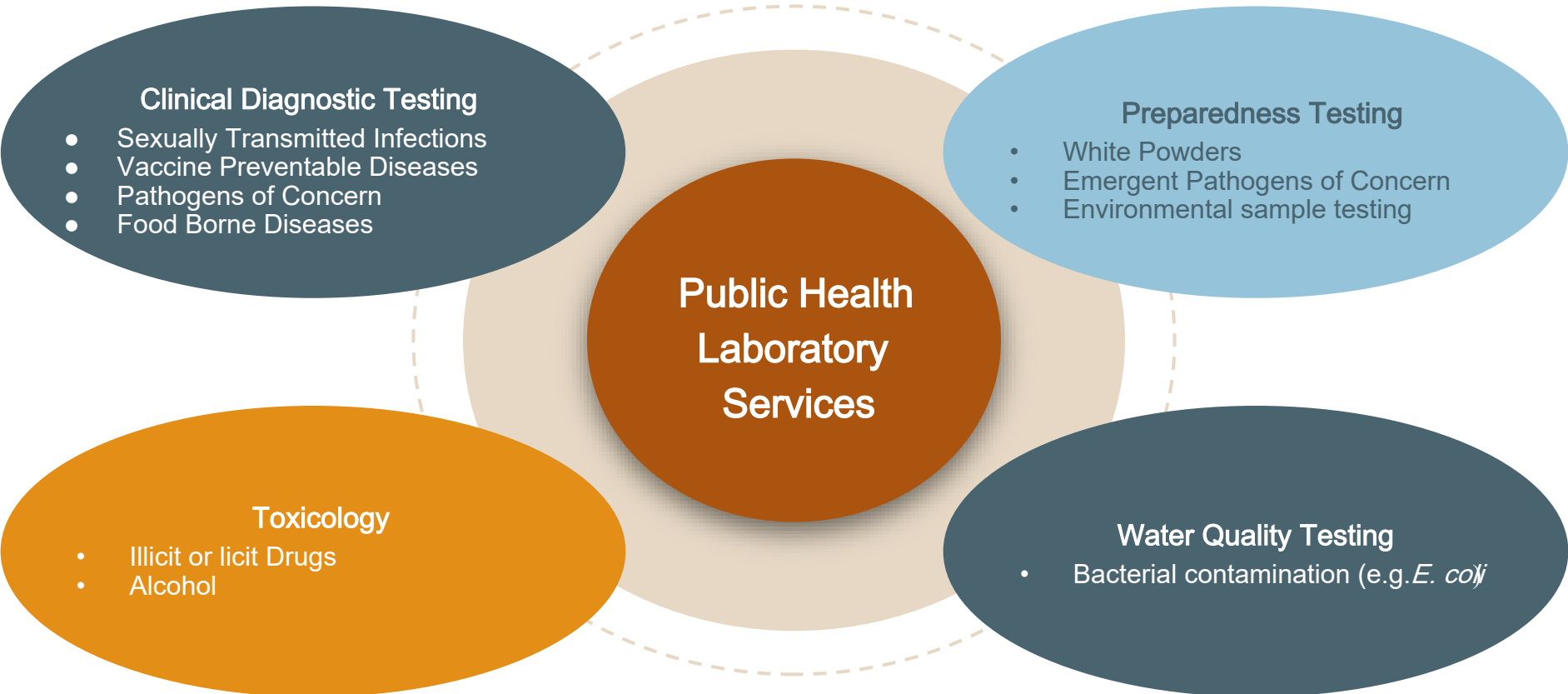
Key Takeaways

Advice and future goals from the Wyoming Team

Welcome to Wyoming



- State Laboratory Services
 - Department of Agriculture
 - Wyoming Game and Fish Department
 - Department of Environmental Quality
 - State Veterinary Lab
 - State Crime Lab
 - Public Health Lab
- Rural and Frontier Population
 - State Population: 584,057 (fewest)
 - 97,814 square miles (9th largest)
 - 2.25 Cattle : People



The diagram features a central orange circle labeled "Public Health Laboratory Services". Surrounding this central circle are four colored ovals, each representing a different service area: a dark blue oval for Clinical Diagnostic Testing (top-left), a light blue oval for Preparedness Testing (top-right), a dark blue oval for Water Quality Testing (bottom-right), and an orange oval for Toxicology (bottom-left). A dashed line connects the outer edges of these four ovals, forming a larger circle around the central hub.

Public Health Laboratory Services

Clinical Diagnostic Testing

- Sexually Transmitted Infections
- Vaccine Preventable Diseases
- Pathogens of Concern
- Food Borne Diseases

Preparedness Testing

- White Powders
- Emergent Pathogens of Concern
- Environmental sample testing

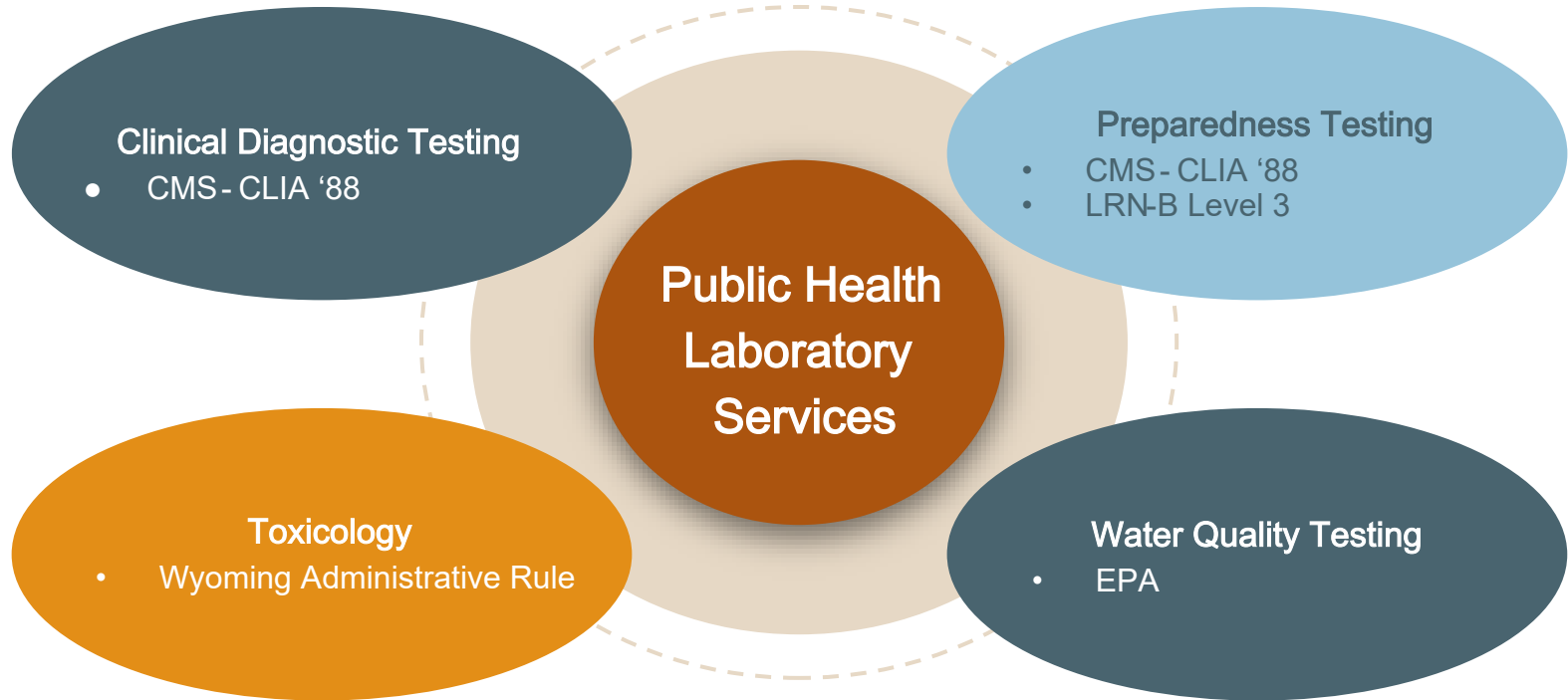
Toxicology

- Illicit or licit Drugs
- Alcohol

Water Quality Testing

- Bacterial contamination (e.g. *E. coli*)

WPHL Regulatory and Compliance Environment



The WDH -PHD Way

Quality Improvement Projects



PDC/SA

Plan-Do-Check/Study-Act



Problem Statement

- Sample transport temperatures and associated protocols are receiving enhanced scrutiny in CMS CLIA '88 regulated laboratories. (PreAnalytical Systems)
- Numerous Public Health Labs have shared their experiences in Collaborate communities, National Conference breakout sessions, and roundtables.

PDC/SA

Plan-Do-Check/Study-Act



Realistic Timelines

- Biannual CMS CLIA '88 inspection occurs in November (even years)
- Return from Quality and Management Exchange with South Dakota Public Health Lab in July 2024
- Planning begins for process implementation in early 2025
- Six months to implementation

Planning: Two Prong Approach

Experimental Data Gathering



Stakeholder Communication



What are our test types?

CMS FORM 116

VIII. NON-WAIVED TESTING (Including PPM testing if applying for a Certificate of Compliance or Certificate of Accreditation) Complete this section only if you are applying for a Certificate of Compliance or a Certificate of Accreditation.

Identify the non-waived testing (to be) performed by completing the table below. Be as specific as possible. This includes each analyte, test system, or device used in the laboratory. Use (M) for moderate complexity and (H) for high complexity.

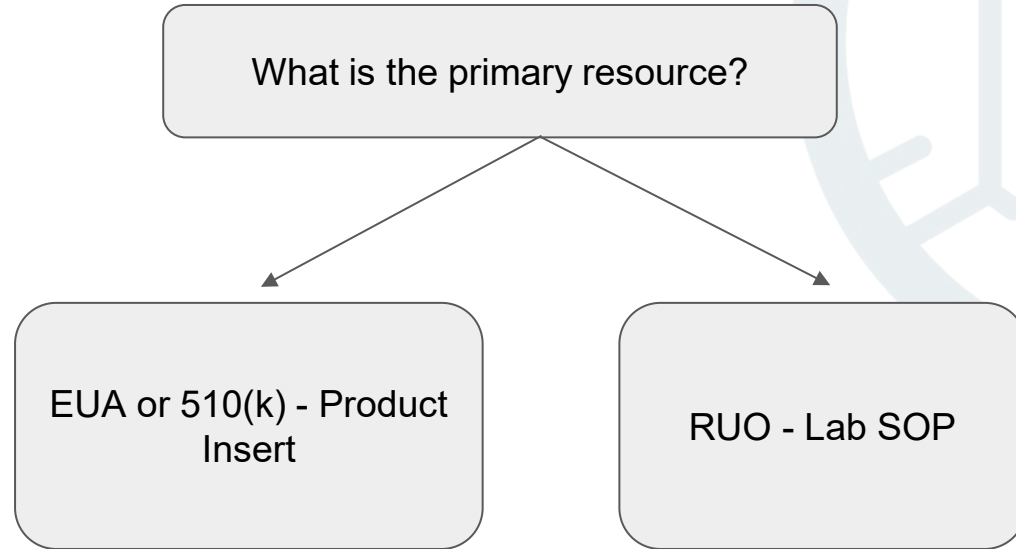
ANALYTE / TEST	TEST NAME	MANUFACTURER	M or H
Example: Potassium	Quick Potassium Test	Acme Lab Corporation	M

If additional space is needed, check here ☐ and attach additional information using the same format.

STARLIMS Test Data

Team	Panel Name	Analyte
Immunology	QuantIFERON TB-Gold Plus	Mitogen
		NIL
		QuantIFERON TB-Gold Plus
		TB1
	Rubella	TB2
		Rubella IgG
		Rubeola
		Rubeola (MSG IgG)
	Varicella-Zoster	Varicella-Zoster IgG
		Mumps IgG
	Vidas MRR	Rubella IgG
		Rubeola (MSG IgG)
	Vidas Panel	Mumps IgG
		Rubella IgG
		Rubeola (MSG IgG)
		Varicella-Zoster IgG

Acceptable Transport Temperatures



Data Collection and Compiling

- Sample Source
- Applicable Tests
- Frozen Temperature
- Frozen Time (Days)
- Refrigerated Temperature
- Refrigeration Time (Days)
- Ambient Temperature
- Ambient Time (Days)
- Acceptable Media/Collection Device
- WPHL Specific Criteria
- Additional Comments
- MediaLab SOP Number

- **Sample Source Types: 29 (58)**
- **Total Assays: 71**
- **99.4% of all submission**

PDC/SA

Plan-Do-Check/Study-Act



Do: Submission Guidelines

- WPHL to create WPHL specific submission guidelines
- End Product:
 - Updated
 - Easy to navigate
 - Unified
 - Lab Web Portal Ordering Information
- PHL Partner Models:
 - Utah
 - Virginia
 - Montana
 - Georgia



Identification of Stakeholders

Internal (Within Laboratory):

- Laboratory Director
- Quality Assurance Coordinator
- Microbiology Manager
- LIMS Administrator
- Testing Area Supervisors

External (Within Department of Health):

- State Health Officer
- Epidemiologists
- Prevention Partners

PDC/SA

Plan-Do-Check/Study-Act



Study: Review Process

- Feedback from partners:
 - Laboratory Director
 - Microbiology Manager
 - LIMS Administrator
 - Testing Area Supervisors
 - State Health Officer
 - Epidemiologists



Document Features

- Linked, Clickable Table of Contents
- Single Page Summaries
- Divided by Testing Area
- Test Costs
- Uniform Layout for all Summaries
- Highlighted Deviations



Single Page Summaries

Chlamydia (CT) and Gonorrhea (GC)

Cost of Test: \$14.00

Test name as listed in Lab Web Portal: Chlamydia (CT) / Gonorrhoeae (GC)

Specimen Collection Kit: Aptima Urine Tube, Aptima Unisex Tube (swab for endocervical and urethral specimens), and/or Aptima Multi-Site Tube (swab). Specimen collection kits may be ordered through the Wyoming Public Health Laboratory website and submitted via email or fax.

Type of Test: Qualitative target amplification test using target capture, TMA, and DKA.

Specimen Requirements:

- Eye, pharyngeal, oral, rectal, and vaginal samples collected in APTIMA Orange Multi-Site Swab Collection Tube.
- Endocervical and urethral samples collected in APTIMA Purple/White Endo Swab Collection Tube.
- Urine samples collected in APTIMA Yellow Urine Collection Tube.
- Collection tubes contain a lysis buffer that should not be poured out.
- Fill urine to the window presented on the collection tube and ensure that labels do not cover any fill windows or tube expiration dates.
- Ship sample(s) according to Category B Infectious Disease Packaging (Class 6.2) requirements. Ensure specimens are shipped by personnel that are properly trained in shipping Category B infectious substances.

Transport Temperature:

- Extragenital Swab (Oropharyngeal, Rectal swabs):
 - Frozen: -20°C to -70°C (for 60 days)
 - Ambient: 4°C to 30°C (for 60 days)
- Urine Specimen:
 - Frozen: -20°C to -70°C (for 12 months)
 - Ambient: 2°C to 30°C (for 30 days)
- Endocervical and Vaginal Swabs:
 - Frozen: -20°C to -70°C (for 12 months)
 - Ambient: 2°C to 30°C (for 60 days)

Turn-around Time:

- 7 days

WPHL Reporting:

- Results are reported within 24 hours of test completion. Both positive and negative samples are available on the Lab Web Portal (LWP) and can also be sent by fax to meet notification requirements. Additionally, a courtesy call is made to inform providers of Positive results.



PDC/SA

Plan-Do-Check/Study-Act



Act: Deployment of Submission Guidance

- Laboratory Web Portal Access
 - Laboratory Web Portal Communication
 - Website Update
-
- Go live: Feb 18, 2025



Key Takeaways

- Internal Communication Strategy
 - Multi -platform communication
- Leverage data compilation from multiple sources
- Stakeholder Engagement
 - Epidemiology involvement for individuals receiving 24/7 emergency calls
- Diverse reviewer backgrounds



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