



Waived Testing: Tips for Resolving Noncompliance Standards

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August 15, 2019



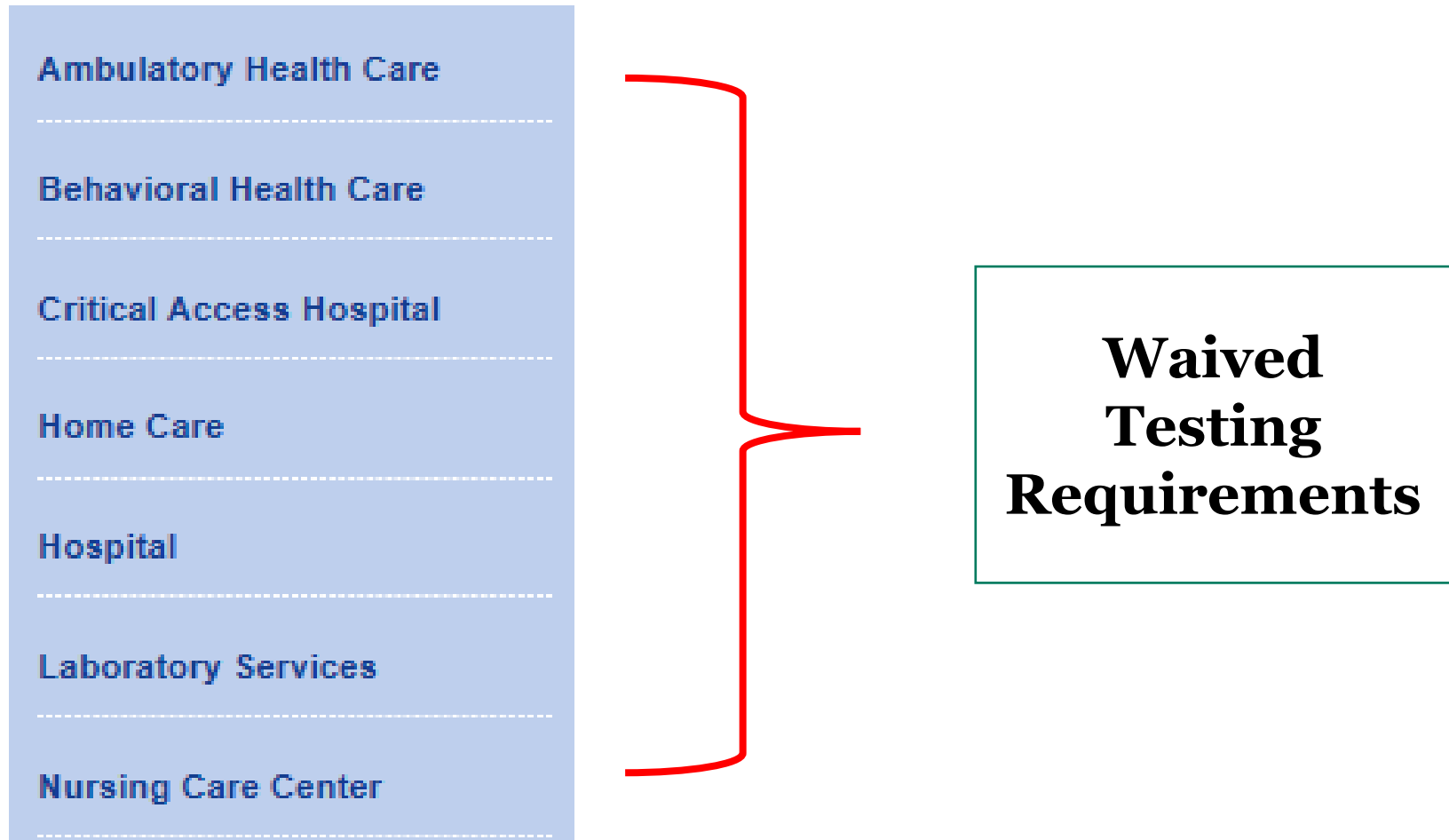
Session Objectives

1. Outline The Joint Commission Laboratory Standards on Waived Testing
2. Provide Recommendations for Meeting Requirements
3. Overview of Waived Testing Tracer Methodology Approach
4. Question and Answers

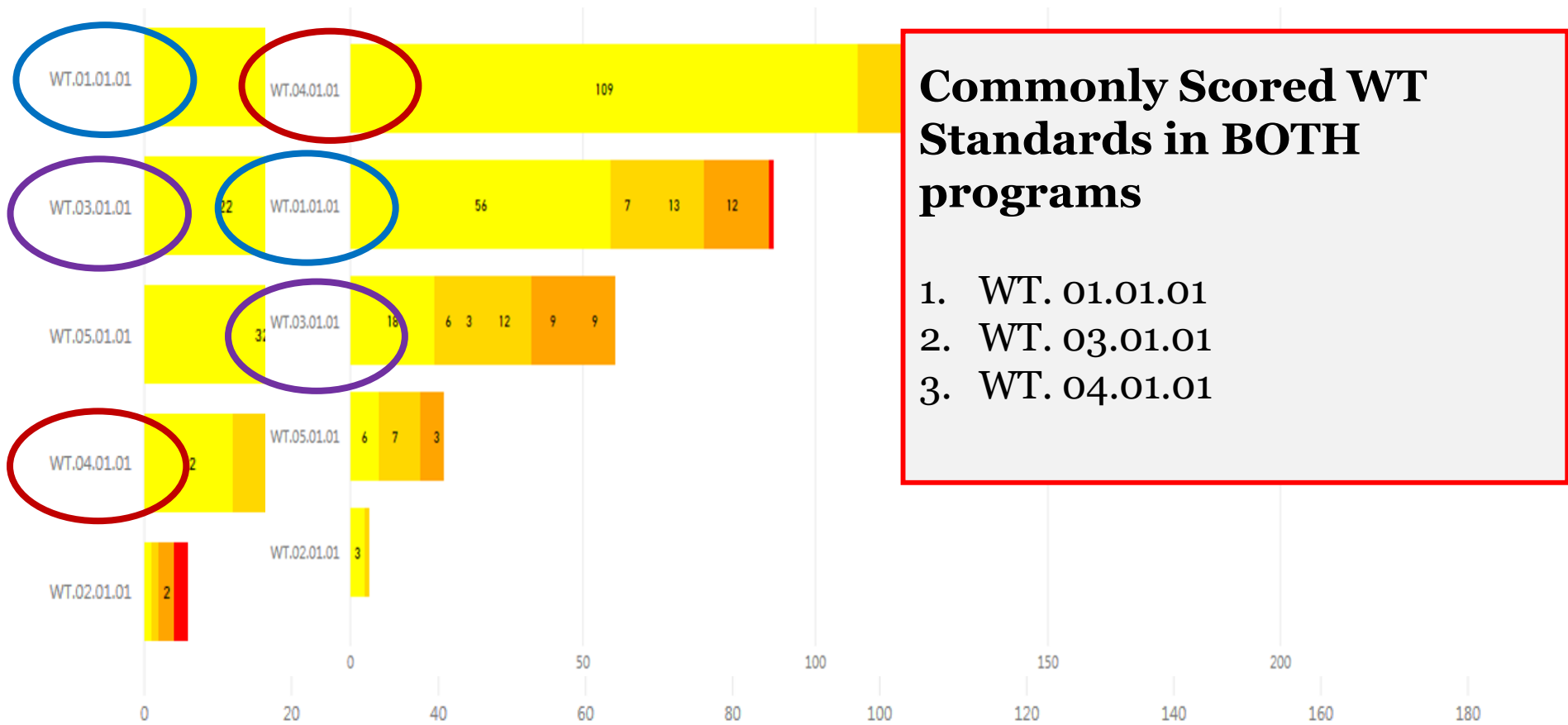
13 Standard Chapters in Laboratory

1. Accreditation Participation Requirements
2. Document Control
3. Environment of Care
4. Emergency Management
5. Human Resources
6. Infection Control and Prevention
7. Information Management
8. Leadership
9. National Patient Safety Goal
10. Quality System Assessment
11. Performance Improvement
12. Transplant Safety
13. Waived Testing

The Joint Commission Waived Testing Requirements



Data Comparison: 2017 Scored WT Standards in HAP and LAB



Commonly Scored WT Standards in BOTH programs

1. WT. 01.01.01
2. WT. 03.01.01
3. WT. 04.01.01

Meeting The Joint Commission Standards on Waived Testing

CLIA Waived Testing Requirements

1. no routine oversight and no personnel requirements and are only required to obtain a Certificate of Waiver (CW), pay certificate fees, and follow manufacturers' instructions.
2. Tests that are determined to be "simple tests with an insignificant risk of an erroneous result"

<https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfClia/analyteswaived.cfm>

The Joint Commission Requirements

5 Standards

1. WT.01.01.01: *Policies and Procedures*
2. WT.02.01.01: *Staff Responsibilities*
3. WT.03.01.01: *Personnel Competencies*
4. WT.04.01.01: *Quality Control*
5. WT.05.01.01: *Record Maintenance*

WT.01.01.01: Policies and Procedures

Current, approved, and available

6 Element of Performances

1. Approved by person on CLIA certificate
2. Address specific items (*next slide*)
3. When manufacturer recommendations are used, they are enhanced to include specific organizational policy
4. Approved before use
5. Available for testing personnel
6. Followed

WT.01.01.01: Policies and Procedures

Element of Performance 2 – Address the following:

<ul style="list-style-type: none">– Test use and limitation– Specimen requirements– Instrument maintenance– Storage conditions	<ul style="list-style-type: none">– Quality control– Result reporting– Reagent use– Manufacturer recommendations
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WT.01.01.01: Policies and Procedures

Sample Observations

The procedure for waived glucose tests did not include the limitations of use defined by the manufacturer. The manufacturer prohibited using the test method for critical patients. The policy did not include the restriction nor define “critical patients”

WT.01.01.01, EP 2:

written policies and procedures for waived testing that address the following:

- ✓ Test use and limitation
- ✓ Quality control
- ✓ Manufacturer recommendations

WT.01.01.01: Policies and Procedures

Sample Observations

No enhancements or quality controls to manual of manufacture and package insert

WT.01.01.01, EP 3:

If manufacturers' manuals or package inserts are used as the policies or procedures for each waived test, they are enhanced to include specific operational policies

WT.02.01.01: Staff Responsibility

Identify staff responsible for performing and supervising waived testing.

2 Element of Performances

No
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1. Identify testing personnel
2. Identify supervising personnel

Note 2: Responsible staff may be identified within job descriptions or by listing job titles or individual names.

WT.02.01.01: Staff Responsibility

Sample Observations

The organization had not identified in writing staff responsible for performing waived testing.

WT.02.01.01, EP 1:

The person from the organization whose name appears on the Clinical Laboratory Improvement Amendments of 1988 (CLIA '88) certificate, or a qualified designee, identifies, in writing, the staff responsible for performing waived testing

WT.03.01.01: Personnel Competencies

Staff performing waived tests are competent

6 Element of Performances

1. Training are provided and competency assessed
2. Aligned with organization policy
3. All staff are trained on all test systems
4. Incorporate operator maintenance
5. Competency on 2/4 methods
6. Frequency of training

WT.03.01.01: Personnel Competencies

- ✓ Assessment performed by the LD or designee
- ✓ Documentation of orientation, training, assessment for each waived test performed

Each Test System

CLIA defines test system as “the instructions and all of the instrumentation, equipment, reagents, and supplies needed to perform an assay or examination and generate test results”.

WT.03.01.01: Personnel Competencies

- ✓ Assessment includes at **least 2** of the following
 1. Performance of a test on a blind sample
 2. Periodic observation of routine work by supervisor or a qualified designee
 3. Monitoring of user quality control performance
 4. Written test specific to test assessed

- ✓ Assessment performed at orientation and at **least annually** thereafter

WT.03.01.01: Personnel Competencies

Requirements	Nonwaived and PPMP	Waived
Methods	Use 6 methods <ol style="list-style-type: none"> 1. Blind Testing 2. Direct Observation of routine testing 3. Monitoring of QC 4. Problem-solving skills 5. Direct observation of instrument checks 6. Monitoring result reporting 	Use 2 of 4 methods <ol style="list-style-type: none"> 1. Blind testing 2. Direct observation of routine testing 3. Monitoring of QC performance 4. Written test
Assessment	Initial Orientation and Training Semi-annual for first year Annual Assessment	Initial Orientation and Training Annual Assessment

WT.03.01.01: Personnel Competencies

Sample Observations

No approval by CLIA certificate medical director of the competencies or orientation training.

WT.03.01.01, EP 1:

Staff and licensed independent practitioners who perform waived testing have been trained for each test that they are authorized to perform. The training for each waived test is documented.

WT.03.01.01: Personnel Competencies

Sample Observations

Review of the HR files of the RN's revealed that the organization had not assessed Waived Testing competency at least annually. The organizations policy is every 2 years or as needed

WT.03.01.01, EP 6:

Competence for waived testing is assessed according to organization policy at defined intervals, but at least at the time of orientation and annually thereafter

WT.04.01.01: Quality Control

Perform quality control for each waived tests

5 Element of Performances

1. Approved QC plan
2. QC based on specified rationale (*next slide*)
3. For non-instrument-based waived testing, QC are performed based on manufacturer recommendation
4. QC are performed on each instrument
5. Two levels of QC, if commercially available

Instrument- Based Waived Testing

WT.04.01.01: Quality Control

Perform quality control for each waived tests

Element of Performances 2: The documented quality control rationale for waived testing is based on the following:

- ✓ How the test is used
- ✓ Reagent stability
- ✓ Manufacturers' recommendations
- ✓ The organization's experience with the test
- ✓ Currently accepted guidelines

WT.04.01.01: Quality Control

Sample Observations

The laboratory did not update control ranges when switching lot numbers of urine control materials

WT.04.01.01, EP 2:

The documented quality control rationale for waived testing is based on the following: - How the test is used - Reagent stability - Manufacturers' recommendations - The organization's experience with the test - Currently accepted guidelines

WT.05.01.01: Record Maintenance

Organization maintains records

6 Element of Performances

1. QC records
2. Results in clinical record
3. Reference intervals for quantitative results
4. Instrument records and maintenance
5. All records retained for at least two years

WT.05.01.01: Record Maintenance

Sample Observations

Internal controls for HCG (urine pregnancy) and HIV testing (+ or -) at point of care were not documented (either in a log, flow sheet or medical record).

WT.05.01.01, EP 1:

Quality control results, including internal and external controls for waived testing, are documented. Note 1: Internal quality controls may include electronic, liquid, or control zone. External quality controls may include electronic or liquid. Note 2: Quality control results may be located in the clinical record.

WT.05.01.01: Record Maintenance

Sample Observations

No ability to individually retrieve test results and corresponding quality controls

WT.05.01.01, EP 4:

Individual test results for waived testing are associated with quality control results and instrument records. Note: A formal log is not required, but a functional audit trail is maintained that allows retrieval of individual test results and their association with quality control and instrument records.

The Joint Commission Tracer Methodology on Waived Testing

Tracer Methodology

Evaluates the following

- Compliance with waived testing standards and its impact to overall patient care
- Consistent adherence to policy
- Communication within and between departments/programs/services
- Staff competency
- Personnel requirements and qualifications

Tracer Methodology

- Patients are the framework
- Follows the experience of care
- Begins with a test result
- Reviews three phases of testing
- Involves multiple staff, the patient, and even family
- **Four month track** record of compliance observed for all specialties and subspecialties for initial surveys

Documents Reviewed

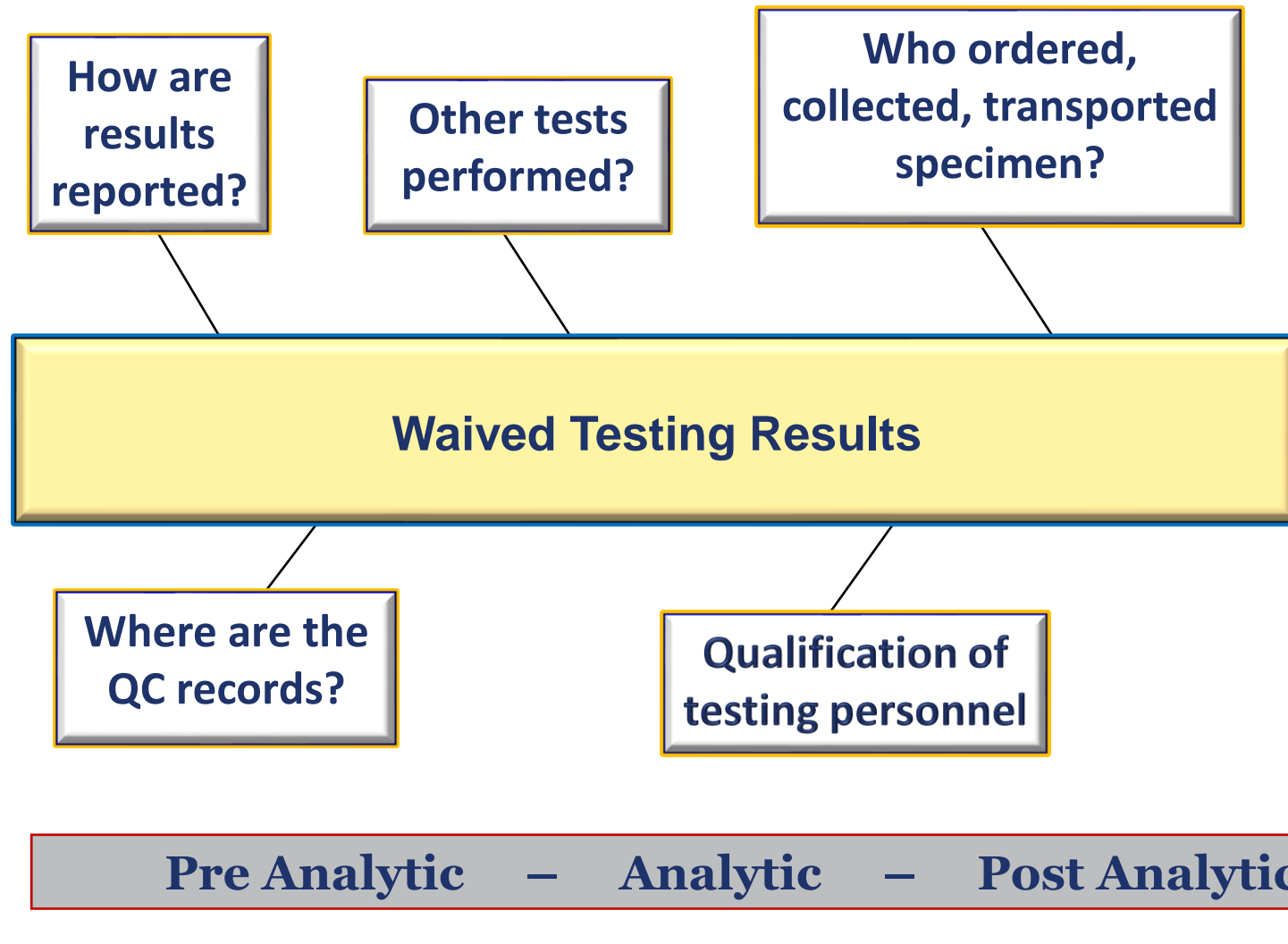
- Instrument maintenance records, calibration verification, quality control, correlations
- Policies and procedures
- Employee competency and qualifications
- Process improvement
- Patient medical records
- Waste disposal records



Interview Laboratory Staff About...

- Processes and compliance with standards
- Intradepartment and interdepartment communication
- Processes and roles to minimize risk
- National Patient Safety Goals
- Orientation, training and competency
- Workload issues
- Validation of information learned

Sample Tracer



Additional Recommendations

Tests Commonly Mistaken as Waived testing

1. ACTs
2. AmniSure
3. AmnioTest
4. I-STAT waived cartridges with venous whole blood samples collected in a syringe

Final Advise

1. Confirm complexity of each test
<https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfClia/analyteswaived.cfm>
2. Review standards and requirements: CLIA, accreditation, organization
3. Perform internal audits
4. Seek Leadership Involvement

Summary

- ✓ Outline The Joint Commission Laboratory Standards on Waived Testing
- ✓ Provide Recommendations for Meeting Requirements
- ✓ Overview of Waived Testing Tracer Methodology Approach

Questions/Suggestions

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The Joint Commission Disclaimer

These slides are current as of July 11, 2019. The Joint Commission reserves the right to change the content of the information, as appropriate.