Status **Pending** PolicyStat ID **15008466**

Origination	11/1999
Last Approved	N/A
Effective	Upon Approval
Last Revised	02/2024
Next Review	1 year after approval

Owner	Jeanna Begay
Area	Administrative - Waived Testing
Applicability	Hopi Health Center
References	WT.01.01.01, WT.02.01.01, WT.03.01.01 + 2 more

Interdisciplinary Waived Testing Policy

BACKGROUND

In 2005, The Joint Commission approved revisions to its waived testing standards to address the growing number of waived testing methods, risks to patient safety and quality of care when waived testing is performed improperly and quality problems revealed by the Centers for Medicare & and Medicaid Services (CMS).

The *Morbidity and Mortality Weekly Report* article "Good Laboratory Practices for Waived Testing Sites" from November 11, 2005 supports the waived testing requirements and drew attention to pertinent risks that if performed incorrectly have potential for serious health impacts. These errors could cause inaccurate results that could lead to inaccurate diagnoses, inappropriate or unnecessary medical treatment and poor patient outcomes.

Tests that produce a result measured as a discrete number are termed "quantitative." Tests that produce a negative or positive result, such as fecal occult blood and urine pregnancy screens, are termed "qualitative." A test that is more precise than a qualitative test (pos/neg), but less precise than a quantitative test (numerical), is usually scored on a graded scale (1+, 2+, 3+) and is termed "semi-quantitative". Tests with analysis steps that rely on the use of an instrument to produce a result are instrument-based tests. These can be qualitative, semi-quantitative or quantitative.

Test results that are used to assess a patient condition or make a clinical decision about a patient are governed by CLIA '88.

Waived testing has fewer requirements and is less stringent then the requirements for non-waived testing. It is the most common complexity level performed by caregivers at the patient bedside or point-of-care (POC).

PURPOSE

To set guidelines addressing the processes and regulatory requirements related to Waived Testing for Laboratory, Nursing and Medical Staff. To establish minimum requirements for quality control, responsibility for testing, personnel, training, orientation, competency assessment, reporting of results, and maintenance of records for waived testing.

JOINT COMMISSION STANDARDS AND ELEMENTS OF PERFORMANCE FOR WAIVED TESTING & HOPI HEALTH CARE CENTER (HHCC) WAIVED TESTING POLICIES

Standard WT.01.01.01
Policies and procedures for waived tests are established, current, approved, and readily available.

EP 1	The Medical Laboratory Director approves a consistent approach for when waived test results can be used for diagnosis and treatments and when follow-up testing is required.
EP 2	The Medical Laboratory Director has delegated this responsibility to the Laboratory Supervisor for establishing written policies and procedures for waived testing to address the following: • Clinical usage and limitations of the test methodology. • Need for confirmatory testing and result follow-up recommendations. • Specimen type, collection, identification, required labeling, and preservation. • Instrument maintenance and function checks, such as calibration. • Storage conditions for test components. • Reagent use, including not using a reagent after its expiration date. • Quality control (including frequency and type) and corrective action when quality control is unacceptable. • Test performance. • Result reporting, including not reporting patient test results unless quality control is acceptable. • Equipment performance evaluation.
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, may be enhanced to include QC and other procedures.
EP 4	The Medical Laboratory Director approves policies and procedures at the following times: • Before initial use of the test for patient testing. • Periodically thereafter, at least once every three years.

	• When changes in procedures occur (for example, when manufacturers' updates to package inserts include procedural changes or when a different manufacturer is used).
EP 5	Current and complete policies and procedures are available for use during testing to the person performing the waived test.
EP 6	Written policies, procedures and manufacturers' instructions for waived testing are followed.

Standard WT.02.01.01
The person from the organization whose name appears on the Clinical Laboratory Improvement Amendments of 1988 (CLIA '88) certificate identifies the staff responsible for performing and supervising waived testing.

EP 1	Identified staff members who perform testing are documented for each point of care waived testing site.
EP 2	Staff members who will direct or supervise testing will be documented. The laboratory staff and each point of care departmental supervisor share responsibility for monitoring waived testing being performed in their departments.

Standard WT.03.01.01
Staff performing waived tests are competent.

EP 1	A qualified designee (POC Coordinator) provides orientation and training to and assesses the competency of staff who perform waived testing.
EP 2	Staff who perform waived testing have received orientation in accordance with the organization's specific services. The orientation for waived testing is documented.
EP 3	Staff who perform waived testing have been trained for each test that they are authorized to perform. The training for each test is documented.
EP 4	Staff who perform waived testing that require the use of an instrument have been trained on its use and operator maintenance. The training on the use and operator maintenance of an instrument for waived testing is documented
EP 5	Competency for waived testing is assessed using at least two (2) of the following methods per person per test: • Performance of a test on a blind specimen. • Periodic observation of routine work by the supervisor or qualified designee. • Monitoring of each user's quality control performance. • Use of a written test specific to the test assessed.
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. This competency is documented. Note: When a provider or licensed independent practitioner performs waived testing that does not involve an instrument and the test falls within their specialty, the organization may

	use the medical staff credentialing and privileging process to document evidence of training and competency in lieu of annual competency assessment.

Standard WT.04.01.01
The organization performs quality control checks for waived testing on each procedure.

EP 1	A written quality control plan for waived testing is included within individual procedures.
EP 2	The documented quality control rationale for waived testing is based on the following: • How the test is used. • Reagent stability. • Manufacturer's recommendations. • The organizations experience with the test. • Currently accepted guidelines.
EP 3	For non-instrument based waived testing, quality control checks are performed at the frequency and number of levels recommended by the manufacturer and as defined by the policies.
EP 4	For instrument-based waived testing, quality control checks are performed on each instrument used for patient testing per manufacturers' instructions.
EP 5	For instrument-based waived testing, quality control checks require two levels of control, if commercially available.

Standard WT.05.01.01
The organization maintains records for waived testing

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.*
EP 2	Test results for waived testing are documented in the patient's clinical record.
EP 3	Quantitative test result reports in the patient's clinical record for waived testing are accompanied by reference intervals (normal values and units of measure) specific to the test method used and the population served.
EP 4	Individual test results for waived testing are associated with quality control results and instrument records. Therefore, patients result logs will be maintained by entering information for each new lot number placed into use.
EP 5	Quality control result records, test result records, and instrument records for waived testing are retained for at least two years.

GENERAL POLICY

A. Quality Control: The laboratory will define the quality control procedures to be performed with each waived test procedure.

1. The laboratory and nursing personnel will be responsible for performing **external** QC at specified intervals for the majority of waived testing.
2. All testing personnel remain responsible for performing and recording internal (procedural) controls as specified by the manufacturer. Tests include:
    - Rapid Strep A Screen
    - Urine Pregnancy
    - Fecal Occult Blood
    - Gastric Occult Blood
3. For glucose meter testing, QC requirements include two levels of control for each instrument used per each day of patient testing to be performed by primary operators at each point of care testing site.
    - Glucose meters are programmed to lock out operators if QC has not yet been performed.
    - Operators are not to share User ID (barcode) when performing QC on the meter.
4. Quality control results are documented including internal and external (liquid and electronic) as specified in each policy and procedure.
5. Quality controls results must be within acceptable limits before starting patient testing.
    a. Remedial action must be taken for unacceptable QC results before patients can be tested and results reported.
    b. Remedial action must be documented.
    c. Additional quality control materials may be instituted if necessary to address specific problems with the procedure or personnel performance.

B. Competency: To ensure competency for non-laboratory personnel performing waived testing laboratory procedures as described in the Clinical Laboratory Improvement Amendments of 1988 (CLIA'88).

1. Upon employment, each staff member is trained and assessed for competency for all waived laboratory tests he or she is expected perform. The assessment includes: direct observation, blind specimen testing, routine patient test performance including patient preparation, specimen collection, handling, processing, and test reporting, and use of an electronic written test specific to the test assessed.
2. Competency assessment is conducted and documented for each staff member on the Competency Assessment Documentation. Official records shall be maintained in the Laboratory.

3. Training and competency assessment is performed by a qualified designee, POC Coordinator, and/or departmental POC trainers.
4. The Laboratory POC Coordinator performs monthly observation, monitoring of each department user's routine work and quality control performance and monthly reports are generated for the departmental nursing supervisors for review.

APPROVED WAIVED TESTS

The following is a list of approved point of care testing locations at the Hopi Health Care Center and the waived tests that can be performed. These are the only lab tests authorized to be performed by identified nursing, medical or laboratory staff.

No new waived testing will be added outside the laboratory for point of care testing without laboratory approval.

Qualitative and/or Semi-Quantitative Tests

	OPD	ED	Lab	Provider	Screening/Diagnostic Test
Manual Dipstick UA	√	√	√		Screening
Urine Pregnancy	√	√	√		Screening
Rapid Strep A Screen	√	√	√		Screening
Fecal Occult Blood		√	√	√	Screening
Gastric Occult Blood		√	√	√	Screening
Nitrazine Test		√	√	√	Screening

Instrument Based Quantitative Tests

	OPD	ED	IPU	Lab	PHN	Dental	Physical Therapy	Optometry	Screening/Diagnostic Test
WB Glucose	√	√	√	√	√	√	√		Screening

PERFORMANCE IMPROVEMENT

1. It will be the responsibility of supervisory staff in each point of care location to monitor staff performance of waived testing to ensure that policies and procedures are followed.
2. The laboratory supervisor or POC Coordinator or designee may conduct random inspections of the areas where waived testing is performed to assess compliance with reagent storage requirements and documentation of results.
3. Chart reviews may be performed as part of a focused study.

REFERENCES

Most Recent, The Joint Commission Comprehensive Accreditation Manual for Laboratory and Waived Testing, Standards.

Approval Signatures

Step Description	Approver	Date
Lab Supervisor	Kendrick Fritz: Supervisory Medical Technologist	Pending
Director of Quality Management	Jose Burgos: Public Health Nurse Director	02/2024
Medical Technologist	Jeanna Begay	02/2024
	Jeanna Begay	02/2024

Applicability

Hopi Health Center

References

WT.01.01.01, WT.02.01.01, WT.03.01.01, WT.04.01.01, WT.05.01.01