

Waived Testing: Current Observations and COLA Solutions

CLIAAC

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Verlin K. Janzen, MD, FAAFP
Member, COLA Board of Directors
Chair, Accreditation and Acceptance Committee

COLA at a Glance

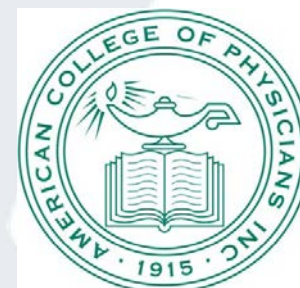
Dedicated to promoting excellence in laboratory medicine and patient care through a program of education, consultation, and accreditation.

COLA currently accredits over 7300 clinical laboratories performing moderate-high complexity testing.

Offers educational programs and IT tools designed to help laboratories move towards continuous compliance.



AMERICAN ACADEMY OF
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Waived Testing

Statutory Descriptive Criteria

§493.15 Laboratories performing waived tests.

(a) Requirement. Tests for certificate of waiver must meet the descriptive criteria specified in paragraph (b) of this section.

(b) Criteria. Test systems are simple laboratory examinations and procedures which—

- (1) Are cleared by FDA for home use;
- (2) Employ methodologies that are so simple and accurate as to render the likelihood of erroneous results negligible; or
- (3) Pose no reasonable risk of harm to the patient if the test is performed incorrectly

Original Waived tests

- **Urine Dipstick**
- **Fecal Occult Blood**
- Ovulation Tests Visual color for LH
- **Urine Pregnancy (visual color comparison)**
- **ESR (manual)**
- Hemoglobin (CuSO₄)
- **Blood Glucose Monitoring (home use)**
- Spun Hematocrit
- Hemoglobin single analyte instrument

100 + Analytes Now Waived

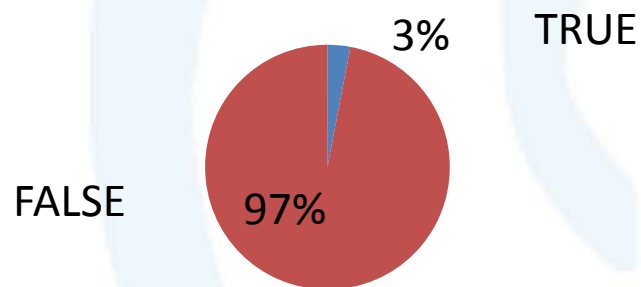
- Comprehensive Metab Profile
- Lipids – total chol, HDL, trigs
- FSH, TSH, LH, urine hCG
- BNP
- A1c, microalbumin, fructosamine
- Ketones – blood & urine
- Hb/Hct, platelet aggregation
- Cannabinoids, cocaine, benzo-diazepines, ethanol, meth-amphetamines, morphine, opiates, propoxyphene, PCP, tri-cyclics
- Lyme disease
- H pylori antibodies
- Mono, influenza a/b, Grp A strep, RSV, adenovirus (eye)
- HIV Antibody
- Trichomonas
- Protine
- Adenovirus (conj fluid)
- Bacterial vaginosis
- Ferning in saliva (ovulation)
- Lithium
- Male fertility (motile sperm > 10M)

Potential for patient harm if performed incorrectly?

<http://www.cms.hhs.gov/CLIA/downloads/waivetbl.pdf>

Waived Test Perception

- University of Washington surveyed over 4100 laboratory personnel from more than 200 laboratories
- True or False: An error in a waived, Point of Care Test cannot harm a patient?



- Laboratory personnel understand that any incorrect result has the potential to influence patient care inappropriately

Laboratory Errors and Patient Safety, Univ. of Washington/ARUP, Volume 3, 6, May-June 2007.

Waived Testing: Common Quality Challenges

- High staff turnover.
- Failure to adequately train personnel and determine if competency is maintained.
- Failure to perform/monitor/respond to QC as specified.
- Lack of knowledgeable lab director or involvement.
- Failure to document test, lot number or expiration.
- Pre- and post-analytic errors.
- Failure to enter results into electronic medical records.
- Failure to follow current instrument or kit instructions.
- Waived sites performing non-waived testing.
- Failure to use correct terminology or units.

Medical Laboratory Errors

PHASE	RATES	OVERSIGHT
Pre-analytical	46-69%	CLIA
Analytical	7-13%	FDA/CLIA
Post-analytical	19-47%	CLIA

A Review of Medical Errors in Laboratory Diagnostics and Where We are Today, Hammering, Lab. Medicine, 2012;43(2):41-44.

Waived Testing: Anecdotal Observations

- Urine test strips inoculated by rubbing the urethral opening rather than dipping in clean catch urine.
- Urine test strips stored in a cabinet over an incandescent light raising cabinet temperature to vastly exceed room temperature requirements for storage.
- Use of urine test strips not validated with automated strip reader.
- Quality control out for one pad on a urine test strip, reported the rest of the strip.

COLA Waived Emphasis

- Laboratory Director minimum requirements
- Quality Assurance Corrective Action Plans
- Competency Assessment
- Specimen Handling and Labeling
- Proficiency Testing Review and Corrective Actions
- Use of COLACentral for Document Control, Lab Operations, PT, QC, Competency Tracker

COLA Waived Testing: Program Supportive Material

- Waived Testing Materials
- Procedure Manual
- On-line Education
- Competency and Personnel Management
- Attestation Management
- Self Assessment and feedback
- COLACentral Repository

MMWR - Waived Testing

<u>Findings</u>	<u>COLA's Solution</u>
High staff turnover	Document Repository & Competency Tracker & On Line Education
5% of sites were performing non-waived testing	Certificate Identification & Storage
12% did not have most recent instructions & 21% did not routinely check product insert for changes	Lab Operations - Attestation & Document Repository
21% did not perform QC as specified	Waived Testing Manual & Coursework
18% did not use correct terminology or units	Waived Testing Courses & Procedure Manual
50% did not document test, lot number or expiration	Lab Operations - Equipment and Inventory Control

Contacts

- Paul Campognone, Chief Operating Officer
- pcampognone@cola.org
- Verlin Janzen MD, Director
- janzenv@hutchclinic.com

Discussion

- Is education enough to insure waived tests are performed correctly?
- Will the growth of waived tests continue to grow?
 - CBC?
 - Serum, plasma?
- Is COLA's approach reasonable?
- Is additional regulatory control required?