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# CAP Programs for Waived Testing

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v. FNL

# Objective

- CAP's model for waived testing
- CAP Accreditation Requirements for waived testing
- CAP Proficiency Testing Program
- Educational tools for waived laboratories

# Waived Testing

Simple laboratory procedures

Insignificant risk of erroneous result

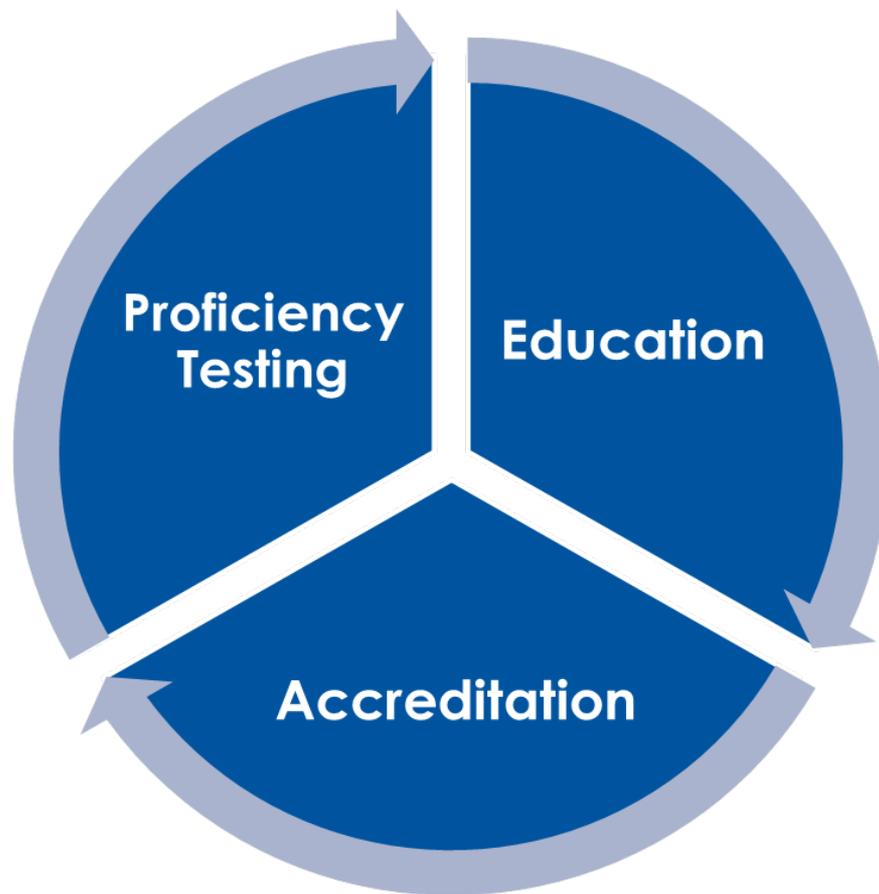
FDA approved for home use

Pose no reasonable harm if performed incorrectly

## CAP's Belief

- No test is so simple to perform that erroneous results cannot occur.
- CLIA regulations for moderate risk testing should be imposed on **waived tests in settings** that pose significant risk for patients. (eg, ER)
- Any tests that may lead to immediate and/or irreversible action and result in patient harm should not be waived from requirements for QC and PT.

# CAP Approach to Waived Testing



# CAP Accreditation – Waived Testing Requirements

- Same as non-waived for most
- Proficiency testing; Instrument maintenance; Procedure manual; Specimen handling; Result reporting; General QC/QC; Safety, etc
- With a few exceptions...

# Accreditation Requirement Exceptions

<b>Element</b>	<b>Waived Testing Requirement</b>
<b>Reagent</b>	<b>Follow manufacturer's instructions for handling and validating</b>
<b>Instrument Correlation</b>	<b>Not required</b>
<b>Quality Control</b>	<b>Follow manufacturer's instructions but must document corrective actions</b>
<b>Calibration and Calibration Verification</b>	<b>Follow manufacturer's instructions</b>
<b>Analytical Measurement Range</b>	<b>Follow manufacturer's instructions</b>
<b>Method Performance Specifications</b>	<b>Required to verify for reference ranges only</b>
<b>Personnel</b>	<b>Same as CLIA; Competency assessment performed annually on elements selected by LD.</b>

# Waived Testing Common Deficiencies

**2012**

PT Interlaboratory  
Communication

Director Off-Site

Document Control

Report Elements

Reagent Handling/Storage

Instrument Maintenance

Method Validation Approval

Competency Assessment

PT Evaluation

Knowledge of Procedures

**2011**

Reference Intervals

Delegation of Functions

Content/Format Report Review

Document QC Results

Instrument Maintenance  
Evaluation

Ungraded PT Challenges

PT Procedure

Test Result Routing

Director Off-site

Personnel Records

# Waived Laboratory Participation in PT

- CAP Accreditation requires PT for **most** waived tests.
- PT for waived tests is offered at lower challenge frequency than required CMS regulated tests, which encourages participation.
- Labs view PT as a simple mechanism to gauge employee competency, test/device performance against peers.

# CAP PT Waived Testing Products

- Whole blood glucose (WBG)
- Coagulation
- Lipids
- Plasma cardiac markers
- Urinalysis/clinical microscopy
- ESR
- Group A Strep antigen
- Mono
- Anti-HIV & Anti-HIV ½
- i-Stat, Piccolo chemistry analyzer

# CAP Waived PT

- In general, the CAP applies the same grading criteria to waived methods as is applied to CMS-regulated analytes.
- Grading is peer group based unless there is a comparative method available.
- As with CMS-regulated analytes, grading occurs only when there is 80% consensus.
- Waived devices/methods, because of the methodologies, use different samples as are used for CMS regulated PT testing.

# CAP Peer Groups

- The Surveys proficiency testing program is designed for hospital laboratories and reference laboratories.
  - Eg, WBG, CZ
- The EXCEL proficiency testing program is geared toward smaller hospital and physician office laboratories.
  - Eg, XLE WBG (L21)\*, XLE Glucose (CH, CH3)

\* This is a peer group of POs only.

# CAP PT Glucose Enrollment – Waived vs. Regulated

Surveys	2012	2013
XLE – Glucose (CH, CH3)	317, 81	293, 67
XLE – Whole Blood Glucose (L21)	557	566
CZ (Chemistry, TDM)	2488	2348
WBG	1909	1944

# PT Performance in CAP 2013 Surveys – Waived vs. Regulated

## Whole Blood Glucose

- +/-12mg/dL or 20%\*
- SD – 1.17 to 22.61
- CV – 2.0 to 25.3

## Serum Glucose

- +/- 6mg/dL or 10%\*
- SD – 1.07 to 7.61
- CV – 0.8 to 5.2

\*whichever is greater

# WB Glucose Performance – POLs

Instrument	No. Labs	Mean	S.D.	C.V
Abbott PRCSN PCx/Xceed	103	72.6	3.8	5.3
Abbott PRCSN Xceed/4xxxxx	83	71.1	3.9	5.5
Bayer Contour 5, 8 Sec	16	78.8	6.5	8.2
Lifescan SureStep 1-9	23	86.3	2.9	3.4
Nova Statstrip	61	83.7	4.6	5.5
Roche Accu-Check Aviva	13	94.7	7.5	7.9
Roche Accu-Check Inform II	23	101.1	1.6	1.6
Roche Comf Curv 55 xxxx	521	49.7	3.5	7.0
All Instruments	880	61.0	15.7	25.7

# WB Glucose Performance – All settings

Instrument	No Labs	Mean	S.D	C.V
Abbott PRCSN PCx/Xceed	1660	72.73	4.13	5.7
Abbott PRCSN Xceed/4xxxxx	4066	71.00	3.73	5.3
Bayer Contour 5, 8 Sec	39	79.13	7.54	9.5
Lifescan SureStep 1-9	899	86.00	4.91	5.7
Nova Statstrip	1971	82.01	4.37	5.3
Roche Accu-Check Aviva	52	89.75	4.32	4.8
Roche Accu-Check Inform II	1536	101.43	2.86	2.8
Roche Comf Curv 55 xxxx	6999	50.62	3.28	6.5

# Education Tools

- Point of Care Testing Tool Kit
- CAP Continuing Education Modules
  - Diabetes Patient
    - Provide benefits and risks in point of care testing for monitoring diabetic patients.
  - Glycemic Control
    - Identify steps to improve the quality of an ICU glucose monitoring program.

# Conclusion

- **As number of waived laboratories continues to grow, the CAP believes that waived testing should have oversight commensurate to the level of harm the test poses to patients.**



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