

The Impact of Waived Tests

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For a Method to be Waived...

- Simple laboratory procedure *or*
- FDA approved for home use
- Insignificant risk of an erroneous result
- Pose no reasonable risk of harm to the patient *if performed incorrectly*

CMS Pilot Data

- 1999 - 50% of Certificate of Waiver labs had quality problems (100 labs visited)
- 2000/2001 - 32% had quality problems (436 labs visited)
- Present - CMS surveys 2% of CW labs per year (~ 126,219 CW labs in US)

CAP Believes That...

- No test is so simple to perform that erroneous results cannot occur
- In settings where waived tests pose significant risk for patient harm these tests should be subject to CLIA regulations for moderately complex testing
- Any test that may lead to immediate and/or irreversible actions that may result in patient harm should not be waived from requirements for QC and PT

Where testing is performed matters

- Regulatory oversight, including QC and PT, should not be waived for any testing done in emergency rooms, radiology departments, and operating rooms
- Waived tests done in POLs would not fall under this requirement because the tests, interpretations and need for retesting are under the oversight of the clinician

Regulators including CMS acknowledge...

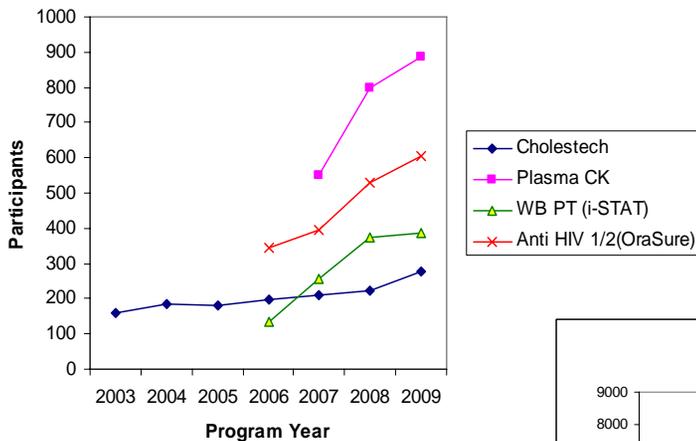
- *“Increased (waived) testing comes with issues:*
 - *Testing personnel less trained, may not ID problems*
 - *No routine oversight, no funding for resources*
 - *Minimal manufacturer recommended QC”*

CAP Experience with Waived Tests

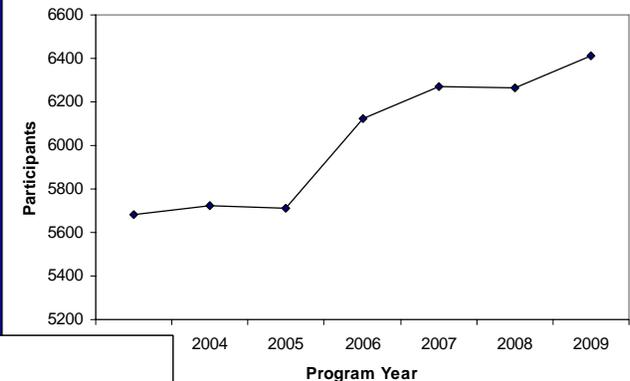
- PT is offered for many waived tests:
 - Whole blood glucose
 - Coagulation
 - Lipids
 - Plasma cardiac markers
 - Urinalysis/clinical microscopy
 - ESR
 - Group A Strep antigen
 - Mono
 - Anti-HIV 1 and Anti-HIV 1/2
 - i STAT, Piccolo chemistry analyzers

Trends in Enrollment for Waived Test PT at CAP

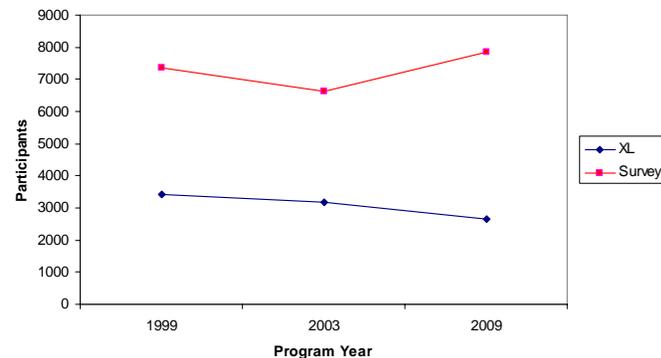
Trends in Voluntary Enrollment For PT Products for Waived Methods



Trends in Voluntary Enrollment for PT Products for Waived Methods - Whole Blood Glucose



Urinalysis PT Enrollment



These products are offered both in EXCEL®, designed for POLs and small hospitals and also in CAP Surveys, designed for large hospitals and medical centers with outreach services

What CAP knows about Enrollment

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

Have PT scores for waived tests changed over time?

- The CAP has data demonstrating that continuous participation in PT improves proficiency and accuracy for all analytes
- Receiving “unsatisfactory” performance scores in PT provides labs an incentive to investigate issues and make procedural adjustments

Waived PT

- In general, the CAP applies the same grading criteria to waived methods as is applied to CMS-regulated counterparts
- 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

PT Performance Specifics

- Whole blood glucose is graded at +/- 20% or +/- 12 mg/dL from the target, whichever is greater.....twice as lenient as mandated by CLIA for serum glucose
- Due to the methodologies of many waived devices/methods, it is not possible to use the same samples as are used for CMS-regulated PT testing

Performance Levels

- For the CMS-regulated analyte **serum glucose**, the standard deviation (SD) from the target tend to range from greater than 1.0 to less than 10.0 with coefficient of variation (CV) at less than 3.0
- For the waived analyte **whole blood glucose**, SD from the target ranges from 3.0 to 7.0 when the target is in the normal range and to greater than 50.0 when the target is in the abnormal range. The higher the target the greater the SD. CVs, regardless of target range from 4.0 to ~16.0.

Performance, continued

- Performance among other waived methods is much the same – SDs and CVs are similar to their CMS-regulated counterparts within the normal range and increase the higher the target level
- Comparing plasma CK-MB (CW) performance data to serum CK-MB data (regulated) reveals that while the CVs for the serum assay are routinely less than 10.0, the plasma CVs are greater than 10.0 but less than 20.0 regardless of the target level

Waived Anti-HIV PT Performance

- CAP offers PT products for anti-HIV1/2 and another for anti-HIV-1; both are offered in a 5 challenge format and in a 2 challenge format.
- Grading for all products occurs when there is 80% participant or referee consensus.

Anti-HIV 1 / 2 CMS Regulated

	AHIV-01		AHIV-02		AHIV-03		AHIV-04		AHIV-05	
MANUFACTURER	Pos	Neg								
Abbott	19	-	-	19	-	19	19	-	19	-
Clearview STAT-PAK	215	-	-	215	-	215	215	-	215	-
Bio-Rad Multispot	6	-	-	6	-	6	6	-	6	-
OraSure OraQuick ADVANCE	384	-	-	384	-	384	384	-	382	2
Ortho	9	-	-	9	-	9	9	-	9	-
Other, & manufacturers with <5 participants	17	-	-	17	-	17	17	-	17	-

Solid Performance

CAP PT Data from 2009 AHIV-A Survey
designed for CMS-regulated analyte reporting

Anti-HIV 1/2 , Waived

ANTI-HIV-1/2 MANUFACTURER		REACTIVE/POSITIVE		NON-REACTIVE/NEGATIVE	
		n	%	n	%
AHIV-11	Clearview STAT-PAK (WB)	-	-	66	100.0
	OraSure OraQuick Advance	2	0.5	415	99.5
	Other	-	-	28	100.0
AHIV-12	Clearview STAT-PAK (WB)	66	100.0	-	-
	OraSure OraQuick Advance	415	99.5	2	0.5
	Other	28	100.0	-	-

Imperfect Performance
False positive
And
False negative

CAP PT Data from 2008 AHIVW-B Survey
designed for CW lab use

Anti-HIV 1

CMS Regulated

Anti-HIV-1 Manufacturers		REACTIVE/POSITIVE		NON-REACTIVE/NEGATIVE	
		n	%	n	%
<i>RHIV-01</i>	MEDMIRA LABORATORIES	354	99.2	3	0.8
	ORASURE ORAQUICK ADVANCE	101	99.0	1	1.0
	TRINITY BIOTECH	337	99.7	1	0.3
	OTHER (a)*	49	98.0	1	2.0
<i>RHIV-02</i>	MEDMIRA LABORATORIES	1	0.3	356	99.7
	ORASURE ORAQUICK ADVANCE	-	-	102	100.0
	TRINITY BIOTECH	-	-	338	100.0
	OTHER (a)*	-	-	50	100.0
<i>RHIV-03</i>	MEDMIRA LABORATORIES	1	0.3	356	99.7
	ORASURE ORAQUICK ADVANCE	-	-	102	100.0
	TRINITY BIOTECH	-	-	337	100.0
	OTHER (a)*	-	-	50	100.0
<i>RHIV-04</i>	MEDMIRA LABORATORIES	354	99.2	3	0.8
	ORASURE ORAQUICK ADVANCE	102	100.0	-	-
	TRINITY BIOTECH	338	100.0	-	-
	OTHER (a)*	50	100.0	-	-
<i>RHIV-05</i>	MEDMIRA LABORATORIES	351	98.6	5	1.4
	ORASURE ORAQUICK ADVANCE	102	100.0	-	-
	TRINITY BIOTECH	337	99.7	1	0.3
	OTHER (a)*	49	98.0	1	2.0

CAP PT Data from 2009 RHIV-A Survey
designed for CMS-regulated analyte reporting

OraSure users at
~100% in this
setting

Anti-HIV 1, Waived

Anti-HIV-1 Manufacturers		REACTIVE/POSITIVE		NON-REACTIVE/NEGATIVE	
		n	%	n	%
<i>RHIV-01</i>	ORASURE ORAQUICK	81	100.0	-	-
	TRINITY BIOTECH	114	100.0	-	-
	OTHER	38	100.0	-	-
<i>RHIV-02</i>	ORASURE ORAQUICK	-	-	81	100.0
	TRINITY BIOTECH	1	0.9	113	99.1
	OTHER	-	-	38	100.0

Trinity Biotech user in the CW Setting has a False positive result.

In Conclusion

- The original concept of waived tests/methods was acceptable in 1988-1992, based as it was on a small number of tests routinely performed in laboratories and in physician offices. However, as technology advanced, the idea that thousands of tests critical to patient care and safety do not need any oversight is disturbing.

“Never forget that it is not a pneumonia, but a pneumonic man who is your patient. Not a typhoid fever, but a typhoid man”

~ William Withey Gull

Every
number
is a life.™

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