

Model Performance Evaluation Program (MPEP) HIV Rapid Testing Survey: Report of Sample Shipment Results, September 2009

www.cdc.gov/mpep/hiv-1rt.aspx

Presented by: Steven Ethridge

Report by: Sandra W. Neal and Leigh Inge Vaughan

Use of trade names and commercial sources is for identification only and does not constitute endorsement by the Public Health Service or the U.S. Department of Health and Human Services.



Background-2009 MPEP External Quality Assessment Survey

- The CDC HIV Rapid Testing Quality Assurance guidelines recommend participation in a External Quality Assessment program.
- The MPEP program is free to all participants.
- MPEP is customized for ease of use in all types of HIV rapid testing venues.
- There are two external quality assessment specimen (challenge) shipments each year. Six samples from five donors are provided in each shipment.

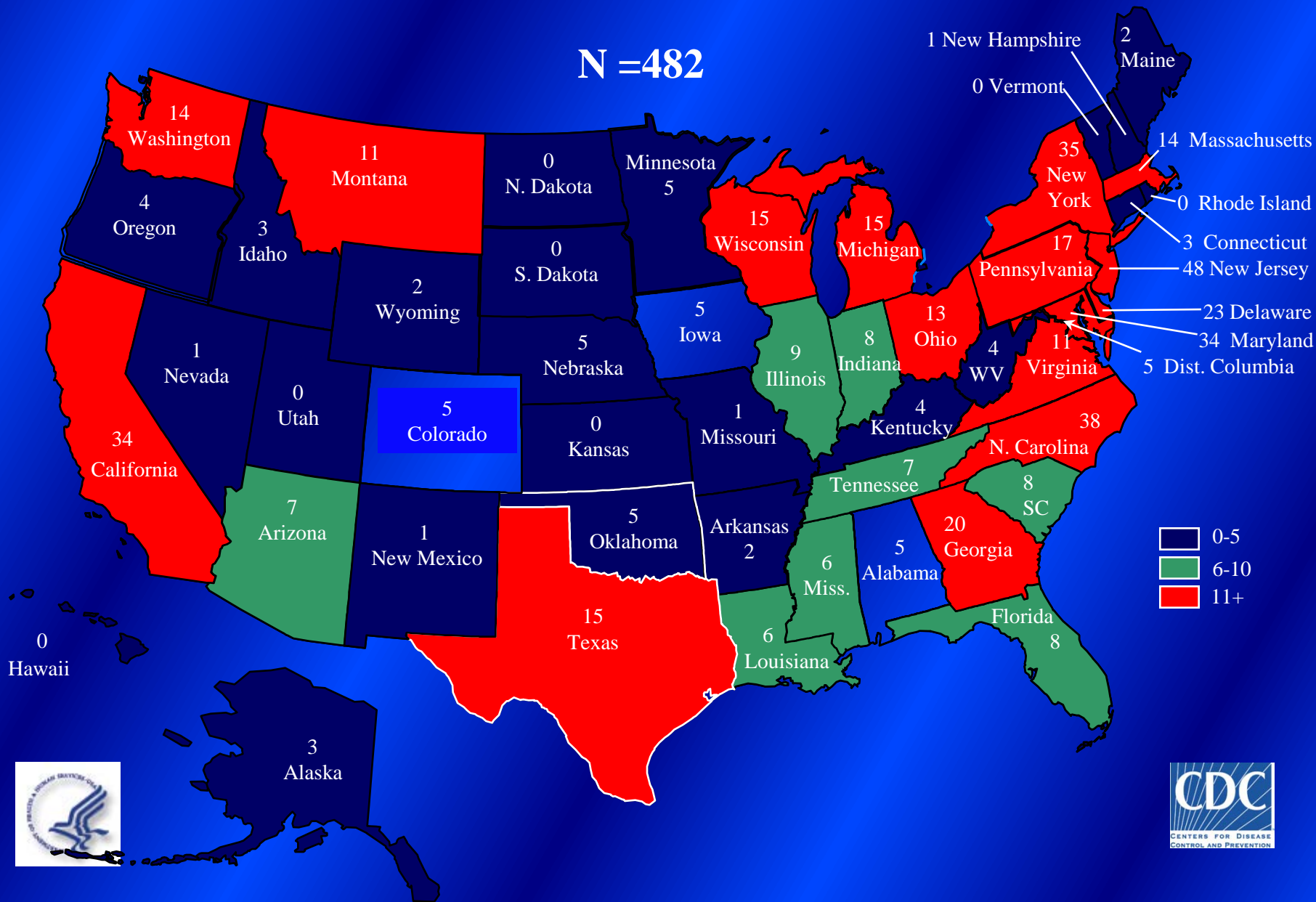


Model Performance Evaluation Program (MPEP)

- Distribution of participants
- Specimens used for testing survey
- Type of participating facilities
- Types of tests used in different facilities
- Testing results by test
- External QC frequencies reported by participants



2009 MPEP Results-Distribution of Participants

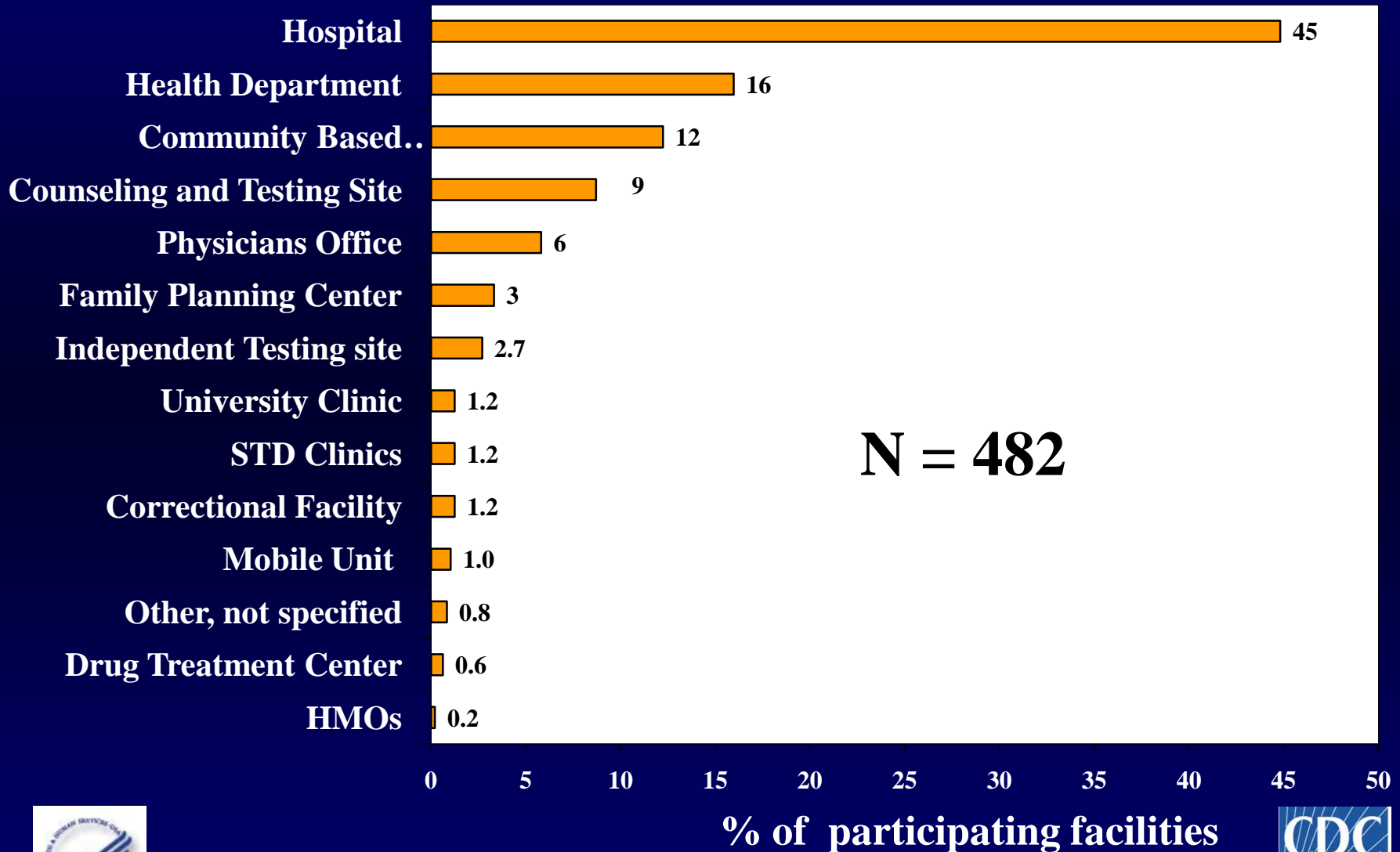


2009 MPEP Methods- Challenge Specimens

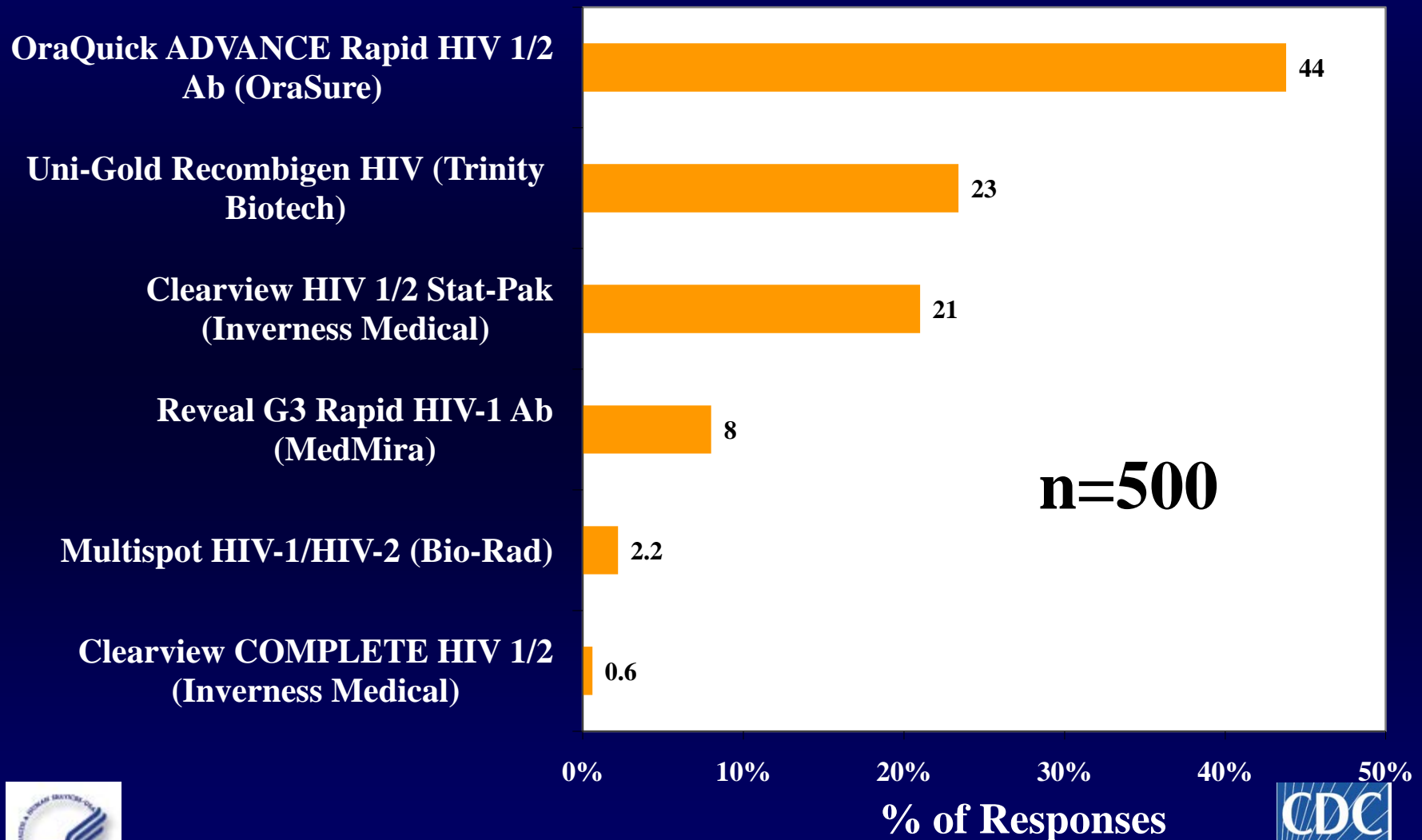
Donors used for panels	Bio-Rad rLAV EIA S/CO reactivity	Western Blot band reactivity
1 (Weak Pos) and 2 (Weak Pos)	3-5	At least two of: gp 41, gp120, gp160
3 (Strong Pos) and 4 (Strong Pos)	> 5	p24, p31, gp41, p51, p66, gp120, gp160
5 (Negative)	Non-reactive on all FDA approved EIA tests	Negative with both FDA approved Western Blot tests.



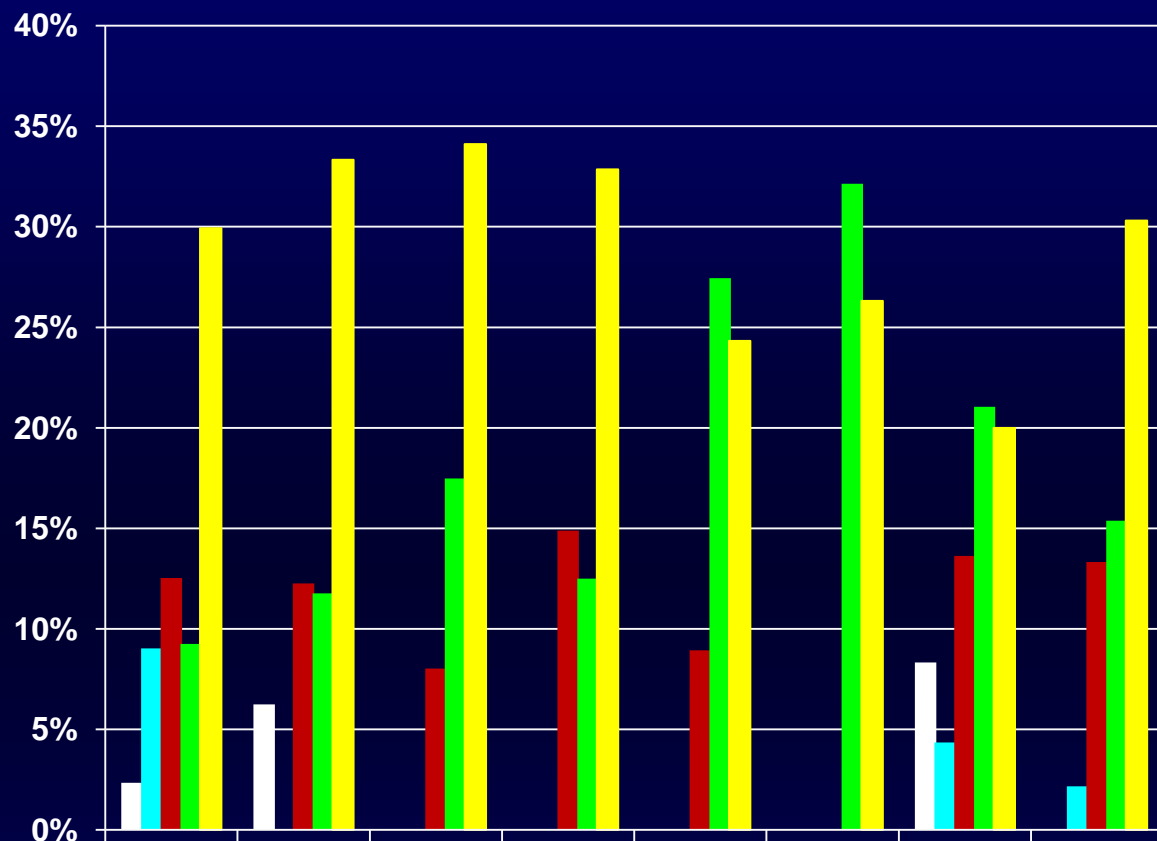
2009 MPEP Results-Types of Facilities



2009 MPEP Results-Rapid Test Use



2009 MPEP Results-Tests Used by Facility



- Bio-Rad Multispot HIV-1/HIV-2
- MedMira Reveal G3 Rapid HIV-1 Antibody Test
- Inverness Medical Clearview HIV 1/2 Stat-Pak
- Trinity Biotech Uni-Gold Recombigen HIV
- OraSure OraQuick ADVANCE Rapid HIV 1/2 Ab Test



2009 MPEP Results-Sensitivity Performance

Manufacturer	Reactive Specimens						Sensitivity Performance	
	# of Sites	# of Results	# Reactive	# Non-Reactive	# Invalid	% Correct	% Sensitivity Using Survey Material and 95% CI	% Sensitivity for Plasma from Product Insert and 95% CI
OraQuick ADVANCE	219	1095	1078	13	4	98%	98.8 (98.0-99.4)	99.6 (98.9-99.8)
Uni-Gold	108	540	540	0	0	100%	100 (99.3-100)	100 (99.5-100)
Clearview HIV 1/2 Stat-Pak	104	520	515	4	1	99%	99.2 (98.0-99.8)	99.7 (98.9-100)



2009 MPEP Results-False Negative Tests

	Weak Pos #2	Strong Pos #3
Hospital	1 OraQuick 1 Stat-Pak	2 OraQuick
Health Dept	2 OraQuick	2 OraQuick
CBO	1 OraQuick	3 OraQuick 1 Stat-Pak
CT		2 Stat-Pak
Other	1 OraQuick	1 OraQuick



2009 MPEP Results-Specificity Performance by Test

	Negative Specimen				Test Specificity		
	# tests	# Reactive	# Non-reactive	# Invalid	% Correct 95% CI	% Specificity Using Survey Material and 95% CI	% Specificity for Plasma from Product Insert and 95% CI
Oraquick ADVANCE	219	5	214	0	98 (94.8-99.3)	97.7 (94.8-99.3)	99.9 (99.6-99.9)
Uni-Gold	108	0	108	0	100 (96.6-100.0)	100 (96.6-100)	100 (99.3-100)
Clearview Stat-Pak	104	0	104	0	100 (96.5-100.0)	100 (96.5-100)	100 (99.6-100)



2009 MPEP Results-Challenge Specimens

Overall Performance

Donor Number	# of Results	# Reactive	# non-reactive	# Invalid	% Correct 95% CI
1 (Weak Pos)	1000	996	1	3	99.6 (99.0-99.9)
2 (Weak Pos)	500	491	7	2	98.2 (96.6-99.2)
3 (Strong Pos)	500	489	11	0	97.8 (96.1-98.9)
4 (Strong Pos)	500	499	1	0	99.8 (98.7-100.0)
5 (Negative)	500	5	494	1	98.8 (97.4-99.6)



2009 MPEP-External Control Frequency

Survey Question:

Frequency of use of QC material for the kit specified in question #1
(check all that apply)

With each Run/Set /Batch of patient tests

By each new operator prior to testing client/patient specimens

When opening new lot number of test kits

When opening new box of test kits

Whenever new shipment of test kits is received at periodic intervals: every shift, daily, weekly, monthly, after x # of tests, other.



External Quality Control Schedules

<i>Facility Type</i>	# sites	New Oper.	New Lot	New Box	New Shipmt	Each Run	Daily	Wkly	Mnthly	After # of tests	Other
<i>Hospital</i>	216	41%	68%	33%	54%	28%	7%	7%	13%	0%	4%
<i>Health dept.</i>	77	51%	71%	36%	53%	29%	6%	48%	14%	10%	13%
<i>CBO</i>	59	34%	66%	37%	56%	7%	10%	47%	8%	7%	10%
<i>CTR</i>	42	33%	64%	45%	88%	10%	7%	55%	17%	12%	21%
<i>Dr Office</i>	28	25%	43%	50%	46%	14%	4%	7%	11%	0%	0%
<i>Family Planning Ctr</i>	16	31%	75%	44%	19%	6%	6%	0%	0%	6%	0%
<i>Independent</i>	13	31%	46%	31%	46%	54%	15%	0%	8%	0%	0%
<i>STD</i>	6	33%	67%	33%	50%	17%	17%	50%	33%	17%	17%
<i>Jails</i>	6	50%	83%	50%	100%	17%	33%	50%	0%	0%	0%
<i>Mobile unit</i>	5	0%	80%	60%	100%	0%	0%	60%	0%	0%	20%
<i>Drug Treat. Ctr</i>	3	33%	33%	33%	67%	0%	0%	67%	33%	0%	0%



2009 MPEP-Limitations

- Survey challenge specimens are not the same specimen type (matrix) that participants use routinely.
- The clear plasma specimens used for this survey may have contributed to the error rate for rapid tests that use the 5ul sampling devices.



Summary

- Overall survey accuracy of the positive challenge samples was 99.0% and 98.8% for the negative challenge specimens.
- The OraQuick Advance, Unigold Recombigen, and the Clearview Stat-Pak performed within the 95% CI of their product inserts for sensitivity.
- Some testing facilities may be performing too much external QC.



Acknowledgements

- Jeanne Bertolli
- Laura Wesolowski
- Kevin Delaney
- Susan Danner

The findings and conclusions in this presentation are those of the author and do not necessarily represent the views of the Centers for Disease Control and Prevention.

