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

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

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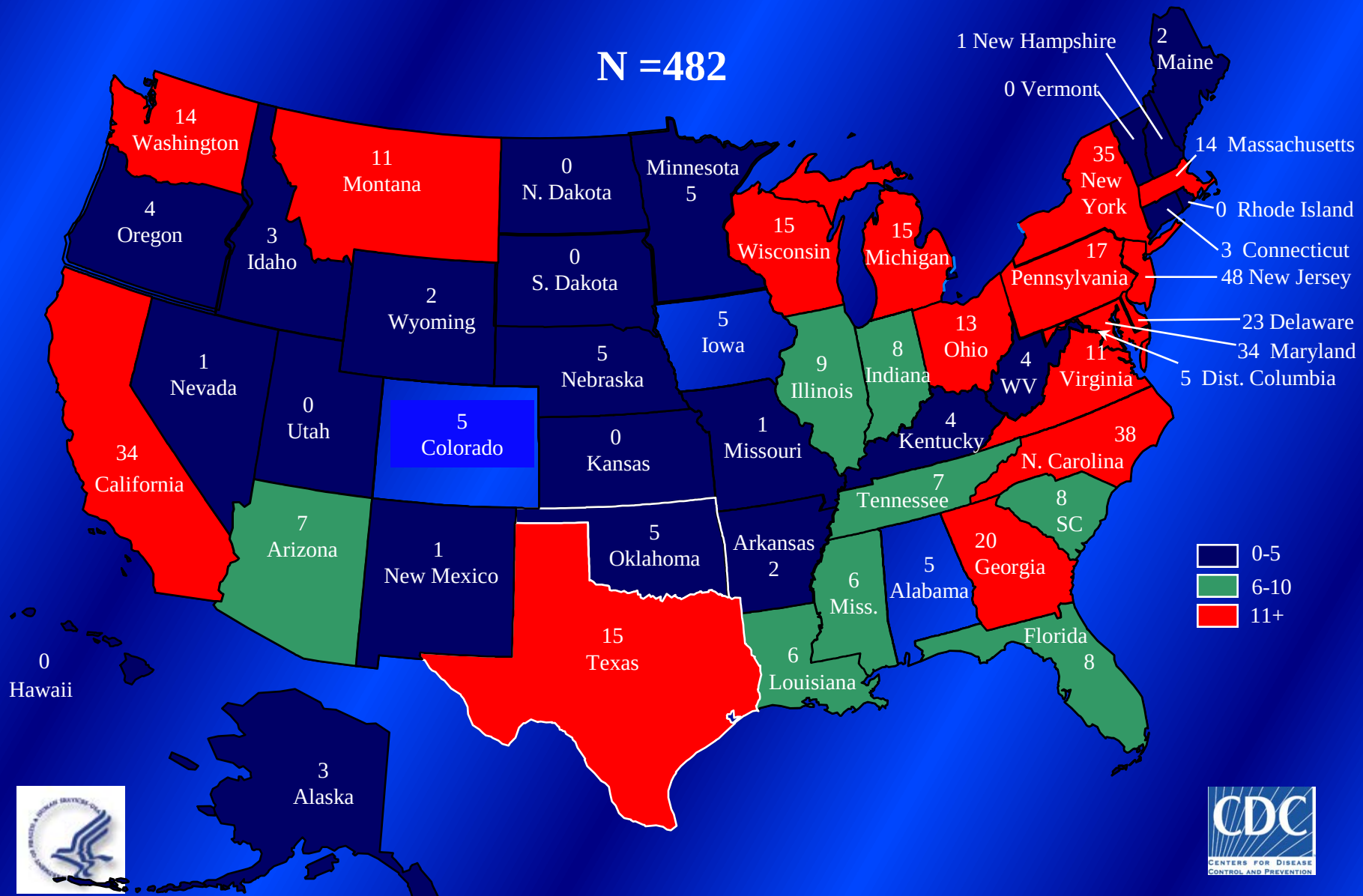
# Background-2009 MPEP External Quality Assessment Survey

- 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

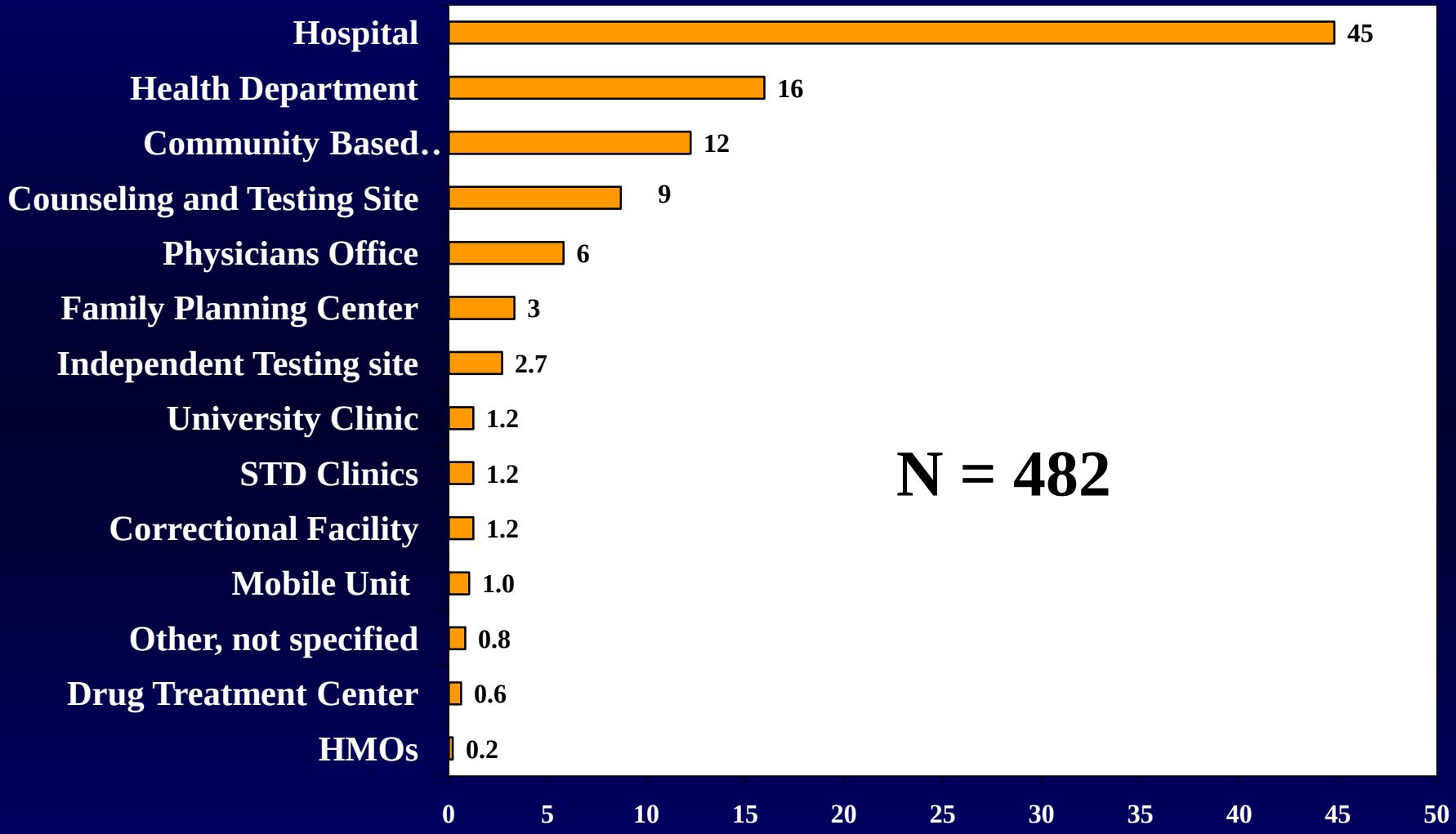
# 2009 MPEP Results-Distribution of Participants



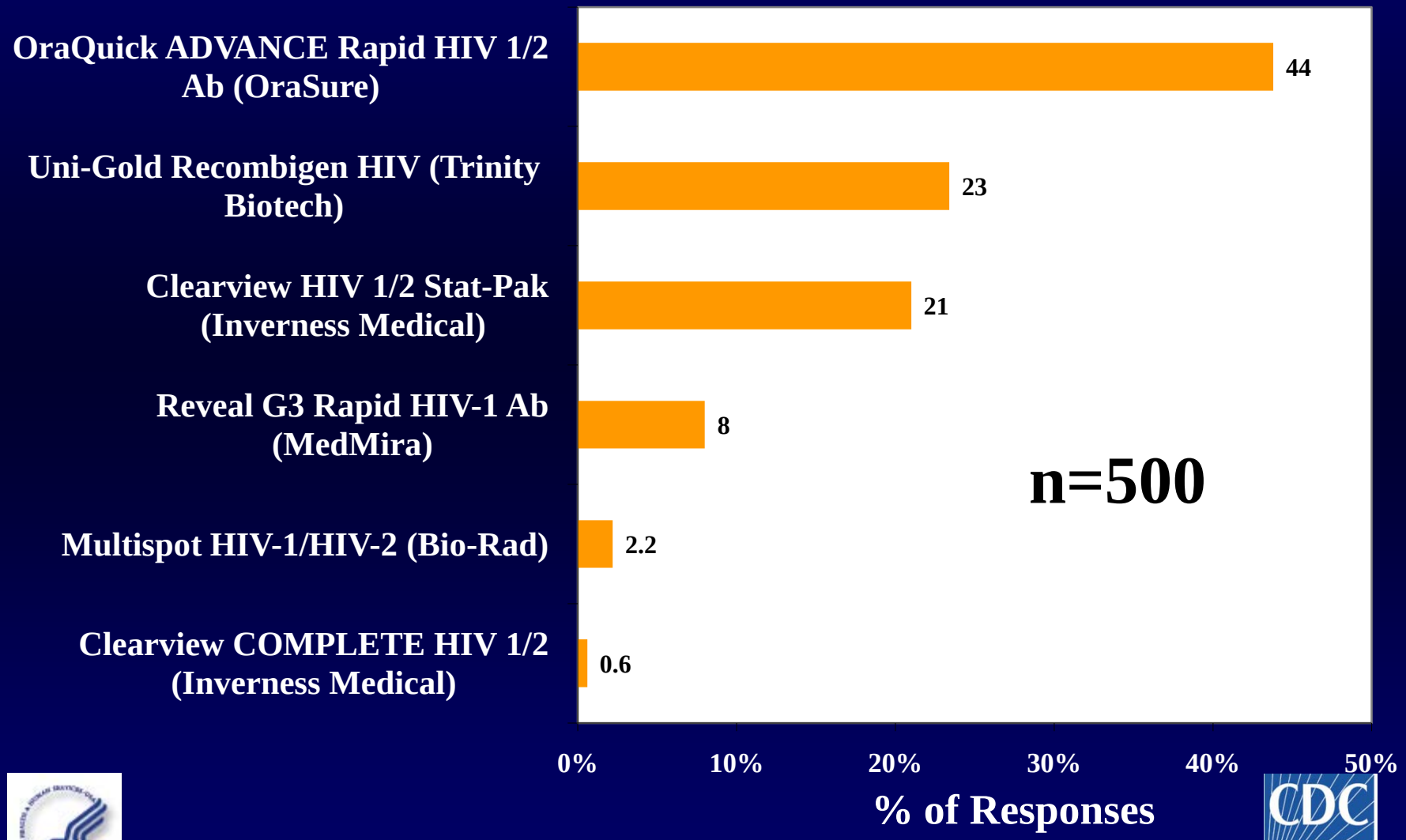
# 2009 MPEP Methods- Challenge Specimens

| 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. |

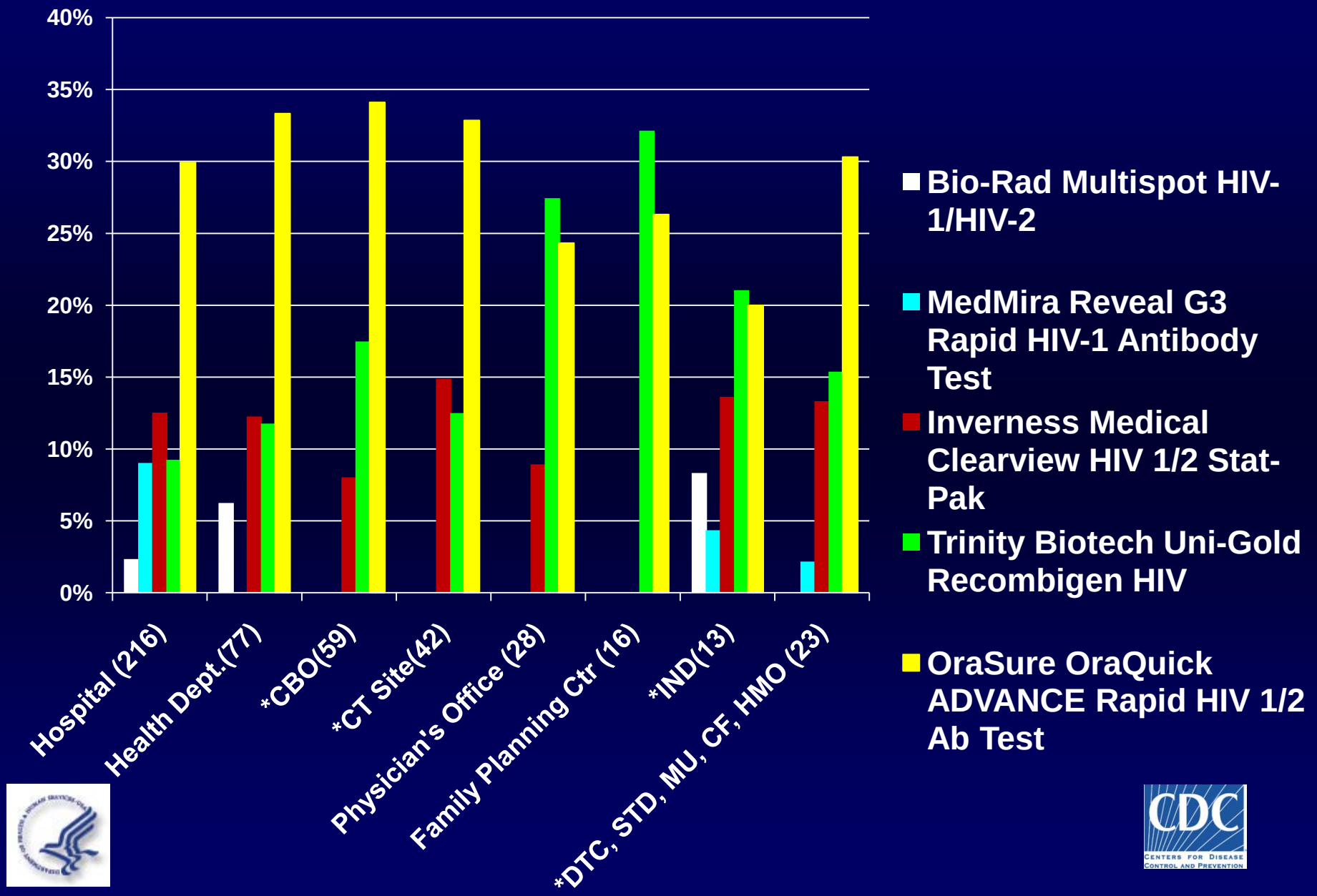
# 2009 MPEP Results-Types of Facilities



# 2009 MPEP Results-Rapid Test Use



# 2009 MPEP Results-Tests Used by Facility



# 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<br>1 Stat-Pak | 2 OraQuick |
| Health Dept | 2 OraQuick | 2 OraQuick |
| CBO | 1 OraQuick | 3 OraQuick<br>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

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