

Performance of Newer Rapid Tests for HIV Antibody with Whole Blood and Plasma

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Background:

- Rapid HIV tests can:
 - Increase the number of persons who learn their HIV test results
 - Provide opportunities to offer perinatal prophylaxis for pregnant women whose HIV infection is not diagnosed antenatally
 - Facilitate HIV screening in high-prevalence settings such as emergency rooms and detention centers
- Newer whole blood rapid tests with subjective (visual) interpretation require evaluation in settings of their intended use, on fresh specimens for which they were designed (serum/plasma, whole blood, or oral fluid)

Methods:

- Six rapid HIV tests were evaluated:
 - 3 Immunoconcentration (flow-through) assays
 - MedMira – whole blood
 - MultiSpot – serum/plasma
 - Single Use Diagnostic System (SUDS) – serum, plasma
 - 3 Immunochromatographic (lateral flow) assays
 - Determine – whole blood
 - OraQuick – whole blood and oral fluid
 - Unigold – whole blood
- Only SUDS has been approved by U.S. Food and Drug Administration (FDA)
- Three part study:
 - Part I: Lab evaluation, 400 stored serum specimens to select rapid tests for further evaluation
 - Part II: Clinical study, 800 persons with known HIV status at Los Angeles Gay and Lesbian Center HIV testing site and West Hollywood STD Clinic. Specimens with discordant initial results (whole blood or plasma) and 10% of those with concordant results were retested on plasma specimens at CDC's HIV serology lab
 - Part III: Prospective study (ongoing), 2,000 persons with unknown HIV status at the two Los Angeles sites and the Maricopa County STD Clinic, Phoenix, AZ
- Rapid test results were compared with EIA/Western blot

Results:

Rapid Test Performance, Stored Serum

	True Positive	False Negative	True Negative	False Positive	Sensitivity	Specificity
MedMira	206	0	192	1	1.000	0.995
MultiSpot	206	0	192	0	1.000	1.000
SUDS	192	5	197	3	0.975	0.985
Determine	197	0	194	4	1.000	0.980
OraQuick	206	0	193	0	1.000	1.000
Unigold	195	2	192	8	0.990	0.960

Rapid Test Performance: Persons with known HIV status

	True Positive	False Negative	True Negative	False Positive	Sensitivity	Specificity
MedMira – blood	327	10	456	7	0.970	0.985
MultiSpot – plasma	331	0	463	4	1.000	0.991
SUDS – plasma	334	3	465	2	0.991	0.996
Determine – blood	334	0	467	0	1.000	1.000
OraQuick – plasma	337	0	466	1	1.000	0.998
Unigold – blood	319	15	466	1	0.955	0.998

MedMira, Determine and Unigold were performed immediately after whole blood was obtained by venipuncture into EDTA. SUDS was performed on fresh plasma; MultiSpot and OraQuick were performed on frozen plasma from these specimens.

Rapid Test Performance: Corrected after retesting on Plasma

	True Positive	False Negative	True Negative	False Positive	Sensitivity	Specificity
MedMira	330	7	465	1	0.979	0.998
MultiSpot	331	0	460	6	1.000	0.987
SUDS	337	1	466	1	0.997	0.999
Determine	335	0	467	0	1.000	1.000
OraQuick	337	0	466	1	1.000	0.998
Unigold	333	3	466	1	0.991	0.998

Rapid Test Performance – Persons with Unknown HIV Status

	True Positive	False Negative	True Negative	False Positive	Sensitivity	Specificity
MedMira – blood	67	5	1581	16	0.931	0.990
MultiSpot – plasma	45	0	769	0	1.000	1.000
SUDS – plasma	72	1	1641	6	0.986	0.996
Determine – blood	73	0	1649	2	1.000	0.999
OraQuick – blood	73	0	1639	2	1.000	0.999
– oral fluid	72	0	1569	18	1.000	0.989
Unigold – blood	33	5	1005	2	0.868	0.998
Unigold – serum	39	4	248	4	0.907	0.984

Specimens were false negative with different tests. Occurrence of a false-negative with the same specimen on more than one test was rare.

Conclusions:

- Each of the six rapid HIV tests was easy to perform in 20 minutes or less.
- Three of the rapid tests – Determine, OraQuick, and MultiSpot – demonstrated better sensitivity and specificity than the FDA-approved SUDS test. Determine and OraQuick appeared to perform well with whole blood as well as plasma. However, more false-positive results occurred when OraQuick was used with oral fluid than when it was used with whole blood.
- The MedMira and Unigold tests performed better with plasma than with whole blood, but neither demonstrated sensitivity comparable to that of SUDS.
- The performance of some of the new tests differed with different specimen types of specimens (i.e., whole blood, serum, oral fluid). Thus, evaluation of new tests must include all specimen types with which the test will be used.



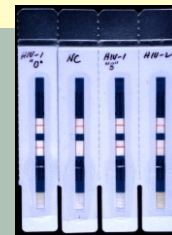
MedMira



MultiSpot



SUDS



Determine



OraQuick



Unigold

