Does Rapid Testing Promote Timelier Testing Among People at High Risk for HIV?

Investigation of High Risk Testers in Oregon 2003-2007

By
Tracy A. Eames

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CERTIFICATE OF APPROVAL

This is certify that the Master's thesis of

Tracy Eames

has been approved

[redacted]

Mentor/Advisor: Dongseok Choi, Ph.D.

[redacted]

Member: Sean Schafer, M.D.

[redacted]

Member: Mark Loveless, M.D.

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Abstract

Background: The Centers for Disease Control and Prevention (CDC) recommend regular, ongoing HIV testing for people who have repeated exposure. Rapid HIV antibody testing can be used in diverse settings, does not require a laboratory, and offers prompt results, making it more accessible than conventional antibody testing.

Objective: To examine whether rapid HIV tests are associated with timelier testing than conventional testing approaches among people in traditional risk groups.

Methods: We conducted secondary data analysis collected at the time of publicly funded HIV tests among people who acknowledged traditional HIV risk behaviors during 2003 – 2007. Type of testing (rapid or conventional antibody testing) was treated as the independent variable. Timely tests were defined as those administered within 6 months of the last reported negative HIV test. Using multivariate logistic regression, the association between test type and timeliness of testing, was examined while controlling for personal and circumstantial confounders.

Results: Rapid HIV tests were more likely to be timely (OR =1.62 CI 1.46, 1.78) after adjusting for race, age group, sex, geography of test location and reason for test.

Conclusions: After controlling for demographic variables and situational factors, rapid tests were associated with timelier testing than traditional antibody tests among people with declared ongoing risk of HIV infection. We believe this is a consequence of the inherent characteristics of rapid testing, in addition to program and client perceptions about relative acceptability and field convenience. Rapid testing is a useful tool to increase rates of regular, timely testing among people with ongoing risk of HIV infection.

Background

Awareness of HIV positive status can improve individual clinical outcomes and reduce secondary transmission.[1] Infected patients who begin antiretroviral therapy can lower their viral load, decreasing risk of transmission to their partners.[2] In addition, patients aware of their status decrease risky behaviors, further limiting HIV transmission.[1] And, early diagnosis allows public health officials to increase serostatus awareness through partner notification.[3]

The latest guidelines from the Center for Disease Control and Prevention (CDC) recommend universal HIV testing of adults and periodic testing of those with ongoing risk of acquisition. In particular, the guidelines emphasize testing high-risk populations and offering HIV tests in a variety of settings using rapid HIV testing.[4] In September 2006, The Centers for Disease Control and Prevention (CDC) began advising low risk patients be tested as needed after potential exposures, and high risk individuals test at least once a year.[4]

Rapid vs. Conventional HIV Testing

Conventional, two-stage serum antibody testing, including enzyme immunoassay (EIA) followed by Western Blot testing for confirmation of EIA-positive sera, has long been utilized for HIV screening and diagnostic testing.[5] Conventional testing is ideal for simultaneously testing large batches of HIV tests, must be done in a laboratory and can be technically demanding. A few days are needed to confirm positive EIAs, entailing two patient interactions, one for collection of the specimen, and a second for delivery of results. Because two contacts are required, approximately a third of people tested never receive the results.[1].

Rapid HIV testing reduces the complexity of HIV testing for the patient and the testing facility, while maintaining the reliability, sensitivity, and specificity of the EIAtest.[2] Rapid HIV tests can be administered in non-laboratory settings, are less technically demanding, and provide at least a preliminary result within the span of a single patient interaction for virtually all clients tested.[4] They can be conducted in disparate field locations, such as STD clinics, needle exchange sites, homeless shelters and bars, thereby bringing the test to the client instead of the client to the test.[8]

With these intrinsic and practical differences, rapid testing has been promoted as more effective tool for screening among people at high risk for HIV infection.[9]. This investigation compared timeliness of testing among high risk persons tested by conventional and by rapid HIV antibody testing in Oregon.

Methods

Study Subjects and Data Set

The data consisted of test results, individual characteristics, risk behaviors, reason for test, location of residence, and date/result of most recent previous HIV test of the person undergoing testing for all HIV tests subsidized by the State Public Health Division of Oregon during June 2003 – March 2007. All tests were conducted by local health departments and community-based organizations. Client names or identifiers were not available for analysis, and it was not possible to know how many unique clients contributed to the sample of tests. Therefore, the unit of analysis was the HIV test, not the person being tested. During this period in Oregon, clients tested could choose to provide their name and contact information to the testing site to be used in retrieving results later or locating the client if the follow-up session was missed. The names were not provided

to the Public Health Division. Some locations offered anonymous testing. Clients who chose anonymous testing did not provide their name but were given a unique identification number that matched a number used to label the specimen. Upon return for results, clients provided the unique identifier; the testing site matched to results and informed the client. If the client misplaced or forgot the identifier, it was not possible to match the client to his or her test result. Anonymous tests were included in our sample.

"High risk" clients were defined as those who were aged ≥13 years at the time of testing, had never previously tested positive for HIV, and acknowledged being a man who had sex with other men (MSM), injection drug use (IDU), exchanging sex for money, drugs or survival, sex or needle sharing with an HIV-infected person, or being a woman who had sex with men who also had sex with other men. We restricted the analysis to these high risk clients. Timely tests were defined as those administered within 6 months of the last reported negative HIV test. Tests missing interval since last negative test or any of the significant co-variables were excluded. This study was approved by the Oregon Health and Science Institutional Review Board in September 2006.

Variables

The exposure variable of interest was test algorithm (rapid or conventional). Covariates examined included race/ethnicity, age group, sex, state of residence, county of residence, reason for test, and confidentiality type (name-based or anonymous). The data on race and ethnicity had been collected as a single categorical variable: "White," "African American" "Hispanic," "Asian," "Native American/Alaska Native," "Hawaiian/Pacific Islander" and "Multi-racial." These were combined into four categories: "White, non-Hispanic," "African-American, non-Hispanic," "Hispanic," and

"Other." Asian, Native American/Alaska Native, Hawaiian/Pacific Islander, and Multi-racial were grouped into the "Other" category because of low numbers in all of these race/ethnicity categories. Age was collected as a categorical variable grouped into: 13-19, 20-29, 30-39, 40-49, and 50+. County of residence was converted to a three-level urbanization category (urban, mixed, rural), according to a schema used by the Oregon Health and Sciences University Office of Rural Health.

Statistical Analysis

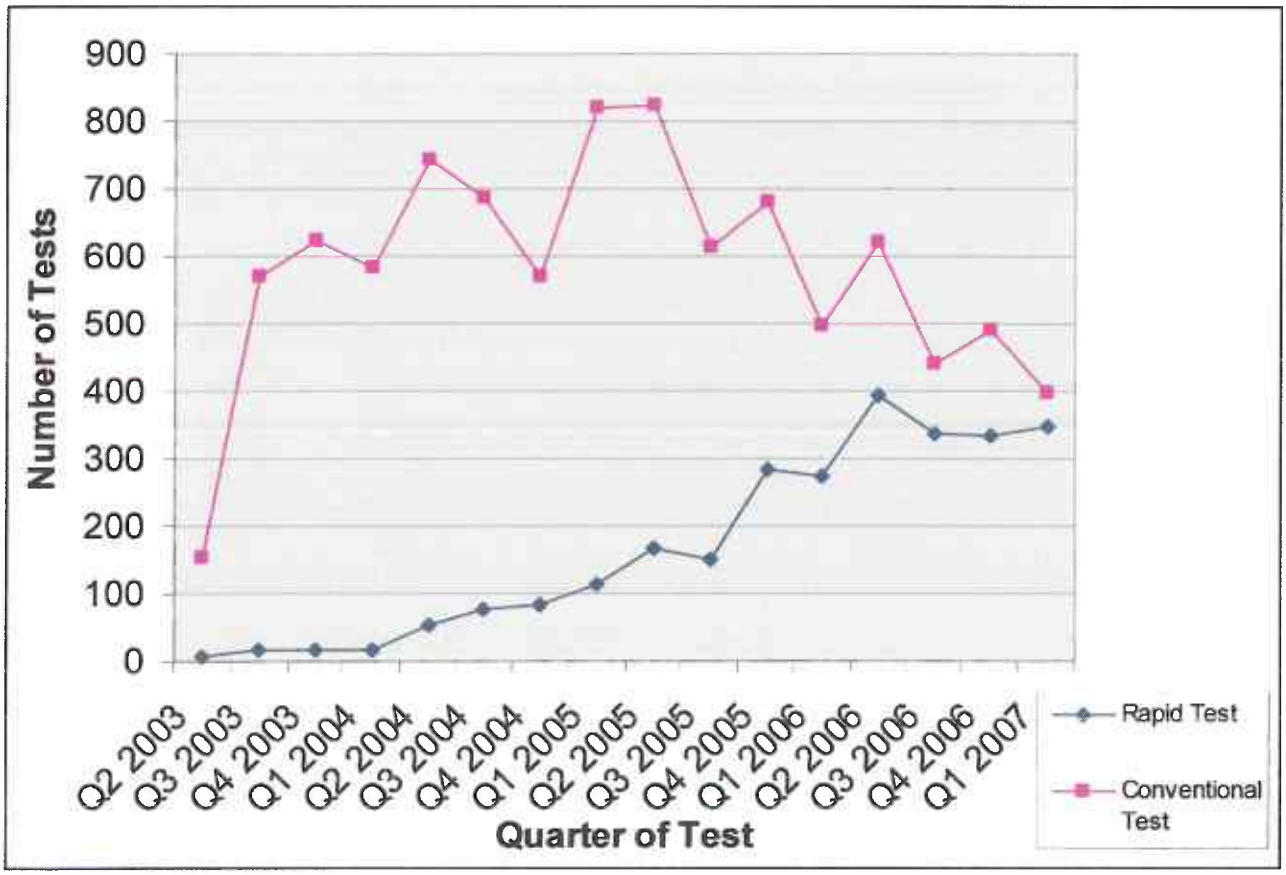
Frequencies of rapid and conventional tests were plotted over time. Frequencies and proportions were calculated for all other variables. We used bivariate, binomial logistic regression to assess the unadjusted association between test type and test timeliness and between each covariate and test timeliness. We used multivariate, binomial logistic regression to estimate the adjusted association between test type and test timeliness. The final model was chosen by backward stepwise selection. All variables significant at $p < 0.10$ in bivariate analysis were initially included in the full model. Variables not significant at $p < 0.05$ were removed, in order of least significant. Confounding and interactions were assessed between test algorithm and all other independent variables. SPSS, Version 15, Regression Module was used for regression analyses (SPSS®, Version 15, Chicago, 2006).

To the extent that an unknown proportion of tests represented repeat tests of individuals within the time period we analyzed, assumptions of independence were violated. To reduce the influence of repeat testers, we repeated the same analysis by year.

Results

During 2003 – 2007, publicly subsidized testing sites conducted 12,716 HIV tests among high-risk clients (Figure 1 and Table 1). From 2003 to 2007, rapid testing increased from zero to approximately 400 tests per quarter, and then leveled off at approximately 350 tests per quarter. Confidential testing increased slightly at the beginning of the period, leveled off at around 800 tests per quarter in 2005, and then decreased though the first quarter of 2007 (Figure 1).

Figure 1: Rapid Testing at Public Test Sites, Oregon



Tested clients were predominantly white (77%), male (66%), aged 20-49 years (95%), and living in urban or mixed urban-rural regions of the state (85%). (Table 1) Most clients reported intravenous drug use (IDU) (35%) or men having sex with men (MSM) (32%) as their HIV transmission risk. The confidentiality type was anonymous for 30% of HIV tests in this data set. Clients reported being asymptomatic for 91% of tests. The interval since previous HIV test was greater than 6 months for 73% of the test clients, while only 27% of test clients tested within 6 months of their previous negative HIV test. (Mean 27.91, SD 35.90). Missing values were infrequent: no independent variable was missing for more than 4% of the tests. Interval since last negative test—the outcome variable—was missing for 7% of the tests.

Table 1: HIV Testing Client and Test Attributes and Testing Intervals

Test Characteristic	**Tests (%)**
Sex	**12716**
Male	848 (66)
Female	4140 (33)
Missing	128 (1)
Age Group	**12716**
13 – 19	651 (5)
20 – 29	4278 (34)
30 – 39	3786 (30)
40 – 49	2836 (22)
50 +	1165 (9)
Missing	0
Race/Ethnicity	**12716**
White, Non-Hispanic	9812 (77)
Black, Non- Hispanic	587 (5)
Hispanic, All Races	1178 (9)
Other Race, Non-Hispanic	921 (7)
Missing	218 (2)
Urbanization Category	**12716**
Urban	5588 (44)
Mixed	5277 (42)
Rural	1787 (14)
Missing	64 (1)

Test Characteristic	Tests (%)
Confidentiality Type	**12716**
Confidential Test	8422 (66)
Anonymous Test	3789 (30)
Missing	505 (4)
Reason	**12716**
Symptomatic	137 (1)
Asymptomatic	11692 (92)
3rd Party Request	189 (2)
Other	475 (4)
Missing	223 (2)
State Residency	**12716**
Oregon State Resident	11768 (93)
Non-Oregon Resident	219 (2)
Missing	729 (6)
Test Algorithm	**12716**
Rapid Test	2752 (22)
Conventional Test	9964 (78)
Missing	0
Interval Since Previous Test	**12716**
≤6 mos.	3232 (27)
>6 mos.	8558 (73)
Missing	926 (7)
Risk/Transmission Group of Client	**12716**
MSM* & IDU**	559 (4)
MSM*	4027 (32)
Sex or Needle Partner HIV-Infected	696 (6)
IDU**	4445 (35)
Partner at Risk	2805 (22)
Sex for Money, Drugs, Survival	184 (1.4)
Missing	0

* Men who have sex with men.
** Intravenous Drug User

In univariate analysis, the odds of earlier testing was 70% higher among rapid tests than among conventional tests [OR 1.71 95%CI (1.56, 1.88)]. All independent variables had p values less than 0.001 except for Race/Ethnicity (p=0.599) and State of Residency (p=0.568).

Table 2: Unadjusted Association of Client Characteristics, Test Confidentiality, and Test Technology with Testing Interval Under Six Months.

Client/Test Characteristic	Testing Within Six Months (%)	p-value	Odds Ratio (95% CI)
Sex		**<0.001**	
Female	915 / 3818 (24)		Reference
Male	2278 /7857 (29)		1.29 (1.18,1.41)
Age		**<0.001**	
13-19	266 / 594 (45)		Reference
20-29	1158 / 3932 (30)		0.51 (0.43,0.61)
30-39	865 / 3521 (25)		0.40 (0.33,0.47)
40-49	643 / 2644 (24)		0.39 (0.32,0.47)
50+	300 / 1099 (27)		0.45 (0.37,0.56)
Race/Ethnicity		**0.599**	
White, NH	2513 / 9112 (28)		Reference
Black, NH	139/ 555 (25)		0.88 (0.72,1.07)
Hispanic	293/ 1092 (27)		0.97 (0.84,1.12)
Other	230/3175 (7)		1.0 (0.85,1.17)
Urbanization Category		**<0.001**	
Urban	1483 / 5228 (28)		Reference
Rural	296 / 1639 (18)		1.06 (0.97,1.15)
Mixed	1437/4863 (30)		0.56 (0.49,0.64)
Confidentiality Type		**<0.001**	
Confidential	2049 / 7754 (26)		Reference
Anonymous	1064 /3573 (34)		1.17 (1.08,1.28)
Reason for Test		**0.036**	
Symptomatic	31 /125 (25)		Reference
Asymptomatic	3979/10928 (27)		1.12 (0.75,1.68)
3rd Party Referral	47 /167 (28)		1.16 (0.69,1.95)
Other	125/368 (34)		1.54 (0.98,2.43)
State of Residency		**0.568**	
Oregon Resident	3225/11768 (27)		Reference
Non- Oregon Resident	55/219 (25)		1.13(0.83,1.53)
Test Algorithm		**<0.001**	
Conventional Test	2290 / 9186 (25)		Reference
Rapid Test	942 / 2604 (36)		1.71 (1.56,1.88)

After adjustment for covariates, rapid tests had 1.62 (95% CI: 1.46 – 1.78) times the odds of being timely (i.e. occurring within 6 months of the previous reported test). No

important confounding or interaction was observed. In addition, earlier testing had a 12% higher odds of being associated with confidential rather than anonymous testing, 31% higher odds of being male than female, almost twice the odds of being urban versus rural, and approximately 2 – 3 times the odds of being 13-19 years than over 20 years. (Table 3)

Table 3: Final Logistic Regression Model – Independent Variables Association with Timely vs. Delayed HIV Testing

Client/Test Characteristic	p-Value	Odds Ratio (95% CI)
Sex	<0.001	
Female		Reference
Male		1.31 (1.19 – 1.44)
Age (yrs.)	<0.001	
13-19		Reference
20-29		0.47 (0.39 – 0.56)
30-39		0.35 (0/29 – 0.43)
40-49		0.34 (0.28 – 0.42)
≥50		0.38 (0.30 – 0.47)
Region	<0.001	
Urban		Reference
Mixed		1.05 (0.96 – 1.15)
Rural		0.54 (0.46 – 0.62)
Confidentiality Type	0.022	
Anonymous		Reference
Confidential		1.12 (1.01 – 1.22)
Reason for Test	0.012	
Symptomatic		Reference
Asymptomatic		1.05 (0.68 – 1.61)
Other Reason		1.55 (0.95 – 2.51)
Third Party Referral		1.20 (0.69 – 2.10)
Test Algorithm	<0.001	
Conventional		Reference
Rapid		1.62(1.46 – 1.78)

After stratified analysis by year of test, odds of timely testing remained significantly higher among rapid testers for each full year during 2004 – 2006. Rapid tests had 1.80 greater adjusted odds of being timely tests than conventional tests [95% CI (1.33, 2.44)] in 2004. In 2005, rapid tests had 1.33 greater adjusted odds of being timely tests than conventional tests [95% CI (1.11, 1.61)]. And in 2006, rapid tests had 1.72 greater adjusted odds of being timely tests than conventional tests [95% CI (1.46, 2.03)]. (Table 4)

Table 4: – Adjusted Odds of Timely Testing among Rapid HIV Tests Compared to Conventional Tests – by Year of Test, 2004 – 2006.

Rapid Testing	p-value	Odds Ratio (95% CI)
2004[1]	<0.001	1.80 (1.33, 2.44)
2005 [1]	0.003	1.33 (1.11, 1.61)
2006 [1]	<0.001	1.72 (1.46, 2.03)

Reference Groups: [1] Conventional test.
Note: Each year's full model matched the investigations final model and included: Age, Sex, Test Reporting, Region, and Reason for Test.

Discussion

After adjustment for patient and circumstantial characteristics of testing, we found that rapid tests had 1.6 greater odds than conventional antibody tests to be associated with testing intervals of six months or less. In September 2006, The Centers for Disease Control and Prevention (CDC) began advising low risk patients to be tested as needed after potential exposures, and high risk individuals to test at least once a year.[4] Our findings suggest that deployment of rapid tests among populations at high risk does indeed increase the likelihood of timelier testing. Oregon currently offers rapid testing in

13 out of 36 counties. Increasing the use of rapid testing statewide could help Oregon meet the CDC recommendations and their goal to increase HIV testing opportunities.[10]

In addition to rapid testing, sex, age, region of residence, and choices about confidentiality were significantly associated with earlier testing. These variables should be considered in tailoring future testing outreach initiatives. To reach delayed testers, outreach could focus on patients older than 20 or specifically on female testers. Additionally, future testing initiatives can address contributing factors to delayed testing in rural areas.

The association between test type and test timeliness persisted after stratifying the analysis by year providing some reassurance that multiple tests for the same individual did not unduly influence the statistical conclusions.

Information about HIV risk and other covariates was obtained from patient interview by staff members at the HIV testing site. All publicly funded sites receive supervised training in client centered counseling and testing, but no systematic examination of validity or quality of these data was conducted. Errors in recording and transcription of data undoubtedly occurred as did intentional or unintentional client response. These errors are likely to have contributed to non-differential bias, and consequently biased findings toward the null.

Future Research

Key improvements to the data set and collection methods could improve future research analyses. Linking patients' previous tests through a unique patient identifier would facilitate future testing pattern analysis while maintaining patient privacy.

The patient risk information was only collected in publicly subsidized HIV testing settings and can only be properly interpreted or generalized in the context of publicly-funded testing directed at people with ongoing risk for acquisition of HIV. Most HIV testing is done in private clinical settings such as doctors' offices and hospitals. During the period examined in this report, systematic data on test results and reason for test were being collected from private settings in Oregon, but risk was not included in these reports. Since that time, Oregon has ceased collecting individual data on HIV tests done in the private sector.

Future investigations could explore if behavior patterns change, favorably or unfavorably, depending on test result. Past investigations have demonstrated that positive patients tend to change their behavior upon learning their status. Future research could explore if similar behavior changes occur in patients who receive a negative HIV result. In addition, investigators could further analyze behavior of patients who receive a preliminary positive in the field. Specifically, do these patients get a confirmatory test and/or do they reduce their risky behavior as is seen with conventional tests? Lastly, future research could build on findings in this investigation and explore additional factors that increase timelier testing. Specifically, analysis could focus on why high risk 13-19 year olds get tested timelier than patients older than 20 or what precludes rural testers from testing timelier.

References

1. Valdisserri, R.O, Holtgrave, D.R., & West, G.R. (1999). Promoting early diagnosis and entry into care. AIDS. 13:2317-2330.

2. Branson, B.M. (2003) Point-of-Care Rapid Tests for HIV Antibodies. J. Lab Med. Vol 27. No7/8, 288-295

3. Beckwith, C.G., Flanigan, T.P, del Rio, C., Wing, E.J., Carpenter, C.J., & Bartlett, J.G. (2005, April) It is time to implement routine, not risk-based HIV testing. CID, 40, 1037-1040.

4. Center for Disease Control and Prevention. Revised Recommendations for HIV testing of adults, adolescents, and pregnant women in health care settings. (2006, September). MMWR. Vol 55.no.RR-14. Department of Health and Human Services.

5. Center for Disease Control and Prevention. Evolution of HIV/AIDS prevention programs—United States, 1981—2006. (2006, June). MMWR, 55(21); 597-603. Department of Health and Human Services.

6. Center for Disease Control and Prevention: Advancing HIV Prevention: new strategies for a changing epidemic-United States, 2003. MMWR 2003,52:329-332.

7. Center for Disease Control and Prevention.OraQuick Rapid HIV Test for Oral Fluid – (2004, November) Frequently Asked Questions.

8. Spielberg, F., Branson, B.M., Goldbaum, G.M., Lockhart, D., Kurth, A., Celum, C.L., Rossini, A., Critchlow, C.W., & Wood, R.W. (2003). Overcoming barriers to HIV testing: preferences for new strategies among clients of a needle exchange, a sexually transmitted disease clinic, and sex venues for me who have sex with men. Journal of Acquired Immuno Deficiency Syndrome. 32:318-328.

9. Greenwald, J.L, Burstein, G.R., Pincus, J., & Branson, B. (2006). A rapid review of rapid HIV antibody tests. Current Infectious Disease Reports. 8:125-131.

10. Oregon Statewide HIV Prevention Planning Group. (2005). Oregon HIV Prevention Comprehensive Plan. Portland, OR. Oregon Department of Human Services HIV/STD/TB Program

DHS
Oregon Department of Human Services

HUMAN IMMUNODEFICIENCY VIRUS (HIV) TEST REPORT FORM

1018573

TO BE COMPLETED BY HEALTH CARE PROVIDER ORDERING THE TEST

The front (white) page of this form may be kept for your records. The second (yellow) and third (pink) copies must accompany any specimen sent for HIV testing to a laboratory in Oregon other than the Oregon State Public Health Laboratory (OSPHL). Use form 44 for HIV test specimens submitted to OSPHL. This individual for whom a HIV test has been requested, has been informed about the HIV test in full accordance with Oregon law and regulations and has consented to be tested. The individual has been given full opportunity to ask questions and receive adequate answers.

Health Care Provider's Name (please print)

Address of Health Care Provider Ordering the Test (please print)

City State Zip

Signature of Health Care Provider Ordering the Test or Designee Date

INFORMATION ABOUT TESTED INDIVIDUAL

1. **AGE** 2. **COUNTY OF RESIDENCE** (or State if other than Oregon)
3. **SEX** (Circle one): (M) (F) (Other)
4. **ETHNICITY** (Check one):
   [ ] Hispanic or Latino [ ] Not Hispanic or Latino
5. **RACE** (Select one or more):
   [ ] Am Indian/AK Native [ ] Asian
   [ ] Black/African-American [ ] Native Hawaiian/Pacific Islander
   [ ] White
6. **PREVIOUS HIV TEST STATUS** (Check one):
   [ ] No Previous Test
   [ ] Previous Test Negative
   [ ] Previous Test Positive
   [ ] Unknown
7. **CLIENT'S REASON FOR TEST** (Check one only):
   [ ] Part of prenatal care.
   [ ] Self-initiated and asymptomatic.
   [ ] Client reports symptoms suggestive of HIV infection.
   [ ] Referred from STD clinic.
   [ ] DIS or epi nurse referral/Notified of HIV contact.
   [ ] Court-ordered.
   [ ] Immigration/travel requirement.
   [ ] Occupational exposure.
   [ ] Victim of sexual assault.
   [ ] Other, specify:

TO BE COMPLETED BY CLINIC OR LABORATORY PERFORMING THE TEST

[ ] RAPID TEST: RESULT: [ ] NEGATIVE [ ] PRELIMINARY POSITIVE
Note: Send this form in to the lab with another serum or *Orasure* specimen if the result is "preliminary positive."

TEST RESULTS: (Check all that apply):		Positive	Negative	Equivocal
1.	Initial EIA	[P]	[N]	[E]
	Confirmatory Tests			
2.	Repeat EIA (if done)	[P]	[N]	[E]
3.	Western Blot (if done)	[P]	[N]	[ ] Indeterminate
4.	IFA (If done)	[P]	[N]	[E]
5.	P24 Antigen Test (if done)	[P]	[N]	[E]
6.	Other (Specify)	[P]	[N]	[E]

Submit pink copy of this form within one week of completion of final testing to: OSPHL, 1717 SW 10th AVE., PORTLAND, OR 97201 • PHONE: (503) 229-5882 • FAX: (503) 229-5682

OPTIONAL

IDENTIFYING INFORMATION - FOR PROVIDER AND LABORATORY USE ONLY. This information **does not** appear on the copy of this form that is sent to the Department of Human Services.

Patient name:

Address:

Phone: Patient Chart Number:

To order more forms, call or write:
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