



Differences among diagnostic testing algorithms in the time from HIV diagnosis to care[☆]



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ABSTRACT

Background: The association between the type of diagnostic testing algorithm for HIV infection and the time from diagnosis to care has not been fully evaluated. Here we extend an earlier analysis of this association by controlling for patient and diagnosing facility characteristics.

Study design: Descriptive analysis of HIV infection diagnoses during 2016 reported to the National HIV Surveillance System through December 2017. Algorithm type: traditional = initial HIV antibody immunoassay followed by a Western blot or immunofluorescence antibody test; recommended = initial HIV antigen/antibody immunoassay followed by HIV-1/2 type-differentiating antibody test; rapid = two CLIA-waived rapid tests on the same date.

Results: In multivariate analyses controlling for patient and diagnosing facility characteristics, persons whose infection was diagnosed using the rapid algorithm were more likely to be linked to care within 30 days than those whose infection was diagnosed using the other testing algorithms ($p < 0.01$). The median time to link to care during a 30-day follow-up was 9.0 days (95% CI 8.0–12.0) after the rapid algorithm, 17.0 days (95% CI 17.0–18.0) after the recommended algorithm, and 23.0 days (95% CI 22.0–25.0) after the traditional algorithm.

Conclusions: The time from HIV diagnosis to care varied with the type of testing algorithm. The median time to care was shortest for the rapid algorithm, longest for the traditional algorithm, and intermediate for the recommended algorithm. These results demonstrate the importance of choosing an algorithm with a short time between initial specimen collection and report of the final result to the patient.

1. Background

The US surveillance case definition for human immunodeficiency virus (HIV) infection was updated in 2014 to accommodate changes in diagnostic practice; for persons aged ≥ 18 months, laboratory test criteria require a positive result from a nucleic acid test (NAT) or from two different serologic HIV tests—an initial antibody or combination antigen/antibody HIV test, followed by a supplemental antibody test that is different from the first test. Several approved testing schemes fulfill these requirements, such as those that use a western blot (WB) or immunofluorescence assay (IFA) as the supplemental antibody test, those that use an HIV-1/2 type differentiation immunoassay (IA) as the supplemental test, or those that use two different antibody or antigen/antibody rapid tests for which the Clinical Laboratory Improvement

Amendments (CLIA) requirements were waived [1–5]. There are other sequences of tests that may meet the surveillance case definition but no laboratory or clinical guidelines have been developed for such sequences of tests.

How quickly a person is linked to medical care for HIV infection has been shown to be associated with the type of diagnostic testing algorithm; persons whose infection was diagnosed using the recommended algorithm were more frequently linked to care within 30 days after diagnosis than those whose infection was diagnosed using the traditional algorithm [6]. Other studies have found that reluctance of patients to schedule healthcare appointments for supplemental testing to confirm a preliminary diagnosis based only on an initial immunoassay was associated with a longer delay before receiving care [7–9]. The rapid algorithm also increased the likelihood of being linked to care

Abbreviations: CDC, Centers for Disease Control and Prevention; CLIA, Clinical Laboratory Improvement Amendments; HIV, human immunodeficiency virus; IDU, injection drug use; NHSS, National HIV Surveillance System; IA, immunoassay; IFA, immunofluorescence assay; WB, western blot; NAT, nucleic acid test; NIR, no identified/reported risk factor

[☆] The findings and conclusions in this article are those of the authors and do not necessarily represent the views of the Centers for Disease Control and Prevention.

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within 90 days in some populations tested for HIV in nonclinical settings [10].

Our previous study [6] of trends in testing algorithms did not control for possible confounding variables, such as patient factors (e.g., demographics) and diagnosing facility characteristics (e.g., clinic type and location). To assess the effect of these factors, we performed multivariate and univariate Cox proportional hazards analysis in which these factors, in addition to the type of testing algorithm, were included as independent variables in the model, with the time from diagnosis to care as the dependent variable. We performed a time-to-care analysis to calculate the median time to care after each type of algorithm.

2. Objective

To examine the association of the type of diagnostic testing algorithm for HIV infection with linkage to care within 30 days after diagnosis.

3. Study design

We analyzed test results for HIV infections diagnosed during 2016 and reported to the National HIV Surveillance System (NHSS) through December 2017. Data were available for the analysis of linkage to HIV care for persons who resided in one of the 40 jurisdictions with complete reporting of HIV-related laboratory tests indicative of care after diagnosis. Jurisdictions were classified as having complete reporting if they had laws or regulations in place before 2016 that required laboratories to report to the health department all levels of CD4 T-lymphocyte test results and all viral load results, laboratories reporting HIV-related tests had reported $\geq 95\%$ of the HIV-related test results to the jurisdictions' health departments, and these health departments had reported to NHSS $\geq 95\%$ of the test results they received by December 2017 [11]. We interpreted various sequences or combinations of test results as representing diagnostic testing algorithms or diagnosis types, and we classified them into 4 categories:

- Traditional algorithm: the first positive test was any HIV-1 (or combination HIV-1/2) antibody IA that was not a CLIA-waived rapid test, followed within 30 days by a positive WB or IFA. A prior positive result from the initial IA was presumed if the first reported result was from a WB or IFA.
- Recommended algorithm: the first positive test was an HIV-1/2 IA that could detect both HIV antigen and antibody and was not a CLIA-waived rapid test, followed within 30 days by a supplemental IA that could detect only IgG HIV antibodies and differentiate between HIV-1 and HIV-2 antibodies. A prior positive result from an initial IA was presumed if the reported first test was an IgG-only type-differentiating antibody test.
- Rapid algorithm: the first positive test was a CLIA-waived rapid IA, followed by a different positive CLIA-waived rapid IA on the same day.
- Other or unspecified test sequences: a sequence of tests that did not fit into the other defined categories of algorithms or for which the only documentation available to surveillance staff was a physician's note in the medical record, rather than a laboratory report.

We used multivariate Cox proportional hazards regression models to estimate the association between the type of diagnostic testing algorithm and the time from diagnosis to care, while controlling for patient and diagnosing facility factors found to be significantly associated with the time to care in univariate analyses (age group, race/ethnicity, transmission category, region of residence at diagnosis, and facility type at diagnosis) [12,13]. To examine the extent to which the type of diagnostic testing algorithm predicted the time to care, and to calculate the median time to care after HIV diagnosis by each type of algorithm, we performed a non-parametric cumulative proportion analysis [14].

Table 1

Comparison of persons included and excluded from the analysis, by demographic and other characteristics, among persons with HIV diagnosed during 2016 who resided in 39 states and the District of Columbia^a.

	Included		Excluded		p value ^h
	N	% ^b	N	% ^b	
Diagnostic testing algorithm type					
Traditional ^c	2770	9.0	476	16.7	< 0.001
Recommended ^d	22,010	71.4	1,795	62.9	
Rapid ^e	353	1.1	84	2.9	
Other ^f	5693	18.5	499	17.5	
Age group at diagnosis					
Aged 13-24 Years	6696	21.7	627	22.0	0.75
Aged 25-34 Years	10,612	34.4	981	34.4	
Aged 35-44 Years	5817	18.9	561	19.7	
Aged 45-54 Years	4668	15.1	416	14.6	
Aged 55+ Years	3033	9.8	269	9.4	
Sex					
Female	5875	19.1	532	18.6	0.59
Male	24,951	80.9	2,322	81.4	
Race/ethnicity					
Black/African American	13,493	43.8	1,528	53.5	< 0.001
Hispanic/Latino ^g	7786	25.3	688	24.1	
White	7745	25.1	509	17.8	
Other	1802	5.9	129	4.5	
Transmission category					
Male-to-male sexual contact	17,487	56.7	1,185	41.5	< 0.001
Injection drug use (IDU)	1060	3.4	85	3.0	
Male-to-male sexual contact/IDU	882	2.9	40	1.4	
Heterosexual contact (HET)	4699	15.2	351	12.3	
No identified risk factor (NIR)	6672	21.6	1,193	41.8	
Other	26	0.1	–	–	
Region of residence at diagnosis					
Northeast	3657	11.9	260	9.1	< 0.001
Midwest	3720	12.1	241	8.4	
South	17,580	57.0	1,689	59.2	
West	5869	19.0	664	23.3	
Facility type					
Inpatient	5321	17.3	299	10.5	< 0.001
Outpatient	14,328	46.5	1,208	42.3	
Emergency room	689	2.2	81	2.8	
Screening	5430	17.6	830	29.1	
Correction	822	2.7	58	2.0	
Other	4236	13.7	378	13.2	
Total	30,826	100.0	2854	100.0	

^a Based on data from the Centers for Disease Control and Prevention's National HIV Surveillance System collected through December 2017.

^b Percentage of the total for the row.

^c The first positive test was an HIV-1 immunoassay (IA), followed within 30 days by a Western blot or immunofluorescence assay.

^d The first positive test was an HIV-1 IA that could detect both HIV antigen and antibody, followed within 30 days by a supplemental IA that could detect HIV antibodies and differentiated between HIV-1 and HIV-2 antibodies.

^e The first positive test was a CLIA-waived, rapid IA, followed by another positive CLIA-waived, rapid IA, on the same day.

^f A sequence of tests that does not fit into the other types of defined algorithms or a diagnosis documented by a physician.

^g Hispanic/Latino may be of any race; all other racial/ethnic groups shown are persons not known to be Hispanic/Latino.

^h From a chi-square test comparing frequencies in the included and excluded groups.

This method allowed both persons who were and persons who were not linked to care during the 30 days of follow-up to be included in the calculation of the median time to care, provided that at least 50% of them were linked to care during that period. The time-to-event variable in this analysis was defined as the time from date of diagnosis to date of linkage to care.

The date of linkage to care was defined as the date of specimen collection for the first CD4 test or viral load measurement after the diagnosis date (not on the same date as diagnosis). The date of HIV diagnosis was defined as the earliest date of specimen collection for the

Table 2
Median time to care, by HIV diagnostic testing algorithm type, for diagnoses during 2016 who resided in 39 states and the District of Columbia^a.

Diagnostic testing algorithm type	Median time to care ^b	
	Days	95% CI
Traditional ^c	23.0	22.0–25.0
Recommended ^d	17.0	17.0–18.0
Rapid ^e	9.0	8.0–12.0
Other ^f	–	–

^a Based on data from the Centers for Disease Control and Prevention's National HIV Surveillance System collected through December 2017.

^b Calculated during a 30-day follow-up period.

^c The first positive test was an HIV-1 immunoassay (IA), followed within 30 days by a Western blot or immunofluorescence assay.

^d The first positive test was an HIV-1 IA that could detect both HIV antigen and antibody, followed within 30 days by a supplemental IA that could detect HIV antibodies and differentiated between HIV-1 and HIV-2 antibodies.

^e The first positive test was a CLIA-waived, rapid IA, followed by another positive CLIA-waived, rapid IA, on the same day.

^f A sequence of tests that does not fit into the other types of defined algorithms or a diagnosis documented by a physician.

patient's positive HIV tests reported to NHSS. To measure accurately the time to care, patients with incomplete dates of diagnosis or linkage to care were excluded from the Cox proportional hazard analysis and the calculation of median time to care. All analyses were performed using SAS v9.4 (Cary, NC).

4. Results

Of the total of 33,680 reported diagnoses of HIV infection in 2016, 2854 (8.5%) were excluded from the Cox proportional hazard analysis and the calculation of median time to care because of incomplete dates of diagnosis or linkage to care (Table 1). The distribution of diagnoses by testing algorithm type among the 30,826 remaining diagnoses differed significantly from that among the 2854 excluded diagnoses ($p < 0.01$) (Table 1). The distributions of included and excluded di-

agnoses also differed significantly by the diagnosing facility type, patient's race/ethnicity, region of residence at diagnosis, and transmission category ($p < 0.01$), but not by sex or age group ($p \geq 0.05$) (Table 1).

Among persons included in the hazard analysis ($n = 30,826$), the median time to care during a 30-day follow-up was 9.0 days (95% CI 8.0–12.0) after HIV diagnosis by the rapid algorithm, 17.0 days (95% CI 17.0–18.0) after the recommended algorithm, and 23.0 days (95% CI 22.0–25.0) after the traditional algorithm. Less than 50% of persons whose infection was diagnosed using other or unspecified test sequence types were linked to care within 30 days, so their median time to care could not be calculated (Table 2). Fig. 1a and b show unadjusted and adjusted cumulative proportion curves, respectively, for linkage to care for persons whose infection was diagnosed using the recommended algorithm, traditional algorithm, rapid algorithm and other test sequences.

Among persons included in the Cox proportional hazard analysis ($n = 30,826$), overall 62.1% were linked to care within 30 days after diagnosis of HIV infection. Compared to persons diagnosed by the rapid algorithm, the percentage of persons linked to care within 30 days after HIV diagnosis was lower for the other testing algorithms in the Cox proportional hazards analysis (Table 3). Persons whose HIV diagnosis used the recommended algorithm were also significantly more likely to be linked to care within 30 days than persons whose diagnosis used the traditional algorithm and other or unspecified test sequences (data not shown). Other variables also were associated with linkage to care within 30 days after diagnosis. In the multivariate Cox model the probability of being linked to care was higher for persons aged 45–54 years at diagnosis than for those who were younger; higher after diagnoses in emergency rooms than after diagnoses in all other diagnosing facility types except inpatient facilities; lower for persons who were non-Hispanic black/African Americans than for non-Hispanic whites, Hispanics, or other racial/ethnic groups; lower for persons who resided in the US South at diagnosis than for those who resided in the Northeast, Midwest, or West; higher for persons reported with a history of male-to-male sexual contact than for persons reported with a history of injection drug use (IDU) or persons with both of these HIV risk factors (male-to-male sex and IDU) (Table 3). We omitted sex from the final multivariate model because it was not associated with linkage to care in univariate or preliminary multivariate analyses.

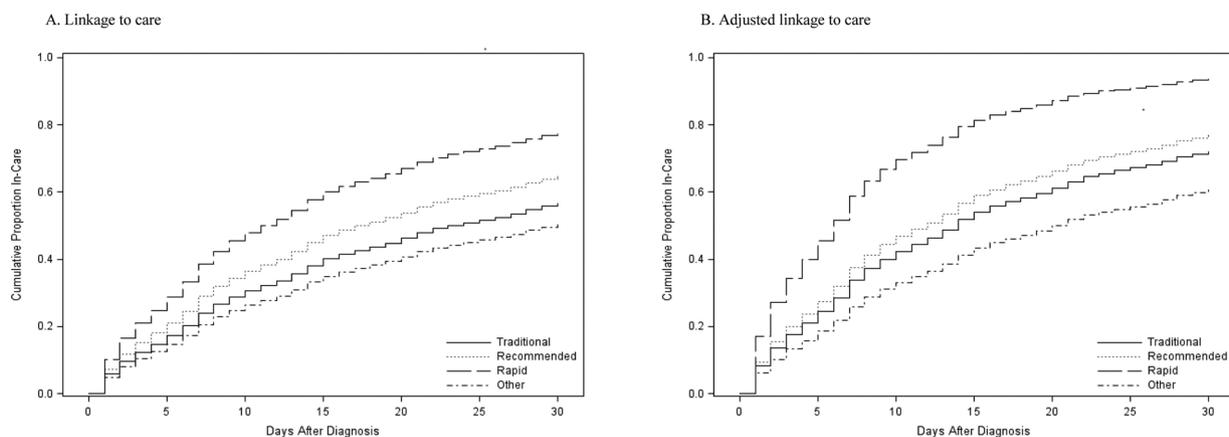


Fig. 1. Cumulative proportion of patients linked to care, by days after HIV infection diagnosis, stratified by type of diagnostic testing algorithm, 2016 who resided in 39 states and the District of Columbia.

A. Linkage to care.

B. Adjusted linkage to care.

Traditional: The first recorded positive test was an HIV-1 immunoassay (IA), followed within 30 days by a western blot or immunofluorescence assay.

Recommended: The first recorded positive test was an HIV-1 IA that could detect both HIV antigen and antibody, followed within 30 days by a supplemental IA that could detect HIV antibodies and differentiated between HIV-1 and HIV-2 antibodies.

Rapid: The first recorded positive test was a CLIA-waived, rapid IA, followed by another positive CLIA-waived, rapid IA, on the same day.

Other: A sequence of tests that does not fit into the other types of defined algorithms or a diagnosis documented by a physician.

Table 3

Variation in linkage to care within 30 days after HIV diagnosis, by diagnostic testing algorithm type, facility type, and demographic characteristics of persons aged ≥ 13 years with HIV diagnosed during 2016 who resided in 39 states and the District of Columbia^a.

	Linkage to Care		Univariate Analysis			Multivariate Analysis		
	No	%	Odds Ratio	95% CI	Adjusted Odds Ratio	95% CI		
Diagnostic testing algorithm type								
Traditional ^b (N = 2770)	1,596	57.6	0.56	0.49	0.64	0.46	0.41	0.53
Recommended ^c (N = 22,010)	14,468	65.7	0.70	0.62	0.79	0.53	0.47	0.60
Rapid (Referent) ^d (N = 353)	271	76.8	1.00	—	—	1.00	—	—
Other ^e (N = 5693)	2,815	49.5	0.47	0.41	0.53	0.34	0.30	0.38
Age group at diagnosis								
Aged 13-24 Years (N = 6696)	3,974	59.4	0.80	0.76	0.84	0.86	0.82	0.91
Aged 25-34 Years (N = 10,612)	6,445	60.7	0.84	0.81	0.88	0.89	0.85	0.93
Aged 35-44 Years (N = 5817)	3,696	63.5	0.93	0.88	0.97	0.94	0.90	0.99
Aged 45-54 Years (Referent) (N = 4668)	3,084	66.1	1.00	—	—	1.00	—	—
Aged 55+ Years (N = 3033)	1,951	64.3	0.99	0.93	1.04	0.97	0.91	1.02
Sex								
Female (N = 5875)	3,666	62.4	1.00	0.97	1.04	not in model ^g		
Male (Referent) (N = 24,951)	15,484	62.1	1.00	—	—			
Race/ethnicity								
Black/African American (Referent) (N = 13,493)	7,984	59.2	1.00	—	—	1.00	—	—
Hispanic/Latino ^f (N = 7786)	4,948	63.6	1.12	1.08	1.16	1.08	1.04	1.13
White (N = 7745)	5,032	65.0	1.17	1.13	1.21	1.14	1.10	1.19
Other (N = 1802)	1,186	65.8	1.18	1.11	1.26	1.12	1.05	1.19
Transmission category								
Male-to-male sexual contact (Referent) (N = 17,487)	10,873	62.2	1.00	—	—	1.00	—	—
Injection drug use (IDU) (N = 1060)	674	63.6	1.09	1.01	1.18	0.89	0.82	0.96
Male-to-male sexual contact and IDU (N = 882)	527	59.8	0.96	0.88	1.05	0.89	0.81	0.97
Heterosexual contact (HET) (N = 4699)	2,890	61.5	0.99	0.95	1.03	0.96	0.92	1.01
No identified risk factor (NIR) (N = 6672)	4,170	62.5	1.07	1.03	1.11	0.97	0.93	1.00
Other (N = 26)	16	61.5	0.88	0.54	1.44	0.93	0.57	1.52
Region of residence at diagnosis								
Northeast (N = 3657)	2,604	71.2	1.43	1.37	1.49	1.26	1.21	1.32
Midwest (N = 3720)	2,316	62.3	1.12	1.07	1.17	1.12	1.07	1.17
South (Referent) (N = 17,580)	10,393	59.1	1.00	—	—	1.00	—	—
West (N = 5869)	3,837	65.4	1.22	1.17	1.26	1.18	1.14	1.23
Facility type								
Inpatient (N = 5321)	3,908	73.4	1.14	1.04	1.25	1.14	1.03	1.25
Outpatient (N = 14,328)	8,950	62.5	0.69	0.63	0.75	0.66	0.61	0.73
Emergency room (Referent) (N = 689)	500	72.6	1.00	—	—	1.00	—	—
Screening (N = 5430)	2,843	52.4	0.50	0.45	0.55	0.48	0.44	0.53
Correction (N = 822)	540	65.7	0.76	0.67	0.85	0.78	0.69	0.88
Other (N = 4236)	2,409	56.9	0.61	0.55	0.67	0.66	0.60	0.73
Total	19,150	62.1						

^a Based on data from the Centers for Disease Control and Prevention's National HIV Surveillance System collected through December 2017.

^b The first positive test was an HIV-1 immunoassay (IA), followed within 30 days by a Western blot or immunofluorescence assay.

^c The first positive test was an HIV-1 IA that could detect both HIV antigen and antibody, followed within 30 days by a supplemental IA that could detect HIV antibodies and differentiated between HIV-1 and HIV-2 antibodies.

^d The first positive test was a CLIA-waived, rapid IA, followed by another positive CLIA-waived, rapid IA, on the same day.

^e A sequence of tests that does not fit into the other types of defined algorithms or a diagnosis documented by a physician.

^f Hispanic/Latino may be of any race; all other racial/ethnic groups shown are persons not known to be Hispanic/Latino.

^g Sex was omitted from the final multivariate model because it had no significant association in the univariate or preliminary multivariate models.

5. Discussion

One of the goals of the Centers for Disease Control and Prevention, Division of HIV/AIDS Prevention Strategic Plan 2017–2020 is to improve health outcomes for persons living with HIV. One objective of this goal is to increase the percentage of persons with diagnosed HIV who are linked to care within one month after diagnosis [15]. Additionally, an estimated 85% of individuals with HIV have received the diagnosis, 73% of whom have received some HIV care and only 60% of whom have achieved viral suppression [16]. Therefore, effective interventions to increase voluntary testing and awareness of HIV status and to strengthen linkage to care should be put in place to achieve this goal. In this study, persons whose HIV diagnosis used the rapid algorithm were significantly more likely to be linked to care within 30 days than

persons whose diagnosis used any other diagnostic method. Other studies have shown that a reluctance to schedule healthcare appointments for supplemental testing to confirm the diagnosis and initiate treatment was associated with a longer time for persons with HIV infection to be linked to care [9]. The rapid algorithm also increased the likelihood of linkage to care within 90 days after diagnosis without reduced test specificity for HIV infection [10]. However, rapid algorithms have a lower sensitivity than the laboratory-based recommended algorithm, particularly during early HIV infection, when CLIA-waived rapid tests are more likely to have false negative results [17].

In this study, the higher percentage of patients linked to care after a rapid algorithm than after other algorithms may be explained by rapid algorithms having shorter times from specimen collection to reporting the result to the patient. This makes possible reporting of the HIV test

result to the patient before they leave the diagnosing facility and without the need to schedule an appointment to confirm diagnosis. Facilities that perform the rapid algorithm likely also have processes in place for linking persons diagnosed with HIV infection to care to initiate treatment. After a meta-analysis of available data an expert review panel has recommended the following to increase linkage to care after diagnosis: immediate referral to HIV care, use of case managers and patient navigators, and proactive engagement and reengagement of patients who miss appointments [18].

This study was subject to several limitations. First, it cannot be determined from NHSS data whether multiple tests belonged to the same diagnostic algorithm. Therefore, some tests that seemed to fit the sequence of an algorithm may have been from independent testing events. Second, some health departments may not have reported to the NHSS negative or indeterminate results from supplemental HIV antibody tests used as part of a recommended algorithm, because reporting of such results by laboratories or healthcare providers to the health department may not have been required by reporting laws or regulations. As a result, some algorithms could have been misclassified in the “other/unspecified” category, leading to undercounting of those in the remaining algorithms. Third, we did not accept a CD4 test or viral load as evidence of care if its specimen collection date was the same as the diagnosis date to avoid mistaking a viral load used for diagnosis as a viral load used to manage care resulting in all persons with infection diagnosed with a viral load as having 0 days to linkage to care. We also did not accept a CD4 test or viral load as evidence of care with incomplete specimen collection dates. As a result, our estimates of linkage to care are lower than those published elsewhere that include viral loads as markers of care despite their being on the same date as diagnosis [11]. Fourth, some NHSS data may have been incompletely or erroneously entered, resulting in over- or under-estimation of the numbers of persons whose diagnoses used particular types of testing algorithms. Fifth, patients with incomplete dates of diagnosis were excluded from this analysis and this group differed from the included group on the distribution of type of diagnostic testing algorithm; nearly 40% of the excluded results were of persons diagnosed using the traditional or other algorithms. This may bias the results presented here and limit the generalizability of our findings to persons with HIV diagnosed at facilities that have complete reporting of test data.

In summary, while controlling for patient and diagnosing facility characteristics, we found that persons whose HIV diagnosis used the rapid algorithm were significantly more likely to be linked to care within 30 days than persons whose diagnosis used any other diagnostic method. Other factors associated with a greater likelihood of linkage to care within 30 days were diagnoses in an emergency room or inpatient facility, older age, race/ethnicity other than black/African American, a history of male-to-male sexual contact, and residence in a US region other than the South. Our findings that the use of the rapid algorithm is associated with increased linkage to care within 30 days after diagnosis highlight the importance of diagnosing HIV infection and reporting the results to the patient on the same day. To take advantage of this, testing facilities must also have programs in place to quickly link the person to care.

CRediT authorship contribution statement

Anne Harwood Peruski: Conceptualization, Methodology, Writing - original draft, Writing - review & editing, Visualization, Supervision. **Baohua Wu:** Software, Formal analysis, Visualization, Writing - review & editing. **Richard M. Selik:** Methodology, Writing - review & editing.

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