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## Trends in testing algorithms used to diagnose HIV infection, 2011–2015, United States and 6 dependent areas

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### Abstract

**Background:** In 2014 the Centers for Disease Control and Prevention (CDC) and the Association of Public Health Laboratories (APHL) issued updated laboratory testing recommendations for the diagnosis of HIV infection.

**Objectives:** To examine trends in the use of HIV diagnostic testing algorithms, and determine whether the use of different algorithms is associated with selected patient characteristics and linkage to HIV medical care.

**Study design:** Analysis of HIV infection diagnoses during 2011–2015 reported to the National HIV Surveillance System through December 2016. Algorithm classification: traditional = initial HIV antibody immunoassay followed by a Western blot or immunofluorescence antibody test; recommended = initial HIV antibody IA followed by HIV-1/2 type-differentiating antibody test; rapid = two CLIA-waived rapid tests on same date.

**Results:** During 2011–2015, the percentage of HIV diagnoses made using the traditional algorithm decreased from 84% to 16%, the percentage using the recommended algorithm increased from 0.1% to 64%, and the percentage using the rapid testing algorithm increased from 0.1% to 2%. The percentage of persons linked to care within 30 days after HIV diagnosis in 2015 was higher for diagnoses using the recommended algorithm (59%) than for diagnoses using the traditional algorithm (55%) ( $p < 0.05$ ).

**Conclusions:** During 2011–2015, the percentage of HIV diagnoses reported using the recommended and rapid testing algorithms increased while the use of the traditional algorithm decreased. In 2015, persons with HIV diagnosed using the recommended algorithm were more promptly linked to care than those with diagnosis using the traditional algorithm.

### Keywords

HIV; Testing algorithms; Linkage to care

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Conflict of interest

None declared.

Ethical approval

Not required.

## 1. Background

The Centers for Disease Control and Prevention, Division of HIV/ AIDS Prevention Strategic Plan 2017–2020 has four main goals for prevention of human immunodeficiency virus (HIV) infection: 1) prevent new HIV infections, 2) improve health outcomes for persons living with HIV, 3) reduce HIV-related disparities and health inequities, and 4) continually improve effectiveness and efficiency of operations [1].

Testing and diagnosis is the first step in the HIV “continuum of care” [2], and people who are aware that they are infected and have had counseling services, are more likely to behave in a way that lowers their risk of transmitting HIV to others, compared to those who are unaware [3]. Linkage to HIV medical care generally occurs after confirmation of the diagnosis by a supplemental antibody test, but there are many variations on the laboratory criteria that satisfy the HIV case definition used by the National HIV Surveillance System (NHSS) [4]. Little is known about whether the types of tests or testing algorithms used to diagnose HIV infection may be associated with linkage to care. Several studies found that reluctance to schedule healthcare appointments for additional testing to confirm the diagnosis was associated with a longer time for persons with HIV infection to receive care [5–8].

In 1985, the US Food and Drug Administration approved the first HIV diagnostic test that detected IgG antibodies. The IgG test was sensitive but had a long window period and a high false-positive rate especially in low-risk populations [9,10]. As a result, a second level of testing was added to improve specificity, and by 1989 the most commonly used HIV diagnostic testing algorithm consisted of an HIV antibody immunoassay (IA) as the initial test, followed by a Western blot (WB) or immunofluorescence assay (IFA) as the supplemental antibody test to confirm reactive results from the initial test [11]. In 2014 the Centers for Disease Control and Prevention (CDC) and the Association of Public Health Laboratories (APHL) issued updated laboratory testing recommendations for the diagnosis of HIV infection to improve the recognition of acute HIV-1 infections and to reduce the time to make a definitive determination of a patient’s HIV status [12–16]. The 2014 algorithm consists of an HIV-1 IA that can detect both HIV antigen and antibody, followed by a supplemental IA that can detect HIV antibodies and differentiates between HIV-1 and HIV-2 antibodies. If the supplemental IA is negative or indeterminate, a qualitative RNA test is done to confirm the diagnosis of HIV. There are various algorithms that may meet the surveillance case definition for HIV infection, including a sequence of two different point-of-care rapid tests [4].

Little is known about the extent to which laboratories have adopted the recommended diagnostic testing algorithm or alternative testing algorithms to diagnose HIV infection. The APHL surveyed US public health laboratories in early 2015 regarding their adoption of the recommended algorithm. They found that 55% of the responding laboratories had adopted the recommended algorithm [17].

## 2. Objectives

We examined the trends in testing algorithms used for diagnoses of HIV infection reported to CDC's NHSS, and determined whether the algorithms used varied with selected patient characteristics and whether the percentage of persons with diagnosed HIV infection who were linked to care within 30 or 90 days after diagnosis varied with the type of algorithm.

## 3. Study design

We analyzed test results for HIV infections diagnosed during 2011–2015 and reported to the NHSS through December 2016. Data were available from 50 US states, Washington DC, and six dependent areas. We interpreted various combinations of test results as representing diagnostic testing algorithms or diagnosis types and classified them into the following 6 categories:

- Traditional algorithm: the first positive test was any HIV-1 (or combination HIV-1/2) antibody IA that was not a point-of-care 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 IA that could detect both HIV antigen and antibody and was not a point-of-care rapid test, followed within 30 days by a supplemental IA that could detect HIV antibodies and differentiated between HIV-1 and HIV-2 antibodies. This classification did not depend on whether the result of the supplemental test was positive or negative or followed by a NAT. A positive result from an initial IA was presumed if the first reported result was from a supplemental IA that could detect HIV antibodies and differentiated between HIV-1 and HIV-2 antibodies.
- Rapid testing algorithm: the first positive test was a point-of-care rapid IA, followed by another positive point-of-care rapid IA, on the same day. These were assumed not to be duplicate reports of a single test only if they were both reported on the same document.
- Virologic test: the first positive test result was a quantitative HIV-1 NAT, a qualitative HIV-1 NAT, HIV-1 culture, or a stand-alone HIV-1 antigen test.
- Other algorithms: a sequence of tests that does not fit into the other defined categories of algorithms.
- Unspecified diagnostic methods: HIV diagnosis was documented by a physician, before any laboratory tests were documented.

To determine whether there was a significant trend in the annual number of diagnoses made using each category of testing algorithm, the estimated annual percent change (EAPC) in diagnoses and its 95% confidence interval (CI) were calculated by fitting a logistic regression model using calendar year as the regressor [18]. A trend was considered statistically significant at  $p < 0.05$ . We classified race/ethnicity as “Hispanic/Latino” if the ethnicity was Hispanic or Latino. Hispanic/ Latino persons could be of any race. Persons in other categories of race/ ethnicity were not known to be of Hispanic/Latino ethnicity.

The analysis of linkage to HIV care was based on data for persons whose infections were diagnosed in 2015 and who resided in one of the 38 jurisdictions with complete reporting of HIV-related laboratory test results at the time of diagnosis. Jurisdictions were classified as having complete reporting if they had laws or regulations in place before 2015 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 testing had reported a minimum of 95% of the HIV-related test results to the jurisdiction and these health departments had reported to NHSS 95% of the test results they received by December 2016. Linkage to care was recognized if at least one reported CD4 test or viral load measurement was done within the specified time period (i.e., within 30 days or 90 days after diagnosis, but not on the same date as diagnosis). The date of HIV diagnosis was defined as the date of specimen collection for the first positive HIV test. Only data with complete specimen collection dates or dates of diagnosis were used in this analysis. Univariate logistic regression analysis, using linkage to care as a binary outcome and algorithm category as the only independent variable, was used to evaluate statistical differences in linkage to care among the different algorithm categories. All analyses were performed using SAS v9.4 (Cary, NC).

#### 4. Results

The percentage of diagnoses of HIV infection that used the traditional algorithm decreased from 84% in 2011–16% in 2015, while the percentage that used the recommended algorithm increased from 0.1% to 64%, the percentage that used the rapid testing algorithm increased from 0.1% to 2%, the percentage that used a virologic test as the first test to diagnose HIV increased from 8% to 10%, the percentage that used the other algorithms increased from 5% to 7% and the percentage that used unspecified diagnostic methods decreased from just over 2% to just under 2% (Table 1, Fig. 1).

During 2011–2015, there were 202,725 reported diagnoses of HIV infection; the annual number of diagnoses decreased 1% during this period. The annual number of diagnoses of HIV infection using the traditional algorithm and unspecified diagnostic methods decreased by 30% and 6.5% per year respectively, while the annual number using the recommended algorithm, rapid testing algorithm, virologic tests and other algorithms increased by 150%, 71%, 5% and 8% per year respectively. These trends were significant ( $p < 0.01$ ) (Table 1).

The distribution of the 40,084 reported diagnoses of HIV infection in 2015 by the category of testing algorithm used was as follows: traditional algorithm: 6198 (16%), recommended algorithm: 25,585 (64%), rapid testing algorithm: 758 (2%), virologic test: 4132 (10%), other algorithms: 2710 (7%), unspecified diagnostic methods: 701 (2%). Stratifying by patient characteristics showed that the recommended algorithm was the most commonly used algorithm, accounting for > 60% of diagnoses among most age groups, racial/ethnic groups, regions, and facility types (Table 2).

During 2015 there were 27,973 reported diagnoses of HIV infection among persons who resided in any of the 38 jurisdictions with complete laboratory reporting in that year. Of these persons, 15,654 (56%) were linked to care within 30 days after diagnosis, 21,277 (76%) were linked to care within 90 days after diagnosis (Table 3), and 25,009 (89%) were

ever linked to care (including linkages more than 90 days after diagnosis reported through December 2016, data not shown).

Persons whose disease was diagnosed using the recommended algorithm were more likely to be linked to care within 30 days after diagnosis than those whose disease was diagnosed using the traditional algorithm, a virologic test or unspecified diagnostic methods ( $p < 0.05$ ) and were not significantly more likely to be linked to care within 30 days after diagnosis than persons whose disease was diagnosed using the rapid testing algorithm (Table 3). Additionally, persons whose disease was diagnosed using the recommended algorithm were more likely to be linked to care within 90 days after diagnosis than for those whose disease was diagnosed using the traditional algorithm, rapid testing algorithm, a virologic test or unspecified diagnostic methods ( $p < 0.05$ ). Finally, persons whose disease was diagnosed using the rapid testing algorithm were more likely to be linked to care within 30 days after diagnosis than those whose disease was diagnosed using unspecified diagnostic methods and virologic tests but not significantly more than other diagnostic methods (data not shown).

## 5. Discussion

Between 2011 and 2015, the percentage of reported HIV infections diagnosed using the recommended algorithm increased, while the percentage diagnosed using the traditional algorithm decreased. By 2014 the recommended algorithm was the most commonly used algorithm used to diagnose HIV among most age groups, racial/ethnic groups, regions, and facility types. This change began before CDC/ APHL guidelines for laboratory testing of HIV were updated in June 2014, but the most rapid changes were in 2014 and 2015. The 2014 APHL survey showed a similar trend; 53 (72%) of responding public health laboratories indicated they had adopted the recommended algorithm by June 2015, and of those 53 laboratories, 35 (66%) said they adopted the recommended algorithm before its publication in June 2014 [17].

In the United States, among persons with HIV, those whose infections were undiagnosed when they transmitted HIV to others were estimated to have accounted for 30% of transmissions, and persons whose infections were diagnosed but who were not retained in care were estimated to have accounted for 61% of transmissions in 2009; together accounting for 91% of transmissions [19]. Factors that increase the number of persons with HIV whose infections are promptly diagnosed and who are then linked to care should have a pronounced effect in reducing new HIV infections. The use of rapid tests has increased the number of persons with HIV who have received a diagnosis, especially in underserved populations [5,8] and reduces the time between testing and receipt of results. In most populations, they also increased the likelihood of being linked to care within 90 days for persons tested for HIV in nonclinical settings. [6]. Here we show that persons whose disease was diagnosed using the recommended algorithm were more frequently linked to care within 90 days than those whose disease was diagnosed using the traditional algorithm, rapid testing algorithm, virologic tests or unspecified diagnostic methods. This discrepancy in linkage results of those whose infection was diagnosed using the rapid testing algorithm [6] may be because this analysis included all reported HIV diagnoses (clinical and nonclinical

settings) rather than results reported from nonclinical settings only. We also did not stratify our linkage results by risk group.

Overall, persons whose disease was diagnosed using the rapid testing algorithm were not significantly different in their likelihood to be linked to care within 30 days than those whose diagnosis was made using the recommended algorithm and, in this analysis the rapid testing algorithm was the least used method for diagnosing HIV infection in 2015 (2% of diagnoses). This may indicate a missed opportunity for the rapid testing algorithm to fulfill its potential to shorten the time required for persons to become aware of their HIV status, and thus reduce HIV transmission [19].

This study had several limitations. The surveillance data did not explicitly state whether multiple tests belonged to the same algorithm, so some tests that seemed to fit the sequence of a recognizable algorithm might actually have been from independent testing events, not part of the same algorithm. In addition, not all health departments reported to the NHSS negative results from supplemental HIV antibody tests when they were used as part of a recommended testing algorithm (negative HIV test results are not required to be reported). Consequently, the testing algorithm may not have been recognized as “recommended,” and could have been misclassified into the “other” category (e.g., apparently consisting of only a positive initial IA result and a positive NAT result without a supplemental antibody test being done). Thus, the recommended algorithm could have been under-represented in our analysis. This implies that the use of the recommended algorithm is likely higher than we found, and further supports our conclusion that the recommended algorithm is the most commonly used algorithm used to diagnose HIV. Because other algorithms included an unknown proportion of tests that were misclassified into this category because of non-reporting, we do not discuss this algorithm in depth. Finally, our definition of the date of receipt of care as the first date when a specimen was drawn for a viral load or CD4 test might have placed it later than the true first date of care in some cases, because some type of HIV health care might have been provided before the date of the first viral load or CD4 test.

Despite these limitations, we show that use of the recommended algorithm and the rapid algorithm to diagnose HIV during 2011–2015 has greatly increased. We also show that persons with HIV diagnosed using the recommended algorithm are more promptly linked to care than those with HIV diagnosed using traditional algorithm or virologic tests, but did not differ from among persons whose infection was diagnosed using the rapid testing algorithm. As use of the recommended algorithm is associated with a higher frequency of persons with diagnosed HIV who are promptly linked to care, use of this algorithm should also help prevent new HIV infections, as studies have shown that persons aware of their HIV infection are likely to reduce their transmission risk behaviors and receive antiretroviral treatment to achieve viral suppression [20]. Further studies are needed to explain factors that influence the use of various testing algorithms and why use of a particular algorithm is correlated with the frequency of linkage to care.

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### Abbreviations:

<b>APHL</b>	The Association of Public Health Laboratories
<b>CDC</b>	Centers for Disease Control and Prevention
<b>CLIA</b>	Clinical Laboratory Improvement Amendments
<b>EAPC</b>	estimated annual percent change
<b>HIV</b>	human immunodeficiency virus
<b>NHSS</b>	National HIV Surveillance System
<b>IA</b>	immunoassay
<b>IFA</b>	immunofluorescence assay
<b>NAT</b>	nucleic acid test
<b>WB</b>	Western blot

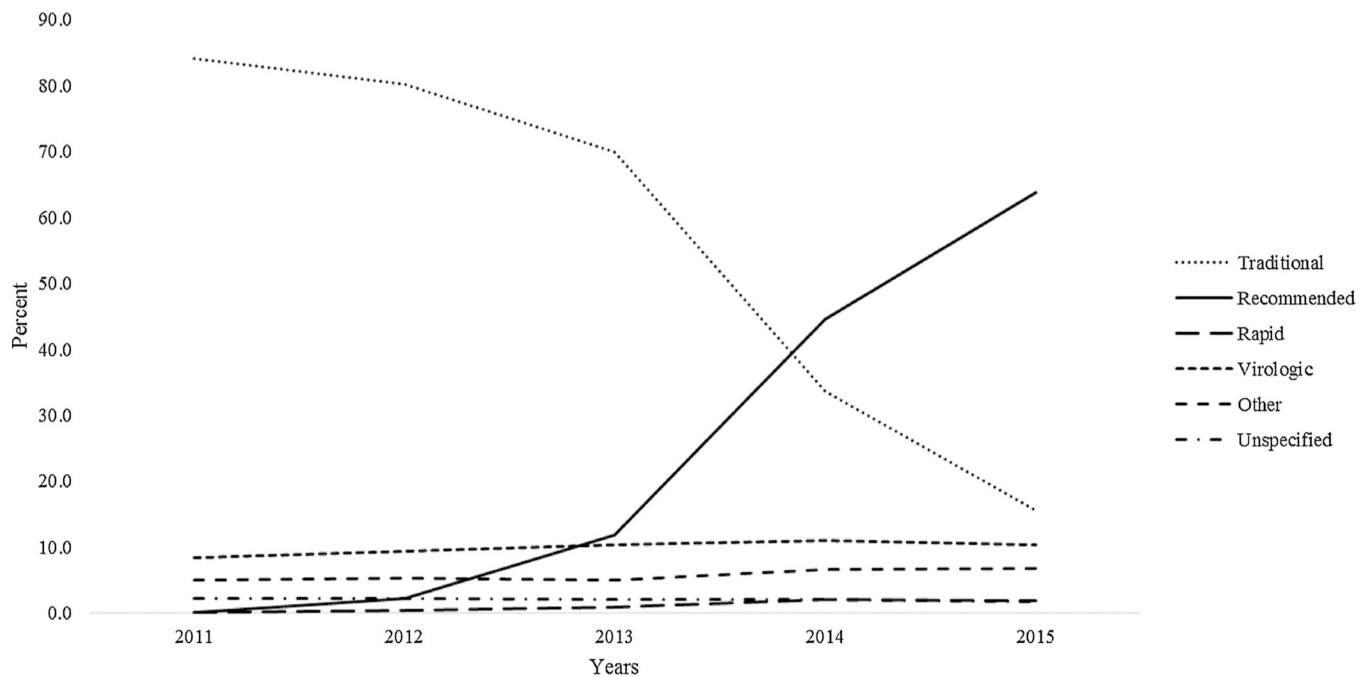
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**Fig. 1.**

Percentage distribution of diagnoses of HIV infection, by category of diagnostic testing algorithm, 2011–2015, United State and 6 dependent areas.

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

**Recommended:** The first recorded positive test 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, point-of-care, rapid IA, followed by another positive CLIA-waived, point-of-care, rapid IA, on the same day.

**Virologic:** The first recorded positive test was a quantitative HIV-1 NAT, a qualitative HIV-1 NAT, HIV-1 culture, or a stand-alone HIV-1 antigen test.

**Other:** A sequence of tests that does not fit into the other defined categories of algorithms.

**Unspecified:** HIV diagnosis was documented by a physician rather than a laboratory diagnosis, before any laboratory tests were documented.

**Table 1.**

Percentage distribution and estimated annual percentage change (EAPC) in numbers of diagnoses of HIV infection, by category of diagnostic testing algorithm, United States, 2011–2015.

Diagnostic testing algorithm category	Year						EAPC	95% CI	p-value				
	2011		2012		2013					2014		2015	
	No.	%	No.	%	No.	%				No.	%	No.	%
Traditional <sup>a</sup>	35,075	84.1	32,833	80.2	27,712	69.9	13,568	33.6	6198	15.5	-29.6	(-29.9, -29.3)	< 0.01
Recommended <sup>b</sup>	44	0.1	945	2.3	4663	11.8	17,950	44.5	25,585	63.8	149.8	(147.4, 152.2)	< 0.001
Rapid <sup>c</sup>	50	0.1	175	0.4	356	0.9	822	2.0	758	1.9	70.5	(64.6, 76.6)	< 0.001
Virologic <sup>d</sup>	3498	8.4	3848	9.4	4083	10.3	4464	11.1	4132	10.3	4.8	(3.8, 5.9)	< 0.001
Other <sup>e</sup>	2083	5.0	2215	5.4	2001	5.0	2701	6.7	2710	6.8	7.7	(6.4, 9.1)	< 0.001
Unspecified <sup>f</sup>	940	2.3	948	2.3	813	2.1	854	2.1	701	1.7	-6.5	(-8.5, -4.5)	< 0.001
<b>Total</b>	<b>41,690</b>	<b>100.0</b>	<b>40,964</b>	<b>100.0</b>	<b>39,628</b>	<b>100.0</b>	<b>40,359</b>	<b>100.0</b>	<b>40,084</b>	<b>100.0</b>	<b>-0.9</b>	<b>(-1.2, -0.6)</b>	<b>&lt; 0.01</b>

<sup>a</sup>The first positive test was HIV-1 IA, followed within 30 days by a Western blot or immunofluorescence assay.

<sup>b</sup>The first positive test 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.

<sup>c</sup>The first positive test was a CLIA-waived, point-of-care, rapid IA, followed by another positive CLIA-waived, point-of-care, rapid IA, on the same day.

<sup>d</sup>The first positive test was a quantitative HIV-1 NAT, a qualitative HIV-1 NAT, HIV-1 culture, or a stand-alone HIV-1 antigen test.

<sup>e</sup>A sequence of tests that does not fit into the other defined categories of algorithms.

<sup>f</sup>HIV diagnosis was documented by a physician rather than a laboratory diagnosis, before any laboratory tests were documented.

Distribution of persons with diagnosed HIV infection during 2015, by diagnostic algorithm category, by selected characteristics—United States and 6 dependent areas.<sup>a</sup>

Characteristics	Algorithm Category <sup>b</sup>												Total
	Traditional		Recommended		Rapid		Virologic		Other		Unspecified		
	No	% <sup>c</sup>	No.	% <sup>c</sup>	No.	% <sup>c</sup>	No.	% <sup>c</sup>	No.	% <sup>c</sup>	No	% <sup>c</sup>	
Total	6198	15.5	25,585	63.8	758	1.9	4132	10.3	2710	6.8	701	1.7	40,084
Sex													
Male	5087	15.6	20,618	63.4	676	2.1	3401	10.5	2165	6.7	569	1.7	32,516
Female	1111	14.7	4967	65.6	82	1.1	731	9.7	545	7.2	132	1.7	7568
Age group at diagnosis													
13–24	1487	16.5	5804	64.5	244	2.7	813	9.0	564	6.3	85	0.9	8997
24–34	2019	15.4	8520	65.0	273	2.1	1239	9.4	863	6.6	198	1.5	13,112
35–44	1176	15.2	4906	63.4	137	1.8	855	11.0	515	6.7	149	1.9	7738
45–54	954	14.8	4046	62.9	79	1.2	746	11.6	465	7.2	145	2.3	6435
55	562	14.8	2309	60.7	25	0.7	479	12.6	303	8.0	124	3.3	3802
Race/ethnicity													
American Indian/Alaska Native	43	21.8	105	53.3	6	3.0	25	12.7	16	8.1	2	1.0	197
Asian	138	14.5	601	63.3	21	2.2	96	10.1	61	6.4	33	3.5	950
Black/African American	2721	15.5	11,289	64.2	336	1.9	1747	9.9	1258	7.2	227	1.3	17,578
Hispanic/Latino <sup>d</sup>	1315	13.3	6623	67.1	230	2.3	896	9.1	592	6.0	218	2.2	9874
Native Hawaiian/Other Pacific Islander	24	28.2	50	58.8	3	3.5	6	7.1	2	2.4	0	0.0	85
White	1790	17.1	6354	60.6	140	1.3	1286	12.3	717	6.8	194	1.9	10,481
Multiple races	167	18.2	563	61.3	22	2.4	76	8.3	64	7.0	27	2.9	919
Region of residence at diagnosis													
Northeast	612	9.5	4180	65.2	247	3.9	526	8.2	611	9.5	236	3.7	6412
Midwest	1081	20.8	3200	61.7	10	0.2	552	10.6	297	5.7	46	0.9	5186
South	2996	14.7	13,487	66.1	269	1.3	2192	10.7	1291	6.3	184	0.9	20,419
West	1470	19.6	4349	57.9	232	3.1	836	11.1	424	5.6	202	2.7	7513
Dependent areas	39	7.0	369	66.6	0	0.0	26	4.7	87	15.7	33	6.0	554

Characteristics	Algorithm Category <sup>b</sup>												Total
	<u>Traditional</u>						<u>Unspecified</u>						
	<u>Recommended</u>			<u>Rapid</u>			<u>Virologic</u>			<u>Other</u>			
	No	% <sup>c</sup>	No.	% <sup>c</sup>	No.	% <sup>c</sup>	No.	% <sup>c</sup>	No.	% <sup>c</sup>	No.	% <sup>c</sup>	
<b>Facility type</b>													
Inpatient	957	15.0	3941	61.8	10	0.2	743	11.7	552	8.7	174	2.7	6377
Outpatient	2339	12.6	12,760	68.5	141	0.8	1837	9.9	1186	6.4	356	1.9	18,619
Emergency room	56	7.5	566	75.9	30	4.0	54	7.2	22	2.9	18	2.4	746
Screening	1603	20.9	4809	62.7	556	7.3	433	5.6	252	3.3	15	0.2	7668
Corrections	144	12.7	803	70.7	10	0.9	91	8.0	65	5.7	23	2.0	1136
Other	1099	19.8	2706	48.9	11	0.2	974	17.6	633	11.4	115	2.1	5538

Abbreviations: HIV, human immunodeficiency virus

<sup>a</sup>Based on data from the Centers for Disease Control and Prevention's National HIV Surveillance System collected through December 2016.

<sup>b</sup>Refer to the figure legend of Table 1 for algorithm definitions.

<sup>c</sup>Represents percentage of the total number for the row.

<sup>d</sup>Hispanic/Latino may be of any race; all other racial/ethnic groups shown are persons not known to be Hispanic/Latino.

Table 3.

Linkage to HIV<sup>a</sup> medical care within 30 or 90 days after HIV diagnosis in 2015, among person aged 13 years, by category of diagnostic testing algorithm –37 states and the District of Columbia.

Diagnostic testing algorithm category <sup>b</sup>	HIV Diagnoses	30 days after diagnosis		90 days after diagnosis	
		No.	%	No.	%
Traditional	4241	2347	55.3	3188	75.2
Recommended	17,921	10,538	58.8	14,050	78.4
Rapid	400	232	58.0	291	72.8
Virologic	2895	1120	38.7	1899	65.6
Other	1995	1228	61.6	1572	78.8
Unspecified	521	189	36.3	277	53.2
Total	27,973	15,654	56.0	21,277	76.1

Note: Data are based on test results reported to CDC by the health department of the jurisdiction where the patient resided at diagnosis. Linkage to HIV medical care was defined as documentation of at least one CD4 T-lymphocyte test or viral load test with a specimen collection date 1 day and 30 days or 90 days after the HIV diagnosis date.

<sup>a</sup>Human Immunodeficiency Virus.

<sup>b</sup>Refer to the figure legend of Table 1 for algorithm definitions.