Performance of Quality Control Materials for Testing of anti-HIV-1 Antibodies in Dried Blood Spots from 2014 through 2018

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Background

- The Newborn Screening Quality Assurance Program (NSQAP) produces dried blood spots (DBS) to assure the quality of laboratory tests for antibodies to HIV-1. HIV methods primarily test serum specimens and may or may not have protocols for DBS, nor are they likely to contain DBS quality control (QC) materials.
- NSQAP QC materials are used by program participants to monitor performance of commercial or in-house immunoassay and Western blot (WB) methods. Twice a year, a 6-month supply of HIV-1 QC materials is sent to participating laboratories.
- NSQAP materials are supplements to commercial kit serum controls, and should be used as part of internal procedures to monitor assay performance. We summarized the performance of NSQAP QC materials over 5 years to assess whether they accurately reflect the target reactivity category, and to determine lot-to-lot variability.

Methods

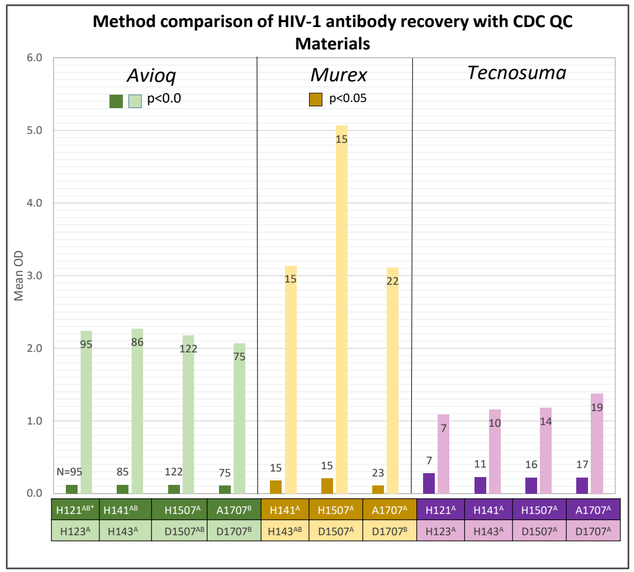
- DBS QC specimens were made using HIV antibody-positive serum (or plasma) and antibody-negative serum combined with red blood cells (RBC's) to a hematocrit of 50%. The desired HIV reactivity was achieved using single-donor negative or positive sera, or by blending two or more HIV-positive sera with different WB banding patterns.
- Prepared blood was dispensed onto filter paper to yield the appropriate enzyme immunoassay (EIA) absorbance values of a negative, low-positive, and high-positive HIV DBS specimens.
- Certified QC materials were sent to participating laboratories and results were returned on a standardized proficiency testing (PT) data report form. Statistical differences across QC lots were assessed using an ANOVA followed by Tukey's Honest Significant Difference post-hoc for multiple comparison testing (Fig. 1).

Table 1. Mean (OD) and descriptive statistics for methods that test for HIV-1 antibodies in DBS using CDC QC materials

Method	QC Material	Mean (OD)	SD	N	MIN	MAX
Avioq Negative	A1507	0.12	0.03	122	0.082	0.212
	A1707	0.11	0.02	75	0.078	0.170
	H121	0.12	0.03	95	0.073	0.221
	H141	0.12	0.03	85	0.073	0.279
	OVERALL	0.12	0.03	377	0.073	0.279
Murex Negative	A1507	0.21	0.27	15	0.069	1.090
	A1707	0.11	0.04	23	0.050	0.201
	H141	0.18	0.21	15	0.053	0.760
	OVERALL	0.16	0.19	53	0.050	1.090
Tecnosuma Negative	A1507	0.22	0.08	16	0.093	0.335
	A1707	0.22	0.08	17	0.105	0.325
	H121	0.28	0.13	7	0.132	0.469
	H141	0.23	0.07	11	0.098	0.317
	OVERALL	0.23	0.09	51	0.093	0.469

Method	QC Material	Mean (OD)	SD	N	MIN	MAX
Avioq High	D1507	2.18	0.37	122	0.937	2.988
	D1707	2.07	0.38	75	1.065	3.230
	H123	2.24	0.38	95	0.856	3.064
	H143	2.27	0.36	86	1.222	3.000
	OVERALL	2.19	0.38	378	0.856	3.230
Murex High	D1507	5.07	3.52	15	1.701	15.030
	D1707	3.12	1.08	22	0.686	4.399
	H143	3.14	1.70	15	0.462	7.820
	OVERALL	3.69	2.34	52	0.462	15.030
Tecnosuma High	D1507	1.18	0.25	14	0.723	1.509
	D1707	1.37	0.43	19	0.906	2.420
	H123	1.09	0.39	7	0.756	1.682
	H143	1.16	0.30	10	0.530	1.451
	OVERALL	1.24	0.36	50	0.530	2.420

Fig. 1



* Results of the Tukey's Honest Significant Difference test based on comparison of group means where A is significantly different than B, and AB is common to both.

Results

- Method and QC data for each lot were summarized from 2014 to 2018. Three commercial EIA kits were routinely reported: Avioq HIV-1 Microelisa System, Murex® HIV-1.2.O. Diasorin and Tecnosuma (Cuba) UMELISA HIV 1+2.
- We summarized data for the negative reactivity and high reactivity QC pools and determined that all method optical densities (ODs) accurately reflected the respective target performance category. Mean ODs significantly differed across the negative QC pools analyzed by the Avioq method, and across the high QC pools analyzed by both the Avioq and Murex methods.

Conclusions

- Summary statistics calculated from data collected from 2014-2018 showed that the commonly used HIV DBS EIA methods accurately reflected the target performance category. ANOVA results indicated significant differences between the QC pools mean ODs over this time period.
- While HIV-1 screening methods are considered qualitative, use of DBS QC materials from CDC documented significant method variability over time. Supplemental DBS HIV QC materials are essential to assure confidence in methods that exhibit considerable lot-to-lot variability.

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