A rapid diagnosis is considered important in HIV care. In 138,911 testing episodes with the Abbott Architect HIV Ag/Ab Combo assay (3,705 reactive samples), a signal-to-cutoff ratio of >151.17 had a positive predictive value of 100% and a sensitivity of 67.4% for the detection of subsequently confirmed HIV infection. We suggest that results higher than this signal-to-cutoff ratio threshold may be reported to clinicians before the completion of confirmatory testing.

A Signal-to-Cutoff Ratio in the Abbott Architect HIV Ag/Ab Combo Assay That Predicts Subsequent Confirmation of HIV-1 Infection in a Low-Prevalence Setting

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To our knowledge, this study presents the largest analysis to date of the PPV of the Abbott Combo S/CO ratio. Knowledge of the S/CO ratio allows for the test result of the Abbott Combo to be used in clinical decision making. We suggest that a result with a sufficiently high S/CO ratio be reported immediately and accompanied by a statement that although a false-positive result is extremely unlikely, confirmatory testing will be undertaken. The clinician may then deliver a positive test result to the patient or direct investigation and treatment of an acute presentation without having to wait for confirmatory testing.

The local Human Research Ethics Committee approved the research.

A total of 138,911 Abbott Combo testing episodes were analyzed, of which 3,705 were repeatedly reactive and 2,542 were deemed to be true-positive results. The cumulative frequency distributions of the S/CO ratios of true and non-true positives in the total sample are shown in Fig. 1. Patient age, proportion of males, and S/CO distribution were not different in the test and train samples (see Table S2 in the supplemental material). Patients with non-true-positive Abbott Combo tests were younger and more likely to be female and had significantly lower mean S/CO ratios than patients with true-positive results.

The highest S/CO ratio in non-true-positive episodes in the train sample was 151.17. When applied to the test sample as the lower discriminatory value, this produced a PPV of 100% with a sensitivity of 67.4% for confirmed HIV-1 infection, meaning that more than two-thirds of all subsequently confirmed reactive Abbott Combo tests were correctly identified. Table 1 shows the PPVs and sensitivities at selected S/CO ratios. The sensitivity may be higher than that reported here due to misclassification of some true positives as non-true positives. A secondary analysis using only the first sample for each individual did not alter the results (data not shown). Since the PPV is directly proportional to the prevalence, it can be hypothesized that a lower S/CO ratio than that reported here may be discriminatory with a similar PPV in higher-prevalence settings.

Potential limitations of this study include the retrospective data collection, the short (2-week) window for inclusion of VL test results in the assessment of each episode, and the HIV-1 subtype B predominance in this population (78% of new diagnoses in 2013 and rare HIV-2 cases), which may limit generalizability (5). Before application of this approach, the threshold S/CO ratio should be reassessed to control for factors such as local isolate variation and host differences.

![FIG 1 Cumulative frequency distribution of the S/CO ratios of true and non-true positive Abbott Architect HIV Ag/Ab Combo assay testing episodes.](jcm.asm.org/.../174.Supplement_2/S176)

| TABLE 1 Performances of selected S/CO* ratios in the Abbott Architect HIV Ag/Ab Combo assay when used as thresholds for a true-positive result in the test sample |
|---|---|---|
| S/CO ratio | Positive predictive value for a true-positive result (%) | Sensitivity for a true-positive result (%) |
| >151.17 | 100 | 67.4 |
| >100 | 99.7 | 73.8 |
| >50 | 99.0 | 80.6 |

* S/CO, signal-to-cutoff.

REFERENCES


