MANUFACTURERS OF RAPID DIAGNOSTIC TESTS & REAGENTS
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# COMPARATIVE EVALUATION OF RAPID HIV TESTS MANUFACTURED WITH AZOG, INC. TEST COMPONENTS.

Predicate devices tested were Smart Check, Capillus, Genie II and Determine. Gold standard was EIA and PCR results were also compared.

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## PRINCIPAL COLLABORATOR: GEDE AIDS AND INFECTIOUS DISEASES REASEARCH INSTITUE GEDE FOUNDATION ABUJA NIGERIA

***SUMMARY***

We validated the HIV 1/2 test kits at the GEDE AIDS and Infectious Diseases Research Institute, Abuja Nigeria. The performance compared favorably with the kits that are presently taken as gold standard. It achieved 97.75% sensitivity and a specificity of 100% across a panel of five other test kits. This was above some kits, which are presently on the reference list of our HIV test kit use. On the room temperature performance (Result not included), it achieved 100% compared to Genie II, which could not produce results after 24 hours on the bench. The specifications for individual specimen testing ware also achieved. It may be useful in healthcare settings with minimal skill where use of high volume reagents may require additional skill.

We may wish to submit this report for your use.

***INTRODUCTION***

Enzyme immunosorbent assays (EIA) are the most widely used serologic HIV screening test in developed nations. Fourth generation assays include a wide variety of antigens parentheses (HIV-1 group M, HIV-1 group O and HIV-2) and detect IgG as well as IgM, reducing the time between HIV exposure and detection of circulating antibody. The use of EIA in resource-poor settings however is by several factors including the need for well-trained personnel, consistent electric supply, equipment maintenance costs and reagent grade water. This led to the development of rapid, instrument free assay which are now widely used in resource-restrained regions of the world. EIA are still suitable for laboratories performing high-throughput testing. But for smaller labs and “points of service’ rapid tests are ideal. There are several HIV rapid test kits now in the

market that are highly sensitive and specific (comparable to that of EIA). Rapid test developed most recently are less reliant on cold chain and provide teat results in 15-20 minutes (allowing counseling, testing and return of results in a single visit).

**Goal:** Validation of HIV rapid test kits to validate its cost effective, sensitivity and specificity and

to explore it possible use in the national algorithm of HIV testing in Nigeria.

**Reasons for validation HIV rapid test kits for use in a testing algorithm**

Routine formal HIV rapid test kit validation is not routine in Nigeria. Individual HIV rapid tests have been evaluated, but multiple test products have not been evaluated with a single specimen set, which allows for the circulation of sensitivity and specificity of various kits in use. Currently within Nigeria there is no standardized use of HIV rapid tests. A large variety of HIV rapid test products are used through out the country, not all these are of high quality or suitable for use in Nigeria. More importantly, not all sites conducting HIV testing adhere to a single, universally acceptable procedure for sample collection and testing or proper reagent storage. There are four rapid tests widely used in Nigeria; Smart Check, Capillus, Genie II and Determine. We adapted to evaluate the Rapid HIV test form AZOG, Inc. along with the performance of these kits and reports are now a as follows. This is a laboratory based validation providing preliminary results on test performance on a single sample set of well-characterized plasma or serum specimens. A structured laboratory environment with trained, supervised laboratorians is the site of this initial validation. Each individual test was evaluated and sensitivity/specificity calculated. The use of a single sample set of allowed for the circulations of sensitivity and specificity of different proposed tests algorithm.

(Summary is attached)

***METHODOLOGY***

Standard methodology with laboratory QC and QA, good specimen population distribution and known characteristics, in commercial enzyme immunoassay, (EIA/ELISA, Western Blot (including indeterminate samples) and Polymerase chain reaction (PCR). The population was spread across the four geographical zones (West, North, North Central, North East).

**Sample Size:** 101 samples were run through the standard steps in kit evaluation procedure, maintaining the specific requirements for each kit.

**Selection of HIV tests for validation**: This was based on circulating HIV test kits.

## Data collection and analysis:

All test results were collected on paper forms and entered into a database (MS Excel) for each kit. The sensitivity and specificity of each rapid test were determined by comparing with positive results with the kit performance. For purposes of validation, the sensitivity of each rapid test was calculated. Specificities were calculated as numbers of test, which are reported as negative by EIA (‘true negatives”). Sensitivity and specificity were calculated for each of the test individually and also.

## GAIDRI Evaluation, rapid tests for HIV ½

**Results of Evaluation of HIV 1/2 Test and other predicate devices**
**Specimens: Plasma collected in EDTA containing tubes.**

| Area | Sample ID | W. Blot | PCR | AZOG, Inc | Smart Check | Determine | Capillus | Genie II | EIA |
|---|---|---|---|---|---|---|---|---|---|
| **North Central Zone** | | | | | | | | | |
| *1* | 1609 | POS | POS | POS | POS | POS | POS | POS | POS |
| 2 | 1974 NC | NEG | NEG | NEG | NEG | NEG | POS | NEG | NEG |
| 3 | 1959 | POS | POS | POS | POS | POS | POS | POS | POS |
| 4 | 2011 | POS | POS | POS | POS | POS | POS | POS | POS |
| 5 | 2091 | POS | POS | POS | POS | POS | NEG | POS | POS |
| 6 | 2231 | POS | POS | POS | POS | POS | POS | POS | POS |
| 7 | 2340 | POS | POS | POS | POS | POS | POS | POS | POS |
| 8 | 2360 | POS | POS | POS | POS | POS | POS | POS | POS |
| 9 | 2399 | POS | POS | POS | POS | POS | POS | POS | POS |
| 10 | 2432 | POS | POS | POS | POS | POS | POS | POS | POS |
| 11 | 2487 | POS | POS | POS | POS | POS | POS | POS | POS |
| 12 | 2465 | POS | POS | POS | POS | POS | POS | POS | POS |
| 13 | 2943 | POS | POS | POS | POS | POS | POS | POS | POS |
| 14 | 2967 | POS | POS | POS | POS | POS | POS | POS | POS |
| 15 | 3067 | POS | POS | POS | POS | POS | POS | POS | POS |
| 16 | 3248 | POS | POS | POS | POS | POS | POS | POS | POS |
| 17 | 3249 | POS | POS | POS | POS | POS | POS | POS | POS |
| 18 | 3908 | POS | POS | POS | POS | POS | POS | POS | POS |
| 19 | 3926 | POS | POS | POS | POS | POS | POS | POS | POS |
| 20 | 4133 | POS | POS | POS | POS | POS | POS | POS | POS |
| **Northern Zone** | | | | | | | | | |
| 21 | 488 | POS | POS | POS | POS | POS | POS | POS | POS |
| 22 | 2050 | POS | POS | POS | POS | POS | POS | POS | POS |
| 23 | 2134 | POS | POS | POS | POS | POS | POS | POS | POS |
| 24 | 2161 | POS | POS | POS | POS | POS | POS | POS | POS |
| 25 | 2368 | POS | POS | POS | POS | POS | POS | POS | POS |
| 26 | 2414 | POS | POS | POS | POS | POS | POS | POS | POS |
| 27 | 2461 | POS | POS | POS | POS | POS | POS | POS | POS |
| 28 | 2642 | POS | POS | POS | POS | POS | POS | POS | POS |
| 29 | 2739 | POS | POS | POS | POS | POS | POS | POS | POS |
| 30 | 2804 | POS | POS | POS | POS | POS | POS | POS | POS |
| 31 | 2836 | POS | POS | POS | POS | POS | POS | POS | POS |
| 32 | 3132 | POS | POS | POS | POS | POS | POS | POS | POS |
| 33 | 3137 | POS | POS | POS | POS | POS | POS | POS | POS |
| 34 | 3248 | POS | POS | POS | POS | POS | POS | POS | POS |
| 35 | 3390 | POS | POS | POS | POS | POS | POS | POS | POS |
| 36 | 3268 | POS | POS | POS | POS | POS | POS | POS | POS |
| 37 | 3566 | POS | POS | POS | POS | POS | POS | POS | POS |
| 38 | 3765 | POS | POS | POS | POS | POS | POS | POS | POS |
| 39 | 3898 | POS | POS | POS | POS | POS | POS | POS | POS |

| Area | Sample ID | W. Blot | PCR | AZOG, Inc. | Smart Check | Determine | Capillus | Genie II | EIA |
|---|---|---|---|---|---|---|---|---|---|
| **Western Zone** | | | | | | | | | |
| 40 | 1972 | POS | POS | POS | POS | POS | POS | POS | POS |
| 41 | 1976 | POS | POS | POS | POS | POS | POS | POS | POS |
| 42 | 1989 | POS | POS | POS | POS | POS | POS | POS | POS |
| 43 | 2020 | POS | POS | POS | POS | POS | POS | POS | POS |
| 44 | 2038 | POS | POS | POS | POS | POS | POS | POS | POS |
| 45 | 2092 | POS | POS | POS | POS | POS | POS | POS | POS |
| 46 | 2203 | POS | POS | POS | POS | POS | POS | POS | POS |
| 47 | 2404 | POS | POS | POS | POS | POS | POS | POS | POS |
| 48 | 2420 NC | NEG | NEG | NEG | NEG | NEG | NEG | NEG | NEG |
| 49 | 2511 | POS | POS | POS | POS | POS | POS | POS | POS |
| 50 | 2528 | POS | POS | POS | POS | POS | POS | POS | POS |
| 51 | 2546 | POS | POS | POS | POS | POS | POS | POS | POS |
| 52 | 2630 | POS | POS | POS | POS | POS | POS | POS | POS |
| 53 | 2839 | POS | POS | POS | POS | POS | POS | POS | POS |
| 54 | 2938 | POS | POS | POS | POS | POS | POS | POS | POS |
| 55 | 3139 | POS | POS | POS | POS | POS | POS | POS | POS |
| 56 | 3165 | POS | POS | POS | POS | POS | POS | POS | POS |
| 57 | 3321 | POS | POS | POS | POS | POS | POS | POS | POS |
| 58 | 3777 | POS | POS | POS | POS | POS | POS | POS | POS |
| 59 | 3912 | POS | POS | POS | POS | POS | POS | POS | POS |
| **Northeastern Zone** | | | | | | | | | |
| 60 | 2 | POS | POS | POS | POS | POS | POS | POS | POS |
| 61 | 3 | POS | POS | POS | POS | POS | POS | POS | POS |
| 62 | 5 | POS | POS | POS | POS | POS | POS | POS | POS |
| 63 | 6 | POS | POS | POS | POS | POS | POS | POS | POS |
| 64 | 15 | POS | POS | POS | POS | POS | POS | POS | POS |
| 65 | 18 | POS | POS | POS | POS | POS | POS | POS | POS |
| 66 | 20 | POS | POS | POS | POS | POS | POS | POS | POS |
| 67 | 21 | POS | POS | POS | POS | POS | POS | POS | POS |
| 68 | 22 | POS | POS | POS | POS | POS | POS | POS | POS |
| 69 | 27 | POS | POS | POS | POS | POS | POS | POS | POS |
| 70 | 168 | POS | POS | POS | POS | POS | POS | POS | POS |
| 71 | 1475 | POS | POS | POS | POS | POS | POS | POS | POS |
| 72 | 2053 | POS | POS | POS | POS | POS | POS | POS | POS |
| 73 | 2385 | POS | POS | POS | POS | POS | POS | POS | POS |
| 74 | 2549 | POS | POS | POS | POS | POS | POS | POS | POS |
| 75 | 2855 | NEG | POS | POS | POS | POS | POS | POS | POS |
| 76 | 3126 | NEG | POS | POS | POS | POS | POS | POS | POS |
| 77 | 3213 | NEG | POS | POS | POS | POS | POS | POS | POS |
| 78 | 2865 | NEG | POS | POS | POS | POS | POS | POS | POS |
| 79 | 3909 | NEG | POS | POS | POS | POS | POS | POS | POS |
| 80 | 4207 | NEG | POS | POS | POS | POS | POS | POS | POS |
| 81 | 2420 NC | NEG | NEG | NEG | NEG | NEG | NEG | NEG | NEG |
| 82 | 3685 NC | NEG | NEG | NEG | NEG | NEG | NEG | NEG | NEG |
| 83 | 23 NC | NEG | NEG | NEG | NEG | NEG | NEG | NEG | NEG |
| 84 | 13 NC | NEG | NEG | NEG | NEG | NEG | NEG | NEG | NEG |

| Area | Sample ID | W. Blot | PCR | AZOG, Inc. | Smart Check | Determine | Capillus | Genie II | EIA |
|---|---|---|---|---|---|---|---|---|---|
| 85 | 3314 NC | POS | NEG | NEG | NEG | POS | NEG | NEG | NEG |
| 86 | 3660 NC | POS | NEG | NEG | NEG | NEG | NEG | NEG | NEG |
| 87 | 3760 NC | POS | NEG | NEG | NEG | NEG | NEG | NEG | NEG |
| 88 | 3768 NC | POS | NEG | NEG | NEG | NEG | NEG | NEG | NEG |
| 89 | 3837 NC | POS | NEG | NEG | NEG | NEG | NEG | NEG | NEG |
| 90 | 4239 NC | POS | NEG | NEG | NEG | NEG | NEG | NEG | NEG |
| | | | | | | | | | |
| 91 | 3394 ID | Indeterminate | POS | POS | NEG | NEG | NEG | NEG | NEG |
| 92 | 3975 ID | Indeterminate | POS | NEG | NEG | NEG | NEG | NEG | NEG |
| 93 | 2981 ID | Indeterminate | POS | NEG | POS | POS | POS | POS | POS |
| 94 | 3210 ID | Indeterminate | POS | POS | POS | POS | POS | POS | POS |
| 95 | 3230 ID | Indeterminate | POS | POS | POS | POS | POS | POS | POS |
| 96 | 3763 ID | Indeterminate | POS | POS | POS | POS | POS | POS | POS |
| 97 | 2428 ID | Indeterminate | POS | POS | POS | POS | POS | POS | POS |
| 98 | 2485 ID | Indeterminate | POS | POS | POS | POS | POS | POS | POS |
| 99 | 2468 ID | Indeterminate | POS | POS | POS | POS | POS | POS | POS |
| 100 | 3243 ID | Indeterminate | POS | POS | POS | POS | POS | POS | POS |
| 101 | 4230 ID | Indeterminate | POS | POS | POS | POS | POS | POS | POS |

## Results of the evaluation of HIV test kits using test components available from AZOG, Inc. and other predicate devices.

| Panel System | Sensitivity TP/TF + FNEG x 100 | Specificity TNEG/TNEG + FPOS x 100 | Positive Predictive Value N. TPN/N. TP + NFPOS x 100 |
|---|---|---|---|
| AZOG, Inc HIV – 1/2 Kit | 97.75% | 100.00% | 100.00% |
| Smart Check HIV – 1/2 Kit | 97.75% | 100.00% | 100.00% |
| Determine HIV – 1/2 Kit | 97.75% | 92.31% | 96.96% |
| Capillus HIV – 1/2 Kit | 97.65% | 100.00% | 100.00% |
| Genie II HIV – 1/2 Kit | 97.75% | 100.00% | 100.00% |
| EIA HIV – 1/2 Kit | 97.75% | 100.00% | 100.00% |

**REFERENCE STANDARD**
**TRUE POSITIVE = 89, TRUE NEGATIVE = 12**
**TOTAL = 101**

| | |
|---|---|
| AZOG, Inc. HIV – 1/2 Kit | True positive = 87, True negative = 12; False positive = 0, False negative = 2 |
| Smart Check HIV – 1/2 Kit | True positive = 87, True negative = 12; False positive = 0, False negative = 2 |
| Determine HIV – 1/2 Kit | True positive = 87, True negative = 12; False positive = 1, False negative = 2 |
| Capillus HIV – 1/2 Kit | True positive = 87, True negative = 12; False positive = 0, False negative = 3 |
| Genie II HIV – 1/2 Kit | True positive = 87, True negative = 12; False positive = 0, False negative = 2 |
| EIA HIV – 1/2 Kit | True positive = 87, True negative = 12; False positive = 0, False negative = 2 |