Detection of Diverse HIV Strains by the m-PIMA™ HIV-1/2 Detect Point-of-Care Assay

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1. Background

- HIV displays exceptionally high virus diversity due to high mutation and recombination rates.[1]
- Genetic diversity can impact detection by diagnostic assays which fundamentally rely on sequence conservation. Therefore, it is important to confirm their performance on the breadth of known HIV strains.[2]
- Rapid Point-of-Care molecular assays have demonstrated excellent sensitivity and specificity in diagnosing HIV-1 and HIV-2 in decentralized settings.[3]
- POC testing is an important tool for screening at risk populations and improving linkage to care after a positive test result.[4]
- The goal of this study was to challenge a rapid molecular POC HIV assay with diverse HIV strains.

2. Methods

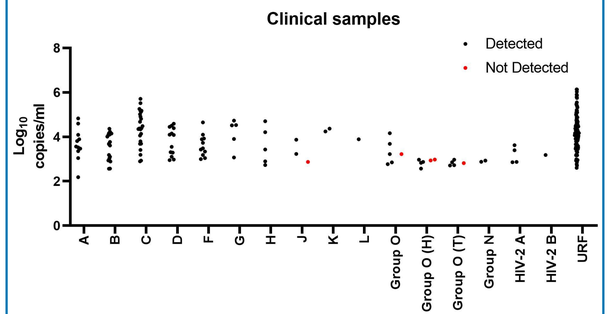
- m-PIMA™ HIV-1/2 Detect (Abbott Rapid Diagnostics Jena GmbH, Germany) was performed according to the manufacturer's instructions. Serum samples from HIV patients or virus cultures with known viral load and classified sequences were tested.
- In total, the panel (n=271) consisted of HIV-1 subtypes A (n=11), B (n=19), C (n=25), D (n=13), F (n=9), F1 (n=2), G (n=5), H (n=5), J (n=3), K Basal (n=2), L (n=1), group N (n=2), group P (n=1), group O (n=16), CRF01 (n=6), CRF02 (n=13), CRF06 (n=7), CRF09 (n=4), CRF11 (n=8), CRF13 (n=4), CRF14 (n=1), CRF22 (n=1), CRF36 (n=2), CRF37 (n=2), CRF43 (n=2), HIV-1 URFs (n=102), and HIV-2 (n=5).
- An *in silico* inclusivity analysis was conducted to further probe virus genetic diversity around m-PIMA™ HIV-1/2 Detect target sequences. 1,107,963 HIV-1 and 7,289 HIV-2 sequences were downloaded from NCBI. After removal of low quality sequences or those lacking m-PIMA™ HIV-1/2 Detect target regions, 53,498 HIV-1 and 68 HIV-2 sequences remained to assess percent identity to assay target regions.

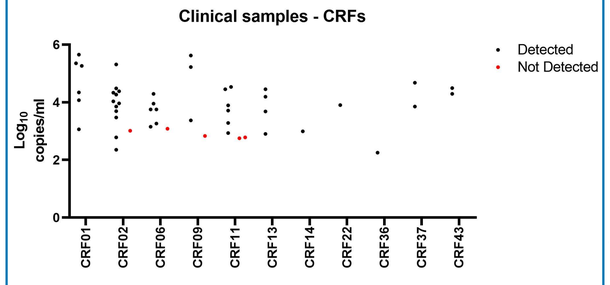
3. Results

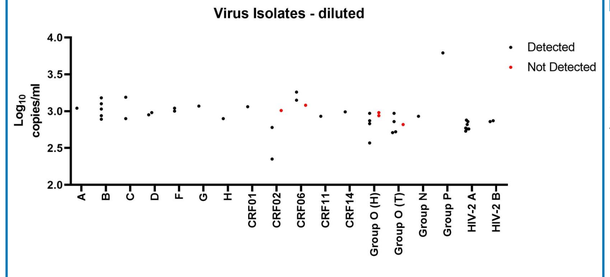
Table 1: m-PIMA™ HIV-M/N Subtypes, HIV-O, HIV-2, and CRF Detection

IDR Subtype	No. Tested	No. Detected	Viral Load Log Copies/mL (Range; Average)
A	11	11	2.18-4.83 (3.67)
B	19	19	2.56-4.23 (3.59)
C	25	25	2.90-5.71 (4.38)
D	13	13	2.95-4.59 (3.80)
F	9	9	3.00-4.10 (3.56)
F1	2	2	3.04-4.65 (3.85)
G	5	5	3.07-4.73 (4.15)
H	5	5	2.90-4.70 (3.59)
J	3	2	2.87-3.87 (3.32)
K	2	2	4.24-4.37 (4.31)
L	1	1	3.89
HIV-N	2	2	2.88-2.93 (2.91)
HIV-O	5	4	2.77-4.16 (3.34)
HIV-P	1	1	3.79
HIV-O (H)	6	4	2.57-2.98 (2.86)
HIV-O (T)	5	4	2.71-2.97 (2.82)
HIV-2 (A)	4	4	2.86-3.62 (3.19)
HIV-2 (B)	1	1	3.18
CRF01	6	6	3.06-5.65 (4.62)
CRF02	13	12	2.35-5.31 (3.84)
CRF06	7	6	3.08-4.29 (3.60)
CRF09	4	3	2.83-5.62 (4.26)
CRF11	8	6	2.75-4.53 (3.54)
CRF13	4	4	2.90-4.45 (3.81)
CRF14	1	1	2.99
CRF22	1	1	3.90
CRF36	2	2	2.25-3.48 (2.87)
CRF37	2	2	3.85-4.68 (4.27)
CRF43	2	2	4.29-4.49 (4.39)
URF	102	102	2.60-6.14 (4.17)
Total	271	261	2.18-6.14 (3.93)

Figure 1: m-PIMA™ Detection of HIV-1/2 Specimens







- Among all samples with HIV VL > 1000 copies/mL (VL > m-PIMA™ HIV-1/2 Detect LOD) 219/222 (98.6%) were detected.
- Representative samples from all tested subtypes were detected at levels consistent with the expected m-PIMA™ HIV-1/2 Detect assay LOD.
- Representative samples from all tested CRFs and URFs were detected by m-PIMA™ at levels consistent with the expected LOD.
- *In silico* analysis identified only 2/53,498 (0.0037%) HIV-1 (group O inclusive) and 1/68 (1.47%) HIV-2 (Subtype F) accessions with mutations in target regions which would reduce % identity below 90%, considered as the threshold to predict reliable detection. Percent identity in these 3 sequences was 89.5%.

4. Conclusions

- POC testing remains a critical pathway to identify HIV infections around the world
- The m-PIMA™ HIV-1/2 Detect POC assay detects each of the major circulating HIV strains as well as rare subtypes and recombinant strains with no observed impact to sensitivity.
- *In silico* analysis confirmed no widespread HIV-1/2 sequences that would be expected to impact m-PIMA™ HIV-1/2 Detect performance.

References

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Affiliations and Financial Disclosures

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