



Abbott

The m-PIMATM HIV-1/2 VL Test

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The m-PIMA™ HIV-1/2 VL Test



Features of the m-PIMA™ HIV-1/2 VL Test

Feature	Benefit
Compact and portable bench top real-time PCR system with single use cartridge (no cold chain required)	Easy to use by trained health care workers and professionals in laboratory and non-laboratory settings
Sample volume 50 µL: EDTA plasma or capillary EDTA plasma generated from fingerstick	Sample can be loaded via transfer tool or volumetric lab pipette
HIV Subtypes	Detects simultaneously HIV-1 and 2
Turn-around time < 70 min	Short time to result
Precision < 0.25 log cp/mL	Comparable to lab-based assays for accuracy and precision
Limit of Detection ≤ 800 cp/mL	Enables decisions below the medical cut-off of 1000 cp/mL
A/C and battery powered device (Internal + External battery)	Enabling use in resource limited settings with interrupted power supply.
Connectivity	Ability to provide real time data for ease of patient monitoring

m-PIMA™ HIV-1/2 VL Cartridge Kit



- 50 pouched m-PIMA HIV-1/2 VL cartridges
 - Cat. No. 27015-W50 (IVD variant)
 - Cat. No. 270150050 (CE IVD variant)
- 60 Transfer tools
- Cartridge Guide

Sample Types m-PIMA™ HIV-1/2 VL Test

Sample Types:

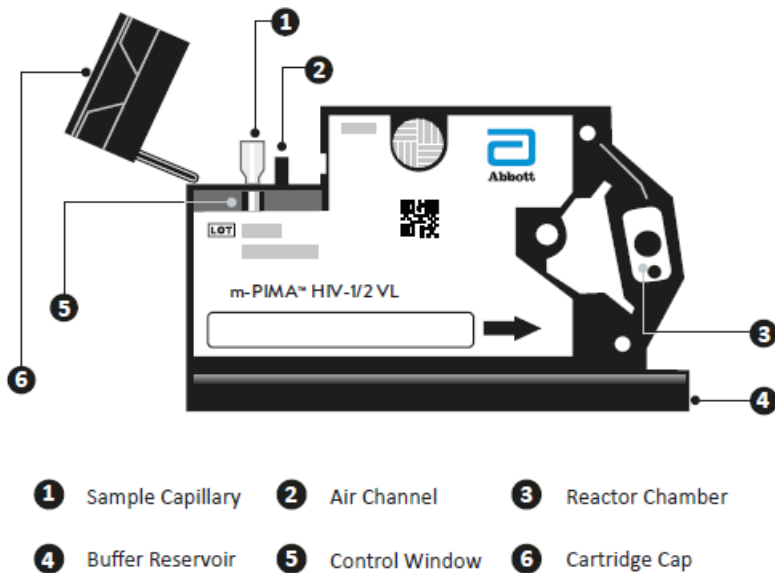
- Venous EDTA plasma is the standard specimen
- Capillary EDTA plasma from finger-stick
 - Alternatively capillary EDTA blood may be collected by finger-stick using the Finger-Stick Sample Collection Set (Cat. No. 270400201)
 - Approx. 300µl capillary EDTA blood needs to be collected to ensure enough plasma is available after centrifugation

Sample Volume:

- 50 µl of venous EDTA plasma or capillary EDTA plasma

Note: Other sample types were not validated and must not be used as this may lead to incorrect results.

Features of the m-PIMA HIV-1/2 VL Test



- Sufficient sample loading can be controlled via a control window
- Consists of several internal compartments containing freeze dried reagents and an on board buffer tank
- No cold chain storage
- On board quality/process controls
- Waste handling – all waste is sealed in the test cartridge

Sample Application

Via Lab Pipette



Always use a new pipette tip for every sample.
DO NOT touch the pellet with the pipette tip!

DO NOT contaminate the plasma sample with
blood cells!

Transfer 50 μL of sample onto the cartridge holding
the pipette tip in a 45 degree angle. Observe the
control window to ensure sufficient sample loading.

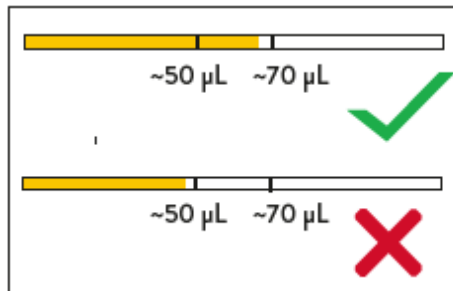
DO NOT introduce air bubbles or blood cells when
applying the plasma sample!

Via Transfer Tool



Fill the transfer tool
with plasma beyond the
first black mark.

Put your finger on the
opposite end of the
capillary to avoid
sample release.



Transfer 50 μL of sample on
to the cartridge holding the
transfer tool with a 45
degree angle.
DO NOT introduce air
bubbles or blood cells when
applying the plasma sample!



Cartridge capillary will fill
when you release sample.
Confirm filling by the control
window.


Specifications of m-PIMA™ HIV-1/2 VL Test

Sample Type	Venous and Capillary EDTA blood plasma
Sample Volume	50 µL
Sample Preparation	One step to prepare plasma
Sample Stability	up to 48 hours after blood draw at ambient temperature (18 - 28°C) for whole blood samples
Cartridge Storage Conditions	4 °C to 30 °C
Shelf Life	10.7 months
Measuring Range	800 – 1000000 cp/mL (LLOQ, ULOQ)
Limit of Detection ≤ 800 cp/mL	HIV-1 M/N: 342 cp/mL [279, 451 cp/mL] HIV-1 O: 228 cp/mL [187, 295 cp/mL] HIV-2: 364 cp/mL [292, 484 cp/ml]
Precision	≤ 0.25 log cp/mL
Diagnostic Specificity	≥ 99 %
Environmental conditions	10 – 40 °C (30 – 85 % humidity)
Test Time	< 70 min

m-PIMA HIV-1/2 VL – Result Interpretation

For HIV-1 (subtypes M/N and O) and HIV-2, independent results are given:

Test Result	Interpretation
Undetected	HIV RNA is not detected.
< 800 cp/mL	HIV RNA is detected below the lower limit of quantitation of 800 cp/mL.
7425 cp/mL	HIV RNA is detected at a viral load of 7425 cp/mL (example). Calculated copies are within the measuring range between 800 cp/mL and 1000000 cp/mL.
> 1000000 cp/mL	HIV RNA is detected above the upper limit of quantitation of 1000000 cp/mL.
Error Code	Invalid test result

 Test Report	
m-PIMA HIV-1/2 VL	
Sample ID 23-03-2017-ABC	
HIV-1 M/N	7425 cp/mL
HIV-1 O	Undetected
HIV-2	Undetected
Result No.	107
Date / Time	2018-03-23 15:50
Cartridge ID	0123456789
Operator	SAM MILLER
Device Serial	NAT-04000035
Software	0.28.0
QC	
Sample Detection	Pass
Device	Pass
HIV-1 Positive Control	Pass
HIV-2 Positive Control	Pass
Negative Control	Pass
Analysis	Pass
Signature	

example
report

m-PIMA HIV-1/2 VL – Result Interpretation

Undetectable result:

- Viral load tests have a cut-off below which they cannot reliably detect HIV; the Limit of Detection (LoD)
- An undetectable result means that the virus is not present or the viral load concentration is below the LoD

Undetectable means:

- Low risk of developing AIDS
- Risk reduced to develop Co-morbidities
- Lower risk of HIV resistance development against the ART's drugs
- Massive risk reduction of vertical transmission as well as sexual transmission

m-PIMA HIV-1/2 VL – Result Interpretation

Detectable results:

- Detectable result means that the concentration of the analyte was high enough to be detected but too low to be quantitated. The result is normally reported as < 800 cp/mL (lower limit of quantitation (LLOQ)).
- m-PIMA HIV-1/2 VL result will be reported, in this case, as below LLOQ of 800 cp/mL.

Viral load concentration reported:

- The concentration of the analyte is within the measuring range of 800 – 1000000 cp/ml and above the LLOQ.
- The result will be reported as X copies/mL.

Service and Support

- Cartridges are made to order – ordering well in advance required
- delivery and deployment of instruments will be managed by Abbott personnel
- Training will be provided by Abbott Rapid Diagnostics GmbH Jena qualified personnel
- Technical Support will be provided via the Abbott Support Network
- Service and Support will be coordinated by Joshua Buule, xxxx
- Do we want to use Connectivity? The Printer?
- How are POs handled? Via local distributors?



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