

# **Current and Future Viral Load Technologies**

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Ped HIV Diagnostic & Treatment  
Monitoring Technologies in RLS

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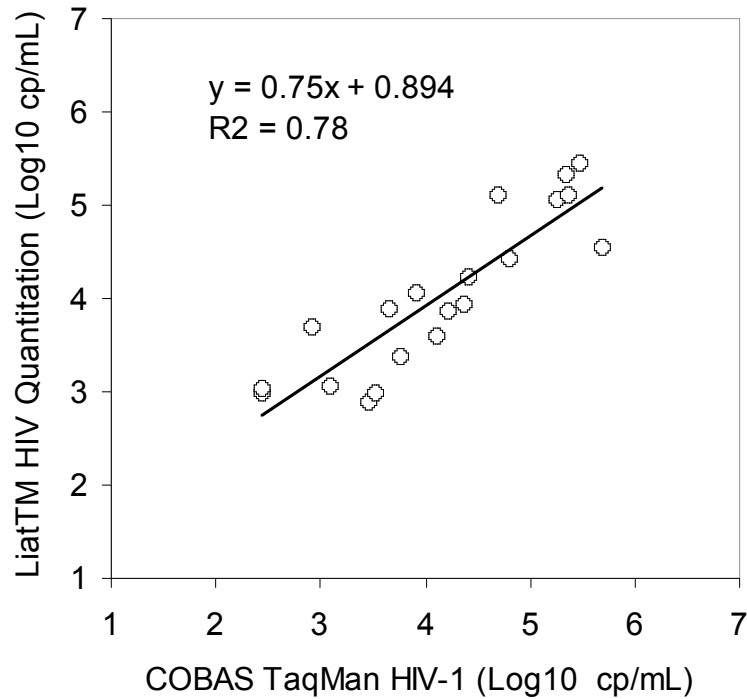
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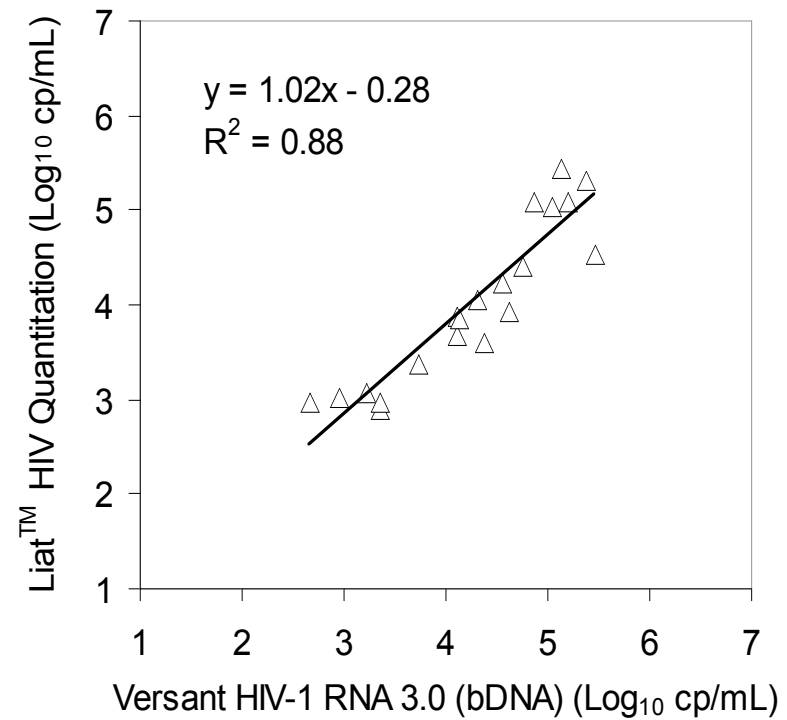
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# Retrospective Clinical Sample Tests



88.4% correlation coefficients



92.0% correlation coefficients



## IMI's CLONDIAG HIV Viral Load Point-of-Care Test

Allows to determine HIV load (HIV) in fingerstick whole blood and plasma.

Multiple HIV-1 and HIV-2 targets are detected simultaneously by a proprietary microarray real time detection method.

The test includes internal controls for performance of nucleic acid extraction, purification, amplification and detection.

The sample is applied directly onto the test cartridge; no sample manipulation, metering, dilution, or mixing are required.

The cartridge is processed by a compact, battery driven instrument (W20cmXL24cmXH14cm).

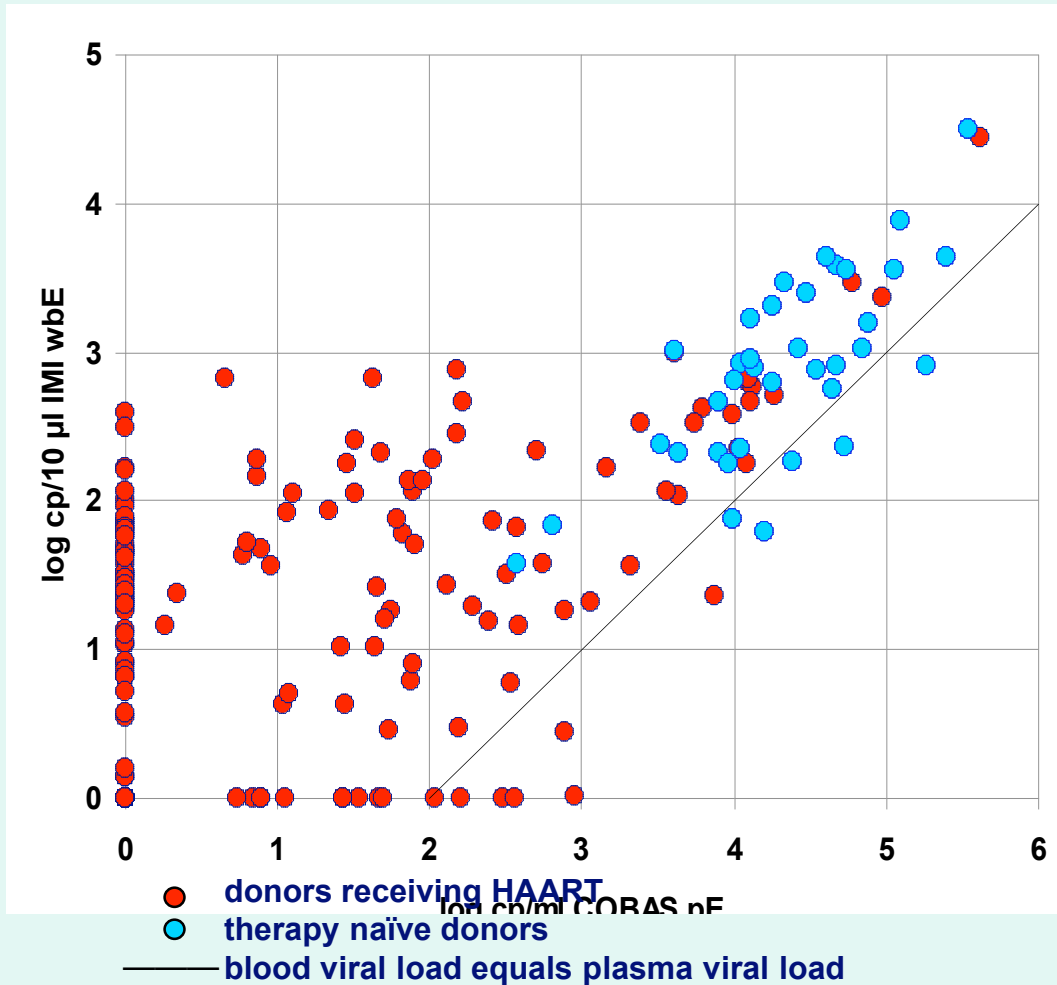
The test is planned to be in trials throughout 2010.



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## IMI CLONDIAG HIV VL Test

Data generated on 1 ml of EDTA Plasma (COBAS Ampliprep/Taqman) versus 10 µl of Whole Blood (IMI's prototype assay)



	IMI negative	IMI positive
COBAS plasma negative	73 (28 %)	56 (22 %)
COBAS plasma <40 cp/ml	8 (3 %)	21 (8 %)
COBAS plasma positive	6 (2 %)	94 (36%)

Percentage of samples with detectable viral load:

COBAS (1 ml plasma) 50 %

IMI VL (10 µl blood) 66 %

*all samples are from HIV-positive donors*

specificity of both assays =1 (32 HIV-negative donors)

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# Obstacles to Implementation

- **Infrastructure** (*may not be needed for POC*)
- **Guidelines and consensus protocols**
- **Lack of trained laboratory personnel** (*less emphasis for POC*)
- **Training tools**
- **Monitoring and evaluation tools**
- **Supply management**
- **Data management**
- **External quality assurance (Proficiency testing)**