HIV
Point of Care Viral Load Test Development

Request for Applications

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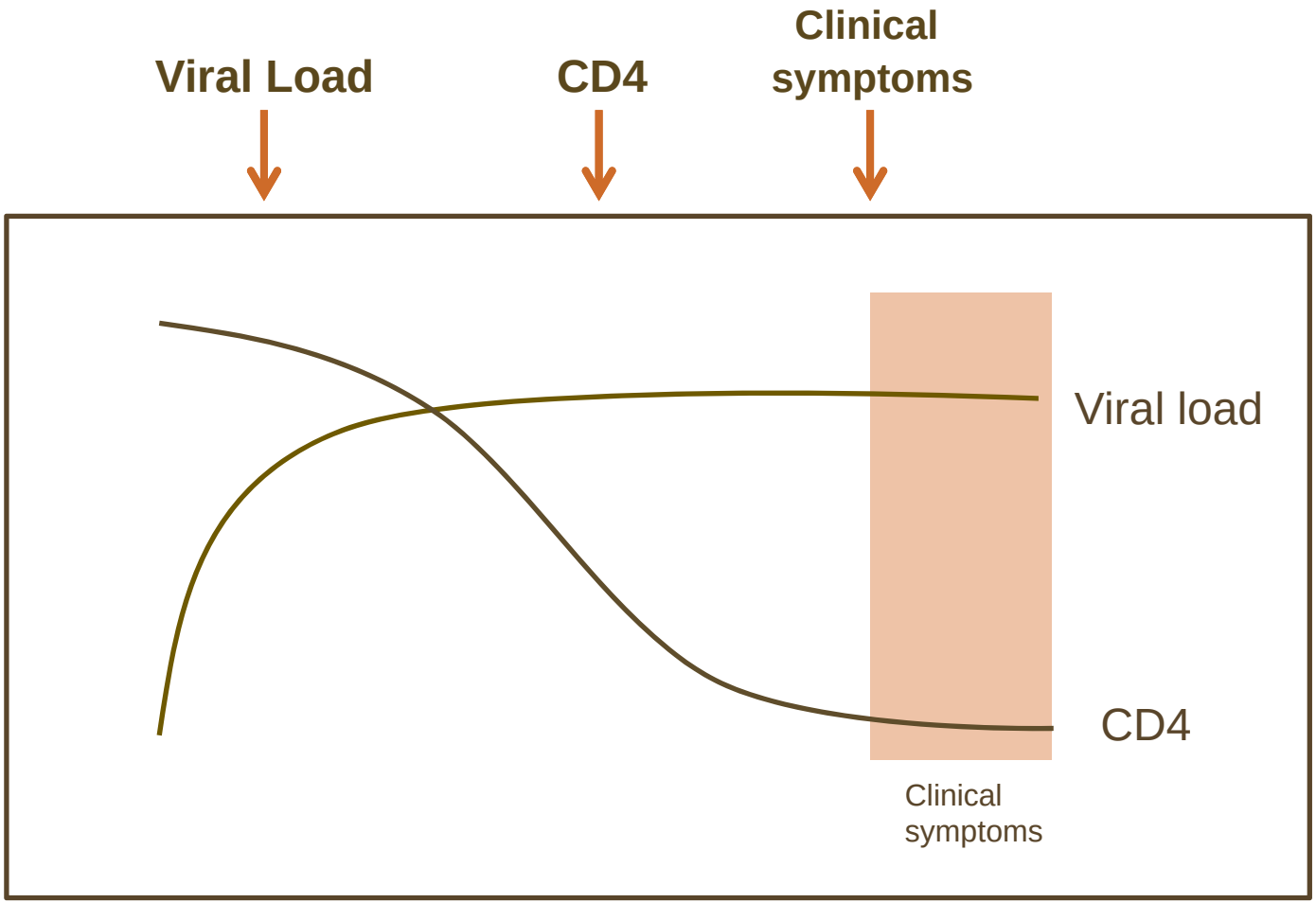
September 2012

BILL & MELINDA GATES foundation

Viral load testing allows earlier detection of viremia leading to earlier control



Goal: prevent onward transmission AND increase survival

The Gates foundation serves as a catalyst, rather than an implementer

President's Emergency Plan for AIDS Relief Commitment in 2008: $6 billion

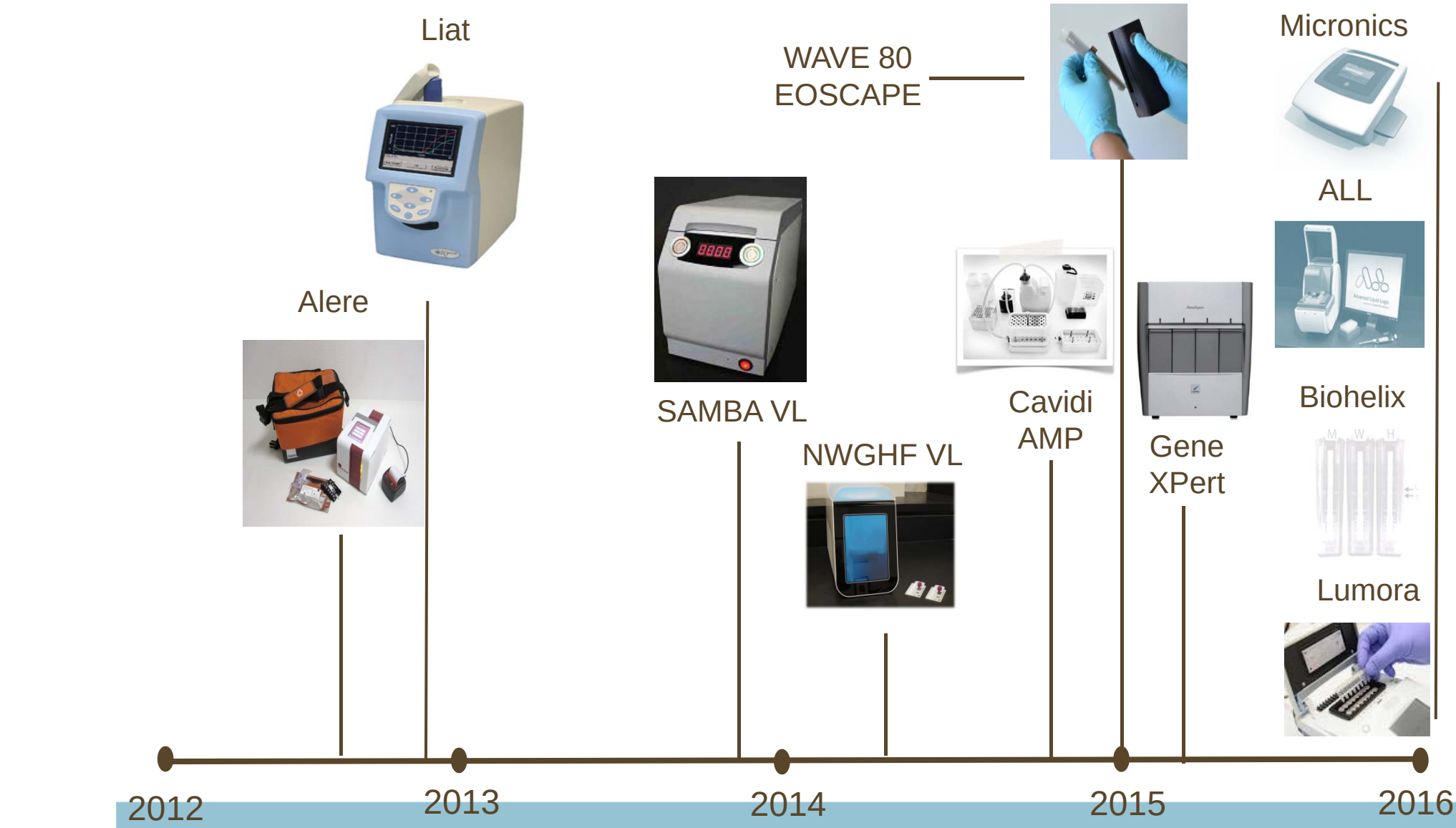
Foundation HIV/AIDS grant total in 2008: $343 million

$6B

<6%

of President's Emergency Plan for AIDS Relief commitment

Technology Pipeline – Viral Load



*Estimated - timeline and sequence may change

Technology Pipeline – Viral Load that meets our TPP

WAVE 80
EOSCAPE

Micronics

ALL

Alere

Biohelix

NWGHF VL

2012 2013 2014 2015 2016

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Viral Load TPP

	Minimal	Optimal
INTENDED USE	This is a diagnostic test to measure HIV nucleic acids in order to monitor HIV+ patients on ART to: (i) identify virological failure; (ii) enable clinicians to provide adherence counseling or switch failing patients to new drug regimens	
Goal of Test	Semi-quantitative viral load measurement and detection of all major HIV-1 subtypes including N and O at each stage of infection from early through advanced disease; HIV-2 optional	Fully quantitative viral load measurement and detection of all major HIV-1 subtypes including N and O at each stage of infection from early through advanced disease; HIV-2 and recombinants preferred
Target User(s)	HIV-infected adults and children for HIV treatment monitoring	
Results	viral copies/mL	
Equipment	Small, table-top device; portable device optional	Small, portable or hand-held device; device-free/disposable preferred
Quantitation	Semi-quantitative (with a cutoff value as close to 1000 copies/mLor blood)	Quantitative (with a dynamic range beyond 1000 to 20,000 copies/mLof blood)
Precision	Less than 0.5 log for semi-quantitative	Less than 0.3 log
Sample Specimen	Plasma or whole blood from venipuncture; DBS/DPS acceptable	Finger prick blood (< 100 µL)
Total number of steps	No more than 3 – 5 steps (requiring operator intervention)	Fully integrated
Cold Chain	None required at any point in supply chain or storage	
Power Requirements	110-220V AC current; DC power with rechargeable battery lasting up to 8 hours of testing	None (i.e. a disposable test that requires no electricity)
Kit Stability and Storage Conditions	Stable for 12 months at 2°C to 40°C, 70% humidity, including transport stress (48h with fluctuations up to 50°C and down to 0°C)	Stable for 24 months at 0°C to 40°C, 90% humidity, including transport stress (48h with fluctuations up to 50°C and down to 0°C)
Thermal tolerance of platform/assay	Operation between 15°C and 40°C at an altitude up to 2,000 meters (3,000 meters preferred)	
Training Required	<1 day, trained technician	<1/2 day, healthcare worker
Clean Water Requirements	None	
Time to result	<2 hours	<30 minutes
Throughput	Minimum of 4 - 5 tests per day; at least 8 tests per day preferred	If device-based, minimum of 15 tests per day
Calibration	Minimal user calibration required	None required
Test/platform size/footprint/Portability	Small, table-top analyzer or portable device (<5 kg)	Small, portable device (<2 kg); handheld or instrument-free preferred
Target price for instrument	<$5,000 (ex-works)	<$1,000 (ex-works)
Target price for cartridge	$6.00 - $10.00 per test or less (ex-works)	$3.00 - $5.00 per test or less (ex-works)

Timelines

- **LOIs due: 14 Dec 2012**
- **Invite full proposals: Feb 2013**
- **Full proposals due: Apr 2013**

EVERY PERSON DESERVES THE CHANCE TO LIVE A HEALTHY, PRODUCTIVE LIFE.