

# A Novel, 2<sup>nd</sup> Generation Device for Ambient Storage and Transportation for Downstream Infectious Disease Testing: ViveST™

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# Healthcare Challenge

- ◆ Millions of people globally suffer from life threatening, blood-borne viruses
  - ◆ 170 million with Hepatitis C (HCV)
  - ◆ 350 million with Hepatitis B (HBV)
  - ◆ 34 million with HIV/AIDS
- ◆ Advancements in drug therapies allow for effective treatment of these diseases
- ◆ Quality patient care requires ongoing testing to determine “viral load” and patient response to various drug treatments



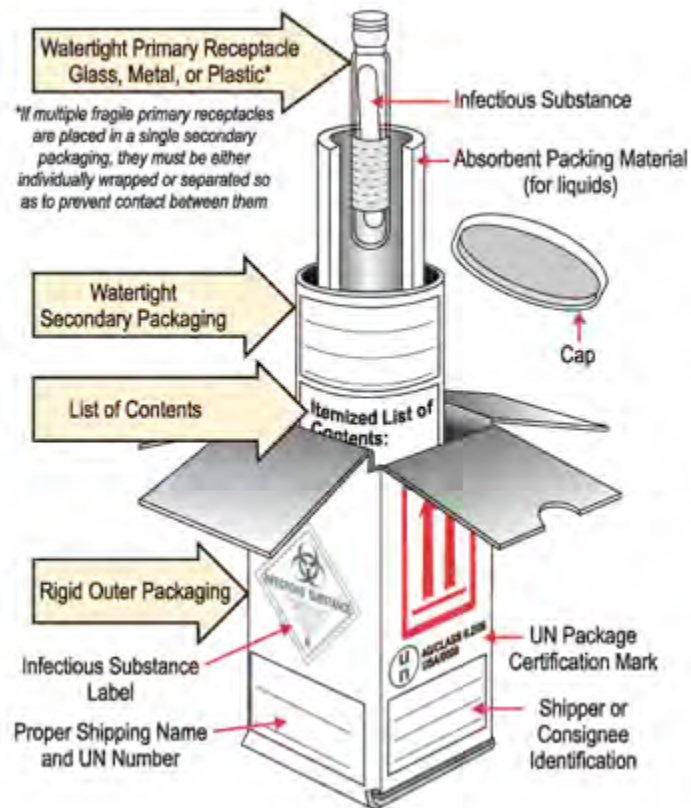
*Without ongoing testing, proper patient care is impossible to provide*

# Patient Diagnostic Process



# Current: Transport & Storage

## Current Specimen Transportation Method



## Current Specimen Storage Method

Requires 24 hr monitoring

Maintains -86 to 50°C via Microprocessor Temperature Control System



# The Biggest Challenge is in Resource Limited Areas

- ◆ The majority of global infections for HCV, HBV and HIV are outside of the US or Western Europe where the shipping of samples is more prevalent...
- ◆ In resource limited areas, the transportation and storage of blood samples to centralized labs can be cost prohibitive or virtually impossible



<b>Number infected in millions</b>	HIV	HCV	HBV
<u>Region</u>			
United States	1.2	4.0	1.5
Western Europe	0.7	5.0	4.0
Rest of World	32.1	161.0	344.5
Total	34.0	170.0	350.0

*Over 94% of people infected with HCV,  
HBV and HIV are in regions outside of the US and Europe*

# Introducing ViveST™

- Novel dried sample matrix holds up to 1.5 mL of liquid biological sample
- Eliminates dry ice and cumbersome packaging, Reduces shipping costs
- Environmental monitoring using color-indicating desiccant
- Recovered sample can be used in downstream molecular testing



# ViveST Design Features



# Simple Workflow

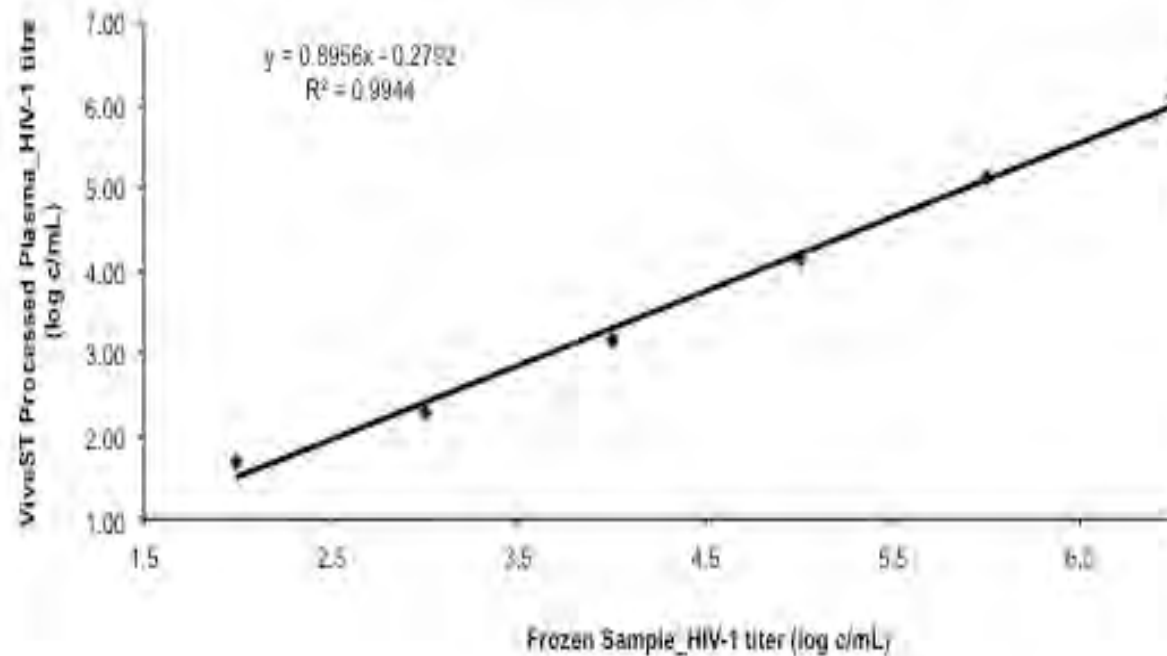




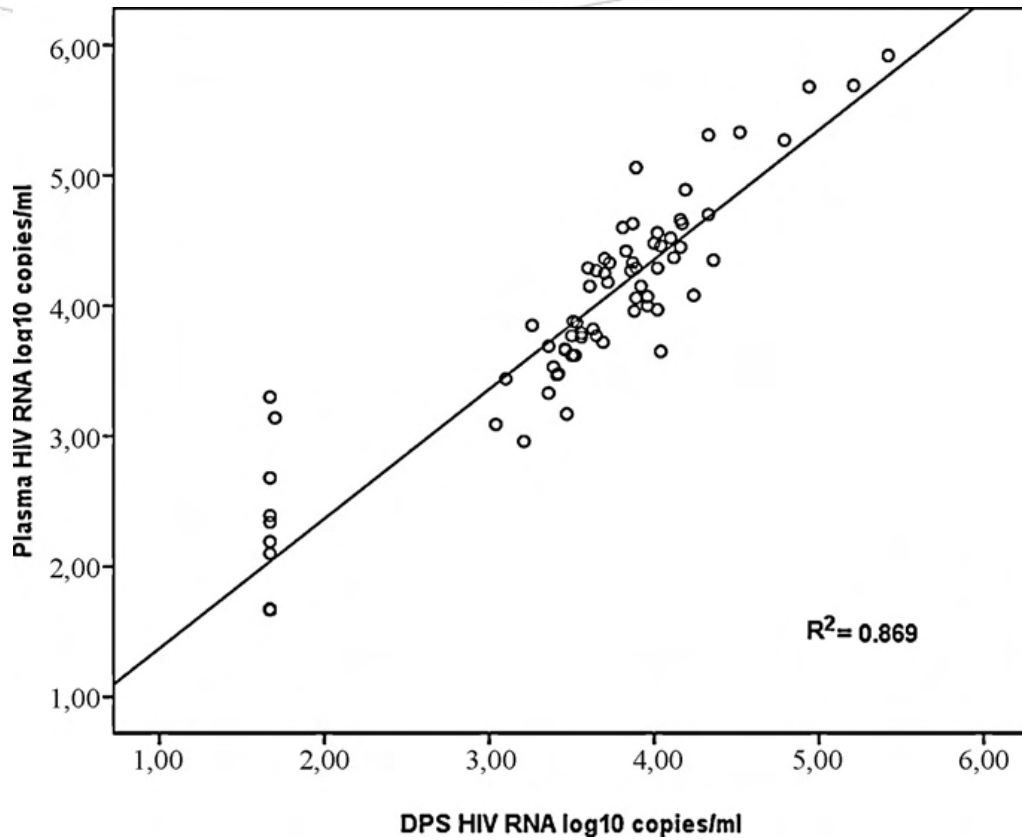
# HIV-1 Sample Correlation

## Abbott RealTime HIV-1 Assay

ViveST\_Abbott RealTime HIV-1 Linearity

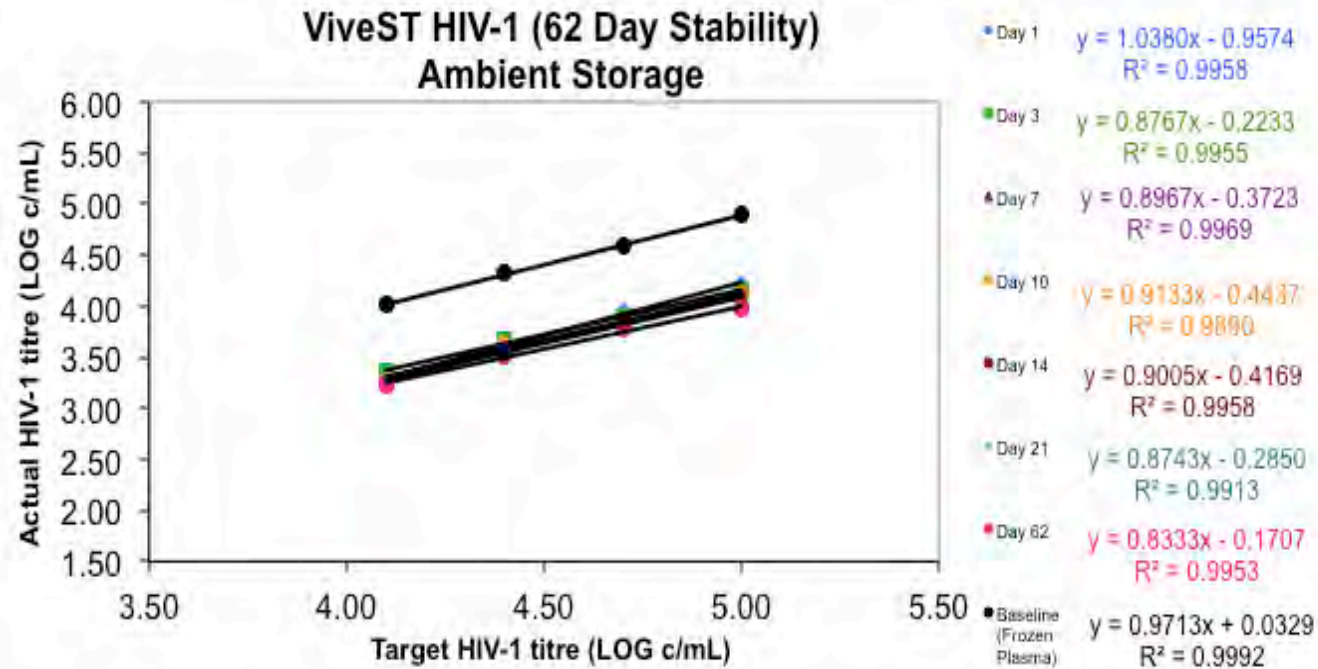


# Dried Plasma Spots



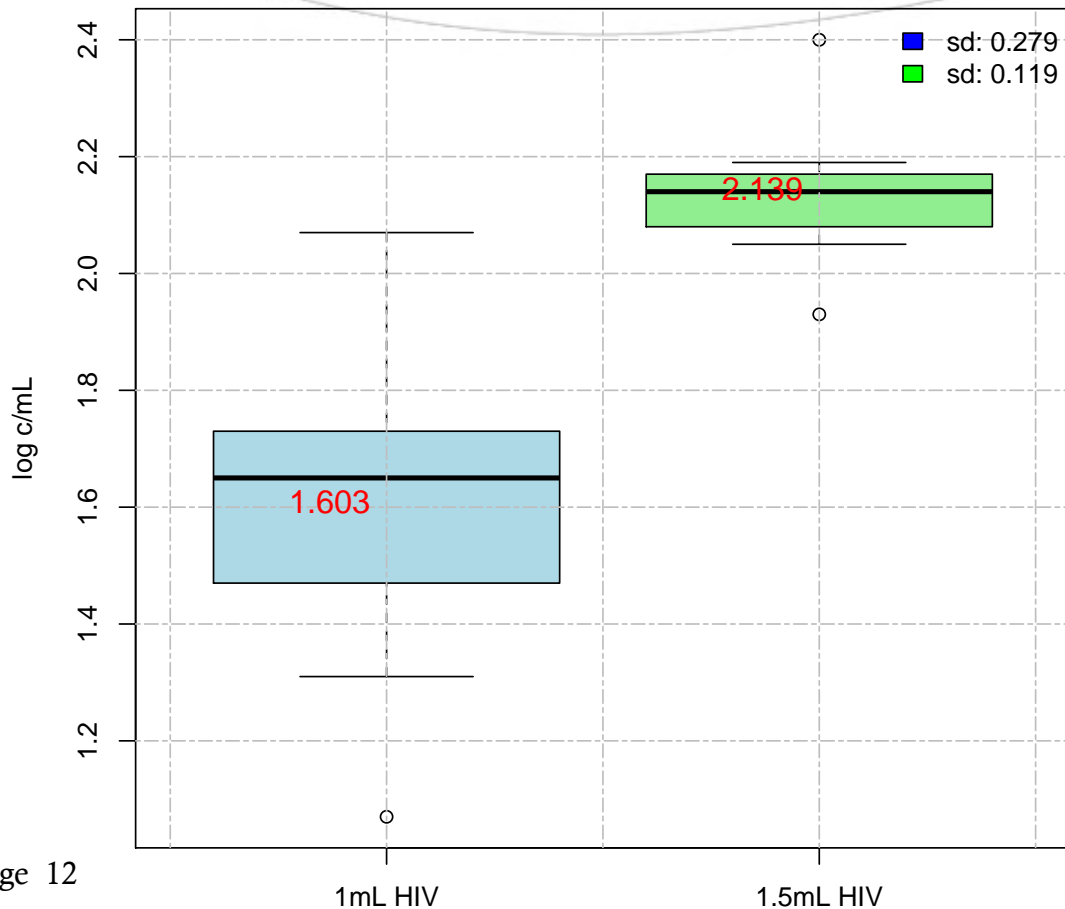
# HIV-1 Sample Stability

## Abbott RealTime HIV-1 Assay



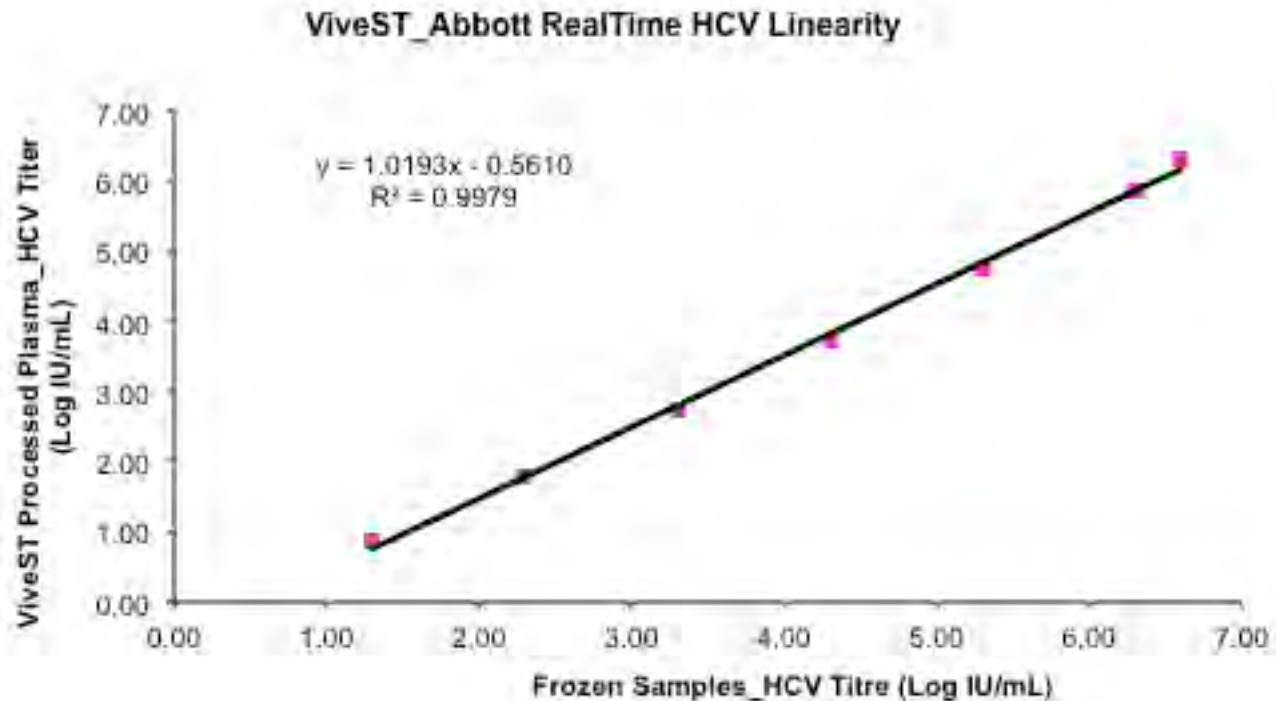
# HIV-1 Concentration

## Abbott RealTime HIV-1 Assay

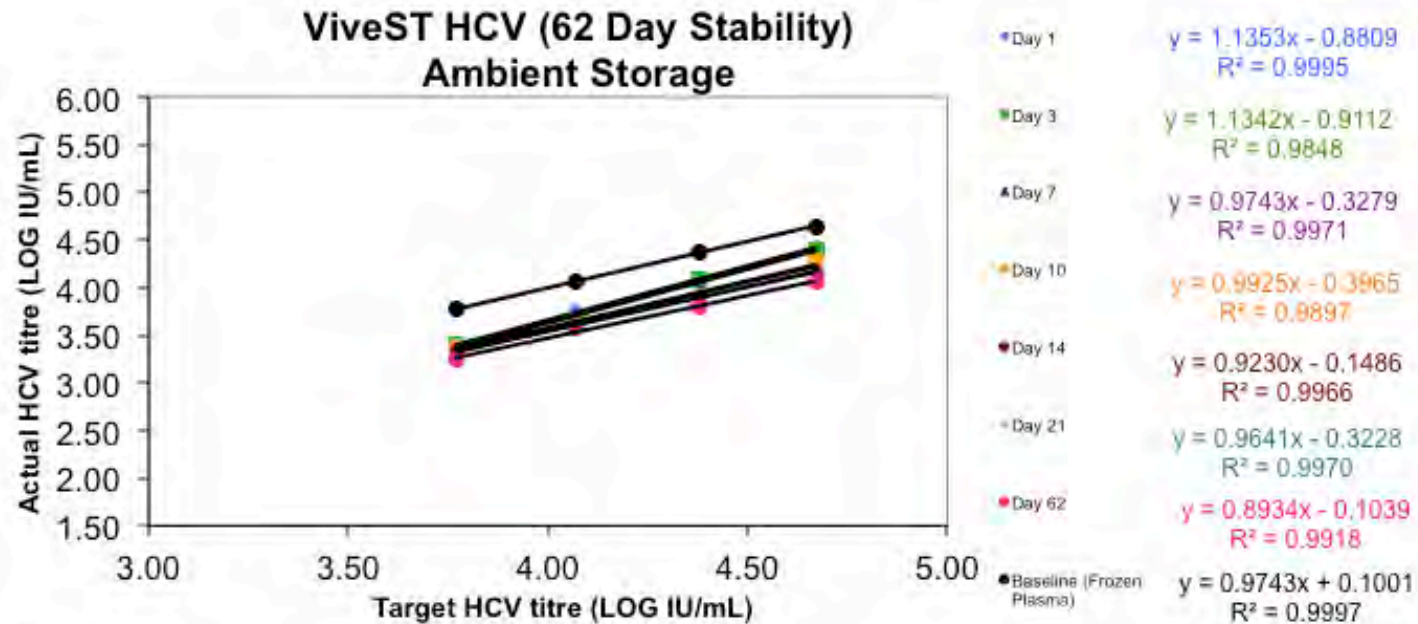


An average value of 2.14 LOG c/mL was obtained when 1.5 mL of a low titer HIV-1 infectious plasma sample was loaded on ViveST and recovered using 1.0 mL of molecular grade water compared to an average value of 1.6 LOG c/mL when 1 mL was loaded and recovered using 1.0 mL molecular grade water.

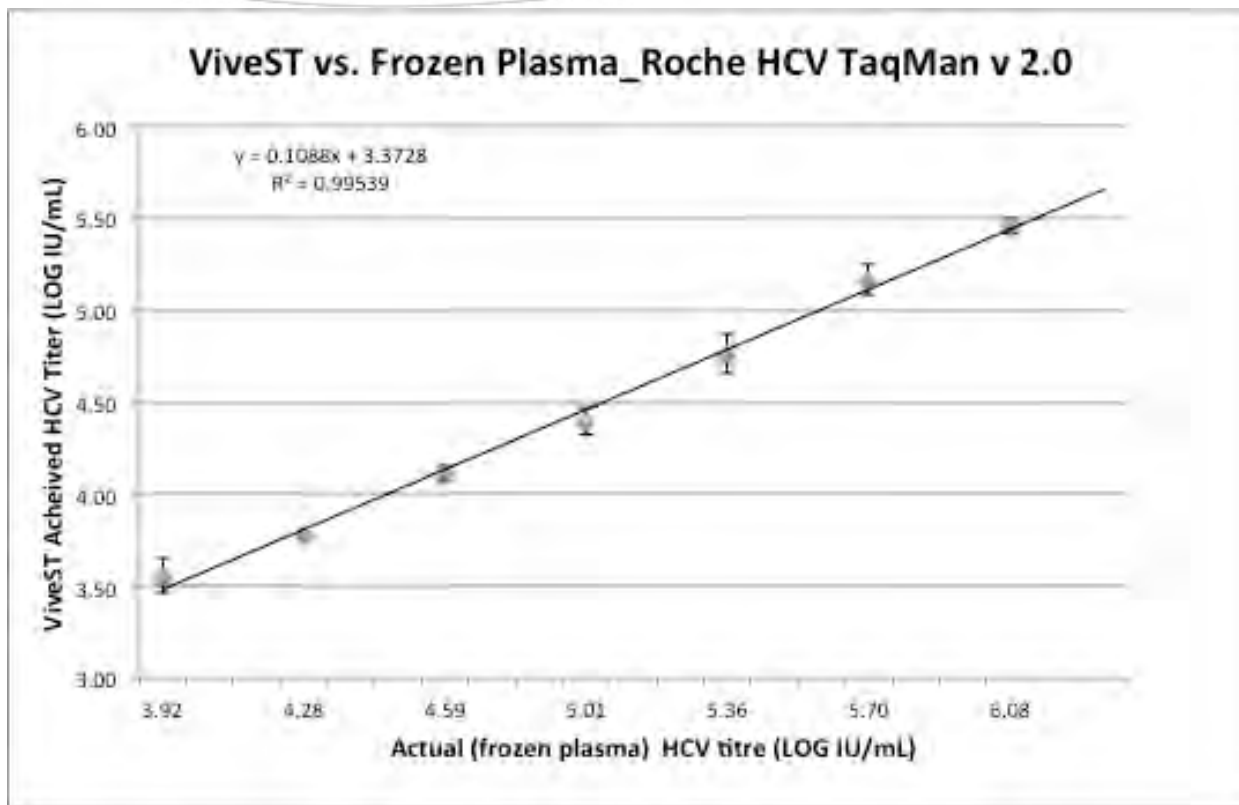
# HCV Sample Correlation Abbott RealTime HCV Assay



# HCV Sample Stability Abbott RealTime HCV Assay

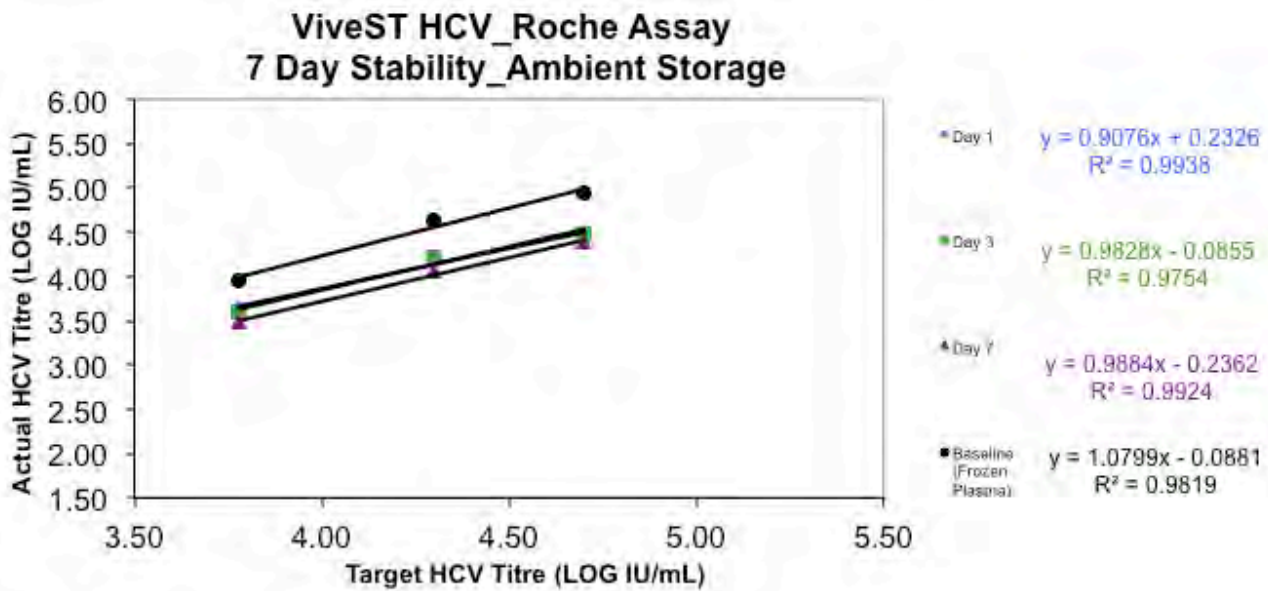


# HCV Sample Correlation Roche COBAS TaqMan HCV v2.0



# HCV Sample Stability

## Roche COBAS TaqMan HCV v2.0





# HCV Genotyping\_Sample Correlation

## Abbott RealTime HCV Genotype II RUO

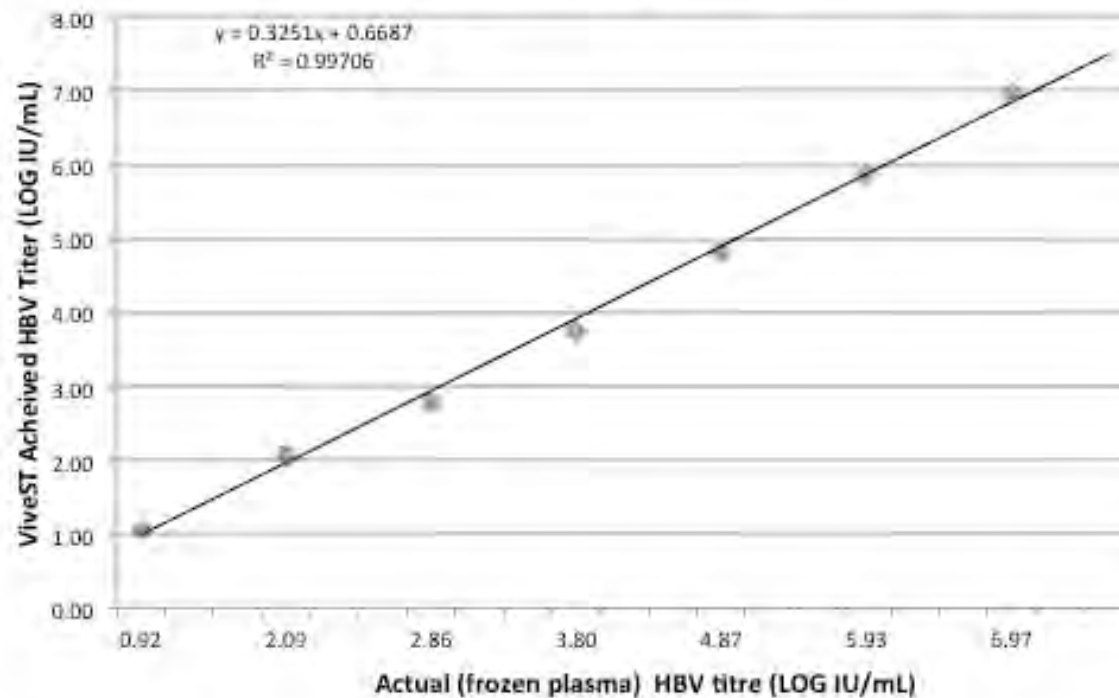
Viral Load Range  
 Analyzed: 2.64 LOG  
 IU/mL to 5.75 LOG  
 IU/mL

Assay Cut-off: 2.69  
 LOG IU/mL (500 IU/  
 mL)

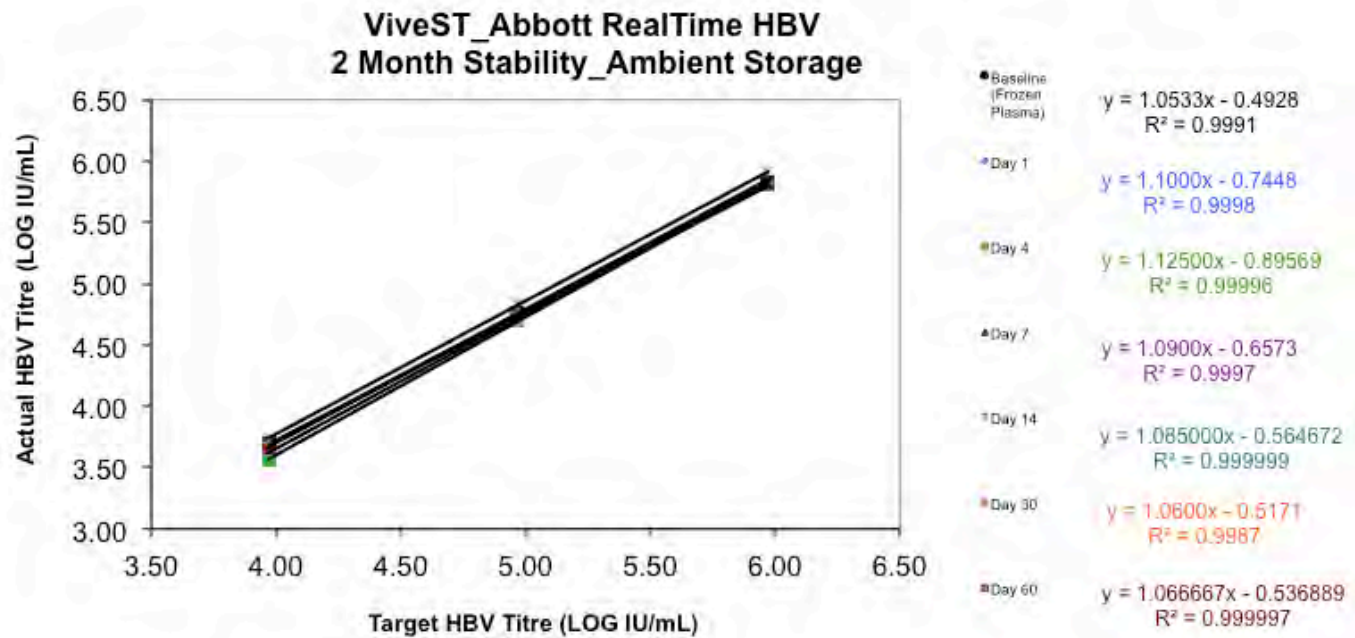
Sample ID	Fresh Plasma	ViveST Processed
b1169-1	2	2
b1170-2	1, 1a	1, 1a
b1171-3	1, 1a	1, 1a
b1172-4	1, 1a	1, 1a
b1173-5	1, 1a	1, 1a
b1174-6	1, 1a	1, 1a
b1175-7	1, 1a	1, 1a
b1176-8	1, 1a	1, 1a
b1177-9	1, 1a	1, 1a
b1169-10	2	2
b1179-11	3	3
b1180-12	1, 1a	1, 1a
b1184-13	3	3
b1178-14	3	3
b1172-15	1, 1a	1, 1a
b1185-16	1, 1a	1, 1a
b1186-17	1, 1b	1, 1b
b1172-18	1, 1a	1, 1a
b1187-19	1	1

# HBV Sample Correlation Abbott RealTime HBV Assay

ViveST vs. Frozen Plasma\_Abbott RealTime HBV

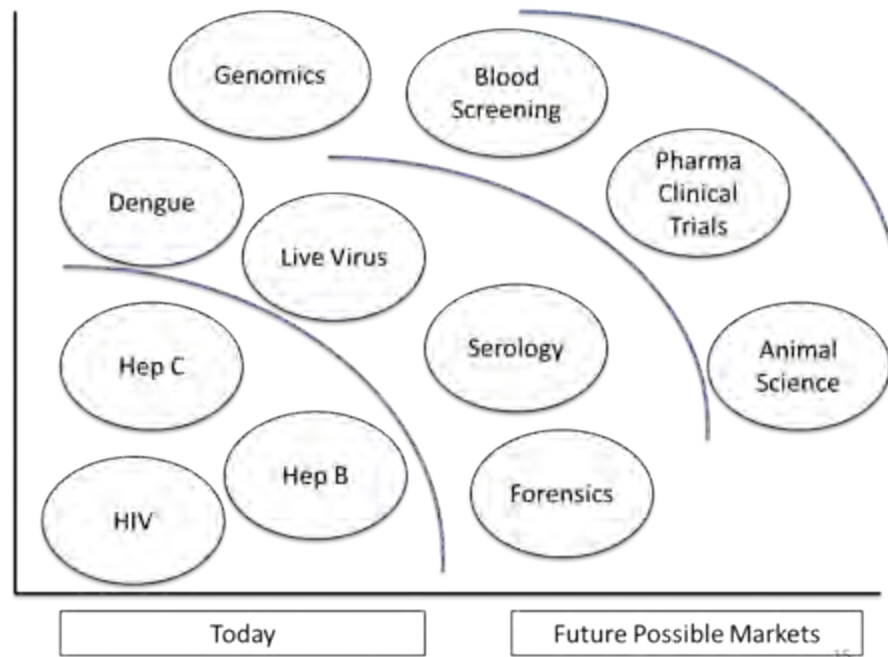


# HBV Sample Stability Abbott RealTime HBV Assay



# Dried Specimen Opportunities

The use of a dried matrix for transporting specimens can extend healthcare to resource limited areas for applications beyond HCV, HBV and HIV



# ViveST: Technology Comparison

## DBS:

- Small sample volume capacity
- Non-controlled storage environment

## Plasma:

- Must remain frozen
- Expensive transport
- Careful handling required

	ViveST	DPS	Plasma
1 mL (or more) Sample Volume	✓		✓
Dried Sample Matrix	✓	✓	
Ambient Transport/Storage	✓	✓	
Quantitative Reproducibility (linear dynamic range for VL assays)	✓		✓
Reduced Shipping Costs	As low as \$2.51/sample**	✓	Over \$11.05/sample**
Controlled Sample Environment	✓		

\*Dried-plasma transport using a novel matrix and collection system for human immunodeficiency virus and hepatitis C virus virologic testing. RM Lloyd, Jr., et al. J Clin Microbiol, 47(5), May 2009, p. 1491-96.

# Summary & Conclusions

- ViveST™ shows great potential for use in transport and storage of plasma for VL and genotypic testing
- For some targets, VL results from ViveST slightly lower compared to frozen plasma...consider a correction factor
- Plasma recovered from ViveST can be directly utilized in numerous downstream applications; no additional processing required
- The use of ViveST can enhance access to VL and genotypic testing in resource-limited countries and significantly reduces the burden associated with shipping frozen samples

# THANK YOU

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