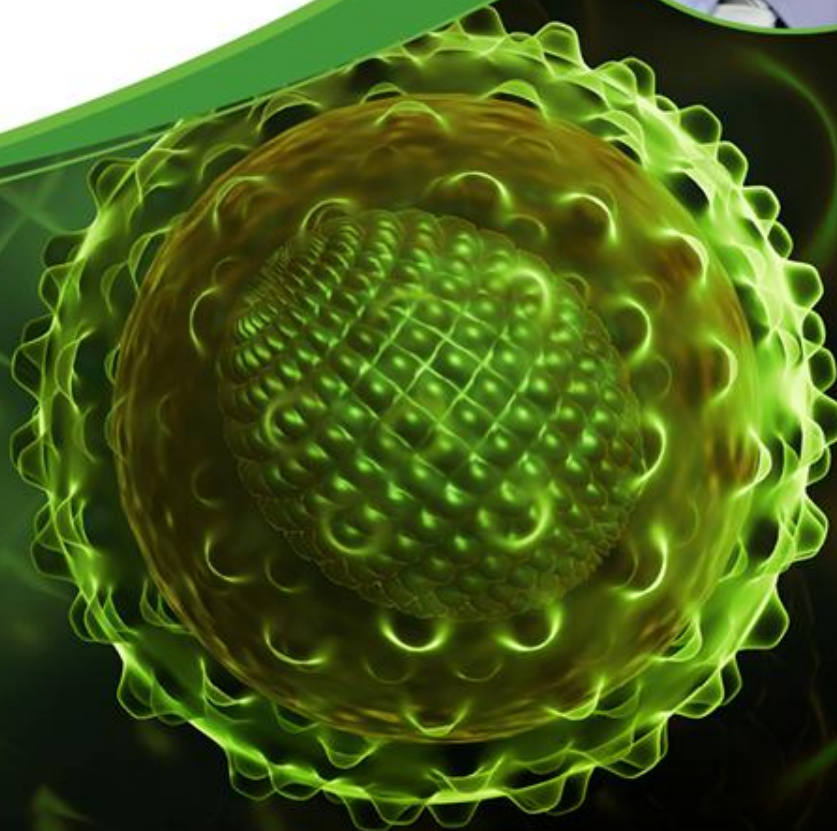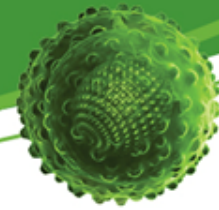# Abbott RealTi*me* HCV Assay

Acceptance Criteria for HCV VL Assay in Clinical Trials

Basic Requirements
- Realtime PCR
- Sensitivity / Linearity
- Accuracy
- Precision
- No Genotype Bias

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Not all realtime PCR assays are the same
- Probe Design
- Cycling Conditions
- Extraction Chemistry
- Calibration Strategy

Does it matter?

Abbott RealTi*me* HCV Cycling Conditions
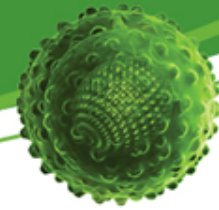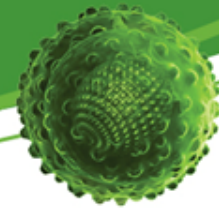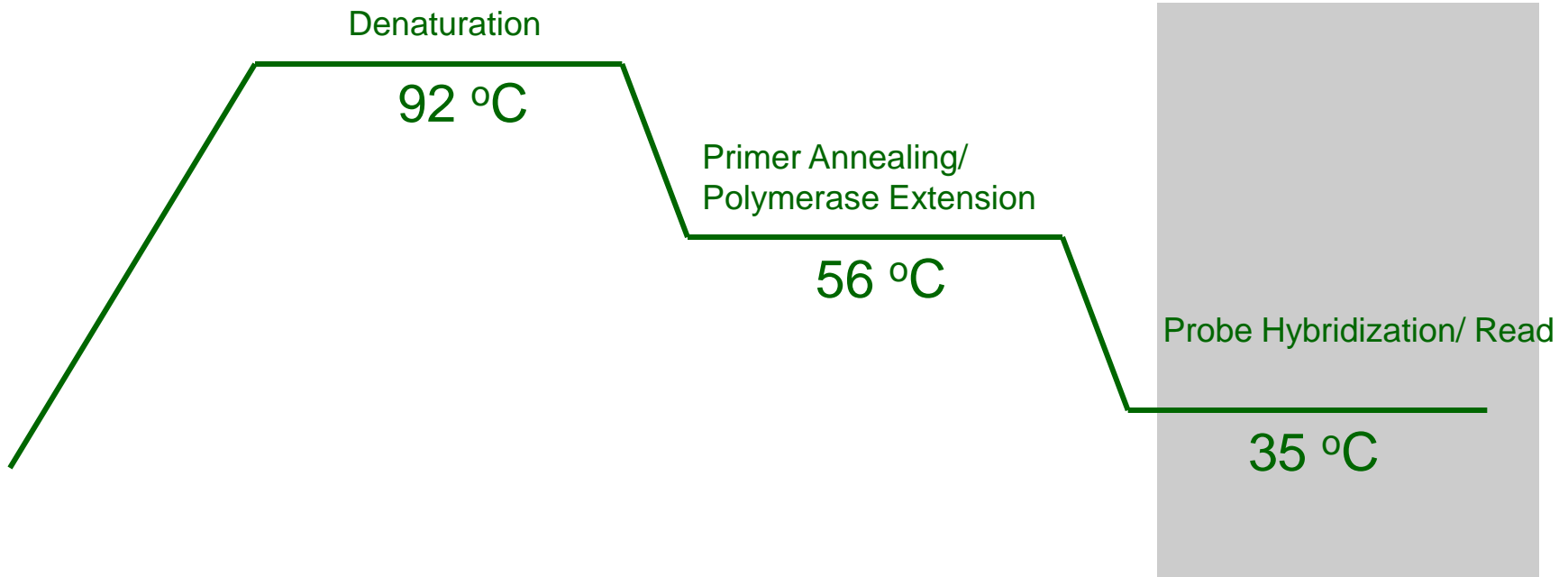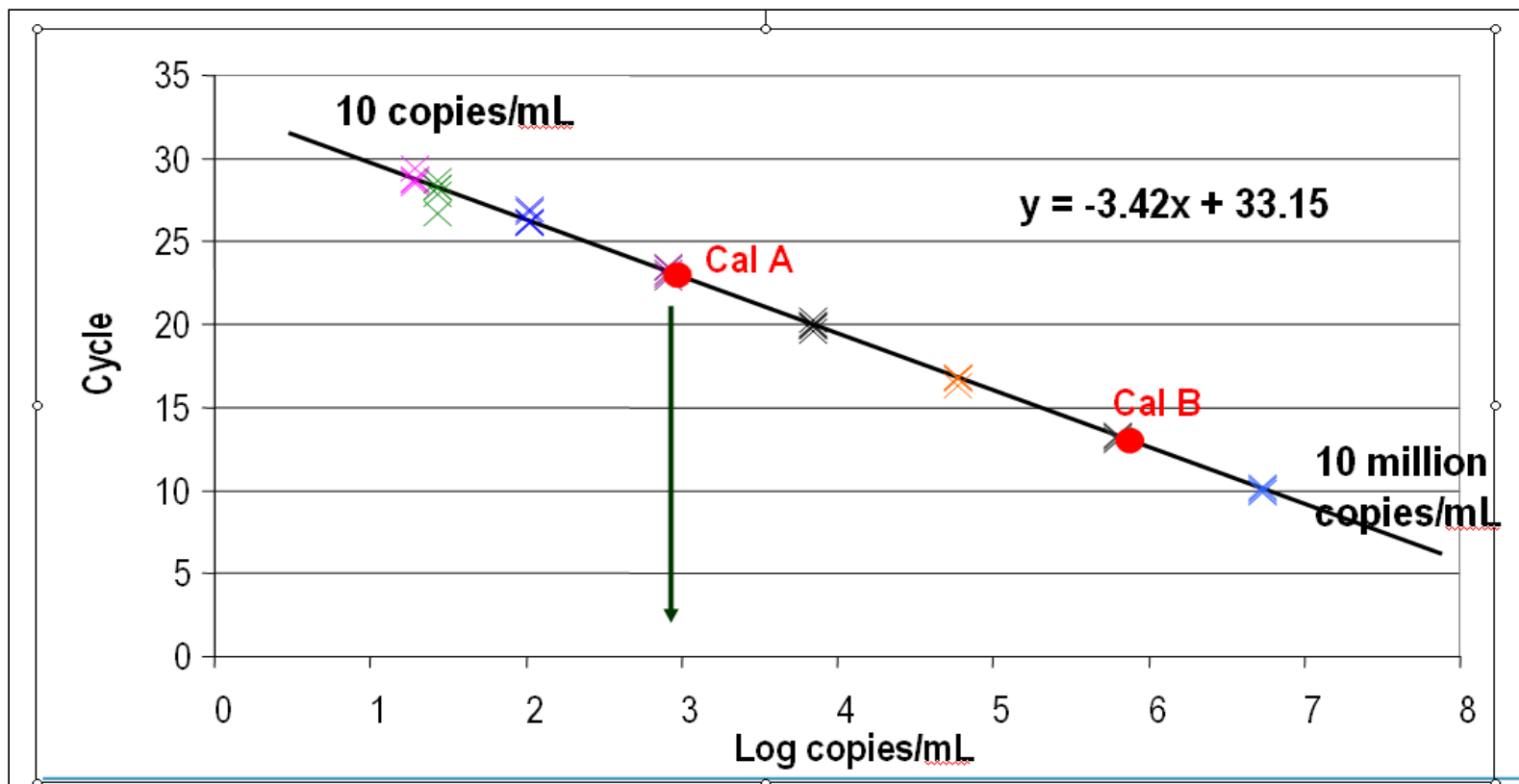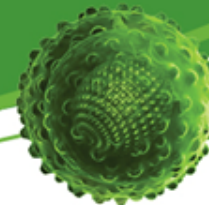
At The Center of Innovation

Low Temperature Read Cycles
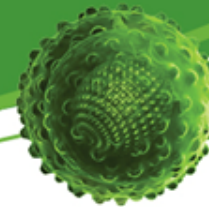
- Abbott RealTime HCV assay encompass a low temperature read cycle which allows the probe to tolerate mismatches more effectively.

Denaturation

92 °C

Primer Annealing/
Polymerase Extension

56 °C

Probe Hybridization/ Read

35 °C

Abbott
Molecular

Abbott RealTi*me* HCV Calibration Strategy

The figure shows a calibration plot of Cycle (y-axis, 0 to 35) versus Log copies/mL (x-axis, 0 to 8), with labels "10 copies/mL", "10 million copies/mL", "Cal A", "Cal B", and the equation:

$$y = -3.42x + 33.15$$

Abbott RealTi*me* HCV Linearity

Abbott RealTi*me* HCV
Linearity with Plasma

$y = 1.00x - 0.01$
$r = 0.999$
$n = 106$
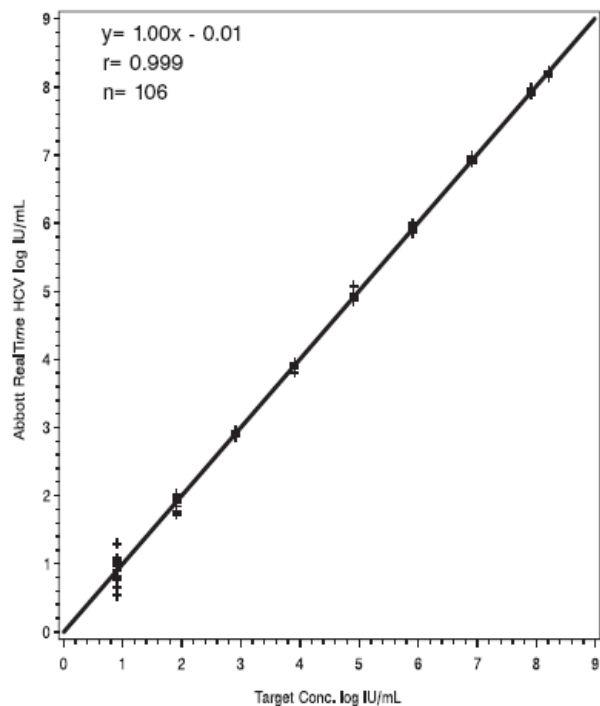
Abbott RealTime HCV (1N30) 51-608374/R1 package insert

Abbott RealTi*me* HCV Linearity

**Abbott RealTi*me* HCV
Linearity with Plasma**
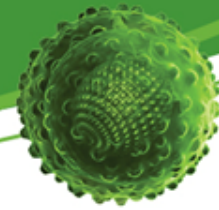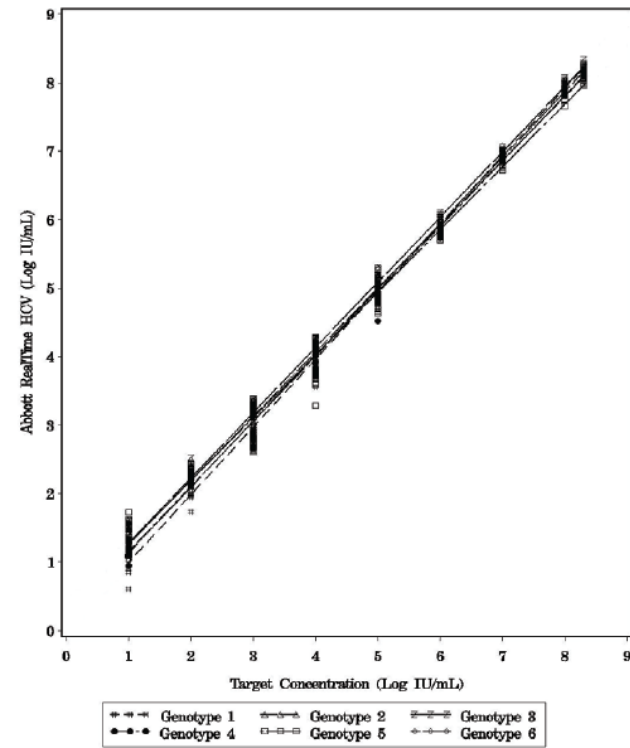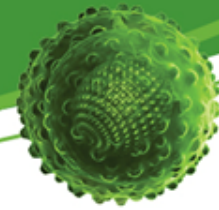
$y = 1.00x - 0.01$
$r = 0.999$
$n = 106$

**Figure 4
Abbott RealTi*me* HCV
Linearity By Genotype**
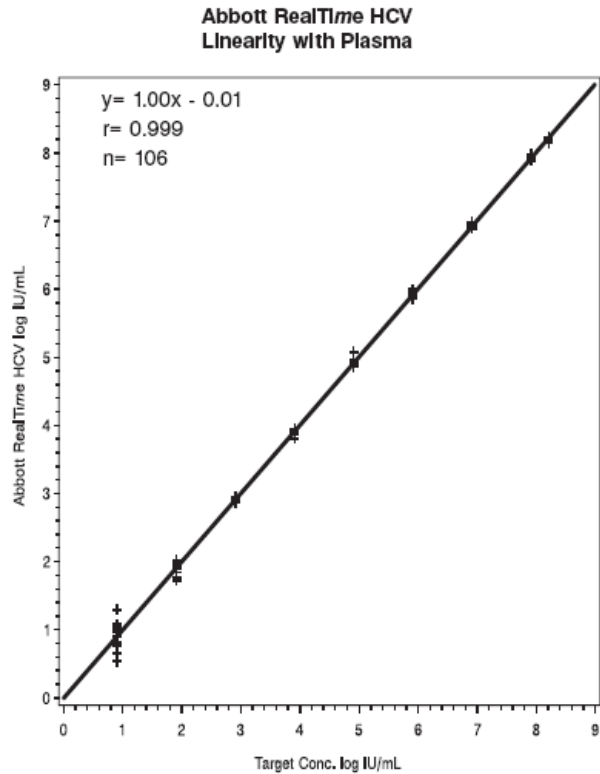
Abbott RealTime HCV (1N30) 51-608374/R1 package insert
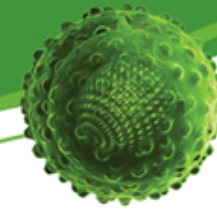
Abbott
Molecular

HCV VL Assay LOD/LOQ Comparison

	Abbott RealTime HCV m2000 (Automated)	Roche TaqMan HCV 1.0 CAP/CTM (Automated)	Roche TaqMan HCV 1.0 HighPure (Manual)
Limit of Detection	12 IU/mL	18 IU/mL	15 IU/mL
Limit of Quantitation	12 IU/mL	43 IU/mL	25 IU/mL

Abbott RealTime HCV VL assay LOD = LOQ

Abbott Molecular

Reproducibility in a multi-site study

Twenty-one laboratories used Roche Taqman and nine used Abbott RealTime

Roche Taqman — **Low Positive**
Abbott RealTime

Roche Taqman — **High Positive**
Abbott RealTime

Source: Pisani et al., JCM 2009

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Note: This study was conducted with the CE marked Abbott RealTime HCV assay

Abbott Molecular