

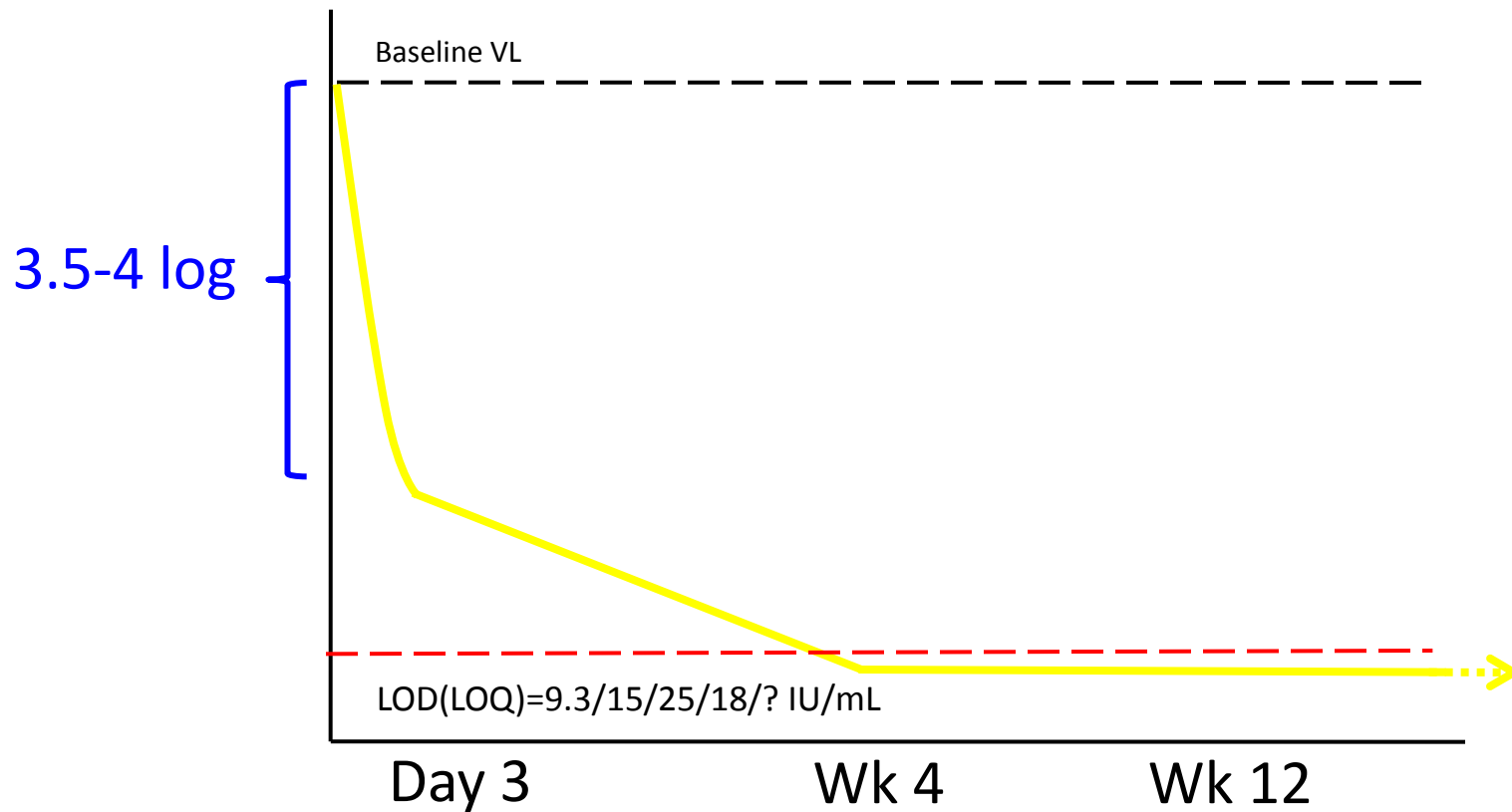
HCV RNA Viral Load Assays: Consensus on how to report results

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HCV RNA in PI/Peg-IFN/RBV-treated patients



COBAS® TaqMan® HCV, v2.0 Test for Use with the High Pure System

Results Reported

Specimen results are interpreted as follows:

Titer Result	Interpretation
Target Not Detected	No Ct value for HCV obtained. Report results as "HCV RNA not detected".
< 2.50E+01 IU/mL	Calculated IU/mL are below the lower limit of quantitation, (LLoQ) of the assay. Report results as "HCV RNA detected, less than 25 HCV RNA IU/mL, HCV RNA is not quantifiable."
≥ 2.50E+01 IU/mL and ≤ 3.00E+08 IU/mL	Results greater than or equal to 2.5E+01 IU/mL and less than or equal to 3.00E+08 IU/mL are within the Linear Range of the assay.
> 3.00E+08 IU/mL	Results are above the range of the assay. Report results as "greater than 3.00E+08 HCV RNA IU/mL". If quantitative results are desired, the original specimen should be diluted 1:100 with HCV-negative human serum or EDTA plasma, depending on the matrix of the original specimen, and the test repeated. Multiply the reported result by the dilution factor.

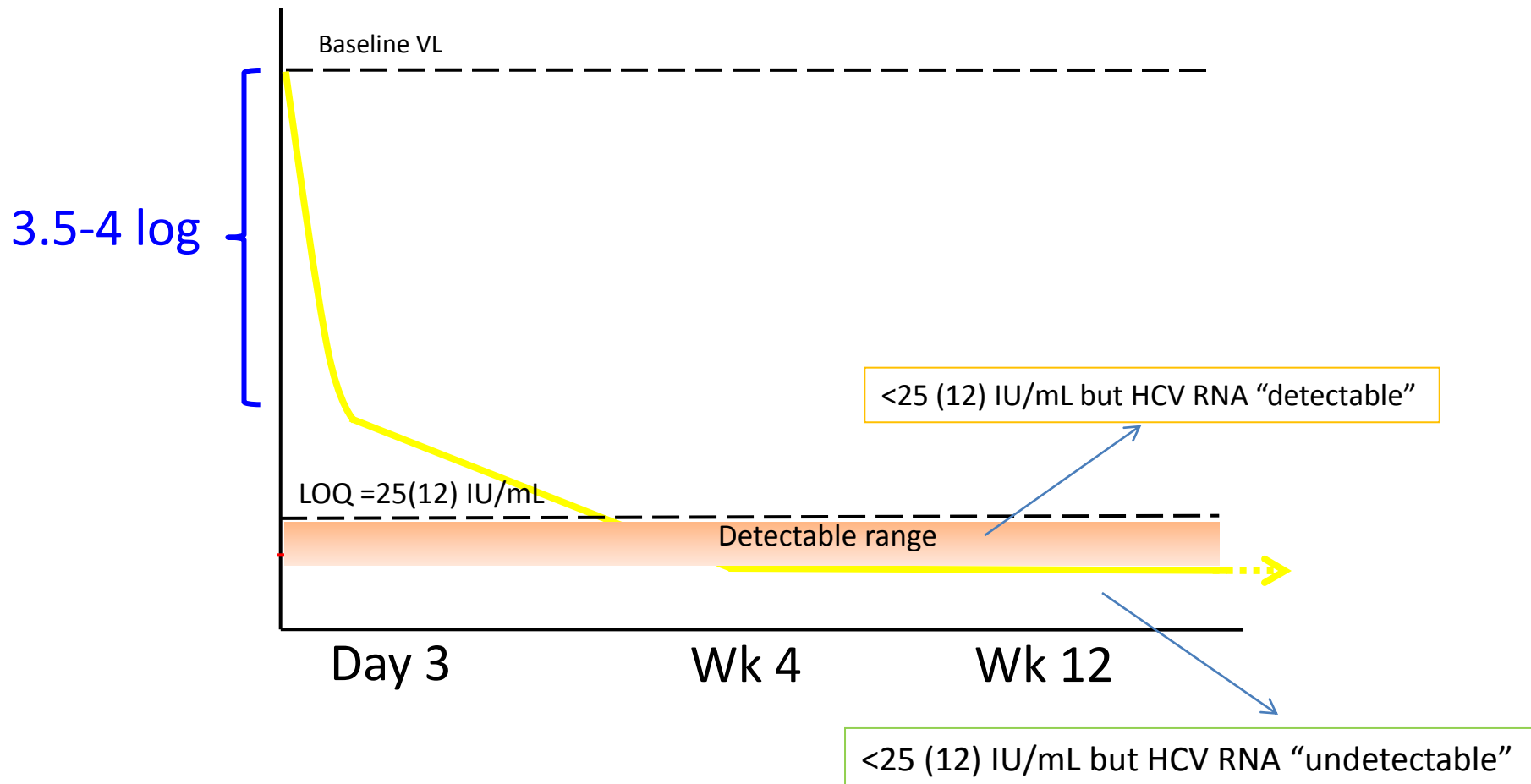
COBAS® TaqMan® HCV, v2.0 Test for Use with the High Pure System, Package Insert

Linear Dynamic Range: HCV RNA 25 – 300,000,000 IU/mL,
Clinically Reportable Range: HCV RNA 25 – 30,000,000,000 IU/mL

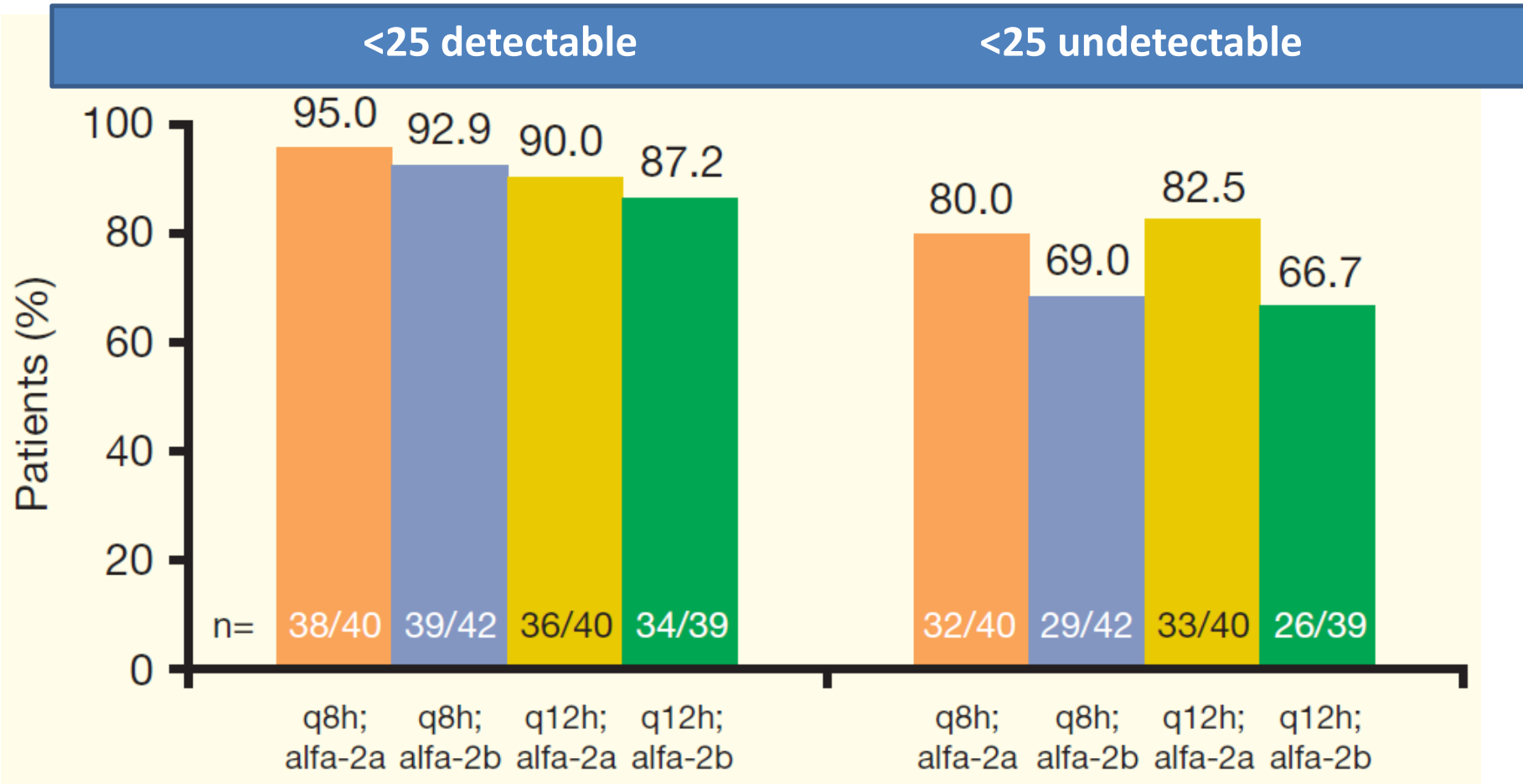
HCV Assay Overview (CE)

Assay Format	Realtime PCR	
Approval Status	CE approved, IVD FDA (submitted / pending approval)	
Probe Format	Single Stranded Linear Probe	
Target Region	5' - UTR	
Sample Requirements	ACD-A or EDTA, Plasma or Serum 0.5 mL or 0.2 mL sample input	
Genotype Detection	Genotypes 1, 2, 3, 4, 5, 6	
Specificity	>99%	
Limit of Quantitation	12 IU/mL (95% CI all Genotypes)	
Limit of Detection	12 IU/mL (95% CI all Genotypes)	
Linear Range	12 IU/mL to 100 million IU/mL	
Reporting Format	<u>Result</u>	<u>Interpretation</u>
	1.08 to 8.00 Log IU/mL	Detected
	< 1.08 Log IU/mL	Detected
	Not Detected	Target Not Detected
	>8.00 Log IU/mL	> Upper Limit of Quantitation

HCV RNA in PI/Peg/RBV-treated patients



C208: Virologic response rate at Week 4



No treatment group comparisons were statistically significant

- Propose to adhere to label language and report results as <LLOQ, either “detectable” or “undetectable”
- Explore Response Guided Therapy (RGT) using less stringent thresholds?