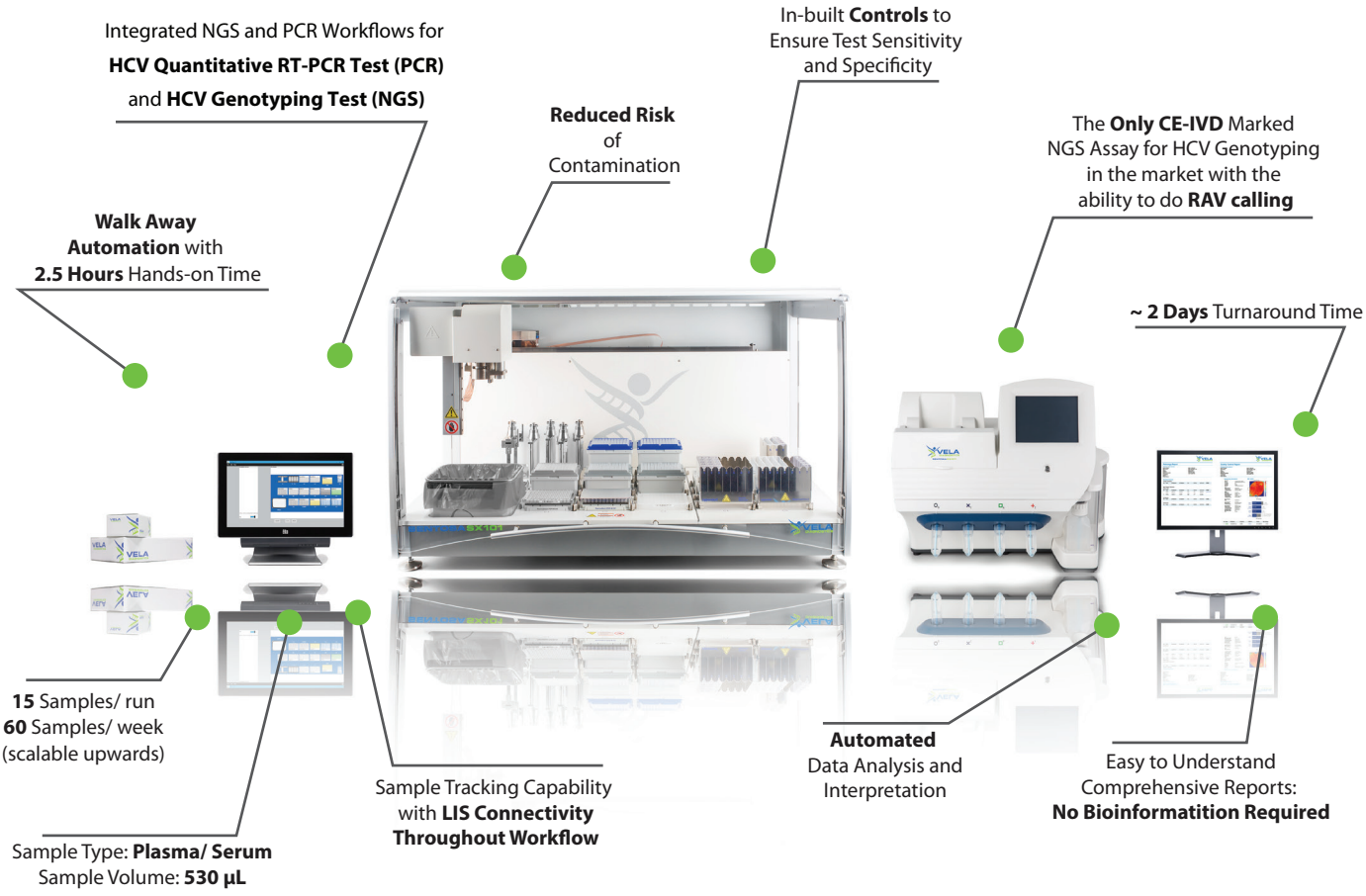
Precise Detection of HCV Genotypes and RAVs

Automated End-to-End NGS Solution

The *Sentosa*® SQ HCV Genotyping Assay is a clinically validated Next-Generation Sequencing (NGS) test for genotyping and variant calling for Hepatitis C Virus (HCV) in clinical samples.

- Achieves 100% genotyping correctness[1]
- Enables highly reproducible results for routine diagnostics, through automation of sample processing, library prep, sequencing, result reporting on a single platform[2]
- Validated and approved for *in vitro* diagnostic use (CE-IVD)

The *Sentosa*® NGS Workflow- Automated from Sample-to-Variant Call



The *Sentosa*® SQ HCV Genotyping Assay greatly minimizes the occurrences of indeterminate results, as compared to probe-based genotyping assays[1,3]

Genotyping methods that are based on either reverse hybridization targeting 5'UTR/ core regions or real-time PCR targeting 5'UTR/ NS5B have been reported to cause up to 10% of inaccurate and incomplete genotype assignment. [4,5,6] This leads to risk of treatment failure and consequently undue pharmacological costs driven by inappropriate genotype characterization.[5] The use of sequence analysis of HCV genotype could lead to a decrease in direct medical costs for the treatment of HCV-infected individuals, due to savings for the lower number of retreated patients and lack of disease progression.[5]

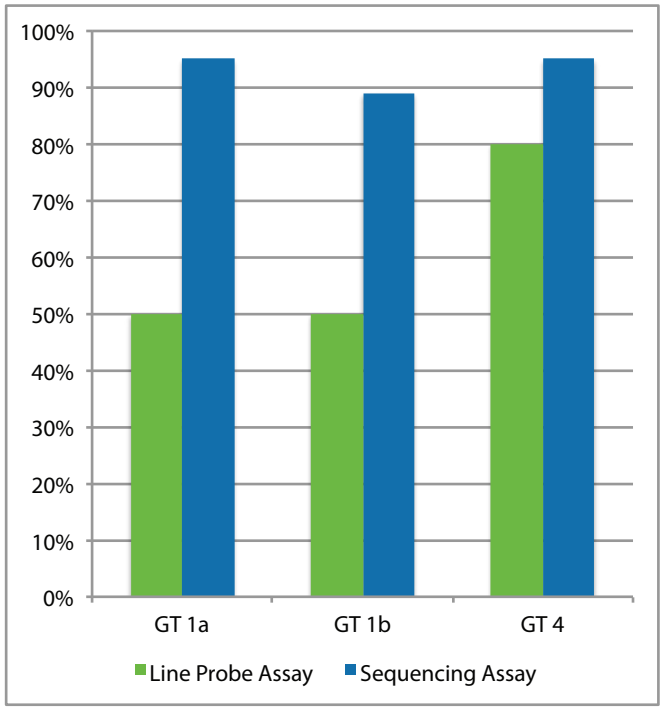


Figure 1: Estimated efficacy of treatment prescribed on the basis of line probe genotype assay vs treatment prescribed on sequence analysis results. Sequencing assay greatly minimizes the occurrences of indeterminate results as compared to line probe assay. [4,5,6]

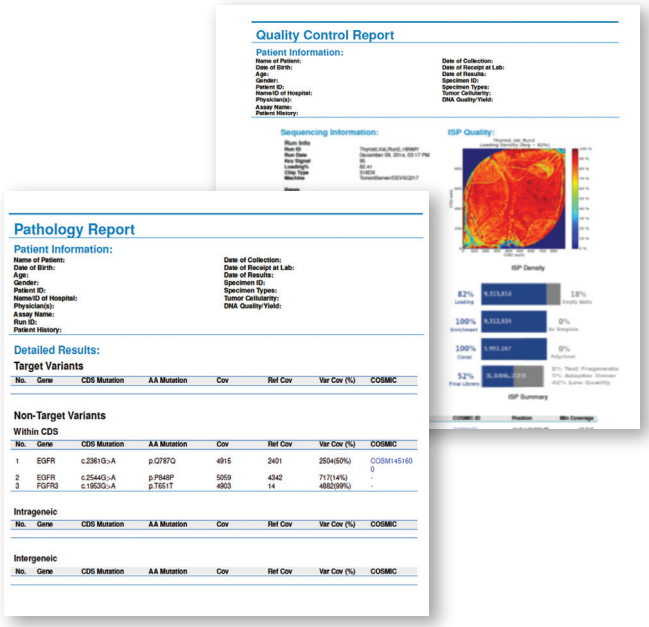


Figure 2: Automated sequence analysis and reporting- The *Sentosa*® SQ Reporter automatically generates a Pathology and Quality Control Report. The Pathology report provides information of the HCV Genotyping Assay, genotypes detected and the contigs and target variants. The QC report generates the run QC data, sequencing information, genotypes and coverage and all technical measurements of sequencing quality.

Visit www.veladx.com/NGS-Virology for more information about the workflow and to download a sample report.

References
[1,2,3] Data on file
[4] Chronic Hepatitis C Virus Infection: Developing Direct-Acting Antiviral Drugs for Treatment Guidance for Industry, by FDA/CDER, Revision 2, published May 2016
[5] Polilli, Ennio et al. Consequences of Inaacurate Hepatitis C Virus Genotyping on the Costs of Prescription of Direct Antiviral Agents in an Italian District. ClinicoEconomics and Outcomes Research: CEOR 8 (2016): PMC. Web. 8 Nov 2016.
[6] Ceccherini-Silberstein F, Di Maio VC, Aragri M, Ciotti M, Cento V, Perno CF. Hepatitis C virus gene sequencing as a tool for precise genotyping in the era of new direct antiviral agents. Hepatology. (2016) 63 (3):1058-1059

IVD: For *in-vitro* diagnostic use. Not for distribution in US.

Vela Operations Singapore Pte Ltd
Reg No: 201106974H
50 Science Park Road
#05-07 The Kendall
Singapore 117406
T: +65 6672 6060
T: 1800 225 8352 (Toll-Free)
F: +65 6672 6066
E: infoAPAC@veladx.com

Vela Diagnostics Germany GmbH
Albert-Einstein-Ring 15
22761 Hamburg
Germany
T: +49 40 890 662233
F: +49 40 890 662299
E: infoEMEA@veladx.com

Vela Diagnostics Australia Pty Ltd
PO Box 4045
North Curl Curl 2099 NSW
Australia
T: 1300 012 391
F: +61 2 9423 6970
E: infoANZ@veladx.com

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