

Product Information

Update IFU of the RoboGene HCV RNA Quantification Kit 3.0 to Revision 6 – 31.05.2022

Hereby, please be informed, that Roboscreen GmbH has updated the Instruction for use (IFU) of the RoboGene HCV RNA Quantification Kit 3.0 to Revision 6. This includes the following order numbers: 847-0207610032 (32 reactions), 847-0207610096 (96 reactions) and 847-0207610192 (192 reactions). The applicable revision level of the IFU is indicated on the label of the product packaging.

Please be sure to inform your customers and users about the changes mentioned in this product information and adjust the product information on your website.

Major update of the IFU Rev. 6 of the RoboGene HCV RNA Quantification Kit 3.0 is the extension of the validated qPCR platforms with the Quant Studio 5, RealLine Cyclers 48 & 96. This leads to changes in the following chapters of the IFU:

- 1.1 Intended use: Extension of the Intended use with the qPCR platforms with the Quant Studio 5, RealLine Cyclers 48 & 96.
- 3.2 Explanation of the HCV RNA quantification test: Update of the number of known genotypes of HCV from 7 to 8 with new reference [4].
- 4.1 Analytical Sensitivity: Extension of table 1b of determined device specific limits of detection and confidence intervals using automated nucleic acid purification with data for the qPCR platforms Quant Studio 5, RealLine Cyclers 48 & 96.
- 4.5 Robustness: Adding of table 5b with data for the qPCR platforms Quant Studio 5, RealLine Cyclers 48 & 96.
- 6 Necessary laboratory equipment and additives: Extension of table 8 to include consumables for the qPCR platforms Quant Studio 5, RealLine Cyclers 48 & 96.
- 8.7 Preparation of reaction set: Extension of table 11 with the thermal profile of the RealLine Cyclers 48 & 96. Adding of table 12 with the Quant Studio 5 thermal profile.
- 9 Data analysis: Extension of the notes for data analysis to the qPCR platforms Quant Studio 5, RealLine Cyclers 48 & 96.

Further changes of the IFU Rev. 6 of the RoboGene HCV RNA Quantification Kit 3.0 include:

- 7.1 Collection and handling of clinical samples: Changes of advice for handling of serum and plasma samples as well as storage of samples at ≤ -20 °C with new references.
- 11 References: Added references [9] and [10].

For further information on the RoboGene HCV RNA Quantification Kit 3.0 please visit our homepage www.roboscreen.com or get in contact with us.

