# RealFast<sup>™</sup> Confirmation Service





# Purpose:

The RealFast<sup>TM</sup> Confirmation Service is designed to assist ViennaLab customers in establishing and regularly monitoring the proper use of RealFast assays in their particular laboratory setting. This external survey can be implemented in the customer's quality management (QM) system as kind of a performance control and quality assurance, and may also be useful to obtain and maintain laboratory accreditation by regulatory bodies.

# **Description:**

DNA samples (min. 5) provided by the customer shall be analyzed using RealFast assay(s) in parallel in the customer lab and by ViennaLab. Results shall be compared, and if matching a Certificate will be issued.

# Ordering and pricing:

Orders shall be sent through the local ViennaLab distribution partner to <a href="mailto:order@viennalab.com">order@viennalab.com</a>. One "unit" of CS-045 comprises testing of 5-10 samples using one particular RealFast assay. If more samples shall be tested in the same RealFast assay, any additional package of 10 samples comprises another unit which is offered at 10% discount. If samples shall be tested using more than one RealFast assay, the unit price will be multiplied by the number of RealFast assays.

Examples: (1.) 10 samples for RealFast assay X = 1x CS-045 at regular price

- (2.) 30 samples for RealFast assay X = 1x CS-045 at regular price + 2x CS-045 at 10% discount
- (3.) 10 samples for RealFast assays X, Y and Z = 3x CS-045 at regular price

## Materials and information to be supplied:

Any correspondence about samples and results shall be sent by email to diagnostics@viennalab.com.

- DNA samples sent in appropriately sealed tubes labelled with a unique identifier (e.g. sample number).
  <u>Amounts (per RealFast assay)</u>: DNA obtained using GenXtract (suitable for all RealFast assays except for 7-4xx CNV assays) min. 50 μl; DNA obtained by other methods min. 100 ng in min. 25 μl (note: testing samples in more than one RealFast assay requires mutiples of this amount).
  - <u>Required further information</u>: extraction method used and DNA concentration.
- RealFast assay(s) to be performed (name and cat.no.).
- RealFast assay results (genotypes or gene copy numbers) obtained by the customer, clearly referring to the nomenclature used on the sample tubes. Providing results in advance by the customer is mandatory!
- Institution (name, postal address) to whom the certificate shall be issued. If requested and provided, the name and titles of a particular person may be added.

### Certification:

A Certificate in pfd-format will be issued and provided by ViennaLab upon successful participation (100% accordance of results). Customers will be informed and may revise their results once in case of discordances. No additional documentation (e.g. original results) will be provided.

#### Disclaimer:

The RealFast™ Confirmation Service will be invoiced, but no Certificate will be issued if:

- the quality or quantity of DNA samples is inappropriate
- customer and ViennaLab results do not match 100% after review

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