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To all customers of Venor[®]GeM-qEP Type 1

Changes of Venor[®]GeM-qEP as of July 2009 and their influences on current validations

Dear valued customers,

the product VenorGeM-qEP, Type 1, was modified in July 2009 for increased user convenience:

1. Replacement of the fluorescent dye of the internal control probe by an innovative dye providing a stronger signal/noise ratio
2. Simplifying the pipetting procedure by adding the separate Internal Control Probe into the individual Primer/Probe/Nucleotide Mixes
3. Using the reaction buffer for rehydration of the Primer/Probe/Nucleotide Mix and increasing the rehydration volume from 65 to 365 μ l for more reliable rehydration of the reagents
4. As a consequence of change 3 the pipetting volume of the Primer/Probe/Nucleotide Mix for the master mix was increased.

The performance of the kit has been tested intensively for analytical and diagnostic specificity and sensitivity as well as robustness. No reduction in performance has been found in comparison to the former kit version.

We therefore confirm that all validation data generated with Venor[®]GeM-qEP type 1 before July 2009 are still valid. The updated version of Venor[®]GeM-qEP type 1 can be used as usual without a specific need for revalidation.

With kind regards

A handwritten signature in black ink, appearing to read 'Dirk Vollenbroich', is written over a light blue horizontal line.

Dr. Dirk Vollenbroich
CEO