

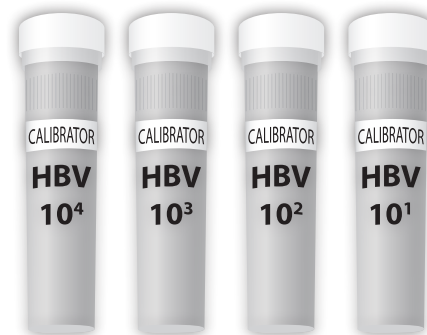


Calibration range adjustment has been introduced for this kit. The calibration range has been changed by one common logarithm.

The benefit of this calibration range adjustment consists in the following:

1. Increase in stability of the manufactured calibration kit due to physical and chemical influences
2. Quantification accuracy increase

THE NEW CALIBRATION KIT SHALL BE SUPPLIED IN CONCENTRATIONS



### 1. STABILITY INCREASE

The introduction of a new diluent used for diluting and storing of the calibration standards (certified manufacturing process of GeneProof a.s.) resulted in higher stability:

#### FROM PHYSICAL INFLUENCES

- tested by means of 260 nm wavelength UV light for 10 minutes. For the analysis results see Chart 1.

#### FROM CHEMICAL INFLUENCES

- tested by means of DNase I breakdown (concentration 5 IU/250 µl) for 10 minutes. For the analysis results see Chart 2.

#### UV light stability

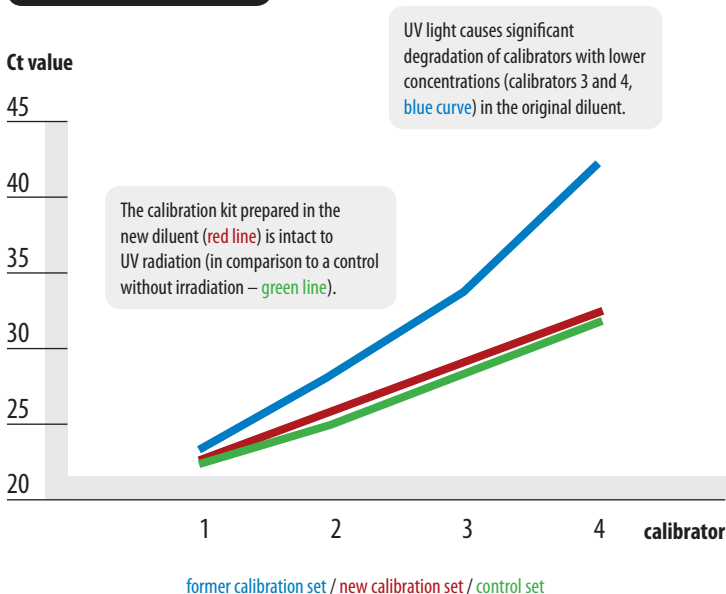


Chart 1 / UV radiation influence on calibration kit degradation

#### DNase I stability

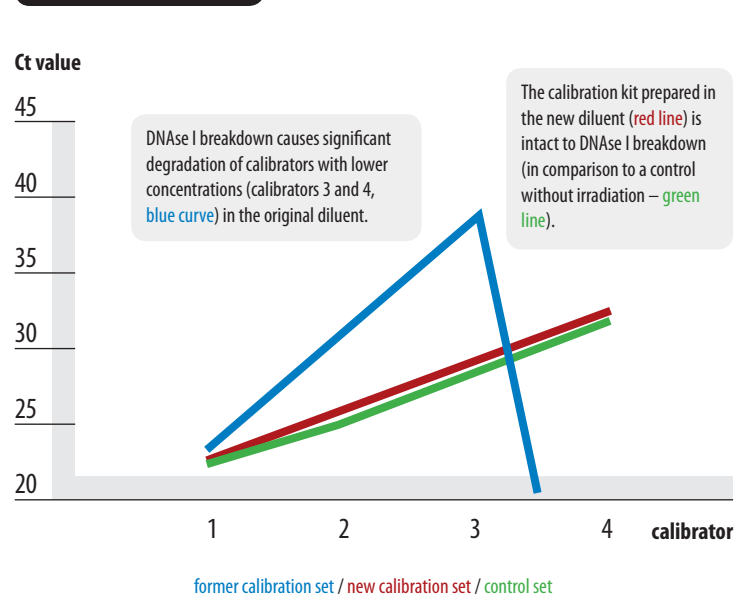


Chart 2 / DNase I breakdown influence on calibration kit degradation

## 2. QUANTIFICATION ACCURACY INCREASE

The influence on the measurement accuracy within the range of  $10^4$  IU/ $\mu$ l –  $10^1$  IU/ $\mu$ l was tested by means of QCMD HBV 2011A panel reanalysis. For the results of the quantitative establishment accuracy see Table 1 and Chart 3.

QCMD sample HBV11A	Reported value (log)	QC result (log)
HBV11-01	0,000	0,000
HBV11-02	1,758	2,010
HBV11-03	2,188	1,943
HBV11-04	3,741	3,953
HBV11-05	2,745	2,724
HBV11-06	3,158	3,18
HBV11-07	4,133	3,892
HBV11-08	2,745	2,762

Table 1 / Results of the QCMD panel accuracy establishment in IU/ml (presented as log)

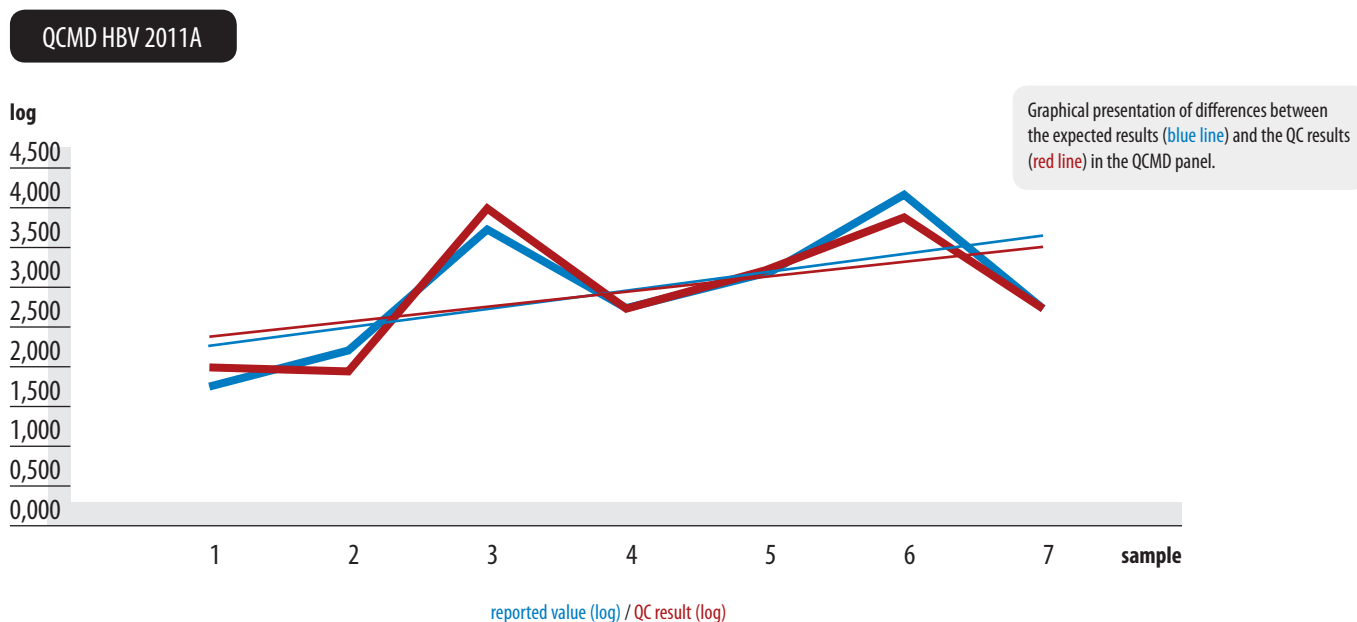


Chart 3 / Results of the QCMD panel accuracy establishment in IU/ml (presented as log) as compared to the expected concentration