

## Certificate of Analysis

Product name:	Plasma-Control for Biogenic Amines, lyophil., Level I, II
Order nos.:	8810, 8811, 8809
Lot no.:	308
Expiration date:	02/2016
Storage Temperature:	2-8°C

**Date of QC - release: 03.09.2014**

### Results of QC:

#### *Lyophilisation:*

- Lyophilisation process according to fixed program; no irregularities.
- Lyophilised material (pellets) optically o.k.

#### *Reconstitution:*

- Completely soluble in 5 ml of HPLC-Water.

#### *Mean values established for the following ClinRep<sup>®</sup> Complete Kits:*

- 1000: Catecholamines in Plasma
- 6000: Serotonin in Plasma
- differences between spiked amounts and established mean values within QC specs.

#### *Functional assay with the other kit components:*

- Recovery within QC specs.
- Control values found within the given ranges
- No interfering peaks from matrix

#### *Infectiousity:*

The human plasma that was used for manufacturing the controls was tested for the following infectious markers and found negative: HIV 1/2- and HCV-antibodies, hepatitis B-surface antigen, HIV 1/2- and HCV-genome (PCR).

Munich, 31.10.2014

Iris Wendler  
(QC-Manager)

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