GT Analytics - Capsid AAV9-ELISA

SOP-234702

# Objective

Capsid concentration is determined for unknown samples.

# Method Status

For detailed method status see either SOP-234702 and/or method history file DMD-211328.

# Results - Current Reference

## Plate 1

|  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- |
| Sample type | Sample Name | Pre-dilution | Result [cp/ml] | CV [%] | Comment |
| control 01 | Kontrolle01 | 1 | [ 2.152e+10 ] | 4.0 | test invalid |
| sample 01 | EDP\_2321\_H01\_T01\_CT | 10 | **<2.805e+9** | NA | <2.805e+9 |
| sample 02 | EDP\_2321\_H02\_T01\_CT | 10 | **<2.805e+9** | NA | <2.805e+9 |
| sample 03 | EDP\_2321\_H04\_T01\_CT | 10 | **<2.805e+9** | NA | <2.805e+9 |
| sample 04 | EDP\_2321\_H05\_T01\_CT | 10 | **<2.805e+9** | NA | <2.805e+9 |
| sample 05 | EDP\_2321\_H06\_T01\_CT | 10 | **<2.805e+9** | NA | <2.805e+9 |
| sample 06 | EDP\_2321\_H07\_T01\_CT | 10 | **<2.805e+9** | NA | <2.805e+9 |
| sample 07 | EDP\_2321\_H08\_T01\_CT | 10 | **<2.805e+9** | NA | <2.805e+9 |
| sample 08 | EDP\_2321\_H09\_T01\_CT | 10 | **<2.805e+9** | NA | <2.805e+9 |
| sample 09 | EDP\_2321\_H11\_T01\_CT | 10 | **<2.805e+9** | NA | <2.805e+9 |
| sample 10 | EDP\_2321\_H12\_T01\_CT | 10 | **<2.805e+9** | NA | <2.805e+9 |
| sample 11 | EDP\_2321\_H13\_T01\_CT | 10 | **<2.805e+9** | NA | <2.805e+9 |
| sample 12 | EDP\_2321\_H14\_T01\_CT | 10 | **<2.805e+9** | NA | <2.805e+9 |
| sample 13 | EDP\_2321\_H15\_T01\_CT | 10 | **<2.805e+9** | NA | <2.805e+9 |
| sample 14 | EDP\_2321\_H16\_T01\_CT | 10 | **<2.805e+9** | NA | <2.805e+9 |
| sample 15 | EDP\_2321\_H17\_T01\_CT | 10 | **<2.805e+9** | NA | <2.805e+9 |
| sample 16 | EDP\_2321\_H18\_T01\_CT | 10 | **<2.805e+9** | NA | <2.805e+9 |
| sample 17 | EDP\_2321\_H20\_T01\_CT | 10 | **<2.805e+9** | NA | <2.805e+9 |
| sample 18 | EDP\_2321\_H21\_T01\_CT | 10 | **<2.805e+9** | NA | <2.805e+9 |
| sample 19 | EDP\_2321\_H22\_T01\_CT | 10 | **<2.805e+9** | NA | <2.805e+9 |
| sample 20 | EDP\_2321\_H24\_T01\_CT | 10 | **<2.805e+9** | NA | <2.805e+9 |
| sample 21 | Platte1, Pr. 21 | 10 | **<2.805e+9** | NA | <2.805e+9 |

## Plate 2

|  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- |
| Sample type | Sample Name | Pre-dilution | Result [cp/ml] | CV [%] | Comment |
| control 01 | Kontrolle01 | 1 | [ 1.997e+10 ] | 7.9 | test invalid |
| sample 01 | EDP\_2321\_H01\_T02\_CT | 10 | **<2.805e+9** | NA | <2.805e+9 |
| sample 02 | EDP\_2321\_H02\_T02\_CT | 10 | **2.804e+10** | 7.7 |  |
| sample 03 | EDP\_2321\_H04\_T02\_CT | 10 | **2.863e+10** | 5.3 |  |
| sample 04 | EDP\_2321\_H05\_T02\_CT | 10 | **5.630e+09** | 19.4 |  |
| sample 05 | EDP\_2321\_H06\_T02\_CT | 10 | \*\*\*\* | NA |  |
| sample 06 | EDP\_2321\_H07\_T02\_CT | 10 | **1.143e+11** | 7.7 |  |
| sample 07 | EDP\_2321\_H08\_T02\_CT | 10 | **1.250e+11** | 5.4 |  |
| sample 08 | EDP\_2321\_H09\_T02\_CT | 10 | **4.112e+10** | 7.5 |  |
| sample 09 | EDP\_2321\_H11\_T02\_CT | 10 | **<2.805e+9** | NA | <2.805e+9 |
| sample 10 | EDP\_2321\_H12\_T02\_CT | 10 | **8.774e+10** | 3.1 |  |
| sample 11 | EDP\_2321\_H13\_T02\_CT | 10 | **9.610e+09** | 0.3 |  |
| sample 12 | EDP\_2321\_H14\_T02\_CT | 10 | **8.468e+10** | 6.3 |  |
| sample 13 | EDP\_2321\_H15\_T02\_CT | 10 | **4.697e+10** | 13.4 |  |
| sample 14 | EDP\_2321\_H16\_T02\_CT | 10 | **4.639e+10** | 6.1 |  |
| sample 15 | EDP\_2321\_H17\_T02\_CT | 10 | **4.794e+10** | 5.4 |  |
| sample 16 | EDP\_2321\_H18\_T02\_CT | 10 | **7.472e+10** | 12.8 |  |
| sample 17 | EDP\_2321\_H20\_T02\_CT | 10 | **6.507e+10** | 8.3 |  |
| sample 18 | EDP\_2321\_H21\_T02\_CT | 10 | **8.027e+10** | 8.5 |  |
| sample 19 | EDP\_2321\_H22\_T02\_CT | 10 | **7.689e+10** | 8.6 |  |
| sample 20 | EDP\_2321\_H24\_T02\_CT | 10 | **3.688e+10** | 10.5 |  |
| sample 21 | Platte 2, Pr. 21 | 10 | **<2.805e+9** | NA | <2.805e+9 |

## Plate 3

|  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- |
| Sample type | Sample Name | Pre-dilution | Result [cp/ml] | CV [%] | Comment |
| control 01 | Kontrolle01 | 1 | [ 2.066e+10 ] | 6.6 | test invalid |
| sample 01 | EDP\_2321\_H01\_T03\_CT | 10 | **<2.805e+9** | NA | <2.805e+9 |
| sample 02 | EDP\_2321\_H02\_T03\_CT | 10 | **5.154e+10** | 2.5 |  |
| sample 03 | EDP\_2321\_H04\_T03\_CT | 10 | **5.390e+10** | 5.2 |  |
| sample 04 | EDP\_2321\_H05\_T03\_CT | 10 | **8.738e+09** | 6.2 |  |
| sample 05 | EDP\_2321\_H06\_T03\_CT | 10 | ( 3.500e+09 )\* | NA | 1 valid point |
| sample 06 | EDP\_2321\_H07\_T03\_CT | 10 | **1.956e+11** | 2.9 |  |
| sample 07 | EDP\_2321\_H08\_T03\_CT | 10 | **2.203e+11** | 1.7 |  |
| sample 08 | EDP\_2321\_H09\_T03\_CT | 10 | **7.101e+10** | 3.6 |  |
| sample 09 | EDP\_2321\_H11\_T03\_CT | 10 | **<2.805e+9** | NA | <2.805e+9 |
| sample 10 | EDP\_2321\_H12\_T03\_CT | 10 | **1.569e+11** | 5.6 |  |
| sample 11 | EDP\_2321\_H13\_T03\_CT | 10 | **1.302e+10** | 8.8 |  |
| sample 12 | EDP\_2321\_H14\_T03\_CT | 10 | **1.203e+11** | 3.0 |  |
| sample 13 | EDP\_2321\_H15\_T03\_CT | 10 | **6.033e+10** | 8.1 |  |
| sample 14 | EDP\_2321\_H16\_T03\_CT | 10 | **7.122e+10** | 10.9 |  |
| sample 15 | EDP\_2321\_H17\_T03\_CT | 10 | **7.893e+10** | 12.7 |  |
| sample 16 | EDP\_2321\_H18\_T03\_CT | 10 | **1.043e+11** | 7.1 |  |
| sample 17 | EDP\_2321\_H20\_T03\_CT | 10 | **8.428e+10** | 9.9 |  |
| sample 18 | EDP\_2321\_H21\_T03\_CT | 10 | **1.145e+11** | 3.2 |  |
| sample 19 | EDP\_2321\_H22\_T03\_CT | 10 | **1.167e+11** | 5.1 |  |
| sample 20 | EDP\_2321\_H24\_T03\_CT | 10 | **1.115e+11** | 8.2 |  |
| sample 21 | Platte 3, Pr. 21 | 10 | **<2.805e+9** | NA | <2.805e+9 |

\* sample will be retested

# Evaluation criteria

Validity of the assay: Intermediary control sample limits (3s) are 1.888e+12 - 2.703e+12 cp/ml.