GT Analytics - Capsid AAV9-ELISA g9

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. E335

# Results - Current Reference

## Plate 1

|  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- |
| Sample type | Sample Name PP335 | Pre-dilution | Result [cp/ml] | CV [%] | Comment |
| control 01 | Kontrolle01 | 100 | **2.157e+12** | 2.3 |  |
| sample 01 | EHU04\_2309\_EMS\_B\_E1 | 2000 | **2.921e+13** | 8.9 |  |
| sample 02 | EHU04\_2309\_CPX\_B\_E1 | 10 | **4.851e+09** | NA | info only, 1pt valid |
| sample 03 | EHU04\_2309\_SO3\_B\_E1 | 10 | **3.855e+09** | NA | info only, 1pt valid |
| sample 04 | EHU04\_2309\_CPFT\_B\_E1 | 2000 | **3.956e+13** | 3.8 |  |
| sample 05 | EHU04\_2309\_CMX\_B\_E1 | 10 | **<2.805e+9** | NA | <2.805e+9 |
| sample 06 | EHU04\_2309\_EMS\_B\_E2 | 50 | ( 3.982e+12 )\* | NA | 1 valid point |
| sample 07 | EHU04\_2309\_CPX\_B\_E2 | 2000 | **3.894e+13** | 13.2 |  |
| sample 08 | EHU04\_2309\_SO3\_B\_E2 | 2000 | **4.888e+13** | 9.0 |  |
| sample 09 | EHU04\_2309\_CPFT\_B\_E2 | 20 | ( 2.027e+12 )\* | NA | 1 valid point |
| sample 10 | EHU04\_2309\_CMX\_B\_E2 | 2000 | **2.667e+13** | 3.7 |  |
| sample 11 | EHU04\_2309\_EMS\_B\_E3 | 10 | **6.775e+11** | NA | info only, 1pt valid |
| sample 12 | EHU04\_2309\_CPX\_B\_E3 | 200 | **3.308e+12** | 1.7 |  |
| sample 13 | EHU04\_2309\_SO3\_B\_E3 | 200 | **3.856e+12** | 9.6 |  |
| sample 14 | EHU04\_2309\_CPFT\_B\_E3 | 10 | **4.927e+11** | 0.8 |  |
| sample 15 | EHU04\_2309\_CMX\_B\_E3 | 1000 | **1.377e+13** | 12.4 |  |
| sample 16 | EHU04\_2309\_EMS\_B\_E4 | 10 | **5.128e+11** | 1.7 |  |
| sample 17 | EHU04\_2309\_CPX\_B\_E4 | 20 | ( 1.722e+12 )\* | NA | 1 valid point |
| sample 18 | EHU04\_2309\_SO3\_B\_E4 | 20 | ( 1.438e+12 )\* | NA | 1 valid point |
| sample 19 | EHU04\_2309\_CPFT\_B\_E4 | 10 | **3.332e+11** | 9.2 |  |
| sample 20 | EHU04\_2309\_CMX\_B\_E4 | 20 | ( 2.442e+12 )\* | NA | 1 valid point |
| sample 21 | EHU04\_2309\_CEX\_B\_L | 5000 | **7.400e+13** | 9.8 |  |

\* sample will be retested

## Plate 2

|  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- |
| Sample type | Sample Name | Pre-dilution | Result [cp/ml] | CV [%] | Comment |
| control 01 | Kontrolle01 | 100 | **2.099e+12** | 10.1 |  |
| sample 01 | EHU04\_2309\_EMS\_B\_Strip | 10 | ( 8.327e+11 )\* | 24.3 | CV>20.0%(24.3%) |
| sample 02 | EHU04\_2309\_CPX\_B\_Strip | 10 | **6.818e+10** | 14.5 |  |
| sample 03 | EHU04\_2309\_SO3\_B\_Strip | 10 | **1.710e+11** | 9.0 |  |
| sample 04 | EHU04\_2309\_CPFT\_B\_Strip | 10 | **1.443e+11** | 4.8 |  |
| sample 05 | EHU04\_2309\_CMX\_B\_Strip | 10 | **1.079e+11** | 11.9 |  |
| sample 06 | EHU04\_2309\_EMS\_B\_FT | 10 | ( >1.795e+11 )\* | NA | >1.795e+11 |
| sample 07 | EHU04\_2309\_CPX\_B\_FT | 10 | **<2.805e+9** | NA | <2.805e+9 |
| sample 08 | EHU04\_2309\_SO3\_B\_FT | 10 | **<2.805e+9** | NA | <2.805e+9 |
| sample 09 | EHU04\_2309\_CPFT\_B\_FT | 10 | **<2.805e+9** | NA | <2.805e+9 |
| sample 10 | EHU04\_2309\_CMX\_B\_FT | 10 | **<2.805e+9** | NA | <2.805e+9 |
| sample 11 | FF\_028\_X006\_c04\_FDP\_VSM\_0M | 100 | **9.126e+11** | 9.0 |  |
| sample 12 | EHU04\_2309\_CPX\_A\_E4 | 100 | **7.058e+11** | 11.3 |  |
| sample 13 | EHU04\_2309\_SO3\_A\_E4 | 100 | **8.804e+11** | 7.8 |  |
| sample 14 | EHU04\_2309\_CMX\_A\_E4 | 100 | **1.551e+12** | 6.1 |  |
| sample 15 | EHU04\_2309\_EMS\_A\_Strip | 100 | **9.372e+11** | 13.0 |  |
| sample 16 | Platte 2, Pr. 16 | 10 | **<2.805e+9** | NA | <2.805e+9 |
| sample 17 | Platte 2, Pr. 17 | 10 | **<2.805e+9** | NA | <2.805e+9 |
| sample 18 | Platte 2, Pr. 18 | 10 | **<2.805e+9** | NA | <2.805e+9 |
| sample 19 | Platte 2, Pr. 19 | 10 | **<2.805e+9** | NA | <2.805e+9 |
| sample 20 | Platte 2, Pr. 20 | 10 | **<2.805e+9** | NA | <2.805e+9 |
| sample 21 | Platte 2, Pr. 21 | 10 BaX335 | **<2.805e+9** | NA | <2.805e+9 |

\* sample will be retested

# Evaluation criteria TakeDa

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

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