**GT Analytics – Capsid AAV9 ELISA  
SOP-051200**

# Objective

AAV9-capsid concentration is determined in unknown samples.

# Method status

For detailed Method status see either SOP-051200 and/or method History File RPT-000047.

# Results - Current Reference

## Plate 1

| **Nr.** | **Sample name** | **Predilution** | **Result [cp/ml]** | **CV [%]** | **Comment** |
| --- | --- | --- | --- | --- | --- |
| Con. | PP686\_1912POL\_FLT | 100 | 2,411E+12 | 10,2 |  |
| 1 | EHU04\_2311\_AAV9\_FT1 | 10 | **<2,805E+9** | ----- |  |
| 2 | EHU04\_2311\_AAV9\_FT2 | 10 | **<2,805E+9** | ----- |  |
| 3 | EHU04\_2311\_AAV9\_FT3 | 10 | **<2,805E+9** | ----- |  |
| 4 | EHU04\_2311\_AAV9\_W1 | 10 | **<2,805E+9** | ----- |  |
| 5 | EHU04\_2311\_AAV9\_E2 | 1000 | **8,973E+12** | 6,2 |  |
| 6 | EHU04\_2311\_AAV9\_E1+E3 | 50 | (>7,182E+12) \* | +++++ |  |
| 7 | EHU04\_2311\_AAV9\_E\_DIL | 1000 | **1,174E+13** | 10,6 |  |
| 8 | EHU04\_2311\_AAV9\_Reg2 | 10 | **5,388E+10** | 7,4 |  |
| 9 | EHU04\_2311\_AAV9\_Reg4 | 10 | **1,043E+10** | 0,0 | 1 dilution |
| 10 | EHU04\_2311\_AAV9\_Reg6 | 10 | **3,568E+09** | 0,0 | 1 dilution |
| 11 | PPO02\_2307MUQ\_FT | 100 | **5,988E+12** | 9,4 |  |
| 12 | PPO02\_2307AFF\_FT | 10 | **<2,805E+9** | ----- |  |
| 13 | PPO02\_2307AFF\_NE | 10 | **<2,805E+9** | ----- |  |
| 14 | PPO02\_2307AFF\_ELU | 1000 | **2,987E+13** | 15,8 |  |
| 15 | PPO02\_2307SDT\_F | 200 | **6,948E+12** | 11,6 |  |
| 16 | PPO02\_2307POL\_FT | 10 | **8,726E+10** | 6,8 |  |
| 17 | PPO02\_2307POL\_FLT | 1000 | **2,336E+13** | 10,8 |  |
| 18 | EDP\_2313\_S02\_T03\_CT | 10 | **1,081E+11** | 3,8 |  |
| 19 | EDP\_2313\_S03\_T03\_CT | 10 | **9,282E+10** | 2,8 |  |
| 20 | EHU04\_2312B\_UFA\_UDR | 200 | **1,165E+12** | 11,2 |  |
| 21 | EHU04\_2312B\_UFA\_UDR\_conc. | 200 | **1,491E+12** | 4,1 |  |

**\*sample will be retested**

## Plate 2

| **Nr.** | **Sample name** | **Predilution** | **Result [cp/ml]** | **CV [%]** | **Comment** |
| --- | --- | --- | --- | --- | --- |
| Con. | PP686\_1912POL\_FLT | 100 | 2,070E+12 | 12,2 |  |
| 1 | PPO02\_2307HAR\_MEG\_Z2 | 100 | **6,371E+11** | 3,8 |  |
| 2 | PPO02\_2307HAR\_MEG\_Z3 | 100 | **6,874E+11** | 9,6 |  |
| 3 | PPO02\_2307HAR\_MEG\_Z4 | 100 | **7,422E+11** | 4,1 |  |
| 4 | PPO02\_2307HAR\_ECV\_P | 50 | **6,295E+11** | 3,1 |  |
| 5 | PPO02\_2307\_UFA\_UF1\_R | 500 | **1,334E+13** | 5,9 |  |
| 6 | PPO02\_2307\_UFA\_Pool | 1000 | **1,202E+13** | 7,2 |  |
| 7 | PPO02\_2307\_UCE\_P | 500 | **3,343E+13** | 6,6 |  |
| 8 | PPO02\_2307FMB\_T03 | 10 | **6,304E+10** | 10,6 |  |
| 9 | PPO02\_2307\_UFA\_Conc | 1000 | **1,325E+13** | 6,8 |  |
| 10 | PPO02\_2307FMB\_T03\_CT | 50 | **6,800E+11** | 8,4 |  |
| 11 | PPO02\_2307\_UFA\_Flush | 50 | **3,081E+12** | 9,9 |  |
| 12 | PPO02\_2307FMB\_NaCl | 10 | **8,545E+10** | 7,5 |  |
| 13 | PPO02\_2307\_UCE FR | 10 | (>1,436E+12) \* | +++++ |  |
| 14 | PPO02\_2307\_UCE\_F17 | 1000 | (>1,436E+14) \* | +++++ |  |
| 15 | PPO02\_2307\_UCE\_F18 | 1000 | (1,366E+14) \* | 0,0 | only 1 dilution |
| 16 | PPO02\_2307\_UCE\_F19 | 1000 | (>1,436E+14) \* | +++++ |  |
| 17 | PPO02\_2307\_UCE\_F20 | 1000 | (>1,436E+14) \* | +++++ |  |
| 18 | PPO02\_2307\_UCE\_F21 | 1000 | (>1,436E+14) \* | +++++ |  |
| 19 | PPO02\_2307\_UCE\_F22 | 1000 | (>1,436E+14) \* | +++++ |  |
| 20 | PPO02\_2307\_UCE\_F23 | 1000 | (>1,436E+14) \* | +++++ |  |
| 21 | CEX\_2301 Gradient\_Elu | 500 | **2,486E+12** | 7,8 |  |

**\*sample will be retested**

# Evaluation criteria

Validity of the assay:

Intermediary control sample limits (3s) are: 1,888 – 2,703E+12cp/ml

# Comments

Values were masked on plate 1.

HBS-Buffer was produced on 26. April 2023, named 230426/HBS/1/004240-033 and 230426/HBS/2/004240-033, and will be expired 25. October 2023.

PBSB-Buffer was produced on 26. April 2023, named 230426/PBSB/1/004240-033 and 230426/PBSB/2/004240-033, and will be expired 25. October 2023.