

CHO HCP 3G-1

Simple Plex assay for the detection of Chinese Hamster Ovary Host Cell Protein (CHO HCP) in bioprocess samples.

This assay uses Cygnus Technologies 3rd Generation CHO antibodies.

For research use only. Not for use in diagnostic procedures.

Sample Preparation

Bioprocess samples require a minimum 2-fold dilution with Sample Diluent (diluted 1:5). A suggested 2-fold dilution can be achieved by adding 35 μ L of sample to 35 μ L of Sample Diluent SD19. Samples above the ULOQ require further dilution.

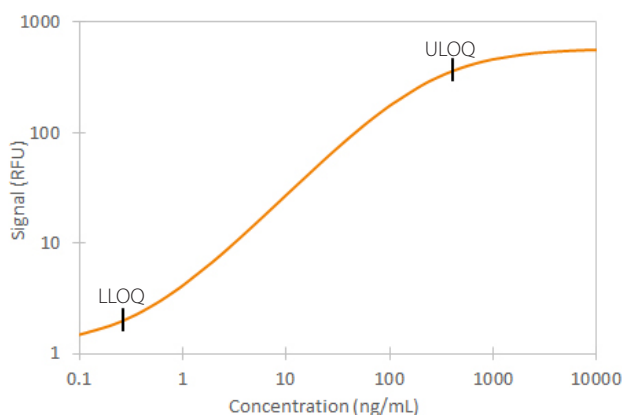
Reagent Preparation

Prior to use, allow reagents to reach room temperature.

SD19 Concentrate (Diluted 1:5) - Add 10 mL of SD19 Concentrate to 40 mL of deionized or distilled water to prepare 50 mL of Sample Diluent SD19 (diluted 1:5).

Calibration Curve

The factory generated calibration curve shown below was compiled by averaging 5 replicates of each calibrator from multiple runs. The 5PL curve fit shows calibrator concentration as a function of signal intensity (relative fluorescent units, RFU).



Limit of Quantitation

Data shown represents typical performance results for Lower Limit of Quantitation (LLOQ) and Upper Limit of Quantitation (ULOQ) of CHO HCP.

| | CONC. (ng/mL) |
|------|------------------|
| LLOQ | 0.26 |
| ULOQ | 403 |

Limit of Detection

The limit of detection (LOD) of CHO HCP is 0.11 ng/mL. The LOD was calculated by adding three standard deviations to the mean background signal determined from multiple runs.

Recovery

Recovery at three different spiked concentrations within the range of the assay was evaluated.

| SAMPLE TYPE | AVG % | RANGE % |
|-------------|-------|---------|
| Low (n=4) | 96 | 76-111 |
| Mid (n=4) | 101 | 92-110 |
| High (n=4) | 110 | 104-116 |

Precision

Intra-assay Precision: Each control was tested 16 times in one assay.

Inter-assay Precision: Replicates of each control were tested in multiple assays performed by at least three technicians using two lots of reagents.

| PARAMETER | LOW QC | HIGH QC |
|--------------------|--------|---------|
| Intra-Mean (ng/mL) | 3.12 | 158 |
| Intra-assay SD | 0.217 | 14.0 |
| Intra-assay CV (%) | 6.9 | 8.9 |
| Inter-Mean (ng/mL) | 3.42 | 162 |
| Inter-assay SD | 0.343 | 23.4 |
| Inter-assay CV (%) | 10.0 | 14.4 |

Notes

Linearity

Samples containing and/or spiked with high concentrations of CHO HCP were serially diluted with Sample Diluent to produce samples within the dynamic range of the assay.

| DILUTION | PARAMETER | BIOPROCESS (n=4) |
|----------|-------------------|---------------------|
| 1:2 | Avg % of Expected | 108 |
| | Range (%) | 95-113 |
| 1:4 | Avg % of Expected | 108 |
| | Range (%) | 100-112 |
| 1:8 | Avg % of Expected | 115 |
| | Range (%) | 102-120 |
| 1:16 | Avg % of Expected | 111 |
| | Range (%) | 100-116 |



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