

## HEK 293 HCP 3G

Simple Plex assay for the detection of Human Embryonic Kidney Host Cell Protein (HEK 293 HCP 3G) in bioprocess samples.

This assay uses Cygnus Technologies HEK 293 HCP 3G resupply 1 antibodies.

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

### Sample Preparation

An appropriate dilution factor for each process matrix should be determined experimentally by assessment of sample linearity and spike recovery.

Samples require a minimum 2-fold dilution with sample diluent. A suggested 2-fold dilution can be achieved by adding 35  $\mu$ L of sample to 35  $\mu$ L of Sample Diluent. Samples above the ULOQ require further dilution.

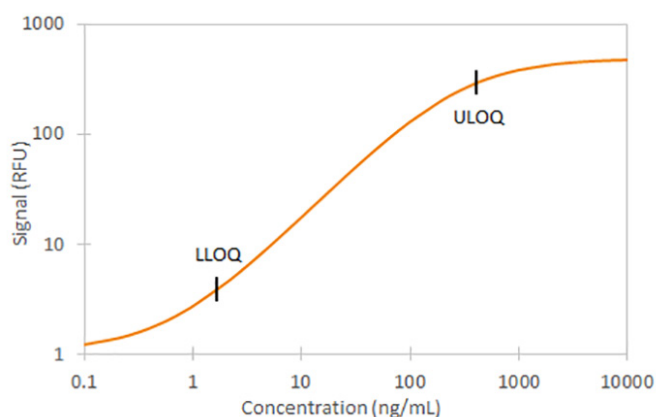
### Reagent Preparation

**Prior to use, allow reagents to reach room temperature.**

**SD19 Concentrate (Diluted 1:10)** - Add 5 mL of SD19 Concentrate to 45 mL of deionized or distilled water to prepare 50 mL of Sample Diluent SD19 (diluted 1:10).

### Calibration Curve

The factory generated calibration curve shown below was compiled by averaging 5 replicates of each calibrator from multiple runs. The 4PL 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 HEK 293 HCP 3G.

	CONC. (ng/mL)
LLOQ	1.64
ULOQ	400

### Limit of Detection

The limit of detection (LOD) of HEK 293 HCP 3G is 0.2 ng/mL. The LOD was calculated by adding three standard deviations to the mean background signal determined from multiple runs.

### Recovery

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

SAMPLE TYPE	AVG %	RANGE %
Bioprocess (n=12)	111	100-123

## Precision

**Intra-assay Precision:** Each control was tested 8 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)	3.16	147
Intra-assay SD	0.380	7.3
Intra-assay CV (%)	12.0	5.0
Inter-Mean (ng/mL)	3.36	141
Inter-assay SD	0.48	14.9
Inter-assay CV (%)	14.3	10.6

## Linearity

Samples containing and/or spiked with high concentrations of HEK 293 HCP 3G were serially diluted with Sample Diluent to produce samples within the dynamic range of the assay.

DILUTION	PARAMETER	BIOPROCESS (n=6)
1:2	Avg % of Expected	102
	Range (%)	97-107
1:4	Avg % of Expected	103
	Range (%)	89-114
1:8	Avg % of Expected	108
	Range (%)	100-123
1:16	Avg % of Expected	109
	Range (%)	99-126

## Precaution

This assay cross-reacts with human proteins found in skin cells, saliva, sweat, and indoor dust. We recommend taking all reasonable precautions to minimize exposure of the cartridge to these sources of potential contamination. Running each sample in replicate sample wells is recommended.



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