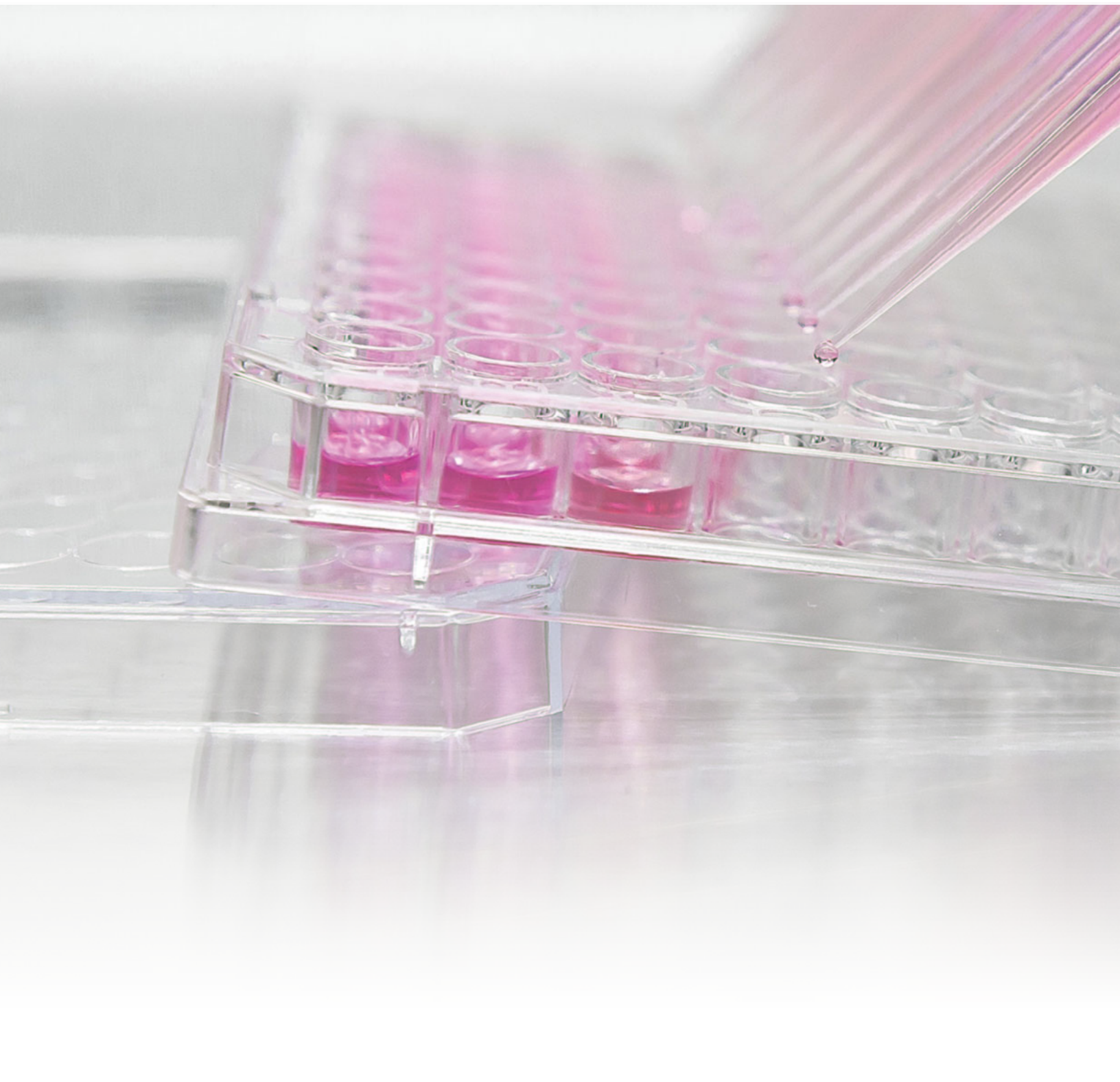




CHO Host Cell Protein ELISA Kit, 3G

The gold standard in CHO HCP analysis

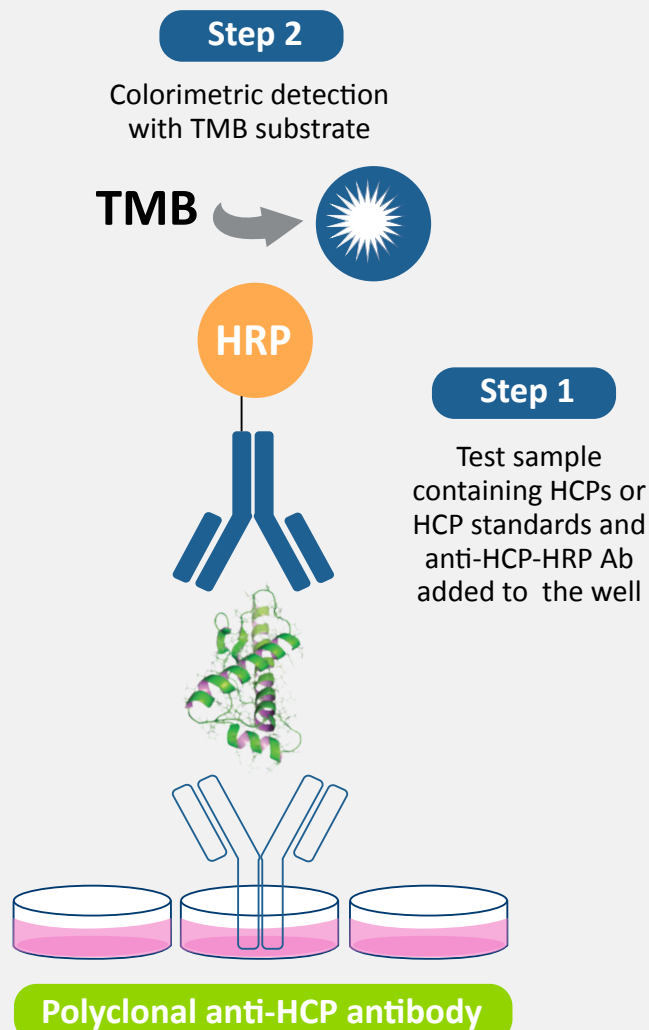


CHO Host Cell Protein ELISA Kit, 3G

Cygnus Technologies **3rd Generation CHO HCP ELISA Kit** provides the specificity and sensitivity to detect CHO host cell protein (HCP) impurities with reproducibility that supports regulatory compliance. The kit has been extensively qualified with many drug substances and in-process samples. The antibody has been evaluated for reactivity to individual HCPs using conventional 2D Western Blot and Antibody Affinity Extraction (AAE). AAE demonstrated the antibody is reactive to more than 1000 individual HCPs from conditioned media and cell lysates in both currently used CHO strains. These 1000+ HCPs represent more than 98% of the total mass of protein as indicated by orthogonal to ELISA protein detection methods. This ELISA is also more robust than the earlier kits showing less sample matrix interference and improved dilution linearity. The kit contains all components to evaluate the presence of HCP impurities in 96 samples, including a set of calibrated CHO HCP standards.

- The most sensitive CHO HCP ELISA kit:
LOD ~0.3 ng/ml, LOQ ~1 ng/ml
- Qualified by comprehensive orthogonal methods
- Based on HCP antibody with the broadest HCP coverage and reactivity to those HCPs that persist through the downstream purification process
- Robust performance supported by decades of in-house technical expertise
- Ease of use across a wide range of analyst skills
- Seamless transfer from purification process development to QC testing and to lot release testing
- Supports multiple commercialized biologics

Cygnus CHO HCP ELISA Kits, 3G



Evaluation of Cygnus CHO HCP ELISA Kit Performance vs Competitor Kits

Kit performance was evaluated using 12 independent biopharmaceutical drug substance samples collected at various downstream processing steps.

Sample Number	Process Step	Cygnus Technologies (ng/ml)	Competitor B (ng/ml)	Competitor CB (ng/ml)	Competitor G/R (ng/ml)
1	Polishing Step	172	191	<LOD	<LOD
2	Drug Substance	3167	3920	<LOD	<LOD
3	Polishing Step	13	<LOD	<LOD	<LOD
4	Drug Substance	62	365	<LOD	<LOD
5	Protein A Eluate	33808	9444	22541	<LOD
6	Harvest	54371	22730	<LOD	<LOD
7	Drug Substance	2809	331	1889	<LOD
8	Anion Exchange	80	<LLOQ	<LLOQ	<LOD
9	Drug Substance	2110	346	395	<LOD
10	Drug Substance	12	12	<LOD	10
11	Drug Substance	182	251	236	<LOD
12	Cation Exchange	2743	2680	104	<LOD

- HCP – Detected, sample shows dilution linearity
- HCP – Detected, no dilution linearity
- HCP – Not detected

Technical Specifications: Cygnus Technologies CHO HCP ELISA, 3G vs Competitor Kits

	Cygnus Technologies CHO HCP ELISA Kit, 3G	Competitor B CHO HCP ELISA Kit	Competitor CB CHO HCP ELISA Kit	Competitor G/R CHO HCP ELISA
Technical Specifications				
CHO HCP antigen used to generate HCP antibody	CHO-S & CHO-K1 Null Harvest CCF	Mock fermentation of CHO-S and CHO-K1	Not available	CHO-K1 cell lysate
LOD	~0.3 ng/ml	0.5 – 1 ng/ml	10 ng/ml	2 ng/ml*
LOQ	~1 ng/ml	2-3 ng/ml	Not available	4 ng/ml
Assay Range	1 – 200 ng/ml	2 – 100 ng/ml	Not available	2 – 200 ng/ml
Precision [Intra-assay CV]	3 ng/ml – 6.7% 12 ng/ml – 2.7% 53 ng/ml – 3.7%	2 ng/ml: 5.3-11.4% 100 ng/ml: 2.1-2.3%	12 ng/ml: 4% 49 ng/ml: 3.6% 91 ng/ml: 6.6%	20 ng/ml: 6.6% 100 ng/ml: 0.9% 250 ng/ml: 1.4%
Accuracy [Recovery/Matrix Interference]	92% -115% [spiking 50 ng/ml HCP]	81% -107% [spiking 2 ng/ml HCP] 97% -107% [spiking 100 ng/ml HCP]	Not available	6%-126% [spiking 50 ng/ml] 95%-109% [spiking 50 ng/ml at 1:10 dilution]

*Competitor G/R CHO HCP ELISA: LOD of 6ng/ml if using rapid, simultaneous protocol format

User Protocol: Cygnus Technologies CHO HCP ELISA, 3G vs Competitor Kits

	Cygnus Technologies CHO HCP ELISA Kit, 3G	Competitor B CHO HCP ELISA Kit	Competitor CB CHO HCP ELISA Kit	Competitor G/R CHO HCP ELISA
Protocol Details				
Assay Preparation	All reagents, including ready-to-use CHO HCP Standards and Detection Antibody	CHO HCP Standards and Detection Antibody preparation required	CHO HCP Standards and Detection Antibody preparation required	CHO HCP Standards and Detection Antibody preparation required
Standard Preparation Time	None	Make standard dilutions ~15 min	Make standard dilutions ~15 min	Make standard dilutions ~15 min
Format	Simultaneous	Sequential	Sequential	Sequential or Simultaneous
Detection System	Anti-CHO:HRP + TMB	Anti-CHO:Biotin + HRP-Streptavidin + TMB	Anti-CHO:Biotin + HRP-Streptavidin + TMB	Anti-CHO:HRP + TMB
Number of Wash Steps	1	3	3	2
Total time to result	2 h 35 min (includes 1 x 5 min wash)	4 h 50 min (includes standard prep and 3 x 5 min washes)	3 h 30 min (includes standards prep and 3 x 5 min washes)	3 h 55 min (includes standards prep and 2 x 5 min washes)
User Protocol*	Comprehensive ++++ Technical Details ++++ Ease of use by inexperienced analyst ++++	Comprehensive ++ Technical Details ++ Ease of use by inexperienced analyst ++	Comprehensive + Technical details + Ease of use by inexperienced analyst +	Comprehensive ++ Technical Details ++ Ease of use by inexperienced analyst ++

*++++ Excellent; ++ Average; +Below Average

Trust Your CHO HCP Assay to the Experts!

Cygnus has used proprietary technologies to obtain antibodies and develop robust assays that react to the most important HCPs, those that co-purify with your product. We evaluated antibodies for reactivity to individual HCPs using the conventional 2D Western blot and Antibody Affinity Extraction (AAE). AAE demonstrated the CHO HCP antibody is reactive to more than 1000 individual HCPs from conditioned media and cell lysates in both currently used CHO strains^[1]. Due to the inherent limitations of the 2D WB method^[1], it is not sensitive and specific enough to determine coverage to those HCPs that persist through a purification process. When coupled with the use of non-process specific antigens such as lysates, even broad reactivity by 2D WB can give a false indication that the antibody is suitable for ELISA detection of HCPs in downstream samples.

[1] E. Bishop, K. Hoffman: "Antibody Affinity Extraction – a Superior Alternative to 2D Western Blot for Determination of Polyclonal anti-HCP Reactivity", 2016 https://www.cygnustechnologies.com/media/productattach/c/y/cygnus-aae-whitepaper_f_v3.pdf

Ordering Information

Product	Catalog No.
CHO HCP ELISA Kit, 3G	F550



Trust Your Assays. Trust Your Results.

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