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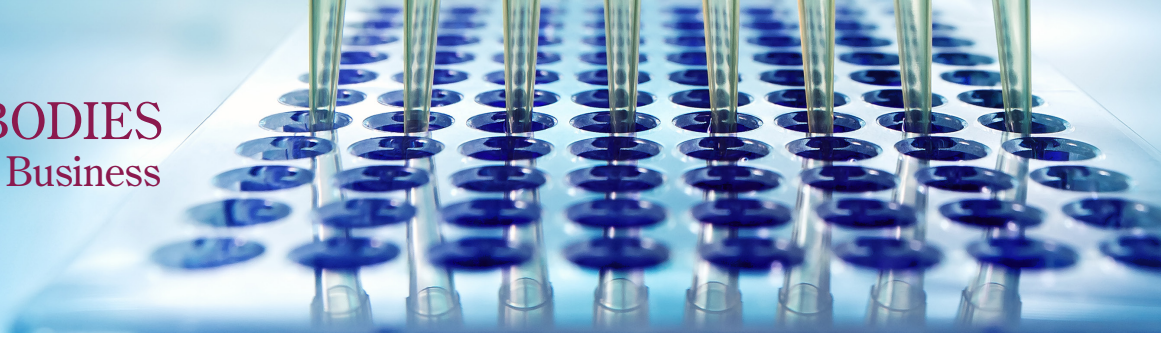


Host Cell Protein Detection in Biotherapeutic Manufacturing and the Significance of PLBL2

Host cell proteins (HCPs) are a major class of impurities produced during biotherapeutic manufacturing. They must be removed from the final drug product to both assure patient safety and maintain drug efficacy. While broad spectrum assays have long been used for confirming that HCP levels meet regulatory requirements, there is a growing trend toward quantifying individual HCP targets. **Our antibodies, antigens, and ELISA kits for Phospholipase B-Like2 (PLBL2) represent some of our best-selling products and are especially popular among those developing and manufacturing biologic drugs.**

How are biotherapeutics produced?

Biotherapeutics are typically produced by introducing an expression vector into host cells, which are then expanded in culture before being harvested for purification of the resultant product. Expression hosts used for biotherapeutic production include insect cells, yeast, and bacteria, although cells of mammalian origin are preferred for their superior ability to emulate human protein production. Chinese Hamster Ovary (CHO) cells are recognized as the gold standard in the production of biologic drugs, largely due to their high protein synthesis capacity, ability to mimic human post-translational modifications, and their adaptability to different growth conditions.

What are HCPs and why must they be removed from biologic drugs?

HCPs are proteins produced by expression hosts, which may co-purify with the recombinant biotherapeutic. They include structural proteins, as well as proteins required for normal cellular growth and function, and vary in both number and concentration depending on the chosen host species and the manufacturing process being used. Critically, HCPs must be removed from the final product to avoid adverse effects. Not only can HCPs trigger potentially fatal immune responses (e.g., cytokine storm), but they can also degrade the drug and any product-stabilizing excipients to limit its efficacy.

How are HCPs detected?

ELISAs are widely used for detecting HCPs, where they are generally configured in a sandwich assay format for improved specificity. In this scenario, a microplate-bound antibody is used for analyte capture, then a second analyte-specific antibody (that binds a different epitope on the target molecule) is added to enable detection. By incorporating a reference standard (e.g., a purified protein) into the assay design, it is possible to quantify the analyte of interest and confirm that its concentration meets regulatory requirements. Advantages of ELISA are that it is extremely sensitive and compatible with high sample throughput – key considerations for biopharmaceutical manufacturing. Other methods for HCP detection include two-dimensional (2D) Western blotting, immunoaffinity chromatography, and various mass spectrometry (MS) based approaches.

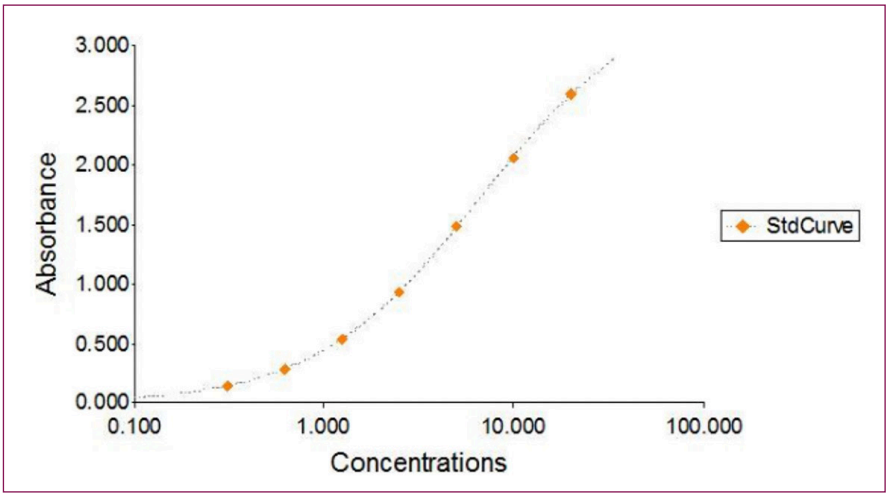
Your trusted supplier for Host cell protein analytics

What is the relevance of PLBL2 to biotherapeutic manufacturing?

Although generic HCP ELISAs are valuable tools for biotherapeutic manufacturing, they do not provide complete coverage for all HCP molecules. For this reason, generic HCP ELISAs are often used during the early phases of process development, before being replaced or augmented by ELISAs for detecting specific host cell proteins. PLBL2 is a 65 kDa HCP that frequently co-purifies with monoclonal antibodies produced in CHO cells, which is known to be immunogenic in humans and responsible for the enzymatic degradation of adjuvants. Many generic HCP ELISAs are thought to under-report the presence of PLBL2 or even fail to detect it. As such, methods capable of specifically monitoring PLBL2 are seeing increased use for biotherapeutic manufacturing.

High-quality products for detecting and quantifying PLBL2

We offer a broad range of products for monitoring PLBL2, including our Hamster (CHO) PLBL2 ELISA Kit. With a detection range of 20 - 0.3125 ng/mL and a total assay time of just 170 minutes, this product is consistently one of our biggest sellers. In addition, we have developed an extensive collection of PLBL2 antibodies and purified proteins, all of which are subject to rigorous testing and quality control, assuring you of results you can trust. For detecting HCPs other than PLBL2, further products in our ever-expanding catalog cover targets such as Annexin A5, Beta 2-Microglobulin, Clusterin, Legumain, MMP-19, and Nidogen-1.



Typical standard curve data for the Hamster (CHO) Phospholipase B-Like 2 (PLBL2) ELISA Kit (catalog # E-65PLB).

PLBL2 Immunoassays - CHO

SKU	ELISA Kit Target	Species Reactivity	Format	Product Type
E-65PLB	Hamster CHO PLBL2 ELISA Kit	Hamster	Sandwich ELISA	ELISA KIT

PLBL2 Antibodies - CHO

SKU	Antibody Target	Host	Format	Product Type
GPLB-65B-Z	anti-CHO PLBL2	Goat	Biotin Conjugated	Primary Antibody
GPLB-65B	anti-CHO PLBL2	Goat	Biotin Conjugated	Primary Antibody
MPLB-65ALY-Z-4D5	anti-CHO PLBL2	Mouse	Unconjugated AP	Primary Antibody
MPLB-65ALY-4D5	anti-CHO PLBL2	Mouse	Unconjugated AP	Primary Antibody
GPLB-65ALY	anti-CHO PLBL2	Goat	Unconjugated AP	Primary Antibody

PLBL2 Controls - CHO

SKU	Target	Species Reactivity	Format	Product Type
AG65-0324-Z	Purified CHO PLBL2 Protein	CHO (3E7 cell line)	Unconjugated AP	Protein Standard
AG65-0324	Purified CHO PLBL2 Protein	CHO (3E7 cell line)	Unconjugated AP	Protein Standard
AG65-0365-Z	Purified CHO PLBL2 Protein	CHO (S cell line)	Unconjugated AP	Protein Standard
AG65-0365	Purified CHO PLBL2 Protein	CHO (S cell line)	Unconjugated AP	Protein Standard