# The CHO CTSB ELISA Kit

## Expose High-Risk HCPs. Stay Ahead. Stay Safe.

With the CHO CTSB ELISA Kit, BioGenes sets a new standard in the targeted monitoring of critical high-risk HCPs. Cathepsin B (CTSB) is considered a proteolytically active risk protein that can significantly impact product stability, efficacy, and immunogenicity. Our new ELISA enables highly sensitive, specific, and regulatory-compliant quantification of this critical HCP for the first time.

**Why monitoring CTSB is essential**

1. **Proteolytic degradation:**
   CTSB can cleave therapeutic proteins even at trace levels, causing fragmentation, loss of potency, and reduced shelf life.

2. **Immunogenic risks:**
   As an endogenous immune modulator, CTSB may amplify undesired immune responses making it a key safety concern.

3. **Regulatory requirements:**
   Authorities increasingly expect targeted monitoring of high-risk HCPs in addition to generic HCP assays.

**Key Features of the CHO CTSB ELISA Kit**

**Ultra-sensitive detection limits:**
- LOD: ~0.039 ng/mL
- LOQ: ~0.117 ng/mL
- Assay range: 0.3125 – 20 ng/mL

**Pre-validated precision:**
- ICH Q2 compliant
- Intra-assay CVs <10%

**High specificity:**
- Polyclonal antibodies minimize cross-reactivity
- CHO antigens expressed in HEK cells eliminate background interference from other HCPs

**Efficient workflow:**
- 96-well sandwich ELISA
- Total assay time: <4 hours
- Compatible with all standard ELISA plate readers

**Application areas:**
- In-process samples
- Drug substance
- Stability testing
- Quality control and process characterization

## Target Market

**Primary target groups:**

- Biopharmaceutical companies using CHO-based production processes
- Manufacturers facing issues such as fragmentation, low stability, or loss of potency
- Companies that must comply with regulatory expectations for high-risk HCP monitoring

**Secondary target groups:**

- CDMOs and CROs focusing on QC, upstream, or downstream processes
- Companies with established risk assessment frameworks
- Organizations evaluating additional high-risk HCP assays (e.g., PLBL2, PRDX1)

**Tertiary target groups:**

- Research institutions in protein engineering, bioprocessing, and analytics

## Unique Selling Points (USPs)

- **A unique product in the market:**
  BioGenes is the leading provider
- **Direct value for customers:**
  Protects against product degradation, loss of function, and immunogenicity risks
- **Regulatory relevance:**
  An ideal complement to generic HCP assays, especially in the context of regulatory submissions
- **Fast implementation:**
  Built on standard ELISA principles, enabling seamless integration into QC workflows
- **Portfolio door-opener:**
  Customers monitoring CTSB often proceed to evaluate additional high-risk HCP kits

## Recommended Sales Strategy for Distributors

**1. Benefit-focused pitch:**
"Our CTSB ELISA Kit closes a critical analytical gap not covered by generic HCP assays. It protects your products from degradation and reduces regulatory risks."

**2. Need-identification questions:**

- Have you observed fragmentation or stability issues?
- Are you working with CHO cells?
- Has your risk assessment already identified CTSB as a potential high-risk candidate?
- Do you want to proactively meet regulatory expectations?

**3. Demo/trial approach:**
Ideal for customers experiencing unclear analytical results or potential process risks

**4. Cross-selling:**
Offer additional CHO-based high-risk HCP kits (PLBL2, PRDX1) as well as Custom Immunoassay Development as complementary solutions, particularly relevant in later drug development phases approaching regulatory submission.

## Conclusion

The CHO CTSB ELISA Kit is a highly relevant solution for modern bioprocesses. It delivers scientific precision, regulatory confidence, and real problem-solving power. For distributors, it opens access to a nearly competition-free market segment and provides strong cross-selling opportunities.