# Charles River Launches Novel IgY-based ELISA Kit for the Detection and Quantitation of Residual Host Cell Protein

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*HCP-ELISA builds upon Company's HCP-GAPex ℠ service, increasing the efficiency and efficacy of HCP assay development*

WILMINGTON, Mass.--(BUSINESS WIRE)--Feb. 13, 2023-- Charles River Laboratories International, Inc. (NYSE: CRL) today announced the launch of its first Enzyme-Linked Immunosorbent Assay (ELISA) Kit for the detection and quantitation of residual host cell proteins (HCP) in CHO-based biotherapeutics. Charles River's HCP ELISA kit achieves industry leading rates for sensitivity and specificity, reaching 0.1 ng/mL and 90 percent antibody coverage, respectively. This increase in sensitivity and specificity can be attributed to the unique chicken immunoglobulin Y (IgY) antibodies utilized.

**The Benefits of IgY Antibodies**

In contrast to other commercially available HCP-ELISA kits, which utilize traditional mammalian immunoglobulin G (IgG) antibodies, Charles River's new HCP-ELISA kit leverages avian IgY antibodies as the primary detection technology. These antibodies are derived from Specific-Pathogen-Free Chicken (SPF) Eggs and developed exclusively by AVS Bio.

The main benefit of using IgY antibodies over IgG is due, in large part, to the phylogenetic differences between birds and mammals. As such, when the Avian immune system comes in contact with a mammalian antigen, it recognizes the antigen as highly foreign and processes an aggressively strong immune response compared to the conventional species (rabbits, goats) used for immunization during ELISA development.

Additional benefits are realized from the IgY antibody production process, which is non-destructive, stable from batch to batch, and provides a consistent supply of *high-quality* antibodies year after year.

**Building Upon Established Expertise**

The newly launched ELISA kit bolsters an already robust Biologics Testing offering from Charles River. The kits can be purchased individually and run by the client at their own facility, but clients are also afforded the opportunity to have Charles River's industry experts perform the assay, providing a wide range of supporting services and decades of bench strength.

Once the drug candidate has progressed into late-phase clinical trials, Charles River's HCP-GAPex ℠ program provides a seamless transition from off the shelf generic ELISA kits to a fully validated product-specific assay, tailor-made for each product. HCP-GAPex is a holistic approach to HCP assay development which combines tools from proteomics, bioinformatics, protein synthesis, and immunology to create manufacturing processes that minimize the risk of unidentified HCP impurities, increasing efficiency and efficacy.

For more information, watch Effective HCP Control Strategies: Avoid Surprises During Late Phase Clinical Trials, a webinar presented by Olaf Stamm, PhD, Technical Business Development Director for Charles River, available on-demand.

**Approved Quotes**

- "With more than 30 years of impurity testing experience, host cell protein assays are one of our core competencies. Building on that expertise to bring our inaugural kit to market was the next logical step to strengthen our Biologics Testing offering." –Kerstin Dolph, Corporate Senior Vice President, Biologics Solutions, Charles River
- "Using optimal tools for impurity control is essential for a quality-by-design approach in drug development. The superior specificity and coverage of our new kit mitigates the risk of undetected host cell proteins during early process optimization, resulting in a faster and smoother transition from early to late phase and registration." – Olaf Stamm, PhD, Senior Business Development Specialist, Charles River
- "We are thrilled to see Charles River leverage the unique properties of our avian IgY antibodies in their new HCP-ELISA kit. As the largest producer of Specific-Pathogen-Free Chicken (SPF) eggs in the United States, we have been dedicated to providing high-quality antibodies for research and development for many years. This collaboration highlights the versatility and effectiveness of our IgY in the field of biotherapeutics and we look forward to continuing to work with Charles River to advance the industry." – Debra Tosto, President, AVS Bio

**About Charles River**

Charles River provides essential products and services to help pharmaceutical and biotechnology companies, government agencies and leading academic institutions around the globe accelerate their research and drug development efforts. Our dedicated employees are focused on providing clients with exactly what they need to improve and expedite the discovery, early-stage development and safe manufacture of new therapies for the patients who need them. To learn more about our unique portfolio and breadth of services, visit www.criver.com.

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**Investor:**

Todd Spencer
Corporate Vice President,
Investor Relations
781.222.6455
todd.spencer@crl.com

**Media:**
Amy Cianciaruso
Corporate Vice President,
Chief Communications Officer
781.222.6168
amy.cianciaruso@crl.com

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