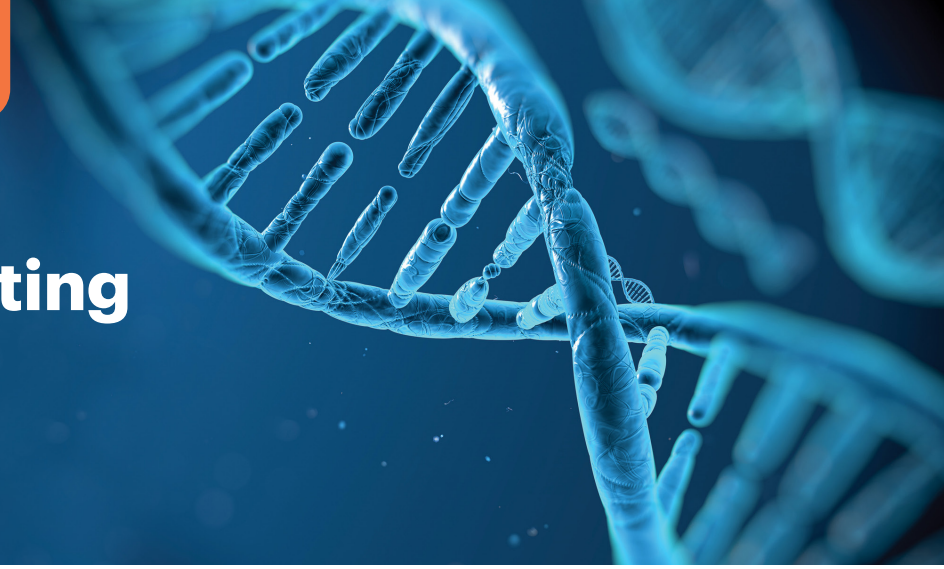
USP General Chapter <509>

Residual DNA Testing



Biologics™

Biologics—such as recombinant therapeutic proteins, vaccines, blood components, tissues and gene therapies—are growing faster than any other class of medications. Just as they do for chemical medicines, manufacturers must ensure the purity and quality of the biologics that make their way to patients. USP, in collaboration with experts and regulators from around the globe, has developed monographs and chapters that support research and development, production, characterization, and lot release of recombinant therapeutic proteins during the manufacture of biopharmaceuticals.

During the manufacture of biopharmaceuticals, including monoclonal antibodies, therapeutic proteins, and vaccines, residual host cell DNA contamination must be controlled to acceptable levels to avoid potential safety risks such as immunogenicity and oncogenicity. Demonstration of host cell DNA reduction or removal from the cell substrate by accurate and sensitive tests to quantify such impurities is required during in-process testing or at release of a drug substance. Developing and validating in-house methods can take time and resources, and may increase regulatory risk. *USP* General Chapter <509> provides a validated method suitable for measurement of residual host cell DNA in recombinant therapeutic products produced in either *Escherichia coli* or Chinese hamster ovary (CHO) cell lines. Residual host cell DNA contamination must be controlled to acceptable levels to avoid potential safety risks such as immunogenicity and oncogenicity.

The method:

- Is highly sensitive and specific
- Contains an optional protein extraction procedure for greater sensitivity
- Does not require the purchase of expensive kits
- Includes optimized and validated primer and probe sequences for each cell substrate giving you flexibility on label choices and instrumentation

Learn more

To learn about all the benefits of USP-NF visit
https://www.uspnf.com/purchase-usp-nf

For more information

Visit us online at **http://www.usp.org/biologics** to learn more.

Reference Standards

USP Reference Standards that support methods in this chapter include:

- CHO Genomic DNA (Catalog #1130710)
- *E. coli* Genomic DNA (Catalog #1231557)

Users employ the respective USP Reference Standards for their cell substrate of interest to serve as a positive spike control during extraction as well as for quantitation of sample DNA relative to a standard curve.

Email **uspbiologics@usp.org** to be notified when USP biologics reference standards are released.

Contact Us

Questions: uspbiologics@usp.org
Ordering information: store.usp.org

USP Online Courses Available

Online courses available

Residual DNA Testing

USP's webinar provides an overview of *USP* General Chapter <509> *Residual DNA Testing* containing validated methods for measurement of either *E. coli* or Chinese Hamster Ovary (CHO) genomic DNA in recombinant products.

Course ID: Bio-509-01
Duration: 60 minutes
Format: On-Demand webinar

Other related courses

USP's webinar provides an overview of USP's recommendations for the evaluation of Host Cell Proteins (HCP) in biopharmaceuticals. *USP* General Chapter <1132> *Residual Host Cell Protein Measurement in Biopharmaceuticals* describes the complexity and challenges in determining such impurities and risks presented by the presence of HCP in biologicals.

Course ID: Bio-1132-01
Duration: 1 hour, 20 minutes
Format: On-Demand webinar

Find additional information and register for the course, visit **www.education.usp.org**.

About USP

USP is an independent non-profit organization that collaborates with the world's top health and science experts to develop high-quality standards that set the bar for manufacturing and distributing safe and effective medicines, supplements and food around the globe. Two billion people world-wide have access to quality medicines, dietary supplements and food as a result of USP's standards, advocacy and education.

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