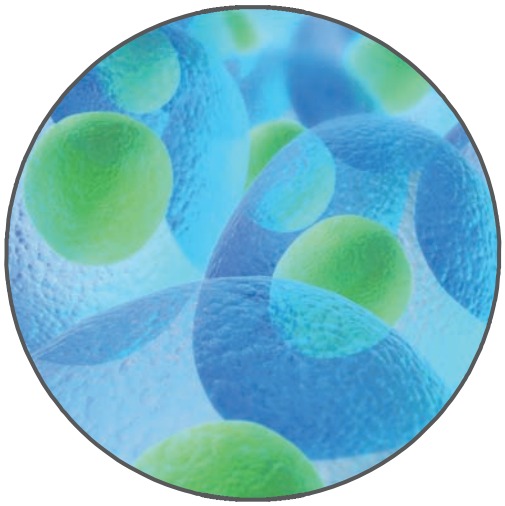
cell line identity testing

Characterization of human and non-human cell lines used in the production of biopharmaceuticals requires technical expertise across a wide range of biological disciplines. WuXi AppTec has this experience, as well as worldwide regulatory knowledge gained through the performance of hundreds of these studies. Our team of experts can consult with you to determine the testing regimens that will stand up to regulatory scrutiny while providing you a program that meets your demanding timelines.



One of the critical elements for characterizing a master cell bank or end-of-production cells is to verify the identity of the host cell species. Historically, the method most often used has been isoenzyme analysis, but technology advances now allow new molecular methods to be used. PCR and sequencing-based methods provide an alternative to traditional isoenzyme tests with greater specificity and shorter turnaround times.

The Regulations

Initial guidance documents from the U.S. FDA – including "Points to Consider in the Manufacture and Testing of Monoclonal Antibody Products for Use" – established the need for manufacturers to confirm identity but did not specify particular methodologies. A more thorough evaluation of methods was published in 2013 in "Annex 3: Recommendations for the evaluation of animal cell cultures as substrates for the manufacture of biological medicinal products and for the characterization of cell banks." This document suggests that DNA profiling – short tandem repeat (STR) analysis and multiple single nucleotide polymorphisms – and can be utilized to identify human cells with a high level of specificity.

Testing Services Include:

Human Cell Line Identity (GLP) *Test Code # 21420.1*
TAT 28 days • Sample Requirements: 1 x 10^7 cells
Short tandem repeat (STR) loci consist of short, repetitive sequence elements typically of 3–7 base pairs in length. These repeats are well distributed throughout the human genome, are highly polymorphic, and can be readily detected using PCR. Alleles of STR loci are differentiated by the number of copies of the repeat sequence contained within the amplified region and are distinguished from one another by fluorescence detection following electrophoretic separation.

This procedure is based on Promega's GenePrint® 10 System. Genomic DNA is isolated from client samples followed by PCR amplification of the genetic loci of interest. The samples and system controls are then prepared for analysis on a Life Technologies' 3500xl Genetic Analyzer. Results are analyzed using GeneMapper® software, and reported out for each of the STR loci.

Non-Human Cell Line Identity (GLP) *Test Code # 21423.1*
TAT 28 days • Sample Requirements: 1 x 10^7 cells
This PCR-based method targets genomic polymorphisms specific to non-human cells. For CHO cells, it targets 15 specific genomic polymorphisms within protein coding genes located on mitochondrial and nuclear chromosomes, with specific PCR primers. Separate PCR primers act as assay controls targeting 6 regions within ribosomal genes that are conserved across species. The amplified PCR products are sequenced using a next-generation sequencing platform. The defined sequence analyses of the15 target proteins and comparison against an internationally recognized database (NCBI) is performed to confirm sequence identity. Identification of the CHO-specific sequences authenticates the presence of CHO cells in the assay, and the final report will provide analyses for the 15 markers and 6 control regions.

Human Karyotyping (GLP) *Test Code # 30012.1*
TAT 49 days • Sample Requirements: 1 x 10^7 cells

Isoenzyme Electrophoresis (GLP) *Test Code # 30330.1*
TAT 35 days • Sample Requirements: 1 x 10^7 cells

Talk to us and find out how our cell line identity testing services can work for you.

Contact a WuXi AppTec Account Manager at 651-675-2000 or email: info@wuxiapptec.com

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