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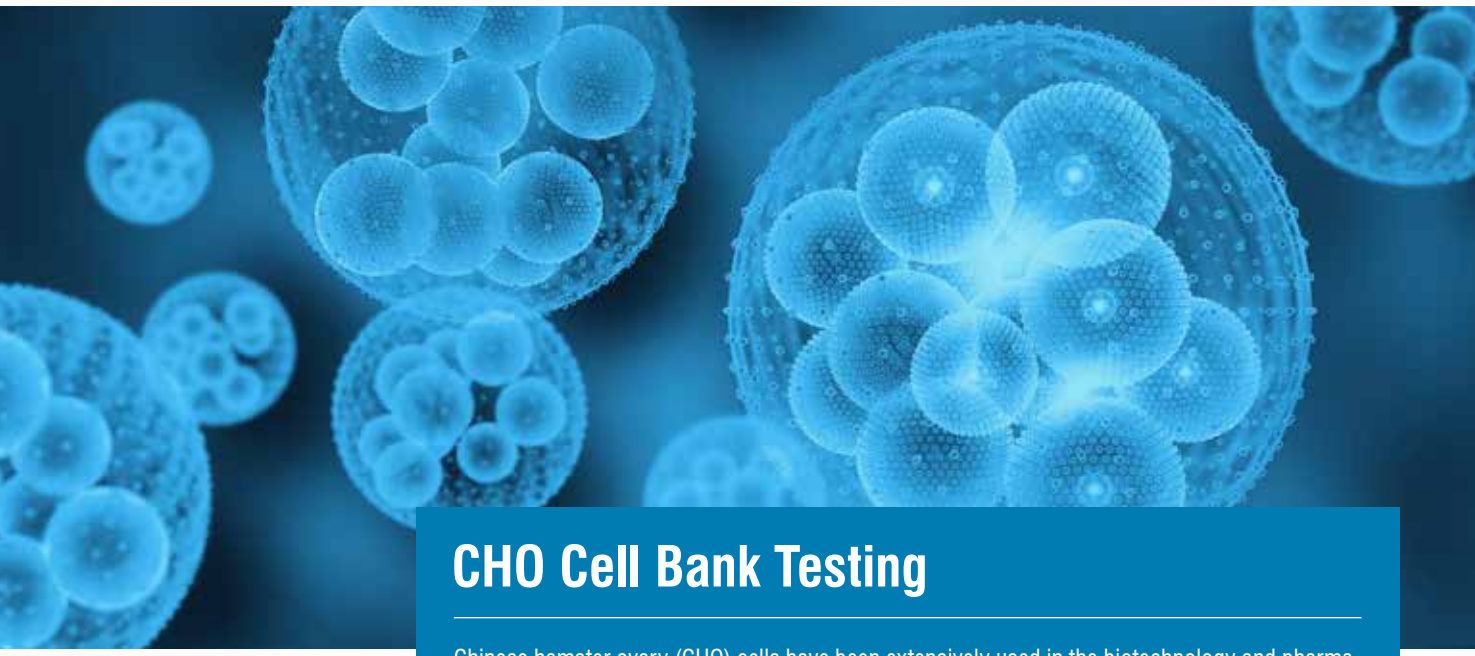

CHO Cell Bank Testing

Chinese hamster ovary (CHO) cells have been extensively used in the biotechnology and pharmaceutical industries for several decades, primarily for the production of therapeutic proteins and biopharmaceuticals. Quality control (QC) of CHO cell banks is crucial in biopharmaceutical manufacturing to ensure the safety, purity, and consistency of the cell lines used for therapeutic protein production.

CHO Cell Bank Development Testing

Critical Quality Attributes	Assay	Description
Characterization	RNA-Seq	Evaluate performance of clones
	Southern blot for Clone Selection	Compare integration profile using Southern blot
	Confirmation of clonality by Southern blot	Evaluate consistency of integration site(s) between cell bank clones
	Northern blot for clone selection	Compare RNA expression profile between clones by Northern blot
	Integration site analysis by NGS	Identification of integration site(s) by targeted sequencing using Illumina or Nanopore NGS
	mRNA Sequencing	RT-PCR Sequencing of transcribed target gene by Sanger
	Protein expression	Evaluate target protein expression and quality

CHO Cell Bank Release Testing

Critical Quality Attributes	Assay	Description
Stability	Southern Blot- Integration Site analysis	Determine number of integration sites within cell bank and stability over time
	Southern Blot- Confirmation of Structure	Confirm no large insertions or deletions within integrated transgene

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CHO Cell Bank Release Testing (Cont.)

Critical Quality Attributes	Assay	Description
Stability	Northern Blot	Confirm stability of transgene expression over time or for clone screening
	Copy Number Analysis- QPCR	Quantitate number of integrated transgene copies per cell and stability over time by QPCR
	Copy Number Analysis- ddPCR	Quantitate number of integrated transgene copies per cell and stability over time by ddPCR
	mRNA Sequencing	RT-PCR Sequencing of transcribed target gene by Sanger
	Viability Assay	Ratio of live to dead cells
Purity	Sterility Testing	Confirm sterility of cell bank
	Mycoplasma Testing	Screen cell bank for presence of Mycoplasma