

# Analytical Testing Services

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Analytical testing service is a deep analysis of samples through biological, chemical and physical method or with high-tech instruments. Utilizing analytical testing, it is accurate and rapid to find the trace contamination of products, including microbes, virus, adventitious cell and reagents. Contamination is considered as the main problem in the manufacturing process of biological and clinic products.



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Host Cell Proteins (HCPs) are proteins produced or encoded by the host organisms that are used to produce biological products. Biological products, especially therapeutic proteins, are usually produced by genetically-modified prokaryotic or eukaryotic cells. During the biological products production, host cells also coproduce proteins related to the normal cell functions such as cell growth, proliferation, survival, gene transcription, protein synthesis etc. which become a major part of process-related impurities.



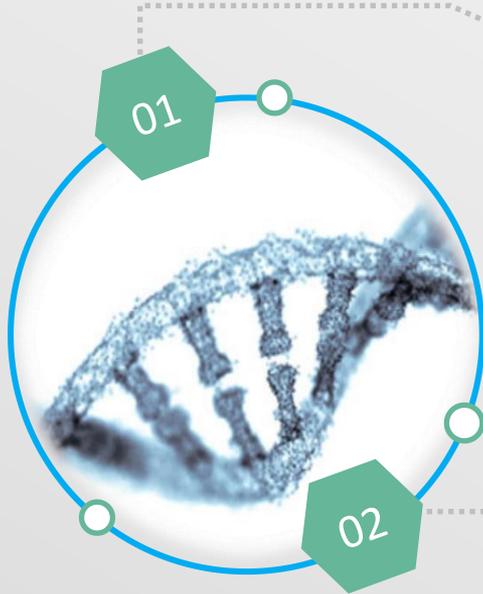
HCPs are critical to drug safety, efficacy and regulatory qualification. Incomplete detection in biotherapeutics development can lead to product degradation, product instability and adverse immunogenic reactions in patients. Therefore, it is a regulatory requirement to monitor the removal of HCPs and assay the residual HCPs in drug product during bioprocess development.

# Host Cell Protein Assay



The methods used for identification and/or quantification of HCPs can be classified as either specific methods, such as ELISA and western blot, or non-specific methods, such as electrophoresis and MS. Among these, ELISA, electrophoresis and MS are the most common techniques and sometimes they are used in combination for detailed characterization. Creative Biogene can offer various methods to detect and assay the amounts of residual host cell proteins, as well as providing a variety of ELISA based HCPs assay kits for your research.

# Residual DNA Testing

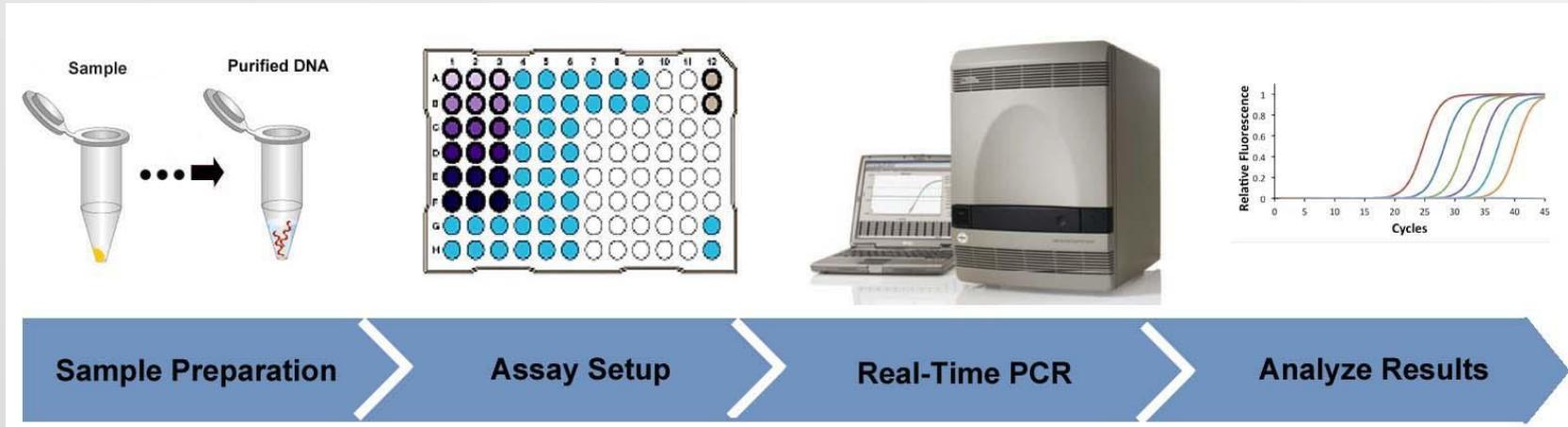


Biopharmaceutical products, such as therapeutic proteins and vaccines, are produced by fermentation using either bacterial or eukaryotic cells. The cells used to produce biopharmaceuticals can be sources of a range of complex, heterogeneous, and potentially unsafe impurities, and host cell DNA is among these. The residual host cell DNA may result in tumors or adverse reactions. Besides, cells used to produce biopharmaceuticals may possibly carry viruses or harbor harmful nucleic acid, and the residual DNA in a given biopharmaceutical product may be infectious.

Therefore, some regulatory agencies have allowed a target of 100 pg or less of residual DNA per dose in biopharmaceuticals, and levels up to 10 ng of residual DNA per dose may be considered, depending on the source of the residual DNA and the product's route.

# Residual DNA Testing

Currently, the most commonly used method of detecting and quantitating residual DNA is quantitative PCR (qPCR). Creative Biogene can offer highly sensitive methods to detect and quantify minute amounts of residual host cell DNA, as well as providing a variety of q-PCR based residual DNA quantification kit for your research.



# Next Generation Sequencing

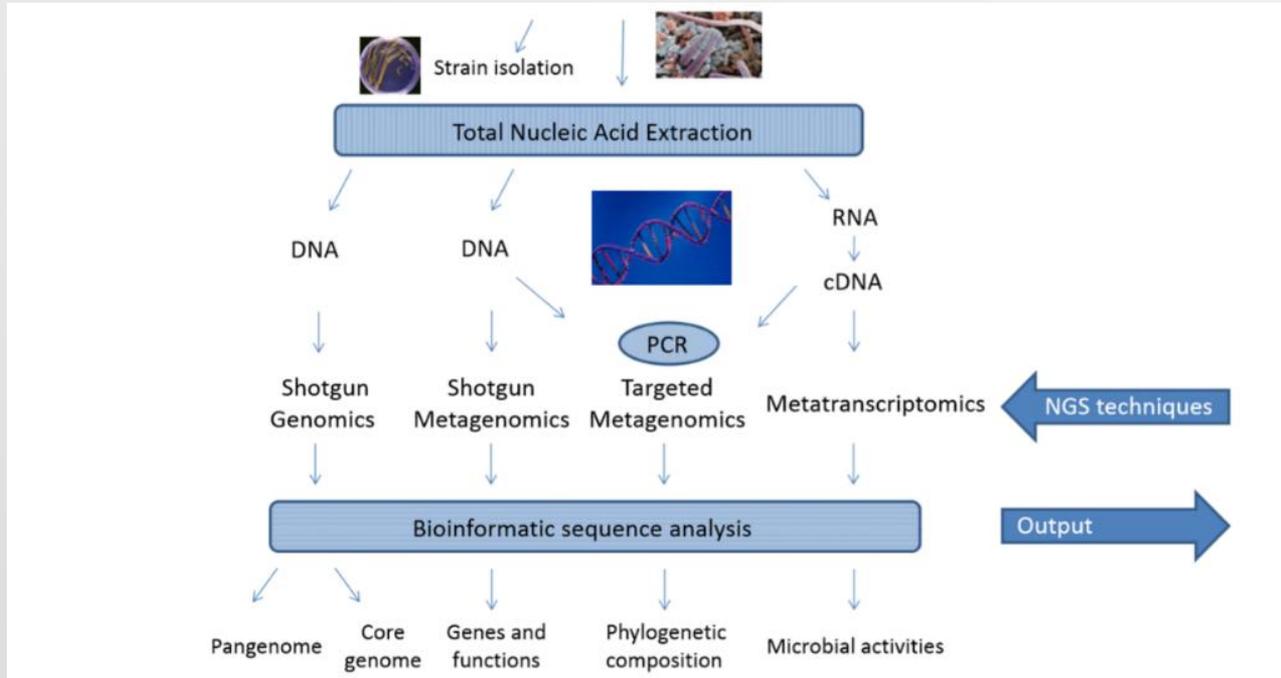
Next generation sequencing (NGS), a massively parallel or deep sequencing technique, has revolutionized genomic research. Compare with the first generation sequencing, the next generation sequencing is characterized by high accuracy, fast speed and low cost. So far, there are many NGS platforms involving different sequencing technologies. Although these platforms differ substantially in terms of their engineering, sequencing chemistry, output, accuracy and cost, all of NGS platforms perform sequencing of millions of small fragments of DNA in parallel.

As a high-throughput sequencing technique (HTS), NGS applies to genome sequencing, genome resequencing, epigenome characterization, DNA-protein interactions (ChIP-sequencing) and transcriptome profiling (RNA-seq). Now, NGS becomes an efficient and effective tool for biosafety testing. Based on the high accuracy and in-depth analysis of nucleic acid, NGS is used for multiple applications including pathogen safety testing and genetic characterization.

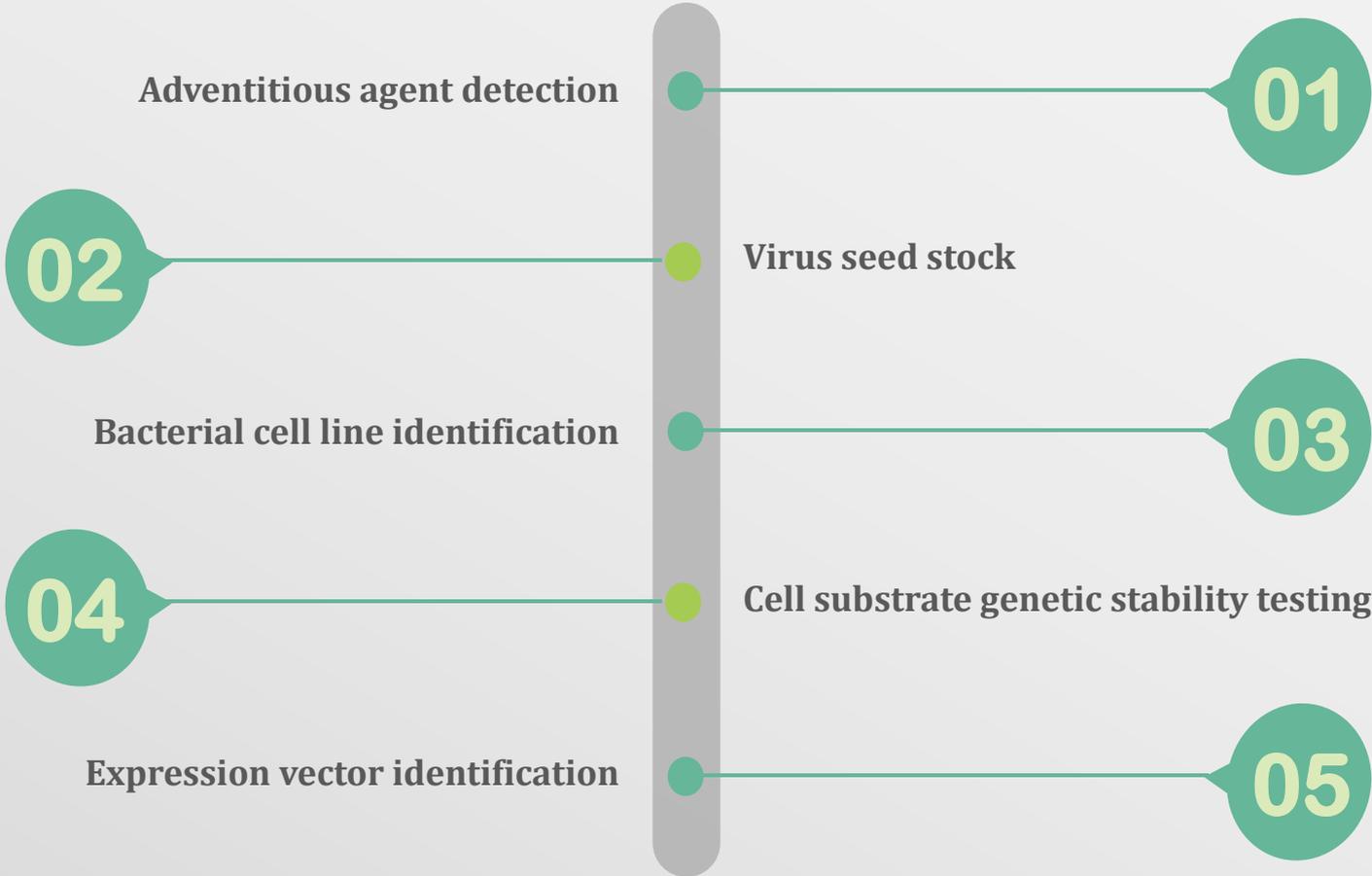


# Next Generation Sequencing

Creative Biogene brings pharmaceutical and biotech companies next generation sequencing service. We provide a complete next generation sequencing service from sample preparation and library preparation through sequencing to data analysis.



# Next Generation Sequencing



# Transmission Electron Microscopy

Transmission electron microscopy (TEM) is a microscopy technique in which microscopes use electrons instead of light as an emission source. Comparing with light microscopy, transmission electron microscopy get a resolution a thousand times owing to its electron source with much lower wavelength. Using TEM, it is possible to capture fine detail, even as small as single column of atoms.

Transmission electron microscopy produces high-resolution and detailed images from which researchers can get more information on element and compound structure. As a major and powerful analytical method, transmission electron microscopy plays an important role in chemical, physical and biological sciences.

Now, TEM is considered as a tool for biosafety testing and applied for viral particles detection, microbial contamination identification, material analysis and so on. Sample preparation is a crucial step before a TEM analysis, which includes dehydration, sputter coating of non-conductive materials, cryofixation, sectioning and staining.



# Transmission Electron Microscopy

Creative Biogene offers an expertise transmission electron microscopy service for clients. Our expertise in TEM-based biosafety service allows us to provide full-service GLP electron microscopy evaluations, from sample preparation through image acquisition to data analysis.



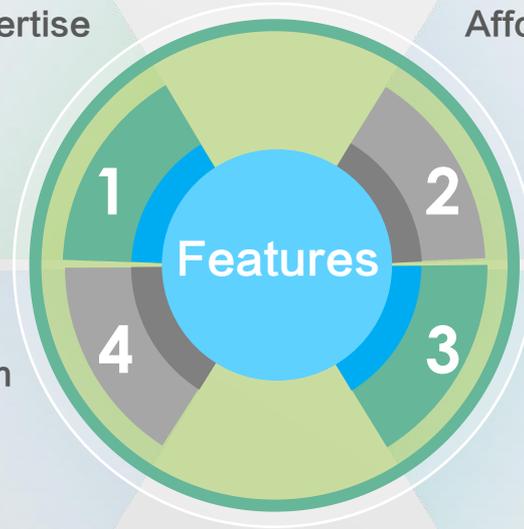
Protocol	A	B	C	D
1. Cultivation	culture flask	culture flask	culture flask	culture flask
2. Fixation	chemical	chemical	chemical	cryofixation
3. Postfixation & en bloc staining				
				Freeze substitution
				
				no staining
4. Dehydration & embedding				
	embedding: silicone mold	embedding: silicone mold	embedding: silicone mold	embedding: Flow-through capsule in gelation capsule
5. Ultrathin sectioning & staining				
6. Visualization	TEM	TEM	TEM	TEM

Leading-edge technology and expertise

Affordable costs and cost-effective prices

Experienced scientist team

Reliable and high-quality data analysis





# THANKS

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