

Media
by Design
Services

Cell culture

Bioproduction analytical services

Actionable insights powered by industry-leading technology and trusted expertise

Analytical expertise Data-driven insights Actionable results

Gibco™ Media by Design™ Services provide a comprehensive suite of bioproduction analytical services, ranging from media and protein analytics to customized investigative analytics projects, to help improve cell culture media performance. Experienced consultation is also available to help you interpret the analytical data and implement process improvements.

Collaborate with a trusted pioneer of bioprocessing innovation and our dedicated global team of bioproduction professionals. We can work with you to provide dependable insights and develop tailored analytical solutions that meet your unique project requirements.

Media analytics

In-depth formulation analysis is a valuable media development tool—enabling you to understand the utilization profiles of key components at different times throughout your process. We offer this service for both fresh and spent media analyses, as well as for supplement analysis. Information gained can be a critical tool when designing future optimization strategies for your cell culture process.

We offer short turnaround times for customizable analysis of a wide range of components, including amino acids, water-soluble vitamins, metabolites, and trace elements.

Upon completion of these services you will receive an easy-to-read quantitative report of the results. If desired, additional support and consultation are available to help you review the results and learn how to use the data to optimize a formulation or process.

Service summary

- 10 business-day turnaround for most routine services*
- Samples tested in multiple facilities located in the United States, Europe, and Asia
- Consultation access is available from our field applications scientists to help analyze your results and identify solutions to help you achieve your goals
- Media development and process design services are available for more comprehensive improvements

* Turnaround times are variable and based on project scope and may vary by site.

Table 1. Standard media analytics: details and recommended sample volumes.

Assay	Method**	Recommended sample volume†	Limit of quantitation
Albumin	LC	200 µL	5 mg/L
Amino acids, free	LC	200 µL	~2.5 µmol/mL
Carbohydrates, total	Plate-based	200 µL	10 mg/L
Cholesterol	LC	200 µL	1 mg/L
Elemental	ICP-MS	2 mL	~5 ppb
Glucose/lactate	LC or bioprocess analyzer	200 µL	1 µmol/mL
L-alanyl-L-glutamine dipeptide‡	LC	200 µL	~2.5 µmol/mL
Insulin	LC	200 µL	5 mg/L
Nucleosides	LC	200 µL	10 mg/L
Organic acids	LC	200 µL	Various
Pluronic/poloxamer	LC	200 µL	50 mg/L
Polyamines	LC	200 µL	5 mg/L
Transferrin	LC	200 µL	5 mg/L
Vitamins, water-soluble	LC	700 µL	1 mg/L

Table 2. Advanced media analytics: details and recommended sample volumes.

Assay	Method**	Recommended sample volume†	Limit of quantitation
Amino acids, total	LC	500 µL	~2.5 µmol/mL
Anions	IC	4 mL	0.25 mg/L
Carbohydrate profile	IC	200 µL	0.1–1 mg/L
Choline	IC	4 mL	1 mg/L
Fatty acids, free	GC-MS	5 mL	0.1 mg/L
Lipids (mono-, di-, and triglycerides)	LC	200 µL	1 mg/L
Vitamins, fat-soluble	LC	2 mL	0.5 mg/L

** LC: liquid chromatography; ICP-MS: inductively coupled plasma mass spectrometry; IC: ion chromatography; GC-MS: gas chromatography–mass spectrometry; NA: not applicable.

† If unable to meet the recommended amounts, please contact your Thermo Fisher Scientific representative.

‡ Analyte is from Gibco™ GlutaMAX™ Supplement.

See Table 4 (page 7) for lists of analytes analyzed within specific assays.

Protein analytics

Consistently meeting the required critical quality attributes (CQAs) of your protein is vital to provide a safe and effective therapeutic.

One key attribute is the **glycosylation profile**. Our analytics team can provide support to enable you to determine the glycan profile of your protein. This information can help you ensure the stability, safety, and quality of your product.

Maintaining the optimal balance of positive and negative charges within your molecule is also central to its structure, stability, and biological function. We can provide **charge variant analysis** to help you understand changes to the charge variants for your antibody at different time points. This understanding can help you optimize process consistency, simplify downstream processing, and improve downstream product yields.

Aggregates of antibodies, whether they are dimers, trimers, or much larger clusters, can impact the therapeutic efficacy of a final product. This aggregation can occur during production, purification, or storage of a drug product. Our **protein aggregation assay** can help accurately measure the relative percentage of monomers and aggregate forms in cell culture or after purification to facilitate optimizing your protein production conditions and maximizing your output of monomeric mAbs.

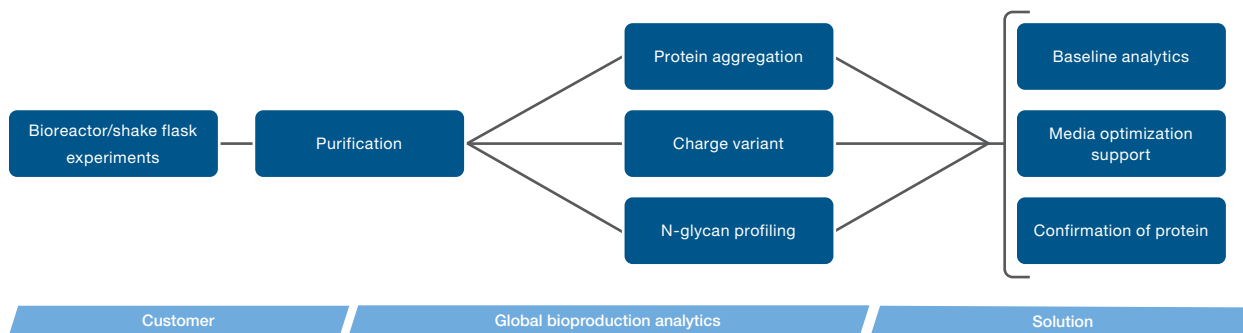
Table 3. Protein analytics: details and recommended sample volumes.

Assay	Method**	Recommended sample amount†	Limit of quantitation
IgG: aggregation	LC	100 µg	NA
IgG: charge variant	LC	100 µg	NA
IgG: N-glycan	LC	100 µg	NA
IgG: purification	NA	1 mg	NA
IgG: quantification	LC	200 µL	10 mg/L

** LC: liquid chromatography; ICP-MS: inductively coupled plasma mass spectrometry; IC: ion chromatography; GC-MS: gas chromatography–mass spectrometry; NA: not applicable.

† If unable to meet the recommended amounts, please contact your Thermo Fisher Scientific representative.

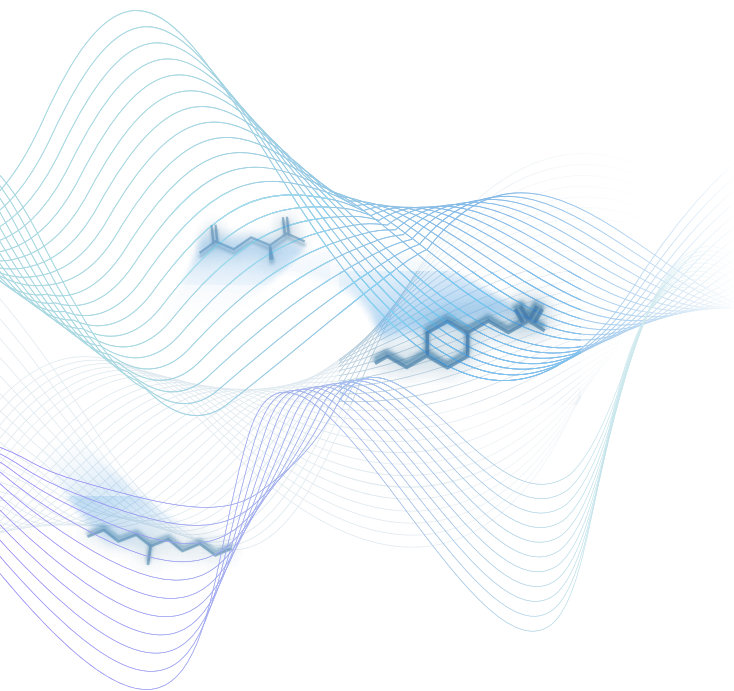
Figure 1. Protein quality workflow. Step-by-step outline of the protein analytics workflow to ensure the stability, safety, and quality of your product.



Investigative analytics

We are also able to provide investigative analytics to help you troubleshoot batch-to-batch variability in your process related to the media.

Depending on your specific needs, we can work with you to develop a customized project that helps you quickly identify the cause of the variability and propose appropriate solutions.



White paper

Achieving consistency: understanding key drivers in cell culture media

Situation: Obtaining consistent protein production and quality attributes is critical in today's bioproduction industry. In order to meet these goals, nutrients such as amino acids, vitamins, and trace metals must be kept within a very specific range for achieving an ideal cell culture medium performance.

Solution: The Media by Design Services team has utilized a key driver identification (KDI) approach with many customers to help better control variability and achieve consistency in a specific process. To accurately assess which components in a complex medium are driving a process, multiple lots (e.g., from 5 to 10) of a medium or supplement of interest are analyzed for components showing a statistical correlation with performance. Optimal ranges are then defined for the key drivers.

Results: The use of predictive mathematical modeling through a staged KDI methodology has been shown to help achieve customer goals. While modifications to a cell line and process can require extensive time and effort, optimization and supplementation of a cell culture medium offers a more rapid option for achieving a consistent and desired bioproduction outcome.

[Read the full white paper](#)

What are key drivers?

Key drivers are media or supplement components that have a significant impact on process performance and must be within a specific concentration range to achieve optimal results. Consequently, identifying key drivers and their ideal concentrations can have many benefits.

[Read our infographic to learn more about key driver identification and how it can help you optimize your process.](#)

Key driver components can be grouped into two categories:



Positive drivers

Components that increase process performance



Negative drivers

Components that decrease process performance

Additional analytical services

In addition to supporting media development and optimization, we provide a range of analytical services to help you achieve long-term manufacturing success.

Manufacturing support analytics

Our Gibco™ trace element testing service can enable you to understand the trace elements to which your specific process or cell line is most sensitive to. Using this insight, you can proactively develop a risk mitigation strategy, such as optimized raw material screening protocols.

We also offer real-time stability testing of your cGMP-manufactured product in your desired packaging configuration. These customizable studies are conducted under conditions and time points determined by you. Our capabilities include a wide variety of quality assays dependent on your specified stability-indicating factors to help you meet your regulatory requirements.

Identity verification method development service

Many regulatory agencies now require identity verification testing on each batch of production raw materials to confirm that they consistently meet specifications (e.g., USFDA Compliance Guidance Q7 GMP for Active Pharmaceutical Ingredients, section 7.3). We have the technology and expertise to help you develop a highly specific, rapid, and compliant identification test for your bioproduction raw materials with pass/fail results.

Our identity verification method development service includes a detailed method development report, written test procedure templates (when applicable), electronic method files (when applicable), support for method transfer to your site, and method validation support.

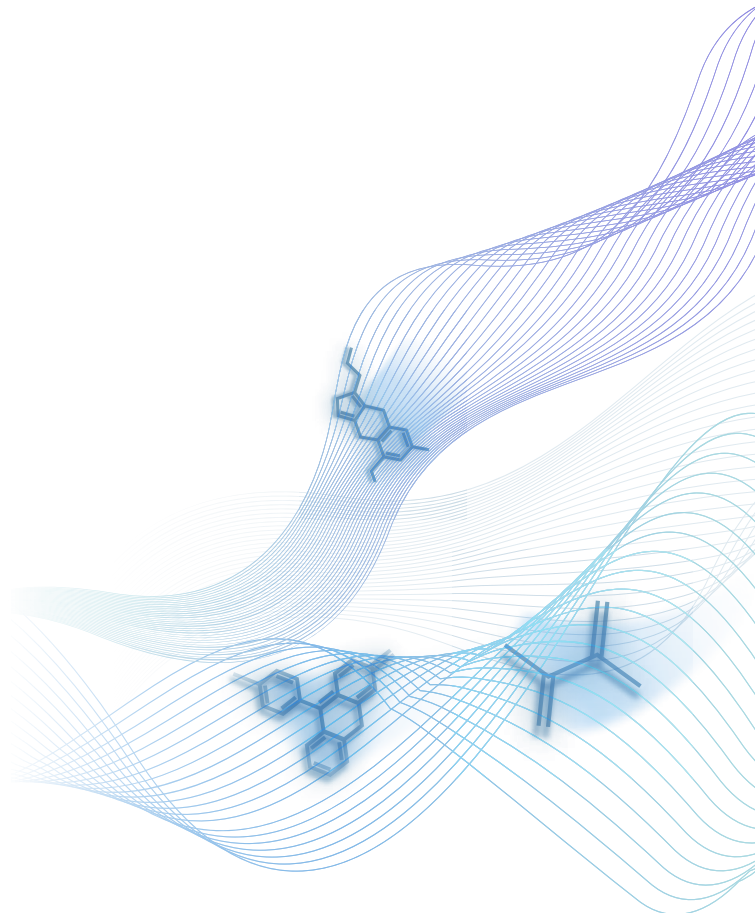
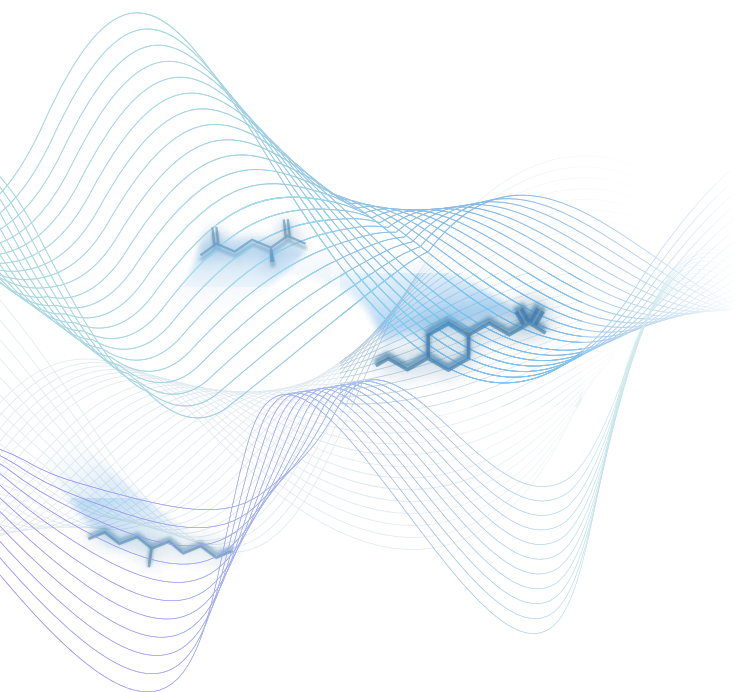


Table 4. Analytes analyzed within selected assays listed in Table 1 and Table 2.

Anions	Carbohydrate profile	Elemental	Amino acids, free	Organic acids	Polyamines	Vitamins, water-soluble
Bromide	2'-deoxy-D-ribose	Aluminum	Alanine	Acetate	Cadaverine	Biotin [§]
Chloride	Arabinose	Calcium	Arginine	Citrate	Putrescine	Cyanocobalamin (B-12)
Fluoride	Fructose	Chromium	Asparagine	Formate	Spermidine	Folic acid
Nitrate	Fucose	Cobalt	Aspartic acid	Fumarate	Spermine	Folinic acid [§]
Nitrite	Galactose	Copper	Cystine	α-Ketoglutarate		Niacinamide
Phosphate	Glucosamine	Iron	Ethanolamine	Lactate		Pantothenate [§]
Sulfate	Glucose	Magnesium	γ-Aminobutyric acid (GABA) [§]	Malate		Para-aminobenzoic acid (PABA) [§]
	Glycerol	Manganese	Glutamic acid	Pyroglutamate		Pyridoxal [§]
	Inositol	Molybdenum	Glutamine	Pyruvate		Pyridoxamine [§]
	Lactose	Nickel	Glycine	Succinate		Pyridoxine [§]
	Maltose	Phosphorus	Histidine			Riboflavin
	Mannose	Potassium	Hydroxyproline			Thiamine
	Raffinose	Selenium	Isoleucine			
	Ribose	Sodium	Leucine			
	Sorbitol	Sulfur	Lysine			
	Stachyose	Tin	Methionine			
	Sucrose	Vanadium	Ornithine [§]			
	Trehalose	Zinc	Phenylalanine			
			Proline			
			Serine			
			Taurine [§]			
			Threonine			
			Tryptophan			
			Tyrosine			
			Valine			

[§] European customers, please contact your representative if required.



Learn more at thermofisher.com/bioproductionanalytics

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