Analytical Support for mRNA Therapeutics

AVANCE BIOSCIENCES

Avance Biosciences is a world-leading CRO that provides CGMP and GLP-compliant biological testing solutions that support the biological drug development pipeline from discovery through manufacturing.

The remarkable success of mRNA vaccines targeting COVID-19 resulted in industry-wide enthusiasm for in vitro (IVT) mRNA-based therapeutics. Consequently, mRNA-based therapeutic development as well as demand for scientifically sound analytical tools for mRNA product characterization and lot release have reached an all-time high.

Extensive analytical testing is required to ensure the identity, purity, and stability of mRNA drugs. The lack of clear guidance from regulatory agencies on the burgeoning mRNA therapeutics sector requires close collaboration among drug developers, CMOs, and CROs.

With several years of experience supporting a world-renowned mRNA COVID-19 vaccine company with raw material and drug substance release, Avance Biosciences is well-positioned to provide industry-leading assay design, validation, and sample testing services that advance our clients' mRNA therapeutic initiatives.

Science-driven, Regulation-compliant, and Customer-centric Organization

We specialize in designing, developing, and validating assays for biologics development and manufacturing. We focus on delivering fast and reliable results using innovative scientific solutions in compliance with FDA 21 CFR Part 210/211, Part 58, and Part 11 regulations. We work hard to ensure we meet our clients' timelines. We are committed to helping our clients be successful in their pursuit of innovative, life-saving drugs, and we are proud to be a part of your efforts to advance human health.

CONTACT US

We are always happy to discuss your analytical requirements for developing and manufacturing mRNA therapeutics. Our experts can support your rapid journey to market and regulatory approval.

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Tests	Descriptions
mRNA DS/DP Testing (CGMP)	
ID	Confirm the sequence of mRNA by sequencing cDNA by Sanger and NGS.
Size	Determine mRNA size using CE, HPLC, Bioanalyzer, and/or northern blotting methods.
Ratio Testing	Determine the ratio of mRNA in a mixture using RT-qPCR or ddPCR.
Residual Plasmid Testing	qPCR-based assay to detect potential plasmid contamination.
Quantification	Quantify mRNA using UV Spectroscopy, RT-qPCR, or ddPCR.
Protein ID	IVT in cell-free medium and detection of the resulting protein using Western blot/ELISA.
Encapsulation Efficiency	Determine mRNA/LNP encapsulation efficiency using RT-qPCR or ddPCR.
dsRNA Detection	Detect various dsRNAs using immunoblotting, native and denaturing gel electrophoresis.
Potency Assay	Develop and validate a custom IVT assay to determine mRNA potency.
Stability Assay	Develop and validate a custom assay to evaluate the long-term stability of mRNA.
Mycoplasma Testing	qPCR-based mycoplasma testing.
Endotoxin Testing	Test potential endotoxin contamination using Limulus amebocyte lysate (LAL) method.
Custom Assays	Develop or tech transfer custom assays from clients and validate/verify the assays for GMP testing.
Preclinical/Clinical Testing (GLP or non-GLP)	
mRNA/LNP Biodistribution Study	Develop and validate RT-qPCR and/or ddPCR assays and test tissues/blood from various animal models under GLP or non-GLP. Recovery will be evaluated with spiked mRNA, and the RNA standard curve will be used to correct RT efficiency. The standard curve method will be used.
mRNA Expression Analysis	Develop and validate RT-qPCR and/or ddPCR assays and test human bodily fluids for mRNA expression. ΔΔCt method or standard curve method will be used depending on the nature of mRNA.
mRNA Human PK Study	Develop and validate RT-qPCR and/or ddPCR assays and test human bodily fluids for mRNA expression. ΔΔCt method or standard curve method may be used.
***E. coli* Cell Bank and Plasmid Testing (GMP)**	
Lytic phage detection	Detect potential lytic phage contamination in *E. coli* cell banks. A positive control is used to evaluate the assay's validity.
Lysogenic phage detection	Determine the presence/absence of lysogenic phage in *E. coli* cell banks with Mitomycin C induction. A positive control is used evaluate assay validity.
Strain Identification	Various assays to confirm the identity of DH10β, K12, B, BL21, Stabl3 cell lines, as well as RecA and LacI genotyping.
Species ID	API 20E test to confirm the species of the cell bank.
Gram Staining	Differentiate Gram Positive from Gram Negative bacteria by staining with dyes.
Viability Testing	A cell line sample is stained with trypan blue, and the percentage of viable cells is reported.
Purity Testing	Aerobic and anaerobic culture to detect potential bacterial and fungal contamination. Various bacteria and fungi are used as controls.
Marker Retention Testing	Percentage of cells that contain a selectable marker, such as an antibiotic-resistant gene.
Plasmid ID	Double-stranded Sanger sequencing or NGS for full or partial plasmid sequence confirmation.
Plasmid Copy Number	Using qPCR, quantify copies of plasmid per cell for characterization and genetic stability evaluation.
Restriction Digest	Restriction mapping for plasmid identification and genetic stability evaluation.