

Creative Diagnostics Launches Validated Inorganic Pyrophosphatase ELISA Kits for mRNA Vaccine Production Quality Control

Creative Diagnostics introduces a comprehensive suite of validated Inorganic Pyrophosphatase ELISA Kits for the research community.

NEW YORK, NY, UNITED STATES, September 15, 2025 /EINPresswire.com/ -- [Creative Diagnostics](#), a leading manufacturer and supplier of antibodies, antigens and assay kits, has expanded its product line and introduced a comprehensive suite of validated [Inorganic Pyrophosphatase ELISA Kits](#) to meet the growing demand for stringent quality control in the manufacturing of mRNA vaccines and therapeutics.

mRNA, a novel active ingredient in vaccines and gene therapy, has received significant global attention. The increasing demand for mRNA molecules requires manufacturers to quickly increase production capacity while maintaining high quality standards. However, during the manufacturing of mRNA vaccines, inorganic pyrophosphatase (PPase) persists as a process-related impurity. Residual PPase poses immunogenicity risks and compromises product purity, necessitating rigorous quantitative detection. Creative Diagnostics has developed a suite of products for controlling the process of mRNA therapeutics to support the development of mRNA platforms.

For example, a validated double-antibody sandwich ELISA assay (DEIA-HP3807) can detect PPase residues in mRNA therapeutics with high specificity. This method provides high-sensitivity monitoring of process-derived impurities during production and is robust against matrix interference. This supports critical quality control and regulatory compliance. In addition, the mPEG ELISA kit determines free mPEG and mPEG-modified proteins containing one or more mPEG chains. Creative Diagnostics' research confirms that this kit recognizes mPEG chains of at least 2 kilodaltons (kDa). The kit includes a 5-kDa mPEG-amine standard to validate the performance of the kit.

Creative Diagnostics also offers the Double-stranded RNA (dsRNA) ELISA kit (DEIA-BZ002P) for the quantitative detection of dsRNA content in samples. This kit uses a double-antibody sandwich assay combined with a biotin-streptavidin system to quantitatively detect double-stranded RNA (dsRNA) levels in samples. This method detects dsRNA sequences of 60 base pairs or longer with no nucleic acid sequence restrictions. The standard procedure for synthesizing mRNA is in vitro transcription mediated by T7 polymerase. However, this process may introduce

dsRNA contaminants through mechanisms such as random primer action, turnaround transcription, and antisense transcription. These contaminants can activate immune responses, leading to the upregulation of various pro-inflammatory cytokines and cell death. Consequently, it contributes to patient pathology. Therefore, to enhance mRNA translation quality and minimize adverse effects, it is essential to rigorously monitor in vitro transcription (IVT) mRNA products and confirm the removal of dsRNA following purification.

Additionally, the Protein A ELISA kit is also designed to detect native and recombinant Protein A in bioprocessing applications. In certain circumstances, Protein A or its fragments may leach from purification columns and bind persistently to the Fc region of therapeutic antibodies. To prevent adverse patient outcomes (particularly during the preparation of pharmaceutical antibodies), these occurrences must be eliminated. This ELISA serves as a quality control measure for detecting Protein A ligand leaching during monoclonal antibody development processes.

For more information about these new products and Creative Diagnostics' full range of research solutions, please visit <https://www.creative-diagnostics.com/mrna-vaccine-production-qc-validated-inorganic-pyrophosphatase-elisa-kit.htm>.

About Creative Diagnostics

Creative Diagnostics is a leading manufacturer and supplier of antibodies, viral antigens, innovative diagnostic components, and critical assay reagents. In addition to providing contract R&D and biologic manufacturing services for diagnostic manufacturers along with GMP biologics manufacturing for the biopharmaceutical market, the company aims to continue to act as a trusted source for all researchers' assay development and manufacturing needs.

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