

# Creative Diagnostics Launches Highly Sensitive T7 RNA Polymerase ELISA Kits for Biopharmaceutical Impurity Detection

*Creative Diagnostics has released T7 RNA Polymerase ELISA Kits for the detection and quantitative determination of T7 RNA Polymerase.*

NEW YORK, NY, UNITED STATES, May 24, 2025 /EINPresswire.com/ -- [Creative Diagnostics](#), a leading manufacturer and supplier of antibodies, antigens and assay kits, has announced the release of its new, highly sensitive and specific [T7 RNA Polymerase ELISA Kits](#) for the detection and quantitative determination of T7 RNA Polymerase in biopharmaceutical samples. These kits provide a critical tool for researchers and manufacturers to monitor and control process-related impurities, ensuring the safety and efficacy of biologic drug products.

Biopharmaceuticals are a class of drugs that are usually produced in living organisms and can be used to treat a wide range of diseases. Biopharmaceutical samples include hormones, enzymes, monoclonal antibodies, vaccines, and blood factors, each of which face different challenges during drug development and production, one of which is the presence and level of process-related impurities in the final biopharmaceutical product. Process-related impurities are any chemical substances or biological entities that are expected to be present during the manufacturing process, not completely removed during purification, or not expected to be present in the API or final drug product.

Process-related impurities can be divided into three categories: first, cell substrate-derived impurities (e.g., proteins/nucleic acids from the host organism, such as host cell DNA); second, cell culture-derived impurities (e.g., inducers, antibiotics, serum and other media components); and third, downstream impurities (e.g., enzymes, chemical and biochemical processing reagents, like cyanogen bromide, reducing agents, inorganic salts, and solvents).

Effective removal of process-related impurities or process residues is important for pharmaceutical and biopharmaceutical development. To meet the requirements of the ICH Q6B guidelines for the monitoring and controlling of process-related impurities and contaminants in biomanufacturing processes, Creative Diagnostics has developed a series of highly sensitive ELISA kits for the analysis of impurity residues. These kits are critical for cell substrate-derived impurities, cell culture-derived impurities and downstream impurities, supporting all phases of biopharmaceutical manufacturing.

The new T7 RNA Polymerase ELISA Kit (DEIANS032) is specifically designed for the detection and quantitative determination of T7 RNA Polymerase, an enzyme commonly used in various bioprocessing applications. The kit uses a double antibody sandwich ELISA method and is highly sensitive with a lower limit of detection (LOD) of 0.1 ng/mL and a lower limit of quantitation (LOQ) of 0.25 ng/mL. In addition, the kit is highly specific with minimal cross reactivity (less than 0.1% with other antibiotics). Its robust design ensures high reproducibility with low within- and between-batch variation (<10%), providing reliable results for process validation and routine monitoring.

The T7 RNA Polymerase ELISA Kit provides biopharmaceutical manufacturers with a reliable and efficient tool for the detection of process-related impurities in biologics. Please note that this kit is for research use only and is not intended for use in diagnostic procedures. For more information about the T7 RNA Polymerase ELISA Kit and other bioprocess impurity detection solutions, please visit <https://www.creative-diagnostics.com/t7-rna-polymerase-elisa-kit-item-deians032-117033.html>.

### 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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