

# Overcoming transgene detection challenges in viral vector therapeutics

## CASE STUDY: TRANSGENE EXPRESSION

### Client profile

Established emerging viruses vaccine developer working at the forefront of vaccinology.

### The challenge

Viral vector-based vaccine development has rapidly increased, particularly during the COVID-19 pandemic. Regulatory authorities such as the FDA, EMA, and MHRA require detailed data on transgene products to approve treatments. Ensuring accurate identification and monitoring of transgene expression is critical for vaccine efficacy. A key challenge in the approval process of a COVID-19 vaccine was the absence of an analytical method to measure transgene expression. This highlights the necessity of reliable detection methods when assessing viral vector-based therapeutics.

RSSL was approached by a client seeking to develop and validate a method for detecting transgene-encoded proteins via Western blot using commercially available antibodies. The target proteins were small, membrane-bound and specific to an enveloped virus strain. This posed a significant challenge, requiring an innovative approach to ensure accurate analysis.



### Extensive capabilities

The first step was to optimise the transgene expression process. RSSL modified existing methods to ensure successful transduction, refining virus-to-cell ratios and conducting time-course experiments. Once optimal transgene expression was confirmed, further enhancements were made to cell harvesting and processing.

Given the hydrophobic nature of the protein, a specialised protocol was developed to solubilise it within the cell lysate whilst maintaining its conformational epitope. Downstream analysis was performed using an adapted Western blot method. By preserving the native conformation, the transgene product was successfully identified using a conformational antibody.



## Scientific excellence

RSSL's multidisciplinary expertise in virology, cell biology and method development was key to overcoming challenges related to sample processing and transgene product availability. The team applied advanced immunoassay techniques to develop a robust detection method that met stringent regulatory requirements.

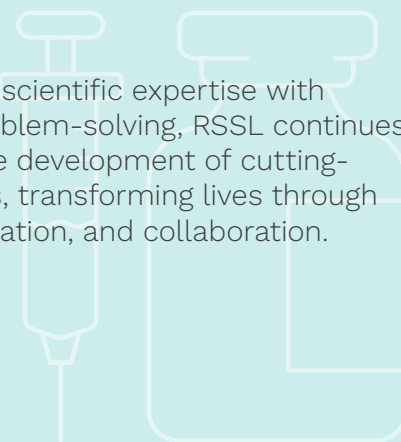
With a deep understanding of GMP biologics, RSSL specialises in developing customised methods for viral vector vaccines, ensuring precise transgene identification. Their proficiency in Western blot techniques and immunoassays guarantees high-quality, reliable results tailored to client needs.



## Outcome

RSSL successfully validated a GMP-compliant method in line with ICH Q2(R2) guidelines for identifying transgene expression from the client's viral vector platform. This achievement underscores RSSL's capability to develop transgene expression methods using various immunoassay endpoints, addressing both regulatory standards and specific client requirements.

By combining scientific expertise with innovative problem-solving, RSSL continues to support the development of cutting-edge biologics, transforming lives through science, innovation, and collaboration.



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