

Short™ AE-IGF-1 in Vaccine Development

COVID-19 and Beyond

With the emergence of COVID-19 pandemic, there is a concerted international partnering effort between governmental research organisations, academia and the broader pharmaceutical and biotechnology industry for the development of an effective vaccine to protect against coronavirus disease. The first vaccine trials started in April 2020.

It is anticipated that many of the treatments for Covid-19, such as monoclonal antibodies, virus vaccines, recombinant proteins, and others in progress, will necessitate the use of mammalian cell-culture based expression systems such as CHO-s, HEK 293, BHK, and PBG.PK2.1.

There is precedence in using insulin-based analogues like IGF-1 in the aforementioned expression systems for the production of influenza vaccines.¹ The knowledge gained with this application can be utilized in Covid 19 vaccine development. The addition of human IGF-1 to chemically defined media has been shown to markedly increase viable cell density and specific viral yields.

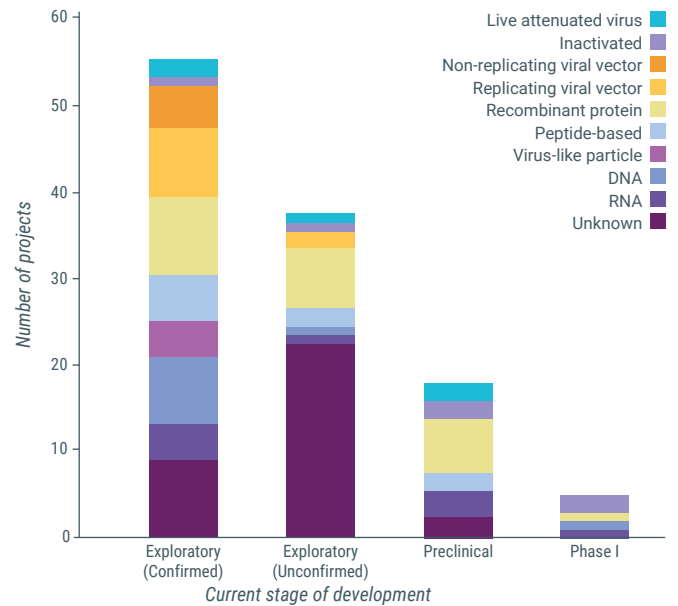
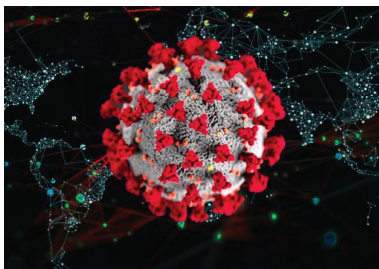


Fig.1 - Pipeline of COVID-19 vaccine candidates by technology platform Nature Reviews Drug Discovery 19, 305-306 (2020)



At CellRx, we are committed to the global mobilisation for the development of Covid-19 based vaccines and offer a proprietary AE version of IGF-1, **Short™ AE-IGF-1**. It has been engineered with an N-terminal Ala-Glu sequence, enabling **higher specific activity versus IGF-1** over a longer time-course, in small to large-scale culture systems and bioreactors. Short™ AE-IGF-1 is a **high-performance, bioactive grade and compellingly priced alternative** to insulin and other insulin-based analogue growth factors with **immediate availability and guaranteed security of supply**.

Short™ AE-IGF-1 is approximately 100x biologically more potent, *in-vitro*, than insulin and consistently matches and outperforms other market leading IGF-1 growth factors in both productivity (recombinant protein production) and viability (reduced apoptosis and higher cell density). All mammalian cell expression systems that have a functional Type-1 IGF receptor will respond to Short™ AE-IGF-1.

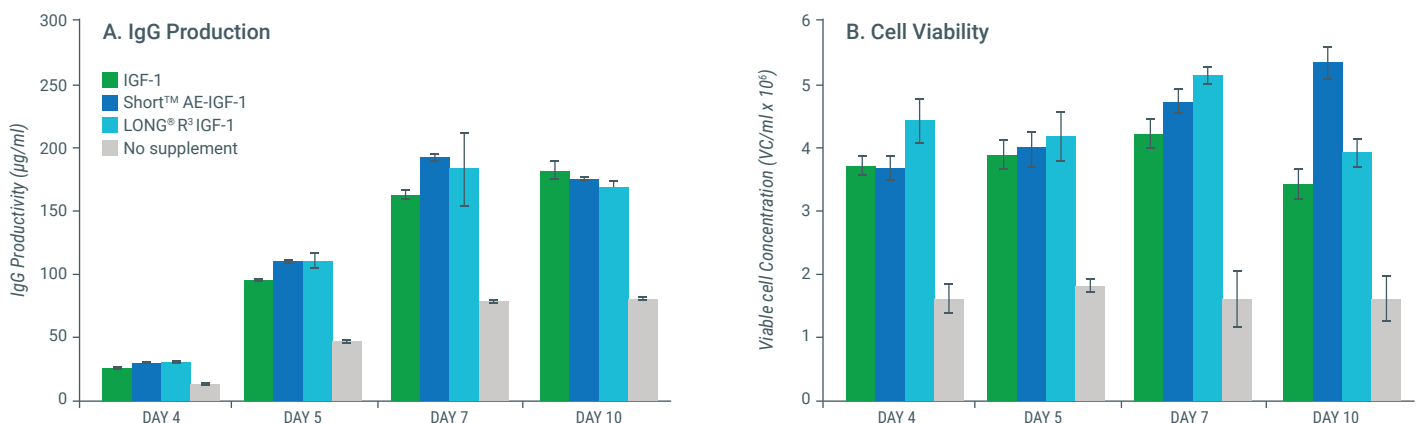


Fig 2 - Comparison of Short™ AE IGF-1 and IGF-1 additives in CHO DG44 for (A) IgG production and (B) cell viability.

CHO DG44 cell suspension was monitored for IgG production and cell viability. Ex-Cell CD CHO Fusion Protein free medium was used with additives as indicated. All values are in triplicate.

1. Vaccine 37, 7019–7028 (2019)

Ease of use

Short™ AE-IGF-1 is available as a liquid formulation in 100mM acetic acid and does not require reconstitution or the use of carrier proteins, excipients and additional stabilizers. It can therefore be added directly into formulation without further handling or risk of influencing cell culture pH and osmolality.

Short™ AE-IGF-1 ships at ambient conditions and can be safely stored at 2-8°C. It therefore eliminates the need for adding carrier proteins or aliquoting into smaller quantities for long-term storage at lower temperatures as required in other products. This advantage also helps reduce the cold-chain shipping and storage costs.

Compliance and Supply Security

Produced under ISO 18001, ISO 9001, ISO 14001 certified conditions, strict FDA, EMA and GMP guidelines, Short™ AE-IGF-1 is a high-quality GMP-like and certified 100% animal-free product. Short™ AE-IGF-1 is a superior bioactive grade growth factor with a comprehensive supply and risk management strategy that includes an inventory surplus equal to 2 years of forecast demand maintained at secure storage facilities.



Value comparison of Short™ AE-IGF-1

Feature	IGF-1	Leading IGF-1 Supplier	Short™ AE-IGF-1
Productivity	2-3x	2-3x	2-3x
Viability	2x	2-3x	2-3x <i>Maximum Performance</i>
cGMP/Animal Free	Yes	Yes	Yes
Liquid Stable	No	Yes	Yes
Storage	-20°C	2-8°C	2-8°C
Carrier Proteins/Stabilizers	Required	Not Required	Not Required <i>Ease of use</i>
Supply Security	Available	Available	Available
Price	3x	3x	1x <i>Unbeatable Value</i>

With a consistent high performance matching and exceeding the leading IGF-1 additives at a lower cost point, Short™ AE-IGF-1 from CellRx can deliver tangible value and measurable impact in bio-manufacturing processes with significant long-term cost savings attained by media optimisation to help maximise savings and drive high viral yields.



About CellRx

CellRx is a specialist manufacturer and supplier of growth factors that serve the technical research and bioprocessing markets. With a proprietary manufacturing platform and decades of innovation and expertise CellRx is filling the much-needed gap in offering top quality, high performance products at an unbeatable price point and adhering to following key advantages:

- ✓ Increased expression through the development of the third generation hyperproducing *E. coli* strain;
- ✓ Resulting in better yields in re-folding and recovery steps during production of challenging proteins;
- ✓ Providing better specific activity per unit mass within bioproduction processes.

Collectively, this translates into a significant reduction in our manufacturing cost of goods (COGs) and thus allowing us to offer high performance, better quality and more user-friendly products at a very competitive price.

For more information about CellRx, our products and services, please contact us or visit cellrxbio.com.

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