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Isolere Bio by Donaldson Launches Research-Grade IsoTag™ AAV Reagent for Rapid, Non-Chromatographic Viral Vector Purification

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Developed from Duke University's cutting-edge technology, the IsoTag AAV reagent offers enhanced reliability, titer-independent process flexibility, and accelerated purification, marking a major advancement in AAV vector production for gene therapies.

Isolere Bio by Donaldson, an innovative bioprocessing technology provider, proudly announces the availability of research-grade IsoTag™ AAV reagent, for the purification of adeno associated viral vectors (AAV). The research-grade IsoTag AAV reagent marks a significant advancement from its prototype grade. It maintains the same non-chromatographic purification capabilities, but now provides enhanced reliability and quality including animal-origin free production under an ISO 9001 certified quality management system.

A first-of-its-kind reagent for the purification of target biologics, IsoTag AAV reagent was developed from cutting edge technology spun out of the Chilkoti biomedical engineering lab at Duke University. The specialized reagent is compatible with a multitude of AAV serotypes, achieves up to 85% yield and provides a 4-log reduction in host cell proteins and DNA with a processing time of less than 4 hours. The novel reagent combines affinity capture and liquid-liquid phase separation, eliminating the need for traditional affinity chromatography. This innovative method features an AAV-specific affinity ligand paired with a stimulus-responsive biopolymer expressed as a single protein in E. coli, which is fully biodegradable and requires no chemical conjugation to a solid scaffold. The product effectively captures AAV capsids into micron-sized, protein rich droplets, which are easily retained using open-pore filters, thereby streamlining the purification process and enhancing overall efficiency in viral vector production.

“Our latest addition to the IsoTag reagent platform represents a significant leap forward in AAV purification for gene therapies,” said Kelli Luginbuhl, General Manager and CoFounder of Isolere Bio by Donaldson. “By accelerating the purification process to under four hours and enhancing yield, purity, and quality, we are addressing key manufacturing bottlenecks that other technologies using a solid base matrix cannot. As our process, thus far, is titer-independent, it will provide process flexibility as upstream titers continue to improve.”

IsoTag AAV reagent is compatible with a wide range of tangential flow filtration (TFF) equipment and off-the-shelf consumables, providing the flexibility needed to meet the growing demand for high-quality AAV vectors from research to commercial production. Isolere Bio by Donaldson is progressing towards manufacturing-grade IsoTag AAV reagent, which will include a suite of quality documentation to facilitate use in a GMP environment.

Manufacturing-grade IsoTag AAV reagent is on track to be available in 2025. Research-grade IsoTag AAV reagent will be available to purchase in a few weeks in North America and Europe.