

Novel analytical technologies for the characterization of adenoviruses in vaccines

<u>Ewoud v</u> Govert Som	an Tricht ^{1,3} sen ⁴	^{,4} , Mar	ta Germano ¹ ,	Cari	Sänger	-	van	de	Griend ^{2,3} ,
¹ Janssen ⁴ Vrije Unive	Vaccines rsiteit Amstero	and dam	Prevention,	² Kantisto	BV,		³ Uppsala		University,

E-mail: evantri@its.jnj.com

Analytical and biological methods are required to monitor the quantity of virus particles and viral proteins throughout the production process to ensure the safety and efficacy of vaccine products. The analytical toolbox was extended with two noval analytical technologies.

A capillary electrophoresis method was developed for the accurate and precise analysis of all samples from the full process containing either cell lysate and cell debri, or high salt concentrations. The method was validated and implemented in the quality control department to monitor the quantify of virus particles. Secondly, a strongly improved RP-UPLC method for the quantitative determination of proteins from adenovirus-based vaccines was developed. The method is currently used to monitor the content of adenovirus proteins in the vaccines. Both methods showed to be of great added value and are superior in terms of precision, accuracy and speed compared to the methods previously used.

