ViruSure launches pioneering viral contamination test for biopharmaceuticals using Oxford Nanopore technology

New adventitious viral agent (AVA) detection test offers rapid, sensitive, and affordable viral screening for biomanufacturers

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Oxford, UK and Vienna, Austria: ViruSure, a global leader in pathogen safety testing for biopharmaceuticals, and Oxford Nanopore Technologies (LSE: ONT) ("Oxford Nanopore") , the company behind a new generation of molecular sensing technology based on nanopores, today announce the launch of the industry's first Good Laboratory Practice (GLP) validated adventitious viral agent (AVA) detection test using nanopore-based sequencing technology.

The ViruSure test has been developed and evaluated under rigorous conditions and is powered by Oxford Nanopore's advanced molecular sensing platform. It will be used for the detection of viral contamination within the manufacturing process, providing biopharmaceutical teams with richer viral detection insights and faster time-to-result, accessibly and affordably. A rapid and sensitive test, it can detect AVAs regardless of virus type, to improve confidence in biomanufacturing safety.

Viral contamination remains one of the most significant threats to biopharmaceutical manufacturing, causing production delays and potential biologic, vaccine and cell and gene therapy product shortages. Traditional viral detection methods can take months to provide the full panel of results, with each individual test often taking more than 14 days, and contaminants still going undetected or reported as false positives.

This innovation addresses a critical need to streamline AVA detection within biomanufacturing, a rapidly growing market currently valued at $20 billion, of which at least $4 billion is related to AVA testing. Global regulatory authorities have also recognised the urgent industry demand for faster and more reliable solutions and actively encouraged the adoption of advanced sequencing-based testing methods.[i]

Dr Andy Bailey, CEO of ViruSure, commented:

"The development of this cutting-edge test for adventitious agents marks a major advancement in the industry's ability to detect a wide range of contaminants with exceptional sensitivity. Offering significantly improved specificity compared to traditional short-read next-generation sequencing methods, this innovation sets a new benchmark in virus detection. Powered by Oxford Nanopore technology, the test produces datasets with minimal background noise, greatly simplifying the identification of potential viral signals. This crucial feature supports biopharmaceutical manufacturers in achieving faster product evaluation and release, enhancing both safety and efficiency."

Gordon Sanghera, CEO of Oxford Nanopore, commented:

"Contamination during the biomanufacturing process can pose considerable risks to patient safety, as well as production delays and drug shortages, which is not wanted by

biopharmaceutical companies – nor the patients and health systems they serve. With the introduction of this first-in-class test, ViruSure is directly addressing the industry's critical demand for rapid, information-rich, and cost-effective viral detection methods, and we're proud to have played a key role in its development."

ViruSure and Oxford Nanopore are also working together to introduce a Good Manufacturing Process (GMP)-validated solution, which they expect will follow shortly.

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About ViruSure

ViruSure, an Asahi Kasei Life Science company, is a leading global Contract Research Organization specializing in virus and prion biosafety testing for the biopharmaceutical and life science industries, with more than 20 years of experience. Located in Vienna, Austria, ViruSure partners with industry to support their quality control testing needs and ensure the safety and purity of biopharmaceuticals, cell & gene therapies, and vaccines. ViruSure is an integral part of the Biosafety Testing Services Unit of Asahi Kasei Life Sciences. To learn more about ViruSure, visit www.virusure.com.

About Oxford Nanopore Technologies

Oxford Nanopore Technologies' goal is to bring the widest benefits to society through enabling the analysis of anything, by anyone, anywhere. The company has developed a new generation of nanopore-based sensing technology for faster, information rich, accessible and affordable molecular analysis. The first application is DNA/RNA sequencing, and the technology is in development for the analysis of other types of molecules including proteins. The technology is used in more than 125 countries to understand and characterise the biology of humans and diseases such as cancer, plants, animals, bacteria, viruses, and whole environments.

Oxford Nanopore Technologies products are intended for molecular biology applications and are not intended for diagnostic purposes. For more, visit: https://nanoporetech.com/

[i] https://www.ema.europa.eu/en/ich-q5ar2-guideline-viral-safety-evaluation-biotechnology-products-derived-cell-lines-human-or-animal-origin-scientific-guideline