

Virusure launches first GMP-validated viral safety test based on Oxford Nanopore sequencing

First-in-class solution consolidates multiple assays into a single test, enabling broader viral detection, faster time-to-result and more confident decision-making in regulated biopharmaceutical quality control

Oxford, UK, and Vienna, Austria [10 March 2026] – Virusure, an Asahi Kasei company and global leader in pathogen safety testing for biopharmaceuticals, today announced the launch of the world’s first GMP-validated adventitious viral agent (AVA) detection test based on Oxford Nanopore sequencing. Designed for use in regulated biopharmaceutical quality control (QC) environments, this process is designed to ensure biologics medicines are free from viral contamination.

The first-in-class solution combines Oxford Nanopore’s rapid, information-rich molecular sensing technology with Virusure’s GMP expertise, delivering broader viral detection and a more streamlined approach to viral safety testing in commercial biologics manufacturing. This has the potential to enable rapid testing and support confidence in batch release, thus strengthening supply chain resilience.

The launch follows the industry’s first GLP-validated (Good Laboratory Practice) AVA detection test using Oxford Nanopore sequencing in August 2025. Progression to GMP (Good Manufacturing Practice) validation, the standard required for routine use in commercial biopharmaceutical manufacturing, demonstrates the regulatory readiness of Oxford Nanopore sequencing-based approaches for viral safety testing and marks an important step toward wider adoption in regulated environments.

Francis Van Parys, CEO of Oxford Nanopore Technologies, said:

“Rapid Oxford Nanopore sequencing offers a fundamentally different level of resolution for detecting viral contaminants. Through this collaboration with Virusure, that capability is now available in a GMP-validated format, making advanced sequencing accessible for routine safety testing across biologics manufacturing.”

Faster and boarder AVA detection from a single, comprehensive test

Biopharmaceutical manufacturing underpins the supply of many critical medicines used worldwide. With the global biologics market estimated in excess of £300 billion, and a biosafety testing market alone valued at approximately £3.2 billion, even isolated viral contamination events can have cascading effects across healthcare systems, resulting in patient safety concerns, drug shortages, and substantial financial impact.

Quality control is central to ensuring safe, reliable biologics manufacturing, and new technologies are creating opportunities to make this process more reliable and efficient. While traditional AVA testing has long supported the industry with a broad panel of established assays, the Virusure and Oxford Nanopore approach brings the benefit of consolidating multiple steps into a single, information-rich test.

Traditional AVA testing relies on numerous parallel and sequential assays to complete a full viral safety panel. Individual tests can take more than 28 days and depending on the level of characterisation can cost tens to hundreds of thousands of pounds, with full panels often taking months. As a result, viral safety testing represents a significant operational component of biologics production, and quality control can account for up to half of the total manufacturing timeline.

Despite their complexity, these approaches can still produce false negatives and false positive results. False positives can trigger unnecessary manufacturing pauses and emergency investigations, creating additional cost and potential supply disruption.

The ViruSure and Oxford Nanopore solution introduces a sequencing-based alternative capable of consolidating many of these individual assays into a single, integrated test that has been demonstrated to have the required sensitivity and specificity necessary to provide assurances around the absence of adventitious agents. By generating a comprehensive and information-rich dataset in one run, manufacturers have the potential to reduce the number of required tests from multiple assays to one, shorten overall testing timelines by weeks, and simplify laboratory workflows within GMP-regulated environments.

Oxford Nanopore's unique ability to sequence reads of any length enables broader AVA detection and clearer differentiation between background noise, false positives, and true viral contaminants. This supports more confident, data-driven decision-making while reducing the need for unnecessary follow-up investigations, helping to maintain continuity in manufacturing operations.

Dr Andy Bailey, CEO of ViruSure, said:

"Manufacturers need viral safety tests that detect the whole range of potential contaminants, are fast and practical for GMP environments with a low rate of false positives. By validating nanopore sequencing for adventitious viral agent detection, our workflow has demonstrated that we can provide a robust and sensitive solution, with a low risk of false positives, that can strengthen safety assurances for the whole range of biological products."

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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 real-time, high-performance, accessible and scalable analysis of DNA and RNA. The technology is used in more than 120 countries to understand 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/>

About ViruSure

With over 20 years of experience, ViruSure is a leading global Contract Research Organization specializing in virus and prion biosafety testing for the life sciences industry. Located in Vienna, Austria, ViruSure offers analytical testing solutions, virus and prion validation services covering a broad portfolio of tests necessary to support drug development and ensure the safety of biopharmaceuticals, cell & gene therapies, and vaccines. ViruSure is integral to the Biosafety Testing Services Unit of Asahi Kasei Bioprocess. To learn more about ViruSure, visit www.virusure.com