ABL Diagnostics Announces CE-IVD of DeepChek® Whole Genome HIV-1 Genotyping v1.2

The first and only CE-IVD whole genome HIV assay, with 500 copies/mL sensitivity for comprehensive drug resistance testing

WOIPPY, FRANCE, July 31, 2026 /EINPresswire.com/ -- ABL Diagnostics (Euronext Paris – Compartiment B – ISIN: FR001400AHX6), a molecular diagnostics company specializing in infectious diseases, today announced the successful CE-IVD registration of DeepChek® Whole Genome HIV-1 Genotyping v1.2, its latest-generation assay for comprehensive HIV drug resistance testing using Next-Generation Sequencing (NGS). The assay has been CE-IVD registered by ABL SA (Luxembourg), the legal manufacturer of the product.

Building upon the proven performance of previous versions, DeepChek® Whole Genome HIV-1 Genotyping v1.2 introduces significant analytical improvements while preserving the validated workflow already adopted by clinical laboratories worldwide. The updated assay maintains the same validated primer design and overall PCR amplification strategy, continuing to amplify five complementary HIV-1 genomic fragments prior to NGS sequencing and downstream bioinformatics analysis. Importantly, laboratories already using previous versions of the assay can immediately benefit from the enhanced analytical performance without modifying their existing workflow, protocols or downstream analysis software. This optimized version delivers equivalent overall analytical performance while significantly improving analytical sensitivity for clinically relevant genomic regions.

A major enhancement of version 1.2 is its improved analytical sensitivity. Analytical performance evaluation confirmed an overall Limit of Detection (LoD) of 500 HIV RNA copies/mL for genomic Fragments 1, 2, 4 and 5 and 25,000 copies/mL for Fragment 3. The assay demonstrated excellent analytical performance at even lower viral loads of 250 copies/mL, achieving successful detection of 95% for Fragment 1 and 100% for Fragments 4 and 5, further highlighting the robustness of the assay beyond its CE-IVD evaluated performance.

Unlike conventional HIV genotyping assays that interrogate only selected viral genes, DeepChek® Whole Genome HIV-1 Genotyping sequences virtually the complete HIV-1 genome, including the 5' and 3' Long Terminal Repeats (LTR), gag, pol (protease, reverse transcriptase and integrase), vif, vpr, tat, rev, vpu, env (gp120 and gp41) and nef.

This comprehensive genomic coverage enables simultaneous characterization of resistance-associated mutations across all major antiretroviral drug classes, including:
- Capsid inhibitors (including Lenacapavir)
- Nucleoside Reverse Transcriptase Inhibitors (NRTIs)
- Non-Nucleoside Reverse Transcriptase Inhibitors (NNRTIs)
- Protease Inhibitors (PIs)
- Integrase Strand Transfer Inhibitors (INSTIs)
- Fusion inhibitors
- Post-attachment inhibitors

The whole genome approach also provides laboratories with a future-proof solution capable of supporting both current and emerging HIV therapies. As innovative treatments such as Lenacapavir, the first approved capsid inhibitor, and future long-acting antiretroviral agents continue to reshape HIV management, comprehensive whole genome sequencing allows laboratories to identify both established and newly emerging resistance mechanisms without requiring redesign of the assay.

To the best of ABL Diagnostics' knowledge, DeepChek® Whole Genome HIV-1 Genotyping is currently the only commercially available CE-IVD Whole Genome HIV drug resistance assay, providing clinical laboratories with a unique regulatory-compliant solution for comprehensive HIV genomic characterization.

DeepChek® Whole Genome HIV-1 Genotyping is compatible with the major Next-Generation Sequencing (NGS) platforms routinely used by clinical laboratories, including Illumina® (MiSeq™ i100, MiSeq™, iSeq™100, MiniSeq™, NextSeq™ and others), MGI Tech (E25, G99, G400 and others), Ion Torrent™ (S5™, PGM™), Oxford Nanopore Technologies (MinION™, GridION™ and others), Element Biosciences (AVITI™), PacBio® and Salus™ sequencing platforms.

The assay has also been verified using the majority of manual and automated nucleic acid extraction workflows routinely implemented in molecular laboratories, facilitating seamless integration into existing laboratory infrastructures while minimizing workflow changes.

DeepChek® Whole Genome HIV-1 Genotyping seamlessly integrates with ABL Diagnostics' CE-IVD bioinformatics solutions, including DeepChek® HIV and MicrobioChek HIV, available either through local installation or via a secure HDS-certified cloud infrastructure. Combined with OpenChek laboratory automation and ABL Diagnostics' rapid NGS library preparation portfolio—including an ultra-fast library preparation workflow completed in approximately two hours—the solution provides laboratories with a complete end-to-end workflow designed to reduce hands-on time, improve standardization and accelerate turnaround time. Laboratories can further optimize sequencing efficiency by multiplexing HIV samples together with other DeepChek® infectious disease assays within the same sequencing run, maximizing instrument utilization while reducing cost per sample.
In addition to the CE-IVD version intended for routine clinical diagnostics, DeepChek® Whole

Genome HIV-1 Genotyping is also available in a Research Use Only (RUO) version, supporting academic research, pharmaceutical development, clinical studies and HIV surveillance programs worldwide.

"DeepChek® Whole Genome HIV-1 Genotyping v1.2 perfectly illustrates our commitment to continuously improving analytical performance while preserving the validated workflows already implemented by our customers," said Dr. Sofiane Mohamed, Head of Research & Development at ABL Diagnostics. "By significantly enhancing sensitivity while maintaining our proven whole genome design, we provide laboratories with a future-ready solution capable of supporting today's therapeutic strategies as well as tomorrow's innovations in HIV treatment. We believe whole genome sequencing represents the future of HIV drug resistance testing, enabling laboratories to rapidly adapt to new therapeutic classes without changing their molecular workflow."

HIV remains one of the world's most significant infectious diseases, with nearly 40 million people currently living with HIV and approximately 1.3 million new infections each year. As antiretroviral therapy becomes increasingly personalized and treatment options continue to expand, genotypic resistance testing has become an essential component of precision HIV care. International treatment guidelines recommend resistance testing in multiple clinical settings, while the emergence of novel therapeutic classes—including long-acting injectable therapies and capsid inhibitors—is driving demand for more comprehensive genomic characterization than conventional targeted assays can provide.

By combining whole genome amplification, broad workflow compatibility, integrated CE-IVD bioinformatics, laboratory automation and rapid library preparation technologies within a single ecosystem, ABL Diagnostics is uniquely positioned to support this evolution and strengthen its leadership in next-generation infectious disease diagnostics.

This new CE-IVD registration further expands ABL Diagnostics' regulated portfolio of molecular diagnostic solutions and reinforces the Company's strategy of delivering fully integrated workflows spanning sample preparation, molecular testing, sequencing, bioinformatics and laboratory automation for infectious diseases.

Regulatory Statement:
DeepChek® Whole Genome HIV-1 Genotyping v1.2 is CE-IVD marked and intended for professional use by qualified laboratory personnel in accordance with the Instructions for Use. Product availability may vary according to local regulatory requirements. The Research Use Only (RUO) version is intended solely for research purposes and is not intended for use in diagnostic procedures.

Dr Sayada
ABL Diagnostics SA
+33 7 83 64 68 50

email us here