

ABL Diagnostics announces the release of its DeepChek®-HPV Assay, to be used for Human Papillomavirus screening, genotyping, and discrimination through sequencing.

Thursday 18 January, 2024

- Next Generation Sequencing (NGS) assay and software to screen, to genotype and to discriminate the Human Papillomavirus.
- ABL Diagnostics strives to offer innovative solutions providing to healthcare personnel relevant information about high-risk HPV types which are known to cause genital warts or cancer.

Woippy (France) – ABL Diagnostics (FR001400AHX6 – ABLD, the “Company”), a Euronext-listed company that develops molecular biology assays and software for microbiology laboratories is pleased to announce today the release of its DeepChek®-HPV Assay for the screening, the genotyping, and the discrimination of the Human Papillomavirus (“HPV”). The assay uses an innovative design which allows laboratories to perform a reflex genotyping (Research Use Only) through Next Generation Sequencing (“NGS”) on positive samples, for further genetic evolution analysis, prevention and control, therapeutic regimen development, and other product development. It uses as an input the amplicons of a CE-IVD qPCR assay intended for HPV detection, distributed by ABL Diagnostics.

Validated on several NGS platforms, the solution integrates a CE IVD marked downstream analysis software accessible through secured Cloud or local installations, allowing a precise genotyping of the viruses and able to discriminate oncogenic versus non-oncogenic strains.

Through the DeepChek® technology, HPV processed samples can be pooled with other types of samples (like HIV, viral hepatitis...); this creates efficiency, reduces turnaround time and sequencing costs, and allows laboratories with high throughput to smoothly move to NGS technology.

The overall HPV testing market worldwide is estimated to US\$2.2 Billion in 2021 with a forecasted market value of US\$15 Billion in 2032.

“Implications related to the HPV infection are clear as it impacts any population on a worldwide basis. Proposing to our customers and partners a robust solution to screen, to discriminate and to genotype this virus is an important step for ABL Diagnostics. It is completing our portfolio of microbiology applications and has the potential to become a flagship product together with the GenomeMe technology.” said **Dimitri Gonzalez, Head of Diagnostics**.

Sofiane Mohamed, Head of Research and Development added that “being able to quickly screen HPV infection and to genotype and to discriminate oncogenic versus non-oncogenic strains is critical. Our team used the cumulated experience in viral genomics gained over the years, and the collaboration with GenomeMe to provide a high-quality, efficient, and cost-effective services for HPV genetic evolution analysis, infectious disease prevention and control, therapeutic regimen development, and product development to limit as much as possible clinical complications in the general population”.

ABOUT ABL DIAGNOSTICS

ABL DIAGNOSTICS S.A. (ABLD) is a worldwide leading international company offering innovative and proprietary molecular biology assays and end-to-end solutions intended to be used for molecular detection by Polymerase Chain Reaction (PCR) – UltraGene® and for genotyping through DNA sequencing – DeepChek® (a very sensitive, robust and sustainable technology allowing precise identification of relevant genomic variations like single nucleotide polymorphisms (SNP), amino-acid mutations, quasispecies like variants of concern, already published or which will be discovered in the future, with known impact on disease prognosis, drug efficacy, pathogen activity...).

These molecular biology products are generating recurring revenues and cover one of the largest portfolio of microbiology applications, growing fast year after year to stick to the market needs, with a primary focus on HIV (with CE-IVD marked target-specific assays covering all relevant genes used for drug resistance assessment like reverse transcriptase, protease, integrase and with the disruptive Whole

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Genome Kit), on SARS-CoV-2, on Tuberculosis (with a CE-IVD marked multiplex assay targeting genes relevant for first line, second line and new-drugs resistance determination), on viral hepatitis B and C, 16s/18s RNA for taxonomy and microbiome analyses and other viral and bacterial targets. Please consult ABL Diagnostics team for further information about registration status of the ABL Diagnostics' products in your territory.

ABL Diagnostics commercializes its entire line of products on a worldwide basis through its own sales team and through a network of exclusive distributors active on all continents. ABL Diagnostics clients are academic clinical pathology labs, private reference labs and researchers willing to implement an innovative and robust microbiology content in constant expansion.

ABL Diagnostics also develops, manufactures, and markets kits for clinical specimen collection – MediaChek® and digital solutions like Nadis®, an CE-marked Electronic Medical Record (EMR) system used in France in more than 200 hospitals managing patients infected by HIV or Viral Hepatitis.

ABL Diagnostics, based in Woippy, is a public company listed in compartment B of Euronext's regulated market in Paris (Euronext: ABLD – ISIN: FR001400AHX6).

For further information, please visit www.abldiagnostics.com

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