

ABL DIAGNOSTICS EXPANDS ITS HIV GENOTYPING ASSAYS OFFERING

Thursday 30 November, 2023

- ABL Diagnostics keeps investing to strengthen its expertise and leadership in HIV drug resistance testing by genotyping through the release of a new revolutionary kit, **DeepChek® Assay HIV-1 Full PR/RT/INT Drug Resistance**.
- ABL Diagnostics provides a comprehensive portfolio of applications for HIV Genotyping by sequencing including assays & software targeting all relevant genes and even Whole Genome designs.
- ABL Diagnostics consolidates its worldwide leading position on genotyping-through-sequencing for microbiology.

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 the expansion of its HIV genotyping menu of applications with the release of a new revolutionary assay, DeepChek® Assay HIV-1 Full PR/RT/INT Drug Resistance. The company keeps innovating and devoting maximal focus and investment in the field of HIV drug resistance testing with this new assay which targets, in a single PCR reaction, the *protease*, the *reverse transcriptase* and the *integrase*

genes which are the key targets for assessing the level of resistance of the drugs currently prescribed for treating patients infected by the HIV-1 virus.

Analytical outcomes performed using both RNA and proviral DNA samples achieve excellent outcomes in terms of specificity and sensitivity (with a Limit of Detection (LOD) below 1000 copies/mL). This assay, currently available for Research Use Only (RUO), is a good candidate to go for IVDR marking. It would confer to virologists an efficient way to perform genotyping tests for naïve and treatment-experienced patients, for which targeting DNA becomes more and more critical.

The design of the assay, with one single PCR for covering the entire length of all genes, provides to laboratory great efficiency in terms of turnaround time and hands-on time. Tested with different combinations of next generation sequencing (NGS) systems and the DeepChek®-HIV Software, ABL Diagnostics can provide an end-to-end solution to a large variety of microbiology labs involved or willing to implement genotyping through sequencing for HIV-1 drug resistance testing but also for other applications using the portfolio of assays developed by ABL Diagnostics for many years.

With the release of the DeepChek® Assay HIV-1 Full PR/RT/INT Drug Resistance, ABL Diagnostics reinforces its leadership and worldwide position in HIV genotyping, gained with the CE IVD marked [assays](#) and downstream analysis [software](#) suited to SANGER and NGS settings. It completes as well the unique and largest portfolio of genotyping by sequencing microbiology applications in the world.

Dr. Sofiane Mohamed, Head of Research and Development, explained that “with the development of this new assay in our laboratory in Woippy, we had to face substantial technical challenges that we were able to overcome with the entire team’s focus and dedication, and the support from the French State and “Region Grand Est” through the R&D Grant PIA4 (« France 2030 régionalisé – projet d’innovation »).” “We keep innovating by constantly adapting our strategy to fulfil the natural evolutions of the virus, to overcome the related scientific challenges, and to meet regulatory requirements.”, added Dr Mohamed.

Dimitri Gonzalez, Head of Diagnostics, expressed his satisfaction, saying, “the release of this disruptive assay strengthens the leading position of the company in the field of Microbiology genotyping through sequencing. Our DeepChek® technology is an open system allowing to pool different microbiology applications in the same sequencing run”. He outlined that “the technology confers to any laboratory an efficient way to add samples to HIV from other ABL tests (e.g., HCV genotyping and drug resistance, HBV, Hepatitis Delta, CMV, HSV, Influenza A, Influenza B, RSV, SARS-CoV-2, Tuberculosis, 16s RNA and 18s RNA)..”

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

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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 disruptive Whole Genome Kits), on SARS-CoV-2 (with a CE-IVD marked Whole Genome assay), 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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