

# ALCEDIAG

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## **ALCEDIAG receives BPI France grant for EDIT-B® blood test clinical utility study –**

### **An aid for differential diagnosis of depression and bipolar disorder based on RNA Editing biomarkers**

**[Paris & Montpellier, Dec. 7<sup>th</sup>, 2023]** – ALCEDIAG is proud to announce the initiation of a pioneering clinical utility study aimed at determining and validating the positive impact the EDIT-B® test will have on depressed and bipolar patients' outcomes and on reducing the social and economic burden caused by delayed or inaccurate diagnosis of bipolar disorder. This study represents an additional significant step forward in our commitment to advancing patient care and improving mental healthcare outcomes by working towards a reimbursement of our test in France and then in Europe.

EDIT-B® is a Precision Psychiatry blood test designed to serve as a decision-support tool for mental healthcare professionals, enabling them to expedite the differentiation of patients suffering from depression into two distinct categories: Unipolar depression or Bipolar depression known as bipolar disorder. This innovative test leverages RNA editing modifications of specific targets measured in blood and artificial intelligence (AI). The test surpasses 80% sensitivity and specificity.

Following regulatory approvals, the clinical utility study is planned to be initiated in the first quarter of 2024, in France, and enroll 450 patients. The study will be led by Prof. Chantal Henry, a renowned expert in neuropsychiatry. The research team is dedicated to rigorously evaluating the clinical utility of EDIT-B® in real-world thus advancing the inclusion of the test in healthcare reimbursement plans.

"In France alone, it is estimated that up to 2.5% of the population is affected by bipolar disorder, i.e., up to 1,700,000 people, with even higher global figures. The EDIT-B® test is an aid for clinicians in their diagnostic toolbox, which accelerates the path to diagnosis of bipolar disorder and personalizing treatment". Prof. Chantal Henry, psychiatrist and principal study investigator at GHU Paris Psychiatrie & Neurosciences, emphasized the need to enhance patient care through personalized diagnosis utilizing biomarkers.

The study has been awarded 1.4 million Euro in funding from the French government as part of the France 2030 Program administrated by the French Bank of public investments (BPI). This financing has been obtained following a rigorous selection process conducted by BPI since last January.



This project was financed by the French Government within the framework of France 2030  
Funded by the European Union - Next Generation EU as part of the France Relance plan

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“We are delighted and deeply appreciative of the funding received from both the French Government and the European Union. This not only reflects the growing awareness of mental health issues in Europe but also paves the way for our upcoming clinical utility study for EDIT-B®”, Says Alexandra Prioux, CEO of ALCEDIAG. “By combining these elements, we are poised to significantly expand access to the test for a broader spectrum of patients through healthcare reimbursement plans in France and then other European countries”.

The launch of this clinical utility study underscores ALCEDIAG's dedication to pioneering research and its unwavering commitment to delivering high-quality diagnostics, leading to superior patient-centered care. We look forward to sharing the insights gained from this study and the positive impact it will have on mental healthcare clinical routine.

## About EDIT-B blood test:

EDIT-B is a qualitative in vitro diagnostic (IVD) test able to differentiate between bipolar disorder and unipolar depression (major depressive disorder / MDD). The test measures the RNA editing of specific markers in the blood of patients using NGS technology coupled with artificial intelligence. The quick result, in conjunction with the standard diagnostic methods and clinical practice guidelines, supports the physician diagnosis. The EDIT-B blood test is based on ALCEDIAG's proprietary and patented biomarkers and algorithms.

## About ALCEDIAG:

ALCEDIAG is an innovative diagnostics company focusing on mental health, developing and commercializing innovative in-vitro-diagnostics tests thanks to its platform harnessing cutting-edge molecular biology and Artificial Intelligence to discover and utilize new proprietary RNA editing based biomarkers in clinical routine. ALCEDIAG is a subsidiary of ALCEN, an industrial diversified French group with a strong focus on innovation advancing societal challenges. For more information visit: [www.alcediag-alcen.com](http://www.alcediag-alcen.com)

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