ALCEDIAG

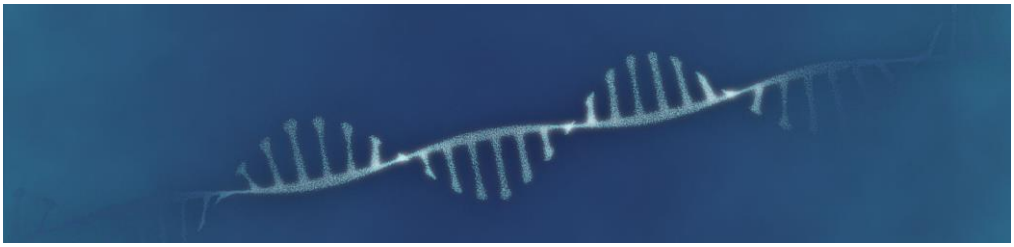
FOR HEALTH

Frequently Asked Questions

for Healthcare Professionals

EDIT-B Test

April 2025



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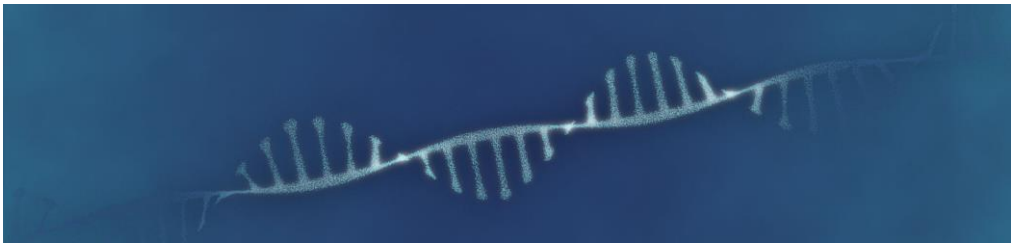
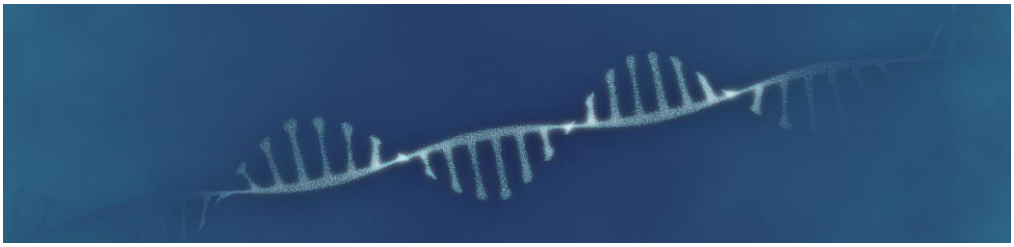




ALCEDIAG FOR HEALTH

Introduction

The EDIT-B test, developed by ALCEDIAG, is the first clinically validated blood test with a sensitivity and specificity greater than 80% for the differential diagnosis of Bipolar Disorder (BD) and Major Depressive Disorder (MDD) in adults (18+) treated for moderate to severe depressive symptoms. It is a decision-support tool for general practitioners and psychiatrists. The goal of EDIT-B is to support, facilitate, and accelerate the diagnostic process as carried out by the physician, in addition to existing clinical scales and tools.

This FAQ is designed to answer any questions you may have about the EDIT-B test.

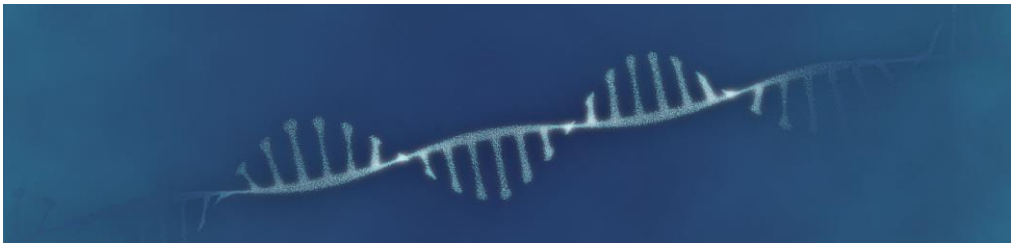
Bipolar Disorders and Depression

What are bipolar disorders and what are their symptoms?

According to the American Psychiatric Association, bipolar disorders are “mental health conditions characterized by periodic, intense emotional states affecting a person's mood, energy, and ability to function. These periods, lasting from days to weeks, are called mood episodes. Mood episodes are categorized as manic/hypomanic episodes when the predominant mood is intensely happy or irritable, or depressive episodes when there is an intensely sad mood or the ability to experience joy or pleasure disappears. People with bipolar disorder generally have periods of neutral mood as well. When treated, people with bipolar disorder can lead full and productive lives.”
There are three types of bipolar disorders:

- **Bipolar I Disorder**: characterized by manic episodes lasting at least 7 days or severe enough to require hospitalization, and usually depressive episodes as well.
- **Bipolar II Disorder**: defined by a pattern of depressive and hypomanic episodes, without full manic episodes.
- **Cyclothymic Disorder (Cyclothymia)**: defined by periods of hypomanic and mild depressive symptoms lasting at least 2 years.
- **Other Specified and Unspecified Bipolar and Related Disorders**: a category for cases that do not fit the above types but still involve episodes of elevated mood.

Additionally, it is important to note that many difficult-to-treat or treatment-resistant depressive disorders, as well as certain personality disorders, hyperthymic temperament, high intellectual potential functioning, addictive behaviors, simple or complex psychological trauma, or social vulnerability, may fall within the bipolar spectrum. Bipolar disorder may even manifest without



any manic or hypomanic episodes, appearing only through depressive symptoms or even misleading delusional states.

Symptoms in patients with bipolar disorder can vary greatly from person to person. The first signs of bipolar disorder typically emerge in late adolescence or early adulthood, but they can appear at any age, even in the absence of clinical history (first depressive episode, family history, postpartum depression, etc.).

For more information, visit: NIMH » Bipolar Disorder (nih.gov).

What is unipolar depression?

Unipolar depression is another name for Major Depressive Disorder. Both terms may be used interchangeably in this document.

How can one differentiate between depressive symptoms, Unipolar Depression, and Major Depressive Disorder?

"Depressive symptoms" refer solely to the symptoms themselves, whereas Unipolar Depression or Major Depressive Disorder refer to the actual medical condition. Depressive symptoms can be present in conditions other than Unipolar Depression / Major Depressive Disorder, such as Bipolar Disorder.

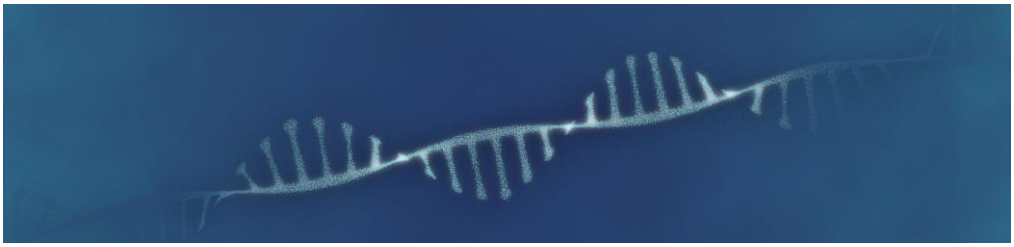
What is the average time to diagnose Bipolar Disorder?

The average diagnostic delay is currently 8 years before a diagnosis of bipolar disorder is made (McIntyre et al., 2020).

How do scientific publications and experts explain the diagnostic delay and the challenges associated with diagnosing Bipolar Disorder?

Bipolar disorder is one of the most complex psychiatric conditions to diagnose today, even though it is among the most disabling mental health disorders (ranked 5th among the most disabling mental illnesses according to the IHME).

As mentioned in the *Lancet* publication by Prof. Phillips and Prof. Kupfer (Lancet. 2013 May 11; 381(9878): 1663–1671) *Bipolar disorder diagnosis: challenges and future directions* – PMC (nih.gov)), one of the main reasons is the difficulty of distinguishing the depressive phase of bipolar disorder from unipolar depression. The publication highlights several key points:



- A much higher prevalence of depressive symptoms compared to manic/hypomanic symptoms
- A large number of patients without clear histories of mania/hypomania
- A lack of recognition of manic/hypomanic symptoms by patients, and under-detection by physicians and families
- Difficulty in identifying mania/hypomania in mixed episodes
- Etc.

For instance, 69% of people with bipolar disorder were initially misdiagnosed (Singh et al., 2006), and up to 40% of patients diagnosed with depression may actually be bipolar (Angst et al., 2011).

Why is an accurate, reliable, and timely diagnosis of Bipolar Disorder essential?

Unipolar and bipolar depression present similar clinical symptoms, but their treatments (pharmacological and otherwise) are different.
As stated in many studies (including McIntyre et al., 2022), delays in diagnosing bipolar disorder negatively impact patients' lives, increase comorbidities (addictions, somatic comorbidities such as cardiovascular disease, etc.), and raise the risk of early mortality (higher rates of suicide attempts and completed suicides) (McIntyre et al., 2022).

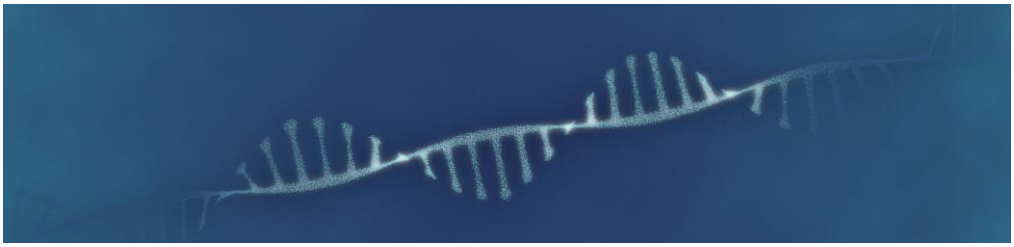
Therefore, Professor McIntyre emphasizes that early and accurate diagnosis is a critical need for patients (*McIntyre et al.*, *The Lancet*, 2020). Moreover, as indicated in the *Vidal*, with an appropriate treatment following a correct diagnosis, a bipolar patient can return to a normal life. It is even stated that after several months of treatment, "manic-depressive cycles (the former term for bipolar disorder) may become less frequent or even disappear completely."

What is the prevalence of bipolar disorder and unipolar depression?

According to the World Health Organization, in 2019, 280 million people were living with depression and 40 million with bipolar disorder. Bipolar disorder may be significantly underdiagnosed due to the difficulties in identifying the condition.

Is bipolar disorder frequently misdiagnosed as unipolar depression?

As noted in the scientific publication: *Bipolar disorder diagnosis: challenges and future directions* (Lancet. 2013 May 11; 381(9878): 1663–1671), “Bipolar disorder is an especially good example of a group of psychiatric illnesses that are difficult to diagnose accurately. For example, although this disorder, along with other psychiatric illnesses, is one of the ten most debilitating of all non-



communicable diseases, misdiagnosis of the illness as recurrent unipolar depression occurs in 60% of patients seeking treatment for depression."

Scientific Background

What is epigenetics?

Epigenetics is defined as the study of mechanisms that can modify gene activity and expression without altering the DNA sequence itself. These modifications influence gene expression through various means and involve a wide range of environmental factors such as nutrition, physical activity, stress, medications, and exposure to pathogens. Unlike genetic changes, epigenetic modifications are reversible. There are several types, including DNA methylation, histone modification, RNA editing, and more.

What is RNA editing?

A-to-I RNA editing is an epigenetic mechanism involving the deamination-based substitution of an adenosine (A) nucleotide with an inosine (I) nucleotide within RNA sequences. Inosine is then interpreted as guanosine (G) by the translation machinery. This process is carried out by a family of enzymes known as Adenosine Deaminases Acting on RNA (ADARs).

Growing evidence supports the crucial role of RNA editing in various aspects of RNA metabolism, including mRNA stability, nuclear export, localization, and protein recoding. RNA editing acts as an early regulatory system of gene expression and contributes to the diversification of the overall protein repertoire.

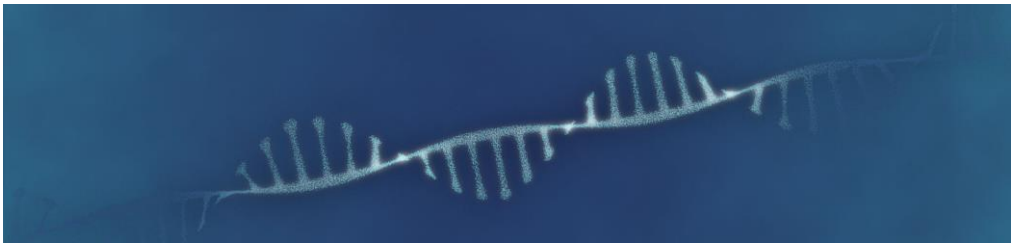
Alterations in RNA editing have been associated with various diseases, including neurological disorders of the central nervous system, cancers, and autoimmune diseases. For example, RNA editing is known to modify neurotransmitter receptors and synapse-related factors, highlighting its central role in neurobiology and the modulation of neurotransmission.

What is a biomarker?

Biomarkers are measurable parameters such as genetic characteristics, proteins, metabolites, and digital biomarkers. They are used to characterize physiological or pathological states, monitor disease progression, or assess responses to treatments.

What is next-generation sequencing, and why is this technique specifically used?

Next-generation sequencing (NGS), also known as high-throughput sequencing, is an advanced



technology that allows for the rapid and parallel sequencing of millions to billions of DNA or RNA strands. Unlike traditional sequencing methods, NGS enables the massive parallel processing of multiple sequences, greatly increasing the speed and efficiency of DNA or RNA analysis. This technology has revolutionized genomics, transcriptomics, and various areas of biological research, enabling whole genome decoding and providing detailed insights into genetic variations, gene expression, and more.

For EDIT-B, next-generation sequencing (NGS) offers a unique opportunity to explore RNA editing events across various regions of the RNA simultaneously.

EDIT-B Test Technology

How was the EDIT-B test developed? What are the biomarkers of the EDIT-B test?

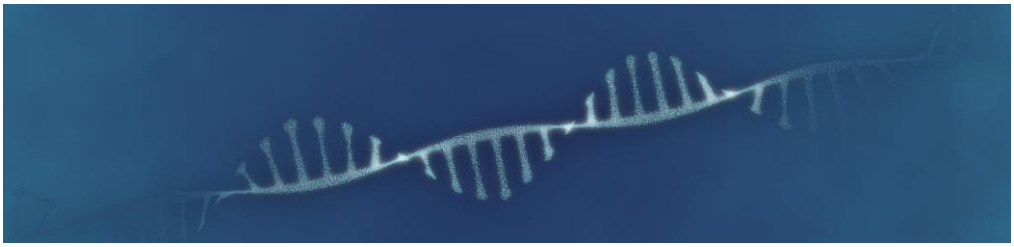
The EDIT-B test is the result of more than a decade of research in the fields of epigenetics (specifically RNA editing), artificial intelligence, and neuroscience.

The biomarkers of EDIT-B test target specific RNA sequences extracted from patient blood samples, which exhibit significant differences between individuals with bipolar disorder and those with depression. Specifically, the analysis of these mRNA sequences focuses on distinct nucleotide changes known as A-to-I RNA editing events, an epitranscriptomic modification caused by enzymes called ADARs. This epigenetic mechanism involves the deamination-based substitution of adenosine (A) with inosine (I) within RNA sequences.

The selection of the specific sequences included in the EDIT-B test is based on studies (notably a clinical study with the Montpellier University Hospital cohort) demonstrating their relevance to the central nervous system, mood disorders, and inflammatory mechanisms. This selection process combines RNA editome analysis, biological network analysis related to these conditions, and the establishment of rigorous analytical and technical criteria (Salvetat et al., 2022; Hayashi et al., 2023).

The work conducted by Alcediag on RNA editing as a means of distinguishing bipolar disorder from unipolar depression has been carried out over more than 8 years and includes two clinical trials. The results from both cohorts are consistent, with test performance exceeding 80% (Salvetat et al., 2024).

- **Study 1**: A monocentric clinical study conducted at Montpellier University Hospital including controls (healthy, non-depressed individuals), unipolar depressed patients,



and bipolar depressed patients. Final results include 245 depressive patients. Recruitment ended in 2018.

- **Study 2**: A multicentric clinical study conducted with the psychiatric clinic network "Les Toises." Recruitment ended in late 2022. An interim data analysis was performed on 94 patients, with a final total of 143 patients included according to eligibility criteria.

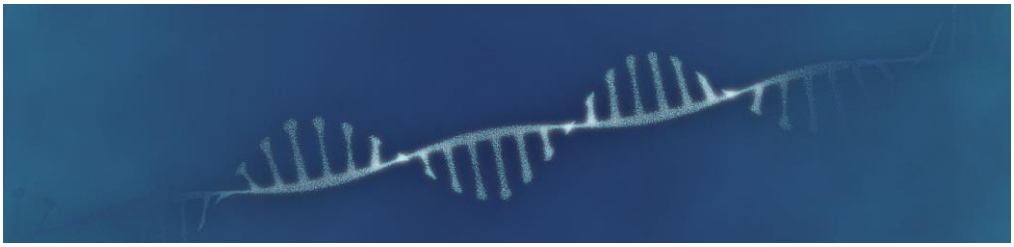
The biomarkers of EDIT-B test are part of the input data for EDIT-B algorithm, to which complementary clinical data (age, sex, addictions, treatments) are added. EDIT-B algorithm was developed using Machine Learning, specifically the Extra Trees Random Forest technique, and has been validated on over 350 patient data entries.

The RNA editing analysis protocol has been optimized from both biological and bioinformatics standpoints. Analytical validation studies of the biomarkers have been conducted, covering detectability, repeatability (consistent results for a patient with the same algorithm), reproducibility (consistent results for different patients using the same algorithm), specificity (including cross-contamination), and more. These studies are essential for obtaining CE marking, as well as for establishing the compliance with the Swiss In Vitro Diagnostic Medical Devices Ordinance (IvDO) which is required to bring a diagnostic test to market in Europe and Switzerland.

What are the different technical steps involved in performing EDIT-B test?

The first phase of analysis for EDIT-B test takes place in a medical biology laboratory and involves a patient blood sample. Initially, RNA is extracted and purified from the blood sample. Then, specific RNA sequences, namely the biomarkers of EDIT-B test (see previous question for more details) are amplified and sequenced using Next Generation Sequencing (NGS) technology (see the "Scientific Background" section for more information on NGS).
The next step takes place on a bioinformatics platform developed by ALCEDIAG, which quantifies RNA editing. Its goal is to interpret the RNA editing events of the EDIT-B biomarkers. Following this, ALCEDIAG uses a proprietary algorithm that takes as input both the biomarker data and clinical patient data (age, sex, addiction, treatment). This model interprets the combination and relationships of these inputs to generate decision values that determine whether a sample corresponds to a bipolar or unipolar profile.

The algorithm was built using artificial intelligence, meaning that it has previously been trained on a robust, reproducible, repeatable, and efficient mathematical model using information from RNA editing targets and clinical data.



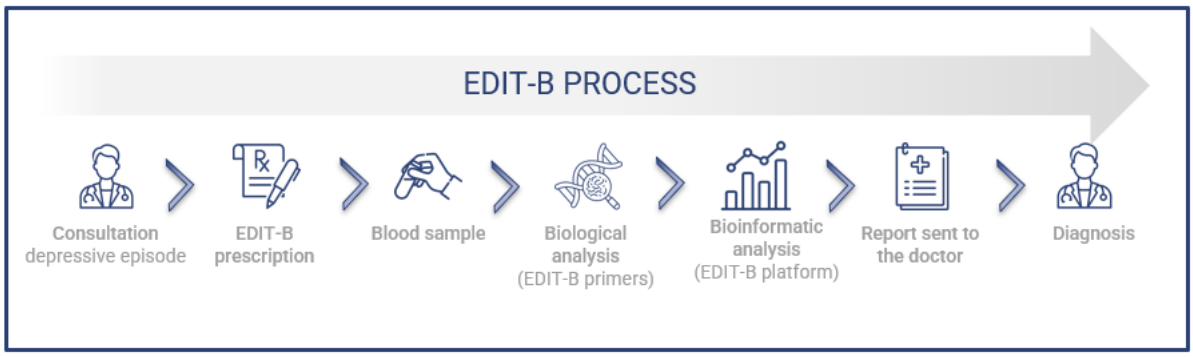
Why did you decide to work on RNA editing as a diagnostic tool for bipolar disorder and depression?

RNA editing is an important mechanism for diagnostics, particularly for diagnosing complex disorders such as depression and bipolar disorder, due to its upstream role in biological cascades. Notably, RNA editing-based biomarkers offer flexibility, they dynamically evolve with patient conditions and are easily accessible via a blood sample. Moreover, RNA editing acts as a dynamic regulator of key molecules controlling neuronal function, including proteins involved in neurotransmission (e.g., HTR2c, GRIA, GRIK, GABA).
Several publications, including those from different groups and ALCEDIAG (Berg 2008, Chimienti 2019, Weissmann 2016), highlight changes in RNA editing in the brains of depressed patients. Similar alterations have been observed in inflammatory diseases like systemic lupus erythematosus, where 50% of patients exhibit depressive symptoms.

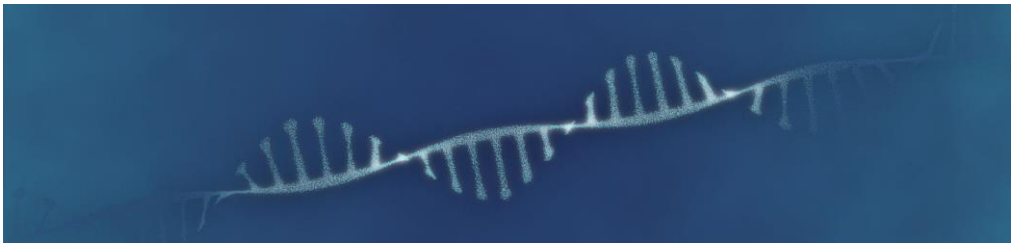
The ALCEDIAG team demonstrated that RNA editing of a target such as PDE8A is altered in both the brain and blood of patients with depression (Salvetat 2019, 2021), as well as in individuals with inflammatory diseases (such as HCV) associated with depression. Recently, ALCEDIAG identified and validated 8 new RNA editing targets for diagnosing depressed patients (Salvetat 2024).

Could you provide a concise overview of the key steps in performing the EDIT-B test?

The test result is obtained following a blood draw from the patient. RNA is extracted, and specific targets are amplified and sequenced using Next Generation Sequencing. A specialized algorithm is then applied to the sequencing data, yielding either a “bipolar profile” or a “unipolar profile” result.



Step 1: Clinicians prescribe EDIT-B test, and the blood sample is collected in accordance with local regulations, for example at a Blood Collection Point affiliated with one of the medical biology laboratories distributing the test.



Steps 2 & 3: Medical laboratories carry out the biological part of the test, including sequencing of specific RNA sequences, by following EDIT-B protocol.
Step 4: The sequenced data is securely uploaded to EDIT-B website, a secure digital platform.
Step 5: ALCEDIAG sends the EDIT-B report back to the medical laboratory.
Step 6: The medical laboratory forwards the EDIT-B report to the prescribing physician.

Are your biomarkers a direct signature of the pathology?

Yes, the test was developed over several years and has undergone many stages to ensure that the biomarkers directly reflect the pathology. For example, the R&D team analyzed blood samples from depressive patients (both unipolar and bipolar) and non-depressed individuals to identify the genes involved in each pathology. In addition, they studied neuronal networks associated with the depressive phases of bipolar disorder and those related to immune diseases.

Is it possible to identify other medical conditions using this test?

This test cannot detect other medical conditions. The EDIT-B bioinformatics pipeline is specifically focused on identifying RNA editing modifications (for example, the system does not screen for SNPs related to other pathologies) and interprets these findings exclusively to classify patients as bipolar or unipolar, without considering other conditions or diseases.

What genetic data about the patient can ALCEDIAG obtain from this blood sample analysis?

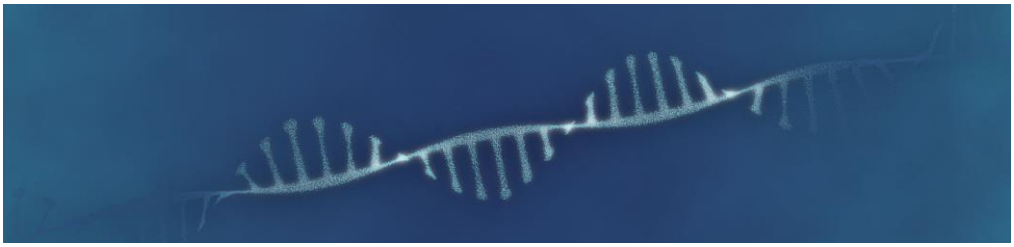
No genetic data is collected through EDIT-B. The EDIT-B test is based on pre-mRNA, and the analysis focuses exclusively on A-to-I RNA editing. All other data is filtered out by the biological and bioinformatics protocols.

Are there any potential risks associated with taking this test?

The only potential risk associated with the test is the blood draw procedure, which is comparable to standard blood collection methods used today.

Can the EDIT-B test be used to monitor a patient's response to treatment?

EDIT-B is intended to differentiate bipolar disorder from major depressive disorder in the adult population, specifically for patients experiencing depressive symptoms and being treated for those symptoms. It is not indicated for other purposes.



Can the EDIT-B test assess the severity of a patient's disorder (depression or bipolarity)?

The EDIT-B test does not assess the severity of the depression or bipolar disorder the patient is currently experiencing. The test provides a result indicating whether the patient's profile corresponds to a bipolar or unipolar condition.

EDIT-B in clinical routine

What is the intended use of the EDIT-B test?

EDIT-B is an in vitro diagnostic blood test designed to differentiate bipolar disorder from major depressive disorder in the adult population, as a diagnostic aid. EDIT-B is indicated for patients over 18 years old who are experiencing moderate to severe depressive symptoms and are being treated for these symptoms.

What does "diagnostic aid" mean in the context of EDIT-B?

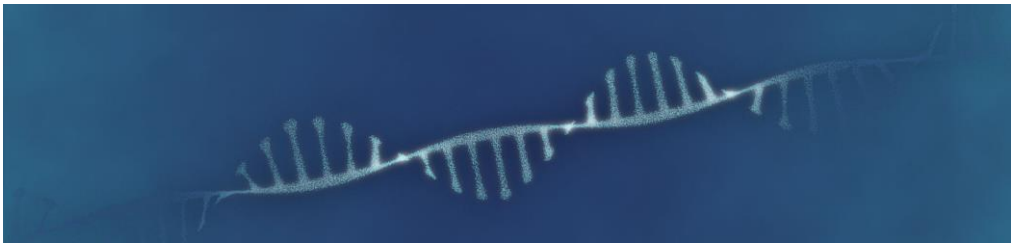
EDIT-B is a diagnostic aid, meaning that it provides information to support the clinician in making a diagnosis. EDIT-B is designed to provide additional insights to the physician and to complement commonly used diagnostic tools such as ICD-11 criteria, the patient's medical history, and clinical rating scales (e.g., MADRS, HDRS, and BDI). The diagnosis must always be made by the physician themself, using all available data and information (EDIT-B and others).

How will this test benefit physicians and patients?

The primary goal of EDIT-B is to support the physician’s diagnostic process, thereby saving valuable time that can be devoted to identifying the most appropriate treatments and improving the care of the patients concerned.

EDIT-B is carefully designed to fit seamlessly into current medical practice. Medical consultations remain unchanged, with the only addition being a prescription for an EDIT-B test. The medical laboratory will send the test result to the prescribing physician. EDIT-B adds a new dimension to existing clinical resources by providing easily interpretable, biologically based, and scientifically validated data. It serves as a complement to clinical interviews, assessment scales, and patient medical histories. The aim of this additional dataset is twofold:

- To increase the level of evidence and confidence, thereby simplifying the initial diagnostic process;
- To inform treatment decisions resulting from the diagnosis.



It can be especially useful in specific and complex cases such as treatment resistance, relapse, or when the patient's medical history is lacking. Additionally, this data can be used, if deemed appropriate, to help patients accept their diagnosis.

Ultimately, the desired outcome is to achieve effective patient management, including medication, psychotherapy, and more, efficiently and quickly.

What clinical evidence is included in the CE regulatory dossier of the EDIT-B test?

EDIT-B is the result of more than a decade of research in the fields of epigenetics (specifically RNA editing) and neuroscience, as detailed in the technology section of this document. Following this initial research phase, two clinical studies were conducted to validate the performance of the EDIT-B test and obtain CE marking. In addition, other studies are ongoing or in preparation to enrich our clinical data set, meet further regulatory requirements, collect real-world data to support utility, and obtain reimbursement. To date, ALCEDIAG has included more than 800 patients in its clinical development.

The first study conducted by ALCEDIAG was carried out in collaboration with the Department of Psychiatry at Montpellier University Hospital in France, as a monocentric trial including 255 patients. The second study (replication study) was conducted in collaboration with Les Toises psychiatric clinics in Switzerland, as a multicentric trial, entirely independent from the first clinical trial.

The research protocols of both studies were approved by the French local ethics committee (CPP Sud-Méditerranée IV in Montpellier, CPP no. A01978-41) and the Ethics Committee of the Canton of Vaud (CER-VD), with written informed consent obtained from all subjects.

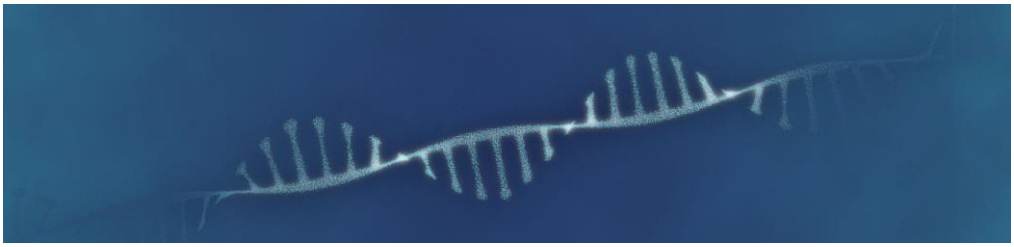
The training and testing of the algorithm were performed on the Montpellier cohort, and external validation was conducted on the independent Swiss cohort. Based on these successful initial trials, EDIT-B is currently CE-marked under Directive 98/79/EC for in vitro diagnostic medical devices and compliant with the Swiss In Vitro Diagnostic Medical Devices Ordinance (IvDO).

Regulatory post-market studies have also been completed or are underway. For more information, see the Clinical Validation page of the website: EDIT-B® - Validation clinique | ALCEDIAG

Clinical Performance

The clinical performance results of the EDIT-B® test from an independent multicentric study are presented in the table below.

Sample type: Whole blood collected in PAXgene® Blood RNA tubes.



Clinical Performances	Results*
Total population size Including: • 38,3% Male / 61,7% Female • 70,2% Unipolar / 29,8% Bipolar	94
Sensitivity (%)	85,7
Specificity (%)	81,8
False Positive Rate (%)	18.2
False Negative Rate (%)	14.3
Positive Predictive Value (%)	66.7
Negative Predictive Value (%)	93.1
Clinical Precision (%)	83,0

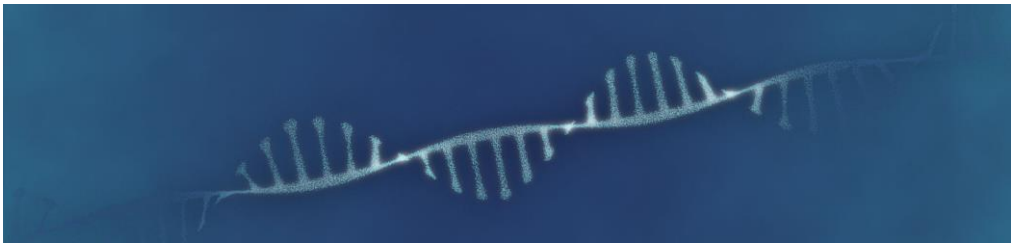
** Results of the clinical replication/validation study conducted at Les Toises psychiatric center in Switzerland*

Analytical Performances

Studies have been conducted to determine the analytical performance of the EDIT-B test.

Sample type: Whole blood collected with PAXgene® Blood RNA tubes, IQC (Internal Quality Control)

Analytical Performances	Results
Precision - Intra-run repeatability for n= 3 runs, CV% (SD) on the score generated by the EDIT-B® algorithm	16.5% CV (ou 0.07 SD)
Precision - Inter-run reproducibility for n= 3 runs, CV% (SD) on the score generated by the EDIT-B® algorithm	10.3% CV (ou 0.05 SD)
Accuracy (bias) (editing in % (±SD))	14.9% (±4.8) mean bias
Limit of Blank (LoB) (editing in %)	0.06%
Limit of Dectection (LoD) (editing in %)	0.09%
Cross-contamination (% of contaminated wells)	4.4%
EDIT-B® primer reactivity (% specificity)	100%
Known endogenous and exogenous interferences, cross-reactions	No statistically significant difference was observed between the test conditions and



	reference conditions for the tested substances (Bilirubin, Hemoglobin, Triglycerides, and Proteinase K)

Who is authorized to prescribe the EDIT-B test?

EDIT-B requires a medical prescription and is a simple blood test. It can be prescribed by the psychiatrist or in some countries by the general practitioner who follows and treats a patient for a major depressive episode.
Integrated into the clinical process, EDIT-B complements traditional clinical diagnostic tools such as DSM-V and ICD-11 diagnostic criteria, the patient's medical history, and clinical evaluation scales (e.g., MADRS, HDRS, and BDI).

Which patients is the test intended for?

EDIT-B is intended for patients aged 18 and older, male or female, presenting with a major depressive episode (moderate or severe), and currently being treated for this depression at the time of testing.
According to the Anatomical Therapeutic Chemical (ATC) classification, five treatment classes are considered: Antidepressants, Antipsychotics, Anxiolytics, Hypnotics/Sedatives, and Antiepileptics.
Contraindications for the EDIT-B test include:

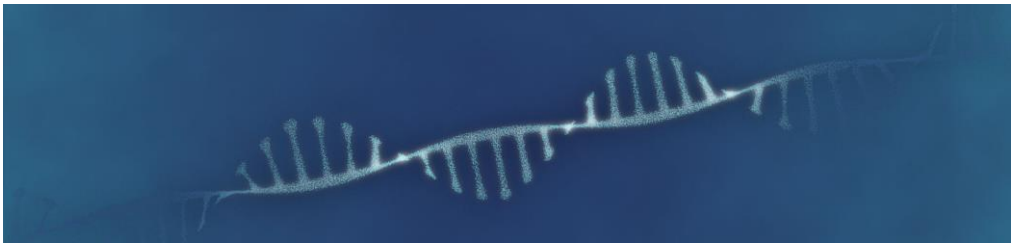
- Patients under 18 years old;
- Patients presenting with manic symptoms;
- Use for autonomous diagnostic purposes.

EDIT-B has not been tested on the following patient groups: Pregnant women.

Regarding the blood test, it is a standard blood draw (in terms of blood volume). There are no requirements concerning fasting or time of day.

What documents must patients bring to the laboratory to perform the blood draw for EDIT-B test?

Please refer to the product page: *EDIT-B, blood test to differentiate Depression and Bipolar Disorder | ALCEDIAG*. You will find all necessary information under the section “How to perform the EDIT-B test?”



Is EDIT-B suitable for diverse populations?

The test has been validated in the EU and is CE-marked under IVDD 98/79/EC. No statistics were collected on different ethnic groups during clinical trials.

Where can a patient go to have the blood drawn for the test?

For more information, please refer to the "How to perform the MYEDIT-B test?" section on the EDIT-B page of the ALCEDIAG website (EDIT-B, blood test to differentiate Depression and Bipolar Disorder | ALCEDIAG).

Can the test be performed on sample types other than blood, such as serum?

Currently, the test can only be performed using one sample type: whole blood. Moreover, the blood must be collected using specific tubes that preserve RNA, called PAXgene tubes.

What format is used for the results report provided to the prescriber by the laboratory?

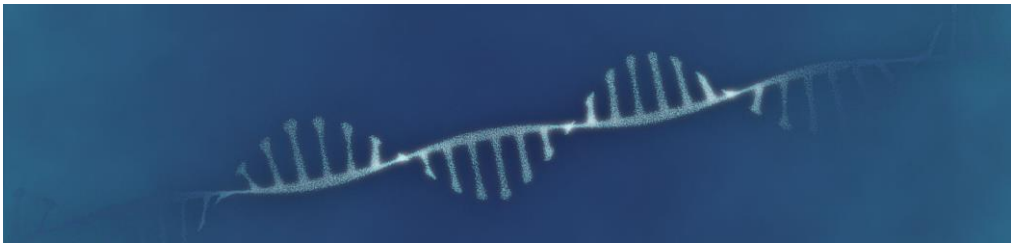
The laboratory will provide a comprehensive report including the patient's EDIT-B profile, indicating either bipolar disorder or unipolar depression. The report will also include additional elements such as quality control reports. It is important to note that patients will not have access to this report. Only the prescribing physician will receive it and determine its use in the diagnostic process and patient communication.

Will patients have access to the report sent by the medical biology laboratory?

Test results will be sent exclusively to the prescriber. The prescriber will decide how to use the results in the diagnostic process and how to communicate them to the patient.

How long does it take to get results after the blood sample is collected?

Although timelines may vary depending on location, the goal is to not exceed 4 weeks between blood collection and sending the results to the prescriber.



What happens to patient data?

In accordance with the General Data Protection Regulation (GDPR) of April 27, 2016, ALCEDIAG protects personal data, including patient data. Data is stored on a certified health data hosting (HDS) server for the time required for processing by the relevant services and for a maximum period of five years, unless the patient objects by email to ALCEDIAG: contact@alcediag-alcen.com.

I am a prescribing physician. Who can I contact about the EDIT-B test?

You can contact ALCEDIAG through the following contact form: *Contact | ALCEDIAG*

How much does the EDIT-B test cost? How was the price set?

For more information on this topic, please contact the laboratory performing the test in your country (Contact | ALCEDIAG).

Is EDIT-B eligible for health insurance reimbursement?

For more information on this topic, please contact the laboratory performing the test in your country (link available on the EDIT-B page of the website).

Regulatory

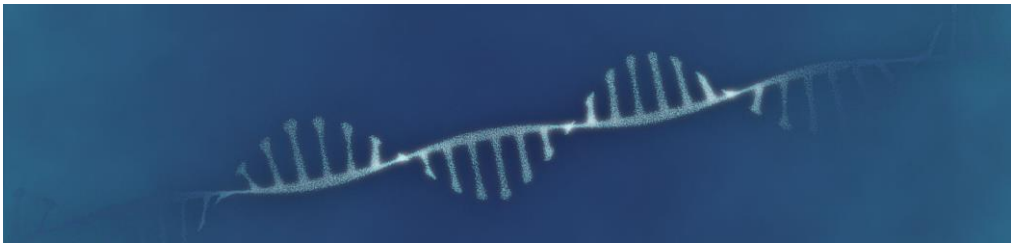
Does this test have regulatory approval? What does this mean in practice?

EDIT-B has been CE marked since May 2022, in accordance with Directive 98/79/EC and is compliant with the Swiss In Vitro Diagnostic Medical Devices Ordinance (IvDO). CE marking means that the test can be marketed within the European Economic Area (EEA) and meets all safety, health, and environmental protection requirements.

Directive 98/79/EC for in vitro diagnostic devices is currently being replaced by a new European regulation (EU) IVDR 2017/746. EDIT-B is currently undergoing compliance with this new regulation.

What type of device is EDIT-B?

According to the definition under Directive 98/79/EC, EDIT-B is a system composed of a biological protocol and software, intended by ALCEDIAG for in vitro examination of RNA editing from blood



samples, with the aim of providing information on a pathological process. In this case, EDIT-B qualifies as an in vitro diagnostic medical device.

About ALCEDIAG

What is ALCEDIAG?

ALCEDIAG is the company that developed EDIT-B and is the regulatory manufacturer of the test. ALCEDIAG has been conducting research and development in the field of neuroscience and psychiatry for over 10 years.
ALCEDIAG's ambition is to develop blood tests for mental health to promote biology and personalized medicine for the central nervous system, aiming to make a positive impact for patients.

What is ALCEDIAG's website address?

Website: https://www.alcediag-alcen.com/

How can I contact ALCEDIAG?

You can contact ALCEDIAG via the website or by sending an email to: contact@alcediag-alcen.com.