SYNLAB

SCHEACC041
TEST REQUISITION FORM
myEDIT-B

Rev.1 of 20/12/2023

myEDIT-B: Bipolar and Unipolar depression differential diagnosis

BARCODE LABEL

*Required fields

PATIENT*

Name*

Surname*

Date of birth* Gender: M F
(The test can only be made by 18+)

Personal number/Fiscal code*:
(Or other personal identification code)

Address

Telephone

INFORMATION OF REFFERING PHYSICIAN*

CODE CLIENT/PROVENANCE*:

Name*:

Surname*:

Telephone*:

Mail:

Medical center:

CLINICAL INFORMATION*

The patient is currently in major depressive episode (moderate or severe)? No Yes
(The test can only be required during the depressive episode)

Tobacco smoke No Yes

Alcohol consumer No Yes

DRUGS CURRENTLY IN CLINICAL USE (for correct classification see table in this form)*

☐ Anxiolytics (N05B)

☐ Hypnotics and sedatives (N05C)

☐ Antidepressants (N06A)

☐ Antipsychotics (N05A)

☐ Antiepileptics (N03A)

(Examination may only be required by patients undergoing treatment)

Date of sampling*: / / (day/month/year)

ETHNIC ORIGIN OF THE PATIENT

☐ African ☐ Indian

☐ Arabian ☐ Caucasian

☐ Asian ☐ Other (specify):

SIGNATURE OF THE REQUESTING PHYSICIAN

I am aware that the myEDIT-B test can only be performed on patients diagnosed with depression.
The purpose of the test is to provide a differential diagnosis between Bipolar Disorder and Unipolar Depression. I am also aware that the test must be carried out during the depressive episode and treated, and that it can only be required for patients over the age of 18. Based on the information listed above, I therefore request the myEDIT-B test for the patient identified above and confirm that, to my knowledge, the data indicated in this form are correct. I also declare that I have informed the patient about the required test and confirm that the patient has received a diagnosis of depression and therefore can undergo this test.

Signature of physician*: Date: / / (day/month/year)

SIGNATURE OF THE PATIENT

I hereby declare that I have received clear and detailed information about the investigation, the implications, and the limits of the myEDIT-B test. I declare that I have duly authorized the prescribing physician to receive the result of the test, which will be sent directly from Synlab. I also confirm that, as far as I know, the data indicated in this form are correct and that I have read the information.

Signature of the patient*:

INFORMATION myEDIT-B TEST

WHAT IS EPIGENETICS

The biological component of the myEDIT-B test is part of a specific subcategory of Molecular Biology called Epigenetics. Epigenetics studies how environmental factors activate/deactivate or regulate genes and gene expression. Epigenetic processes are reversible and dynamic. Therefore, epigenetic biomarkers allow a dynamic approach to diagnosis, considering the patient's condition, the potential progression of the disease and the impact of treatment. RNA editing is one of the Epigenetic mechanisms, which occurs in any individual and is influenced by pathologies and/or medication. It consists in the substitution, in specific points of the RNA, of an adenosine (A) with an inosine (I), promoted by specific enzymes. Several studies have shown that RNA editing is involved in many physiological functions it regulates certain synaptic functions through alteration of the functionality of certain receptors, leading to a direct impact on synaptic transmission.

WHAT THIS TEST ANALYSES

The test you are undergoing is carried out using next generation sequencing techniques (NGS) for the detection of RNA profiles editing A to I in 8 biomarkers (MDM2 NM_002392.6, GAB2 NM_080491.3, ZNF267 NM_003414.6, PTPRC NM_002838.5, IL17RA NM_014339.7, IFNAR1 NM_000629.3, LYN NM_002350.4 e PRKCB NM_002738.7). Raw data are analyzed and interpreted using CE-IVD validated software. The platform complies with the European General Data Protection Regulation (GDPR) and health data management standards. The processes of analysis and calculation of the algorithm are patented by the company ALCEDIAG. The test is intended exclusively for physician who are authorized to diagnose psychiatric diseases. myEDIT-B is part of the diagnostic workflow for mood disorders, supporting current diagnostic methods, such as DSM-V, ICD-11 criteria, and clinical scales such as MADRS, HDRS, BDI, etc. The outcome of the test must be assessed by the prescriber, including the clinical picture of the patient and other diagnostic methods. myEDIT-B is intended for patients over the age of 18, male or female, with a major depressive episode (moderate or severe) and treated** for that depression at the time of testing. The test should be carried out during the depressive episode, after medical consultation.

** According to the ATC classification, five classes of treatment are considered: Antiepileptics, Antipsychotics, Anxiolytics, Hypnotics/Sedatives and antidepressants (see table below).

ATC classification (see the drug class in detail at the following link WHOCC - ATC/DDD Index):

Anxiolytics (N05B)	Hypnotics and sedatives (N05C)	Antidepressant (N06A)	Antipsychotics (N05A)	Antiepileptics (N03A)
N05BA Benzodiazepine derivatives	N05CA Barbiturates, plain	N06AA Non-selective monoamine reuptake inhibitors	N05AA Phenothiazines with aliphatic side-chain	N03AA Barbiturates and derivatives
N05BB Diphenylmethane derivatives	N05CB Barbiturates, combinations	N06AB Selective serotonin reuptake inhibitors	N05AB Phenothiazines with piperazine structure	N03AB Hydantoin derivatives
N05BC Carbamates	N05CC Aldehydes and derivatives	N06AF Monoamine oxidase inhibitors, non-selective	N05AC Phenothiazines with piperidine structure	N03AC Oxazolidine derivatives
N05BD Dibenzo-bicyclo-octadiene derivatives	N05CD Benzodiazepine derivatives	N06AG Monoamine oxidase A inhibitors	N05AD Butyrophenone derivatives	N03AD Succinimide derivatives
N05BE Azaspirodecanedione derivatives	N05CE Piperidinedione derivatives	N06AX Other antidepressants	N05AE Indole derivatives	N03AE Benzodiazepine derivatives
N05BX Other anxiolytics	N05CF Benzodiazepine related drugs		N05AF Thioxanthene derivatives	N03AF Carboxamide derivatives
	N05CH Melatonin receptor agonists		N05AG Diphenylbutylpiperidine derivatives	N03AG Fatty acid derivatives
	N05CM Other hypnotics and sedatives		N05AH Diazepines, oxazepines, thiazepines and oxepines	N03AX Other antiepileptics
	N05CX Hypnotics and sedatives in combination, excl. barbiturates		N05AL Benzamides	
			N05AN Lithium	

WHAT KIND OF RESULTS THIS TEST PROVIDES

In the report you will find a result that shows which profile you have bipolar or unipolar. Please note that as an aid of diagnosis, myEDIT-B result brings supplementary data on the patient for the physician. Therefore, a result indicating a unipolar depression profile or bipolar disorder does not necessarily exclude the presence respectively of bipolar disorder or unipolar depression. To follow an appropriate diagnostic path, the outcome of the test must be related to the patient's clinic and included in the context of its clinical follow-up.

PERFORMANCE AND LIMIT OF THE TEST

The test has an analytical sensitivity and specificity >80% and an accuracy of 83% [73.8%-90%]. myEDIT-B cannot replace the prescriber's clinical diagnosis. In the event of a discrepancy between the results of the myEDIT-B test and other diagnostic tools (DSMV, ICD-11, MADRS, HDRS, BDI, etc.), it is imperative to refer to the conclusions of the prescriber. The causes of these discrepancies may be preanalytical, analytical or post-analytical, and/or associated with the false positive and false negative rates related to the test.
It is possible that the RNA extracted from its sample is not qualitatively or quantitatively adequate for the test. In this case you must send a new withdrawal at no extra cost.

In addition to the privacy policy displayed at the Synlab facilities, the patient is informed that the results of the test will be communicated by Synlab directly to the prescribing doctor, whom he has duly authorized, for the purpose of providing advice as an integral part of the test (art. 6, co.1 let. b of the Regulation) and the consequent therapeutic management of the patient.

SYNLAB myEDIT-B

EFTERNAMN och FÖRNAMN _____
SURNAME and NAME

FÖDD DEN _____ DATUM _____
BORN IN DATE

INTYGAR FÖLJANDE
DECLARE

- är medveten om att mitt samtycke till testet när som helst kan återkallas genom ett skriftligt meddelande till Synlab-byggnaden jag hänvisats till.
  be aware that my consent to the test can be revoked at any time by giving written notice to the Synlab structure to which I referred.

- förstår och accepterar att testet inte kan utföras om samtycket till utförandet av testet dras tillbaka. Om samtycket till testet dras tillbaka efter testet kommer de prover som redan tagits och levererats samt eventuella redan publicerade rapporter att förstöras, men eventuella belopp som redan betalats för testet kan inte återbetalas.
  to take note and accept that, in case of opt-out of consent to the execution of the test, the test cannot be performed. In the event of opt-out of consent after the test, the samples already taken and delivered, as well as any reports already released, will be destroyed, notwithstanding it will not be possible to obtain a refund of the amount already paid for the test.

- efter att ha förstått informationen som tillhandahållits till mig av den specialist som begärt analysen, och efter att ha tillhandahållits detaljerad information om innebörden och begränsningarna av de genetiska undersökningar som krävs, samtycker jag till
  having understood the information that was issued to me by the Specialist requesting the analyses and having obtained detailed information on the meaning and limits of the genetic investigations required, I agree

  - att mitt biologiska prov används för diagnostiska ändamål — JA YES / NEJ NO
    use my biological sample for diagnostic purposes

  - att jag får information om resultaten av de undersökningar som förskrivaren kräver — JA YES / NEJ NO
    know the results of the investigations required by the prescriber

  - att det biologiska materialet och mina uppgifter används i enlighet med gällande lagstiftning om skydd av personuppgifter för vidare utredning i diagnostiska syften på den anläggning som utför analyserna — JA YES / NEJ NO
    use the biological material and my data, in compliance with the current legislation on the protection of personal data, for further investigation for diagnostic purposes at the Centre that performs the analyses

  - att resultaten på begäran delas med mina familjemedlemmar — JA YES / NEJ NO
    to share the results with my family members, if they so request

  - Synlabs användning av det avidentifierade restprovet, inklusive genom försökspersoner som fungerar som bearbetare, för kvalitetskontroll, utveckling av laboratorietester och förbättring av laboratorieaktiviteter, i syfte att förbättra testet för framtida patienter. — JA YES / NEJ NO
    the use of the de-identified residual sample by Synlab, including through subjects acting as processors, for quality control, development of laboratory tests and improvement of laboratory activities, in order to improve the test for future patients.

    användningen av det anonymiserade restprovet för vetenskaplig forskning så länge jag blir kontaktad av Synlab och får information om syftet med forskningen och kan ge särskilt samtycke — JA YES / NEJ NO
    the use of the anonymized residual sample for scientific research as long as that I am contacted by Synlab to know the purpose of the research and provide specific consent

Patientens signatur *:
Signature of the Patient

Datum: / / (dag/månad/år)
Date (day/month/year)