



## Biological markers for Neurodegenerative diseases

### Section 1/3: Analysis selection and confounding factors

#### Mandatory Information:

Patient's name / Date of birth: _____		Patient's personal data/ hospital sticker		
Date of CSF sampling: _____				
Rapid progressive neurodegeneration				
Slow progressive neurodegeneration				
Clinical duration: _____ months				
Age at onset: _____				
MMSE: _____ / 30	MOCA: _____ / 30	CDR-SB: _____ / 18	CDR-GS: _____ / 3	
Date: _____				
eGFR: _____ Date: _____				
APOE ε4 status (if known): no ε4 allele / homozygous/ heterozygous (Brum et al. Nature Aging 2023)				
BMI: <18.5 Underweight / 18.5-25 Normal / 25-30 Overweight / >30 Obese		Date: _____		
Clinical diagnose: _____				
Clinical symptoms at onset:	Complaints of memory and/or orientation	Pure cerebellar onset	<b>Fazekas</b> (cerebrovas. DWM lesions)	
	Behavioural symptoms	Stroke-like onset		
	Language difficulties	Pure psychiatric onset		0 1 2 3
	Isolated visual symptoms	Sensory symptoms at onset		
	Extra pyramidal onset	Other _____		
Clinical remarks: _____				

#### CSF:

<p><b>dd Alzheimer's Disease (AD)</b></p> <p>ATN profiling based on proteins: <math>A\beta_{1-42}</math>, <math>A\beta_{1-40}</math>, tTau, pTau<sub>181</sub></p> <p><a href="http://www.uantwerpen.be/ad-atn-interpretation">www.uantwerpen.be/ad-atn-interpretation</a></p> <p>Clin Chem Lab Med. 2021 Nov15;60(2):207-219</p> <p><b>2x 1ml CSF</b> (into 1,5ml PP tubes)</p> <p><a href="http://www.uantwerpen.be/sampling">www.uantwerpen.be/sampling</a> / <a href="http://www.bornbunge.org/en/our-work/diagnostics">www.bornbunge.org/en/our-work/diagnostics</a></p> <p>+ optional 2x 1ml EDTA Plasma for prospective biobanking purposes more info: ICF Ref. EC/PM/AL/2021.020 'prospective sampling and storage'</p> <p><a href="http://www.uantwerpen.be/icfprospect">www.uantwerpen.be/icfprospect</a></p> <p><b>Analysis cost:</b> <a href="https://labogids.uza.be/analyses">https://labogids.uza.be/analyses</a></p>	<p><b>ddCreutzfeldt-Jakob Disease (CJD) - NRC-ddCJD</b></p> <p>Proteins: <b>14-3-3 / PrPsc (RT-QuIC)</b></p> <p>RT-QuIC inclusion only IF :</p> <ul style="list-style-type: none"> <li>• The diagnostic criteria 'possible CJD' according to the WHO/ECDC have been met,</li> <li>• OR 14-3-3 protein analysis returned (weak) positive,</li> <li>• OR tTau concentration is &gt;1200pg/mL,</li> <li>• OR tTau / pTau ratio is ≥14.</li> </ul> <p>Acta Neurol Belg 2018 Sep;118(3):395-403</p> <p><b>2x 1ml CSF</b> (into 1,5ml PP tubes)</p> <p><b>Analysis cost: no cost (due to NRC-ddCJD Consortium)</b></p>
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#### EDTA Plasma:

<p><b>dd Alzheimer's Disease (AD)</b></p> <p>Probability assessment based on proteins: pTau<sub>217</sub></p> <p>Disclaimer:</p> <ul style="list-style-type: none"> <li>• Presence of objective cognitive deficits necessary.</li> <li>• Result can be affected by kidney function and BMI.</li> <li>• Analysis designated RUO pending CE-IVD; may serve as an early, less-invasive prob. assessment indicating early pathological changes, to be confirmed by standard CSF-based ATN profile.</li> </ul> <p>If result returns intermediate, an additional CSF analysis (4 AD markers) will be required.</p> <p>Clin Chem Lab Med. 2021 Nov15;60(2):207-219</p> <p><b>2x 1ml EDTA Plasma</b> (into 1,5ml PP tubes)</p> <p><a href="http://www.uantwerpen.be/sampling">www.uantwerpen.be/sampling</a> / <a href="http://www.bornbunge.org/en/our-work/diagnostics">www.bornbunge.org/en/our-work/diagnostics</a></p> <p><b>Analysis cost:</b> <a href="https://labogids.uza.be/analyses">https://labogids.uza.be/analyses</a></p>	<p>Fig: EDTA plasma pTau<sub>217</sub> distribution in patients with cognitive deficits.</p>
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Please complete specific clinical findings on next page



Patient's name / Date of birth: \_\_\_\_\_

**Section 2/3: Clinical information, imaging and surveillance****Clinical evolution:**

Yes No ?

**progressive dementia**

memory disturbances

orientation difficulties (space/time)

attention difficulties / distractibility

behavioural changes: apathy

behavioural changes: loss of empathy

behavioural changes: disinhibition

hyperorality

perseverative / stereotyped / compulsive behaviour

executive dysfunction

language difficulties / aphasia

dysarthria

**akinetic mutism**

verbal apraxia

Yes No ?

limb apraxia

**visuospatial dysfunction**

hallucinations or delusions

REM sleep behaviour disorder

falls

loss of consciousness

**myoclonus**

frontal release signs

ataxia / **cerebellar signs****pyramidal signs**parkinsonism / **extrapyramidal signs**

depression

*psychiatric problems**epilepsia***Neuro-imaging - if performed - tick when present****MRI / CT**

Normal

Abnormalities - non specific

Abnormalities - affecting striatum or neo-cortex

High signal in caudate lobe and putamen

High signal in posterior thalamus &gt; other areas

Cortical ribbon sign

Enlargements - ventricular

Atrophy - cerebellar

Atrophy - cerebral

/ Predominant regions

frontal	L	R
temporal	L	R
parietal	L	R
occipital	L	R

/ Global atrophy

GCA = 0
GCA = 1
GCA = 2
GCA = 3

/ Temporal atrophy

MTA 0	L	R
MTA 1	L	R
MTA 2	L	R
MTA 3	L	R
MTA 4	L	R

other: \_\_\_\_\_

**EEG**

Normal

Periodic sharp-wave complexes - triphasic

Slowing focal or diffuse

Slowing frontal or frontotemporal

Slowed alfa activity

Decreased beta activity

Increased theta and delta activity

other: \_\_\_\_\_

**PET Amyloid**

Neg

Pos

**PET TAU**

Neg

Pos

**PET FDG predominant hypometabolism**

frontal L R

temporal L R

parietal L R

occipital L R

other: \_\_\_\_\_

**Additional information - Sciensano CJD Surveillance:****Specific risk factors**

Yes No ?

Ever had a stroke

Year of stroke

Ever had a residence in UK

When

Ever had endoscopy

When / which hospital

Ever had surgery

Surgery info

Ever had neurosurgery

Neurosurgery info

Familial history of dementia

Dementia type

**Section 3/3: Consent / opt-out for the patient****A. Consent for diagnostic biomarker-analysis.**

**I give my consent for biomarker-analysis.** It has been explained to me and I understand that:

1. Protein analysis is proposed to investigate the cause of a neurodegenerative disorder in the patient mentioned above.
2. The sample will be analyzed to determine the potential presence of the condition. Costs are associated with this analysis, except for NRC-ddCJD markers.
3. The physician will interpret the results of this analysis and discuss them with me.
4. I may be informed if a serious condition is incidentally discovered for which medical treatment and/or preventive measures are available.
5. This analysis does not exclude the presence of other conditions.
6. All data obtained from this study will be treated with strict confidentiality, and I retain the right to access and correct my data, cf. [www.uantwerpen.be/privacybeleid](http://www.uantwerpen.be/privacybeleid) .

**B. For informative purposes: residual samples can be stored at the IBB-Neurobiobank for future scientific research.** It has been explained to me and I understand that:

7. The residual sample and associated data will be stored in the secure IBB-Neurobiobank (ID BB190113).
8. The purpose of this storage is future scientific research in the field of neurodegenerative and neuromuscular disorders, under the stewardship of a recognised biobank, subject to prior ethical review and appropriate privacy safeguards.
9. My residual sample and data can only be used for future research in pseudonymised form and after approval by a Medical Ethics Committee.
10. Both academic and commercial researchers can submit applications, according to the same conditions.
11. If necessary, specific and pre-approved research may require additional clinical information, which may be requested from my treating physician by the managing physician of the IBB-Neurobiobank.
12. I can stop my participation at any time by informing my treating physician or at [neurobiobank@uantwerpen.be](mailto:neurobiobank@uantwerpen.be) . No new data will then be generated and I will receive written confirmation of this.

**Opt-out storage residual sample:** I do not wish for my residual sample to be stored and used for scientific research. **Tick only if the patient makes objection.**

**C. Optional plasma, only subject to your separate approval:**

13. An optional EDTA-plasma sample may be collected prospectively at the same time as the cerebrospinal fluid sample for storage in the IBB-Neurobiobank. Refusal to consent to the collection of this sample will not affect the diagnostic process. Info and context: ICF Ref. EC/PM/AL/2021.020 'prospective sampling and storage' [www.uantwerpen.be/icfprospect](http://www.uantwerpen.be/icfprospect) / [www.bornbunge.org/en/forms-documents](http://www.bornbunge.org/en/forms-documents) .

**I give my permission to collect and store an optional EDTA-plasma sample for prospective biobanking.**

<b>I give my consent as:</b>	<b>patient</b>	<b>patient</b>
<b>NamY:</b> _____	<b>G][ bUi fY</b>	<b>patiYnt:</b>
<b>DatY:</b> _____		
<b>F Yquesting`clinician`:</b>		
<b>NamY`XcWcf:</b> _____	<b>E-mail:</b>	_____
<b>RIZIV/INAMI nr:</b> _____	<b>G][ bUi fY</b>	<b>XcWcf:</b>
<b>Hospital: "</b> _____		

**To the attention of the clinician:****Sample receipt, validation & reporting**

Labo klinische biologie UZA, route 169  
Drie Eikenstraat 655  
2650 Edegem  
Dr. Khadija Guerti (riziv nr. 11943866860)

**Analysis, interpretation & contextualisation:**

Labo Neuro/Neurobiobank IBB-UA  
E-mail: biomarkers@uantwerpen.be  
Tel. Lab +32 3 265 2605 Fax Lab +32 3 265 8501





## Patient information leaflet

### Lumbar puncture (cerebrospinal fluid) and blood draw (EDTA plasma) - step by step

Your doctor is proposing a lumbar puncture (spinal tap) to collect a small amount of cerebrospinal fluid (CSF). Often, a blood sample is also taken to obtain EDTA plasma. These samples are used to measure certain proteins (biomarkers).

#### 1. Why is this test useful?

- It can help investigate the cause of neurological or cognitive symptoms and distinguish between different conditions.
- Sometimes the test does not provide a clear diagnosis. Your doctor will then discuss the next steps with you.

#### 2. What happens to the CSF and blood sample?

- The CSF and blood are sent to the laboratory. The blood is processed to obtain EDTA plasma.
- The samples are analysed. The results are sent to the requesting physician, who will discuss them with you. The informed consent explains how residual material and data are handled.

#### 3. How is the sampling performed? (step by step)

- Beforehand: let us know if you take blood thinners, have a bleeding/clotting disorder, a fever, a skin infection on the lower back, or if you are pregnant. Never stop medication on your own without medical advice.
- During: you lie on your side with your knees drawn up, or you sit leaning forward. The skin is disinfected and covered with sterile gauze. You receive local anaesthesia.
- The doctor inserts the needle low in the back, between two lumbar vertebrae, and collects a small amount of CSF into tubes. A plaster is then applied.
- Blood draw: blood is taken from a vein in the arm into a tube containing EDTA (a substance that prevents the blood from clotting).
- Afterwards: you are usually observed for a short time. Usually, you can go home the same day. Follow the instructions you receive.

#### 4. Possible risks and discomfort

- Headache after the puncture (typically worse when sitting/standing upright and better when lying flat).
- Lower back pain or stiffness; sometimes a brief shooting sensation down a leg during the procedure.
- Bleeding or bruising at the puncture site and, rarely, infection.
- With the blood draw: bruising, pain or feeling faint.
- Serious complications are rare, but may require additional treatment.

#### 5. Aftercare and when to seek help

- Rest on the day of the puncture and avoid heavy exertion or heavy lifting for 24–48 hours (or as advised).
- Contact a doctor if you have: persistent or very severe headache, fever, increasing redness/warmth/swelling or pus, leakage of fluid, increasing back or leg pain, weakness/severe sensory symptoms, or problems urinating.

#### 6. When will you get the results?

- Laboratory analysis takes time. Your doctor will discuss the results with you (often within the next few weeks).

Do you still have questions or doubts? Discuss them with your doctor. You decide only after you have received enough information and everything is clear to you.

*The above is provided for information only – responsibility remains with the physician performing the procedure.*



**Copy of the signed document.**

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