

Contract information for the "Controlled Drinking" control programme with PEth (phosphatidylethanol) blood testing

1 General information

Evidence of controlled drinking may be required as a precondition for the medical-psychological assessment (MPU). The requirements for acceptable evidence are set out in the CTU (chemical-toxicological investigation) criteria, which form part of the assessment criteria for fitness to drive (1), which have been published since November 2022.

It is in your own interest to read the following information carefully in order to successfully complete the control programme in line with these criteria. We also recommend that you contact a relevant advice centre when preparing for the MPU.

2 Abstinence control programme

2.1 Registration

You can register for the programme via our customer portal at https://synlab.abstinenznachweise.com/synlab/4#/registrierung. This will allow you to see your future results at any time, report any periods of unavailability, or contact us.

Alternatively, you can get in touch with our institute regarding the control programme either over the phone at +49 961 309-270 or via e-mail at forensik@synlab.com and make an appointment for an informational meeting and to sign the contract. Please bring a valid official photo ID (identity card, passport) with you so that we can record your personal details.

You can also have the contract sent to you after registering by phone. The control programme will start once we have received the signed contract and a copy of your photo ID. The date on our "Received" stamp is the official start of the control programme, unless you wish to begin at a later date.

2.2 Contract

The contract regulates the "Controlled Drinking" control programme, based on the CTU criteria. The programme is split into 3 phases:

- 1. Abstinence phase of at least 3 months
 - a. 3x tests for EtG in the urine (scheduled at short notice and without warning) OR
 - b. 3x tests for PEth in the blood (scheduled at short notice and without warning) OR
 - c. 1x test for EtG in the hair (over 3 cm)
- 2. <u>Test phase</u> of 3–4 months:

No analytical review prior to the <u>status report</u> at the end of the test phase: 1x test for PEth in the blood

- = STARTING VALUE
- 3. <u>Control phase*</u> of at least 6 months: 5x tests for PEth in the blood (scheduled at short notice and without warning). When you receive the contract, you will also be sent this information sheet outlining the general requirements for the control programme as well as information on data protection, all of which forms part of the contract.

2.3 Costs

Service	Price incl. VAT	Comments
PEth** in the blood (EDTA blood)	EUR 57.00	per analysis
PEth** in dried blood (finger prick sampling)	EUR 57.00	per analysis
EtG in the urine	EUR 57.00	per analysis

^{*}The terms "control phase" and "stabilisation phase" are used interchangeably in the CTU criteria.



EtG in the hair	EUR 139.90	per analysis
Supervised blood/urine sample collection	EUR 20.00	per sample
Hair sampling	EUR 25.00	per sample

^{**} Phosphatidylethanol

The costs of the tests are payable on the day of sampling, either in cash or by debit card (depending on the sampling centre). At some sampling centres, payment can only be made following receipt of an invoice. A one-off processing fee of EUR 15 incl. VAT is payable for the first sample.

3 Conditions of implementation

3.1 Reachability and availability

According to the CTU1 criteria, the sampling appointments in the abstinence phase must be scheduled at short notice and without warning. You will be required to visit the laboratory no later than the day after being invited for a test for EtG in the urine, and no later than two days after being invited for a test for PEth in the blood.

If you are unable to attend, you must inform the laboratory in good time, stating the reasons. What this means for you:

- You will mainly be sent appointments via text message and e-mail or a phone call. You will therefore need to be reachable at all times. Check your text message and e-mail inbox daily, listen to your voice mails and answering machine messages on a regular basis, and check whether any of your missed calls is from the laboratory phone number. Always call us back! The deadline starts to run from the first time we get in contact with you via the number you provided. We keep a written record of this.
- In principle, sampling can be done any day of the week, including Saturdays, Sundays, and public holidays, so please be aware that you may also receive a message on those days. (Sampling is not restricted to the official opening days of the sampling centre or any holiday periods).
- Unavailability due to illness: If you become ill at short notice and are unable to get to the
 laboratory, you will need to inform the laboratory by phone without delay on the same day or
 notify it in your customer portal. You will also need to provide written evidence in the form of a
 sick note (doctor's certificate) within three working days. Please note that this also counts
 towards your unavailable days.
 - If you have already received an appointment before you inform the laboratory of your illness, you will need to provide confirmation from a doctor that you had already fallen ill on the day of receiving the message. For this you must use the <u>Certificate of unfitness for travel (also saved in your customer portal)</u>, which is provided by SYNLAB on the relevant website. This certificate must be signed by a doctor and submitted within the deadlines stated above. Other certificates will not be accepted.
- Unavailability for work-related reasons (e.g. business trips, working away) or due to holidays:
 The laboratory must be informed of any unavailability due to work or holidays at least three working days in advance, either by post, e-mail or phone, or via your customer portal.
 However, please remember that SYNLAB has numerous sampling centres across Germany.
- **During the first phase of the control programme (abstinence phase)** of at least 3 months, you are permitted to have the following gaps in your availability (regardless of the reasons):

Length of the abstinence phase in months	3	4	6
Max. permissible consecutive days of unavailability	10	13	20
Max. permissible total days of unavailability	14	18	28

If the maximum permissible unavailability period specified in the table is exceeded, the programme will be terminated automatically.

You must not be unavailable in the first two weeks from the start of the abstinence phase. Similarly, you must not have any periods of unavailability spanning more than a week prior to the end of the control programme (last 4 weeks). You can see how many permissible days of unavailability you have left in your customer portal.



During the second phase of the control programme (test phase*) of 6 months, you are permitted to have the following gaps in your availability (regardless of the reasons):

Length of the abstinence phase in months	
Max. permissible consecutive days of unavailability	20
Max. permissible total days of unavailability	28

If the maximum permissible unavailability period specified in the table is exceeded, the programme will be terminated automatically.

You must not be unavailable in the first two weeks from the start of the test phase*. Similarly, you must not have any periods of unavailability spanning more than a week prior to the end of the control programme (last 4 weeks). You can see how many permissible days of unavailability you have left in your customer portal.

3.2 How to avoid influencing the test results

The laboratory results may be influenced by various factors such as medicines and cosmetics that contain alcohol, or foodstuffs containing residual alcohol.

Because you need to provide proof of abstinence, any positive result will initially be interpreted against you, even if it has been caused by the factors listed below.

It is therefore in your own interest to ensure that you follow certain rules.

Medicines containing alcohol:

If you are taking medicines that contain alcohol, you will need to inform your doctor that you will be taking part in the control programme. He or she will find alternative medication for you.

If this is not possible, you will need to obtain confirmation from your doctor. In the case of selfmedication, you must make sure to check the packaging or the enclosed information leaflet to see whether the medicine contains alcohol.

Food:

Under food law regulations, drinks with an alcohol content of less than 0.5 % v/v may be described as "alcohol-free". Also, a variety of foodstuffs contain ethanol as a result of the manufacturing process or if they are incorrectly stored for a long period of time.

"Alcohol-free beer" up to 0.5% v/v (equiv. to 4 g ethanol per litre) Standard fruit juices up to 0.38% v/v (equiv. to 3 g ethanol per litre) Kefir (milk drink containing alcohol) up to 2% v/v (equiv. to 16 g ethanol per litre) Sauerkraut up to 0.5% v/v

Bananas (ripe), grapes up to 1% v/v

If you consume large quantities of these foodstuffs shortly before giving a blood sample, i.e. after you are notified about your appointment, this may lead to a positive test result for PEth, albeit at a borderline level. You should therefore avoid these foodstuffs, particularly after receiving your appointment.

Hygiene products:

Mouthwash and hand disinfectants may contain ethanol. You should refrain from using these products, particularly after receiving your appointment. If you use these products in your work, you may need to change to another disinfectant. Disinfectants containing isopropanol will not influence the test results. Avoid using cleaning agents that contain ethanol in the workplace.

3.3 What to do after receiving your appointment and during the sampling

You will need to bring a valid identity card or passport with you to each sampling appointment to verify your identity. The fees must be paid before the sample is taken. Samples are taken under visual supervision.

Termination criteria

The abstinence control programme will be terminated if any of the following occur:



- Failure to comply with the deadline after being given an appointment
- More than two absences <u>after</u> being given a sampling appointment, even if you have a valid Certificate of unfitness to travel
- Insufficient medical certificates (e.g. failure to present a Certificate of unfitness to travel)
- Exceeding the maximum unavailability period during the abstinence or control phase*
- Positive test result: STARTING VALUE ≥ 100 ng/ml
- Exceeding the STARTING VALUE once by 50% during subsequent tests, or repeatedly
 exceeding the STARTING VALUE by 30% or more

If you wish to terminate the control programme, you will need to do so in writing by post or e-mail, or via your customer portal. If you terminate the control programme before your first sampling test, you will be charged a processing fee of EUR 30.

3.5 Provision of samples

Once your samples have been collected, they are held by the organisation responsible for carrying out the programme. This organisation is, however, only permitted to carry out further analyses at the request of the client (analyses of retained samples/repeat analysis following an appeal by the client).

3.6 Notification of results

Individual results are not issued. If you require individual results, you can download them from the customer portal. Once you have successfully completed the abstinence control programme, you will receive all your results together with a final report in the ORIGINAL (forgery-proof) in accordance with the CTU4 criteria.

If you require an additional copy of the original results (forgery-proof) or an additional copy of the original final report (forgery-proof), these will be charged at EUR 15 incl. VAT per copy.

For reasons of data protection, our employees cannot give you any information about your results over the phone. Please write a message via your customer portal to request information.

Lit.: (1) Brenner-Hartmann, J.; DGVP, DGVM (ed.): Urteilsbildung in der Fahreignungsbegutachtung, Beurteilungskriterien [Judgement of fitness to drive, assessment criteria], Bonn, published by Kirschbaum Verlag, 4th edition 2022

*The terms "control phase" and "stabilisation phase" are used interchangeably in the CTU criteria.