

# **Phe** (Phenylalanine)

**Egoo Phe Test Kit** (e12378)

**In vitro diagnostic medical device**

**Regulatory and Safety Information**

**Instructions for Use – Part A**

[ D R A F T ]

**egoo.health**

## About the Egoo Phe Test Kit

The Egoo Phe Test is a quantitative in vitro diagnostic self-test intended to measure the concentration of phenylalanine (Phe) in a small sample of capillary whole blood collected from a fingertip.

The test is intended for individuals with a confirmed diagnosis of phenylketonuria (PKU) to support regular monitoring of blood phenylalanine levels.

### Contact Information:

**Phone:** +45 7190 5504  
**Email:** Info@egoo.health  
**Website:** www.egoo.health



## How to Use the Instructions for Use – Part A

This booklet **Regulatory and Safety Information** (Instructions For Use – Part A) contains important details about the Phe Self-Test Kit, including its intended use, storage and handling requirements, safety precautions, limitations, and manufacturer contact information.

Please read this booklet together with the Illustrated User Guide (Instructions For Use – Part B), which explains how to perform the test step by step.

Both parts together constitute the complete Instructions for Use for this product and should be read before using the test for the first time.

## Table of Contents

*To follow.*

Intended Use

The Egoo Phe Test is an in vitro diagnostic medical device intended for the quantitative monitoring of phenylalanine (Phe) in human capillary whole-blood specimens, used in conjunction with the Egoo Analyzer P300 (e81805) as part of the Egoo Phe System.

It is intended for use by an adult layperson (non-health-care professional) in a non-clinical, home-based environment for the monitoring of Phe in human blood to support the management of phenylketonuria (PKU) in adults and children (aged 1 month to 17 years).

Intended Users

- The Egoo Phenylalanine (Phe) Test is designed for:**
- Adults with a confirmed diagnosis of phenylketonuria (PKU) who wish to monitor their blood phenylalanine levels at home.
  - Parents or caregivers of children with PKU who perform the test on behalf of the child, following medical advice when needed.

The test is easy to use and intended for self-testing at home without the need for special training. Users should follow the instructions carefully and contact their doctor or healthcare professional if they have questions about the results or their condition.

Device Used with this Test Kit

The Egoo Phe Test is intended to be used only with the Egoo P300 device (e81805). The Egoo P300 is a small, automated device used together with the Egoo Connect app and Egoo Phe Test to measure phenylalanine (Phe) levels in blood.

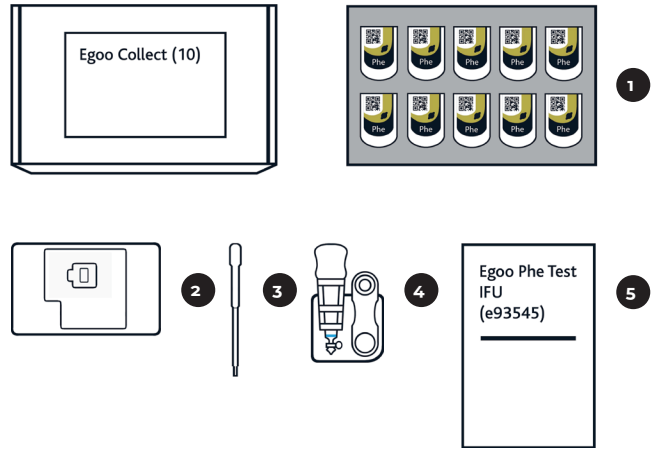
It is designed for people with phenylketonuria (PKU) to use at home for regular monitoring of blood Phe levels.

The test process is simple: the app guides the user step by step, from inserting the test capsule to viewing the result on the smartphone screen. The Egoo P300 device performs the analysis automatically and shows the result directly in the Egoo Connect app.

The Egoo P300 device includes one reusable demo capsule. For further guidance, refer to the Instructions for Use for the Egoo P300 device.

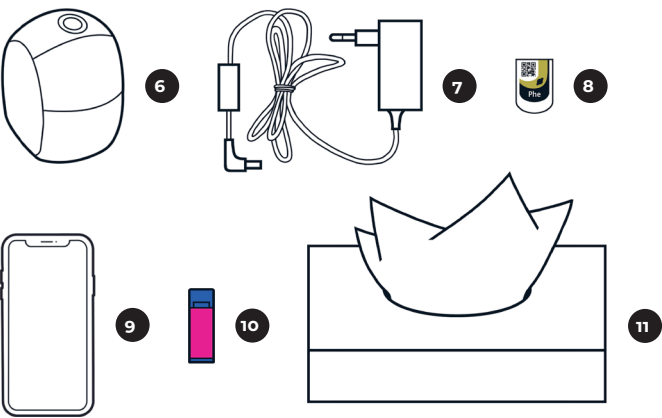
Materials Included in This Test Kit

| Components                             | 1 Kit |
|----------------------------------------|-------|
| 1. Phe capsules                        | 10    |
| 2. Capsule holder                      | 1     |
| 3. Pipette (40 µL))                    | 10    |
| 4. Egoo Collect with transfer stick    | 10    |
| 5. Instructions for Use (Part A and B) | 1     |



Materials Required but Not Included in This Test Kit

| Components                    |
|-------------------------------|
| 6. Egoo P300 device           |
| 7. Egoo P300 power supply     |
| 8. Egoo P300 demo capsule     |
| 9. Smartphone                 |
| 10. Lancet for a finger prick |
| 11. Tissue paper              |



## Phe Test Kit Storage Instructions and Shelf Life

- Store the Egoo Phe capsules at –25°C to –15°C.
- The other components of this test kit can be stored at 20°C to 25°C.
- The test kit remains stable for 18 months.
- Do not open the test kit until ready for use.
- Refer to the expiry date on the kit label.
- Avoid exposure to direct sunlight.
- Once opened, the test kit remains stable for 1 hour at 15°C to 25°C.

## Type of Sample

- Blood collected from your fingertip.
- The freshly collected blood sample must be added and measured immediately.

## Required Sample Volume

- 40 µL of blood collected from your fingertip.

## Test Temperature Conditions

- The test should be performed at room temperature (20°C to 25°C).

## Warnings and Limitations

### Possible Interferences

The Egoo Phenylalanine (Phe) Test has been carefully tested for substances that could affect the result.

### No significant interference was observed from:

- Lipids (fat in blood), haemolysis (breakdown of red blood cells), bilirubin, total protein, or urea within normal or slightly elevated levels.
- Related amino acids such as tyrosine and tryptophan.
- Common medicines including vitamin C (ascorbic acid), paracetamol (acetaminophen), ibuprofen, ampicillin, cefoxitin, N-acetylcysteine, or rifampicin.
- Phenylalanine derivatives such as phenylacetate and phenylpyruvate.

### To ensure correct results:

- Use only test capsules that have been stored at –20 °C.
- Before testing, let the capsule reach room temperature for 15 minutes.
- Do not use capsules that have been frozen and thawed several times or exposed to excessive heat.

### References

Blau N et al. Lancet 2010; 376:1417–27.  
Peña MJ et al. Clin Chim Acta 2012; 413:1496–1502.  
CLSI EP07-A2: Interference Testing in Clinical Chemistry.  
ISO 18113-5:2022: IVD Information Supplied by the Manufacturer – Self-Testing.  
EU IVDR (2017/746), Annex I § 20.4.1 (p–r).

## Limitations of Use

- This test is only for people diagnosed with phenylketonuria (PKU) or for those advised by a healthcare professional to monitor phenylalanine levels.
- It is not a screening or diagnostic test and must not be used for newborn screening.
- Use only a finger-prick (capillary whole-blood) sample. Do not use plasma, serum, or venous blood.
- The test is validated for adults and children aged 1 month to 17 years.
- For children under 18 years, testing should be performed by or under adult supervision.
- Perform the test on a flat, clean surface at 15 °C – 30 °C and below 80 % humidity.
- Each capsule is for single use only. Reusing it may cause incorrect results or infection.
- The device and test capsules are factory-calibrated. Do not attempt to recalibrate or modify them.
- If your result is outside the range recommended by your doctor, repeat the test and confirm with a laboratory test before changing your diet or treatment.
- The test is for in-vitro diagnostic use only. Do not swallow or reuse any part of the test.

## Safety Information

- Treat all blood and used materials as potentially infectious. Dispose of them safely in household waste following local instructions, or use a sharps container if available.
- Lancets are sharp — keep them out of reach of children and discard them carefully after use.
- Children must always be supervised by an adult when performing the test.
- If the analyser shows repeated error messages or no result appears, use a new test capsule. If the problem continues, contact customer support.
- Always seek medical advice if your results stay above or below the target range recommended by your healthcare professional.

Symbols Used on Labels

| Usage                              | Symbol                                                                            |
|------------------------------------|-----------------------------------------------------------------------------------|
| Use-by date                        |  |
| Batch code                         |  |
| Manufacturer                       |  |
| Keep away from sunlight            |  |
| Temperature limit                  |  |
| Consult instructions for use       |  |
| Do not freeze                      |  |
| Contains sufficient for <n> tests  |  |
| Do not use if package is damaged   |  |
| Date of manufacture                |  |
| Do not reuse                       |  |
| Catalogue number                   |  |
| In vitro diagnostic medical device |  |
| Serial number                      |  |
| Self-test                          |  |
| CE marking                         |  |
| Unique device identifier           |  |
| Keep dry                           |  |
| User information website           |  |
| Must be frozen within 48 hours     |  |

Phe Reference Range

Recommended plasma phenylalanine concentration targets according to the European PKU Guidelines

- 120–360 µmol/L for infants and children up to 12 years of age
- 120–600 µmol/L for adolescents (12–18 years) and adults
- 120–360 µmol/L during pregnancy

Reference: van Wegberg, A. M. J., et al. (2025). Revised European guidelines on phenylketonuria: treatment targets and monitoring recommendations. Orphanet Journal of Rare Diseases.

Phe Conversion Table

| µmol/L | mg/dL |
|--------|-------|
| 50     | 0,83  |
| 100    | 1,65  |
| 200    | 3,30  |
| 300    | 4,96  |
| 400    | 6,61  |
| 500    | 8,26  |
| 600    | 9,91  |
| 700    | 11,56 |
| 800    | 13,21 |
| 900    | 14,87 |
| 1000   | 16,52 |
| 1200   | 19,82 |
| 1500   | 24,78 |
| 1800   | 29,73 |
| 2000   | 33,04 |

The table to the left provides a quick reference for converting Phe values from µmol/L to mg/dL.

(Phe (MW 165.19 g/mol; PubChem CID 6140) was converted from µmol/L to mg/dL using (µmol/L×165.19)/10 000(\mu mol/L \times 165.19) /10\,000(µmol/L×165.19)/10000 (SI Brochure, BIPM; IUPAC 2007).

**Conversion Formula**  
This formula is used to convert Phe values from µmol/L to mg/dL.

mg/dL = 
$$\frac{\mu\text{mol/L} \times 165.19}{10\,000}$$

How to Interpret Your Test Result?

- The Egoo Phe Test Kit is intended for in vitro diagnostic use only.
- The result obtained from this test is for informational purposes only.

Disposal and Handling Information

- Dispose of waste in accordance with local waste and environmental regulations. The test kit is classified as non-hazardous waste.
- Each test in the kit is intended for single use only. One test kit contains 10 single-use tests.
- Do not use a damaged or expired Phe capsule.

Guidance for Interpreting Test Results

Positive, Negative, or Indeterminate Results

- A high (positive) result means your phenylalanine level is above your target range. Repeat the test to confirm the result. Do not change your diet or treatment unless advised by your doctor or healthcare professional.
- A normal (negative) result means your phenylalanine level is within or below your target range. Continue your usual management plan and test again as recommended by your healthcare professional.
- An invalid (indeterminate) result means the test did not produce a valid reading, which may be due to too little blood or a test error. Repeat the test with a new capsule and a fresh blood sample.

Test Limitations

This test is designed for measuring phenylalanine in capillary (finger-prick) blood only and must be used according to the Instructions for Use.

Results can be affected by incorrect sampling, expired or damaged capsules, or by performing the test outside the recommended temperature or humidity range.

The test measures phenylalanine concentration only and cannot diagnose or rule out any disease. Always interpret your results together with medical advice from your healthcare professional.

**Possibility of False Results**

As with all diagnostic tests, false high or false low results can occur. Possible causes include using expired or damaged capsules, an inadequate blood sample, incorrect handling, or interference from certain blood components such as high lipids or bilirubin.

If your result does not match how you feel, or if repeated results seem unusual, contact your healthcare professional for further testing or advice.

**Factors That May Affect Test Results**

Several factors can influence your phenylalanine result. To ensure reliable measurements, follow all instructions carefully and consider the points below.

**Sample-related factors:**

- Very high or very low haematocrit (red blood cell levels) may affect the result.
- Too little blood can cause an invalid or indeterminate result.
- Damaged (haemolysed) blood samples or contact with alcohol, water, or other liquids may interfere with the test.
- Samples not tested immediately or stored outside the recommended conditions may give incorrect results. No significant interference was observed from common substances at normal levels, according to CLSI EP07-A3 criteria.

**Physiological and dietary factors:**

- Recent meals or fasting can change phenylalanine levels depending on protein intake.
- Illness, infection, or stress may temporarily influence amino acid metabolism.
- Certain medicines or supplements can affect phenylalanine metabolism; ask your doctor if you are unsure.
- Dehydration can alter blood concentration and affect the result.

**Device and environmental factors:**

- Performing the test outside the recommended temperature or humidity range can affect accuracy.
- Expired or damaged capsules may lead to unreliable results.
- Incorrect handling or device operation may produce an error or invalid result.
- Very high levels of lipids, bilirubin, or other blood components can interfere with detection.

**Caution**

Users should not make any medical decisions without first consulting an appropriate healthcare professional.

This Phe test is intended for self-testing to monitor an existing, previously diagnosed condition. Treatment should only be adapted following the advice of a qualified healthcare professional.

**Reporting of Serious Incidents**

If a serious problem or incident happens when using this test, please report it to the manufacturer and to the national authority in your country.

Contact details for the manufacturer are provided at the end of this document.

**Analytical Performance Characteristics**

The Egoo Phenylalanine (Phe) Test is intended for the quantitative measurement of phenylalanine in human blood using the Egoo System. The test is based on an enzymatic reaction specific to L-phenylalanine, providing results proportional to the phenylalanine concentration.

Analytical sensitivity was established in accordance with CLSI EP17:

Limit of quantification (LoQ): 23 µmol/L

Measuring interval: 23–1,000 µmol/L

Precision was evaluated in accordance with CLSI EP05 and met predefined acceptance criteria (≤ 10 % CV) across clinically relevant phenylalanine concentrations. Method comparison with a laboratory reference met-

hod (LC-MS/MS), performed in accordance with CLSI EP09, demonstrated good agreement and no clinically relevant bias at phenylalanine concentrations relevant to PKU management.

Stability was evaluated in accordance with CLSI EP25. The test kit remains stable for at least 12 months when stored at –18 °C.

Interference testing, performed in accordance with CLSI EP07, showed no clinically significant interference from common endogenous substances, commonly used medications, or PKU-specific therapies.

When used as instructed, the Egoo Phenylalanine Test provides reliable results suitable for home monitoring of phenylalanine in individuals with phenylketonuria (PKU).

**Clinical Performance Characteristics**

The clinical performance of the Egoo Phenylalanine System was evaluated in a prospective clinical study including children with phenylketonuria (PKU) and healthy adults. The study assessed agreement between capillary whole-blood measurements obtained with the Egoo system and dried blood spot (DBS) samples analysed by LC–MS/MS, using paired samples collected across multiple study visits.

A total of 100 paired measurements covering the clinically relevant phenylalanine concentration range were included in the evaluation.

Method comparison, performed in accordance with CLSI EP09-A3, demonstrated good analytical agreement, with regression analyses showing no clinically relevant proportional or constant bias.  
Bias at clinically relevant PKU decision levels (120, 360, and 600 µmol/L) was within predefined acceptance criteria, supporting clinical interpretation for PKU monitoring.

Longitudinal within-patient data showed consistent tracking of phenylalanine levels over time, demonstrating suitability for repeated measurements in home or near-patient settings.

No adverse events, adverse device effects, or device deficiencies were reported during the study.

When used according to the Instructions for Use, the Egoo Phenylalanine System provides clinically reliable results suitable for monitoring phenylalanine in individuals with PKU.

## Safety and Caution Information

Please read all instructions carefully before using the test. Incorrect handling, storage, or interpretation of results may lead to inaccurate outcomes.

### General precautions:

- Use the Phe test only as described in this Instructions for Use to measure phenylalanine in capillary (finger-prick) blood.
- Do not use the device to diagnose any disease or to test other blood components.
- Each test capsule and lancet is for single use only. Do not reuse them.
- Do not use expired or damaged capsules. Check the expiry date before testing.
- Store and use the Phe test only within the temperature and humidity ranges specified in this Instructions for Use.
- Keep the Phe test and all accessories out of reach of children.

### Sample handling:

- Use only fresh capillary blood as described in the Instructions for Use.
- Do not use stored or previously frozen blood unless the Instructions for Use specifically allows it.
- Avoid contact of the blood sample with alcohol, water, or cleaning products.
- If the blood drop is too small or smeared, collect a new sample from another finger.

### Interpreting your results:

- Test results should never be the only basis for medical decisions. Always discuss them with your healthcare professional.
- If your result is outside your target range or does not match how you feel, repeat the test and seek professional advice before taking any action.

- Unexpected or inconsistent results (for example, very high or very low values, or frequent invalid readings) may indicate a problem with the test or device. Contact customer support or your healthcare provider.
- Any serious incident related to the use of this device should be reported to the manufacturer and to the national authority in your country. Contact details are provided at the end of this leaflet.

## Storage and Environmental Conditions

- Keep the device and test capsules away from direct sunlight, heat, and moisture.
- Use each test capsule immediately after opening its pouch.
- Do not use the device if it has been dropped, damaged, or stored outside the specified conditions.

## About Phenylketonuria (PKU) and Why Monitoring Matters

Phenylalanine (Phe) is an essential amino acid that comes from the protein in food. In healthy people, Phe is changed in the liver into another amino acid, tyrosine, by an enzyme called phenylalanine hydroxylase (PAH). People with phenylketonuria (PKU) or related conditions called hyperphenylalaninaemia (HPA) have reduced or

missing activity of this enzyme. As a result, Phe builds up in the blood.

### Why High Phe Levels Matter

If Phe levels stay too high, they can affect brain development and thinking ability, especially in babies and young children. In older children and adults, high levels may cause problems with mood, concentration, or behaviour. Women with PKU who become pregnant need to keep Phe within the recommended range to protect the baby from complications ("maternal PKU syndrome").

### Treatment and Monitoring

PKU is managed through a special low-protein diet and, in some cases, medication such as sapropterin or pegvaliase. Regular monitoring of Phe levels helps to keep treatment effective and prevents long-term complications.

### Typical target Phe ranges:

(European PKU Guidelines, van Wegberg et al., 2017)

- Children under 12 years: 120–360 µmol/L
- Adolescents and adults: 120–600 µmol/L
- Women planning pregnancy or pregnant: 120–360 µmol/L

Your healthcare professional will tell you which range applies to you.

### How Common is PKU?

PKU is a rare inherited condition that affects about 1 in 10 000 babies in Europe. The rate varies between countries – higher in some regions such as Ireland and Turkey, and

lower in others such as Finland. Both boys and girls can be affected. Almost all European countries include PKU in their newborn screening programmes, so most babies are diagnosed soon after birth.

Early detection and regular monitoring help people with PKU maintain normal growth, development, and long-term health.

**Further Support**

For additional information and advice, please visit the Egoo Health website ([www.egoo.health](http://www.egoo.health)) or reach out to your national PKU society and helplines.

**Troubleshooting**

- 1

**The app can't find my Egoo Device. What should I do?**

Check that the device is turned on and that the blue ring light is steady. Turn on Bluetooth on your phone and reopen the app.
- 2

**The capsule doesn't "click" into place.**

Hold the capsule by the top sides only. Align it correctly and press down gently until you hear a click.
- 3

**The tray doesn't open after the test.**

Wait a few seconds. If it stays closed, turn the device off, wait 10 seconds, then turn it on again.
- 4

**The app shows "Device Error."**

Turn off the device, wait 10 seconds, then turn it on again. If the error persists, contact Egoo Support.
- 5

**The app lost connection during the test.**

Move your phone closer to the device. The app will reconnect automatically and display the result when ready.
- 6

**I see air bubbles or not enough blood in the pipette.**

Collect a new sample. Hold the pipette steady until it fills to the line. Do not squeeze your finger; instead, gently massage it from the base to the fingertip. Warm your hands by washing them with warm water.

- 7

**No plasma shows on the transfer stick.**

Wait 30 seconds after closing the lid. If no plasma appears, repeat the procedure with a new Egoo Collect.
- 8

**The result seems too low or too high.**

Make sure the capsule has thawed for 10 minutes, that you used 40 µL of blood, and that you started the test immediately after sampling.
- 9

**The light ring is off and the device won't turn on.**

Check the power plug and socket. Press and hold the button inside the ring for 2 seconds.
- 10

**I spilled a sample on the device.**

Unplug the power cord. Wipe the surfaces with a soft cloth and 75% ethanol or isopropanol. Do not pour liquid directly onto the device.
- 11

**I am unsure how to use the device.**

Practise first using the reusable demo capsule included with the device. This helps you learn tray handling and app operation before running a real test.
- 12

**The tip of the transfer stick did not stay in the capsule after inserting it.**

Press the tip of the transfer stick firmly into the capsule and wait for a click.



# Technical and Customer Support

If the test or device does not work as expected, contact Egoo Health:

- [support@egoo.health](mailto:support@egoo.health)
- [www.egoo.health/support](http://www.egoo.health/support)

Report any serious incident to the manufacturer and your national health authority.

## About This Document

This Instruction for Use consists of two parts (A and B). Please read both parts in full.

**Reference Number:** e80255

**IFU Version:** 2026-01-06

**Revision Date:** 2026-xx-xx

### Manufacturer

Egoo Health ApS  
Hareskovhvilevej 3  
DK-3500 Værløse  
Denmark  
CVR Number: 39507730  
[www.egoo.health](http://www.egoo.health)  
[info@egoo.health](mailto:info@egoo.health)