Instructions for use

sphingotest® penKid®

Immunoluminometric assay for the quantification of Proenkephalin A 119-159 in human EDTA plasma.

For Research Use Only. Not for Diagnostic Procedures.

English

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RUO

2...8°C

Σ 96

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Intended use

The sphingotest® penKid® is a non-automated immunoluminometric assay (ILMA) for the quantitative measurement of Proenkephalin A 119-159 in human EDTA plasma. The product is for research use only. It is not intended for diagnostic or therapeutic purpose.

Background information

Proenkephalin A 119-159 (penKid) is a stable mid-regional fragment of Proenkephalin A and has been established as a surrogate plasma marker for the unstable enkephalin peptides that are derived from the same precursor (1-3). Enkephalins are endogenous pentapeptides that are involved in various physiological processes. Enkephalin and its receptors are highly abundant in the kidney (2, 4)

Test principle

The sphingotest® penKid® is an immunoluminometric assay (ILMA) for the determination of penKid in human EDTA plasma.

Two antigen-specific monoclonal antibodies are used that bind penKid (antigen) at two different epitopes. One of the antibodies is luminescent-labelled (tracer antibody), while the other is immobilised on the inside of the microtiter plate (MTP) wells (capture antibody).

During incubation, both antibodies react with the penKid molecules in the plasma sample. In this way, the tracer antibody is indirectly bound to the surface of the MTP. Afterwards, the residual excess tracer is completely removed by careful washing.

The amount of captured tracer antibody is determined by measuring the luminescence in a suitable MTP luminometer, using sphingotest® Lightning reagents. The luminescence signal is directly proportional to the penKid concentration of the respective plasma sample. Parallel measurement of the included calibrators, with lot-specific assigned concentrations of synthetic human penKid, enables the preparation of a calibration curve, through which the unknown penKid concentration in the sample can be deduced.

Reagents and materials provided

Material	**Quantity**	**Description and Reconstitution**
CAL 1 CAL 2 CAL 3 CAL 4 CAL 5	5 vials in total, lyophilized	Lyophilized calibrators. 1 vial is provided per each calibrator level and has to be reconstituted with 500 µL ZERO MATRIX. Refer to quality report for concentration details.
CON A CON B	2 vials in total, lyophilized	Lyophilized controls. 1 vial is provided per each control level and has to be reconstituted with 500 µL ZERO MATRIX. Refer to quality report for concentration details.
PEKZM ZERO MATRIX	1 bottle, 4 mL, liquid	Ready-to-use ZERO MATRIX for reconstitution of calibrators and controls
PEKMP MICROPLATE	1 microplate (MTP) with 96 cavities	Ready-to-use microplate coated with anti- penKid antibody (mouse monoclonal)
PEKTR TRACER	1 bottle, lyophilized	Lyophilized luminescent labelled anti- penKid antibody in reaction buffer. To be reconstituted in 18 mL BUFFER.
PEKBU BUFFER	1 bottle, 18 mL, liquid	Ready-to-use buffer solution for reconstitution of TRACER.

SPHWA WASH	1 bottle 22 mL, liquid	Concentrated sphingotest® WASH universal solution. To be diluted with 1,100 µL pure water.
Adhesive foil	1	Black colored adhesive foil for light protected assay incubation. Used to cover sampled microplate prior of incubation start
IFU	1	Print version of the instructions for use.
Quality report	1	Lot specific quality report.

Reagents and materials required but not provided

- Microlitre pipettes (50 µL, 150 µL, 500 µL) with replaceable plastic tip
- Multichannel pipette (150 µL) with replaceable plastic tip
- Vortex mixer
- Laboratory water grade 2 (acc. ISO 3696:1987)
- Bottle with lid or screw cap (1,100 mL)

Special material required but not provided

- sphingotest® Lightning (cat. No. LIG30): contains reagents sufficient for up to 3,000 single luminescence measurements; contains controls for daily system suitability test of the MTP luminometer (light inspection check)
- F8 Strip Plate (microplate with 12 strips and each 8 wells, uncoated, white, F-bottom); for running a light inspection check using the low and high sphingotest® Lightning controls
- Automated MTP washing device (e.g. Wellwash, Thermo Scientific)
- MTP luminometer with two injectors, each of 100 µL injection volume (e.g. Centro LB 963, Berthold Technologies GmbH & Co. KG, Wildbad, Germany)
- Software and validation tool compatible with the MTP luminometer (e.g. Instrument Control and Evaluation, Berthold Technologies GmbH & Co. KG, Wildbad, Germany)

Information on device(s) and equipment to combine with sphingotest® penKid®

The sphingotest® penKid® is for use in combination with a flash-type luminometer equipped with sphingotest® Lightning reagents for the measurement and detection of luminescence signals at ambient temperature. For further details concerning the operation of the MTP luminometer, please refer to the manufacturer's instructions for use.

sphingotest® Lightning reagent LIGI1 should be connected to the first injector (injection into well before the measurement position) and sphingotest® Lightning reagent LIGI2 should be connected to the second injector (injection into well in the measurement position) of the MTP luminometer.

It is recommended to use the low and high sphingotest® Lightning controls in combination with a F8 strip from a strip plate (12 x 8, uncoated, white, F-bottom) for a daily system suitability test of the MTP luminometer. For further details please refer to the sphingotest® Lightning instructions for use.

The software used with the MTP luminometer must be programmed with the following specifications to ensure proper measurement of the luminescence signals:

#	Step	Specification
1	Delay	120 seconds
2	Injection of LIGI1 into well before measurement position	100 µL
3	Injection of LIGI2 into well in measurement position	100 µL
4	Measurement duration	1 second

Delay is set for the whole strip plate when inserted into the luminometer.

Ensure that injection and measurement is done together per well (steps 2 to 4) and that there is no significant delay between the injections of LIGI.1 and LIGI.2 and no set delay between the LIGI.2 injection and measurement of the flash luminescence signals. The injection speed should be set to low (200 µL/sec) to prevent sloshing of the reagent liquid.

Key performance characteristics of device(s) and equipment to combine with sphingotest® penKid®

The flash-type MTP luminometer used in conjunction with the sphingotest® penKid® must have the minimum specifications as given in the table below:

Parameter	Specification
MTP type	96-well, flat-bottom, white
MTP dimension (LxWxH)	128.2 x 86.0 x 14.77 mm
Detection unit	Photomultiplier with a spectral range of 340–639 nm
Detection principle	Flash luminescence
Detection sensitivity	< 10 amol ATP
Crosstalk	$< 10^{-6}$
Dynamic range	> 6 decades
Number of injectors	2
Injection volume	100 µL

The acquisition software and validation tool must be compatible with the MTP luminometer.

Restrictions

The sphingotest® penKid® assay has been validated with Centro LB 960 and Centro LB 963 (Berthold Technologies GmbH and Co KG, Wildbad Germany). ICE software (Berthold Technologies GmbH and Co KG, Wildbad Germany) and MikroWin 2010 software (Labsis Laborsysteme GmbH, Neunkirchen-Seelscheid, Germany) were used for instrument control and evaluation.

If another type of MTP luminometer and/or software is used, the user should validate the performance of acquiring the luminescence signals and calculating the results.

Storage and handling of reagents

All reagents must be stored at 2...8°C in the kit packaging until usage. The expiry date specified on the kit packaging and reagents must be observed under all circumstances.

The ready-to-use washing solution can be used for up to four weeks when stored at room temperature. Microbial-contaminated washing solution should be discarded. Contamination can be identified through turbidity or a pH < 6.

The in-use stability of the reconstituted calibrators, controls, ready-to-use tracer and MTP placed in the resealed pouch with desiccant is eight hours when held at room temperature and seven days when stored light-protected at 2…8 °C.

Warnings and precautions

- For research use only. Not for diagnostic procedures.
- The product must only be used by professional users in a laboratory setting.

- Read the instructions for use carefully before performing the test. Test performance can be affected if reagents are improperly prepared or stored under conditions other than those indicated.
- MTP strips cannot be re-used. Use only components belonging to the same kit. Do not combine reagents from kits with different lot numbers or other manufacturers. Do not interchange strips between different MTPs even if they have the same lot number.
- Do not freeze any parts of the test kit.
- Do not use kit components after the expiry date has passed.
- Store the test kit at 2...8°C.
- Do not use damaged kits.
- Wear protective clothing such as laboratory coats, eye/face protection and disposable gloves whenever kit components and human specimens are handled.
- Avoid breathing dust/fume/gas/mist/vapours/spray. (PEKZM (Zero Matrix), PEKBU (Buffer))
- May cause an allergic skin reaction (PEKZM (Zero Matrix), PEKBU (Buffer))
- If on skin, wash with soap and water (PEKZM (Zero Matrix), PEKBU (Buffer))
- If skin irritation or rush occurs, get medical advice.
- Components of this kit contain substances of animal origin.
- Samples should be considered potentially infectious and treated accordingly. At present, no method can guarantee the complete absence of infectious components. All materials should be disposed of as potentially infectious and according to local regulations.
- The strip plate should remain in the sealed pouch until use.
- Bring the test kit and reagent to room temperature before use.
- Use a new pipette tip for each well. Use only unused, disposable material.
- Do not use more than the required amount of liquids.
- sphingotest® penKid® was evaluated with Centro LB 960 and Centro LB 963 (Berthold Technologies GmbH & Co. KG, Wildbad, Germany). Before using any other equipment, a priori assessment by the user is required.
- During the incubation period, proper sealing of the strip plate using the adhesive foil supplied will protect it from light and prevent sample drying, and ensure reproducibility of the results.
- Carefully close all containers after completion of the test.
- Prepared or used reagents and chemicals must be treated as hazardous waste according to the national biohazard safety guidelines or regulations.

Sample collection and handling

- Collect whole blood in a suitable collection tube containing EDTA as an anticoagulant following the instructions provided by the manufacturer of the sample collection device.
- Separate the plasma by spinning the collection tube following the manufacturer's instructions. Suitable collection tubes have been verified with the centrifugation conditions listed in the table below:

Collection tube	**Centrifugation condition (swing-out rotor)**
EDTA S-Monovette®	2000*g* for 15 minutes at ambient temperature
EDTA Vacutainer	2000*g* for 15 minutes at ambient temperature
EDTA Vacuette®	2000*g* for 15 minutes at ambient temperature

- Carefully transfer the EDTA plasma into a fresh vial.
- Do not use lipemic, haemolytic or contaminated EDTA plasma.
- Sample stability for penKid in non-processed EDTA whole blood or respective processed EDTA plasma is given for up to 48 hours when stored at ambient (<30 °C) or refrigerated (2...8°C) conditions.
- For longer-term storage, EDTA plasma must be stored at ≤ -15°C or lower until use. Up to five freeze-thawing cycles do not influence the test result.

Sample preparation

A plasma of freshly collected samples can be processed immediately after its centrifugation and separation from the blood cells.

Where samples from refrigerated or frozen conditions are used, allow them to incubate to ambient temperature for at least one hour.

The native sample material is used without dilution.

Bring all kit components to ambient temperature.

Prepare the reagents as described in the chapter “Reagent preparation”.

All liquid components – including the samples – should be mixed before use (avoid foam formation).

If applicable, prepare an assignment plan for the MTP wells.

Preparation of the assay

Remove the test kit from its storage condition and allow it to reach ambient temperature.

Reagent preparation

1. Reconstitute calibrators CAL 1 to CAL 5 by adding 500 µL of zero matrix into each calibrator vial. Gently mix for 10 minutes and ensure that all lyophilised material is completely resolved.
2. Reconstitute controls CON A and CON B by adding 500 µL of zero matrix into each control vial. Gently mix for 10 minutes and ensure that all lyophilised material is completely resolved.
3. Reconstitute the tracer by adding approx. half the volume (approx. 9 mL) of the buffer to the tracer bottle. Retain the other half of the buffer in the buffer bottle. Gently mix for 10 minutes and ensure that all lyophilised material is completely resolved. Transfer the solution to the buffer bottle to obtain the ready-to-use tracer solution (18 mL).
4. Prepare the washing solution by diluting the wash concentrate provided with 1,100 mL of laboratory water (grade 2).

Quality control

The calibrators and controls must be included in each run and should be run in duplicate.

Quality criteria for calibration standards

The controls (CON A and CON B) supplied with this kit should be used for every preparation and their measurement results must lie within the acceptance ranges specified in the quality report. In case of unacceptable control values, it is recommended to determine the underlying cause and implement appropriate corrective measures.

Internal quality control

The results of the controls must be found within the ranges indicated on the quality report.

If any of the criteria above are not met, the assay is invalid and should be repeated.

Additional controls may be required according to guidelines or local, state, and / or federal regulations.

For further assistance, please contact SphingoTec using the provided contact details.

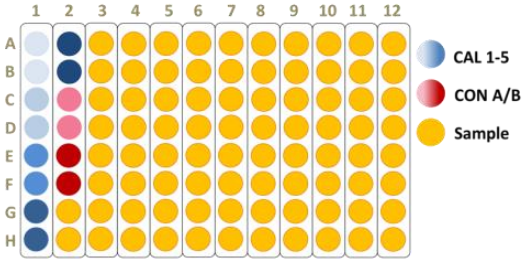
Traceability

The sphingotest® penKid® is calibrated by weighted synthetic human penKid (substance 41). PEKCA.16001 calibrators serve as the reference calibration for the product.

Assay procedure

Microtiter plate layout

Pipette calibrators, controls and samples according to the following scheme



1.	Pipette	Calibrators (CAL1-CAL5) Controls (CONA, CONB) Patient samples (SP1-SP41)	50 µL each
2.	Pipette	Tracer solution	150 µL in all wells
3.	Incubation	Cover the strip plate with the adhesive foil provided. Incubate 1 hour ± 15 min, preferably at 18-29°C (without shaking)	
4.	Aspirate	Aspirate the reaction mixture from all wells	
5.	Wash	Wash each well 4x with 350 µL washing solution; the use of an automatic MTP washing device is recommended.	
6.	Drip off	After the last washing step aspirate all solutions from each well and allow the empty MTP to drip off for 5-10 minutes upside down on cellulose paper.	
7.	Measurement	Measure the luminescence signals in a suitable MTP luminometer equipped with the sphingotest® Lightning reagents and programmed with the measurement procedure as outlined in the section "Information on device(s) and equipment to combine with sphingotest® penKid®".	

Calculation of results

The mean luminescence signals obtained for the calibrators are used for calibration. The mean signal for each calibrator (y-axis) and its respective target concentration (x-axis, refer to the quality report for target values) is used to apply a cubic spline (no smoothing) non-linear fit to generate the calibration curve. The penKid concentrations (pmol/L) for controls, as well as all patient samples, are deduced from this calibration curve using the mean luminescence signal from the respective duplicate measurement.

Calculation example

Example values (RLU = Relative Light Units) measured on a Centro LB960/LB963 (Berthold Technologies GmbH & Co. KG, Wildbad, Germany) operated with ICE software (Berthold Technologies GmbH & Co. KG, Wildbad, Germany) are shown in the table below. The depicted calibrator and control concentrations and signals (CAL1 to CAL5, CON A and CON B) are example values. For lot-specific concentrations, please refer to the enclosed quality report.

Calibrator level	Target penKid concentration (pmol/L)	Obtained mean signal (RLU)
CAL 1	30.5	641
CAL 2	76.2	1,306

CAL 3	190	3,806
CAL 4	476	13,608
CAL 5	1,190	51,685
CON A	55.4	977
CON B	325	7,880

The obtained calibration curve applying a cubic spline non-linear fit (no smoothing) is shown in the figure below:

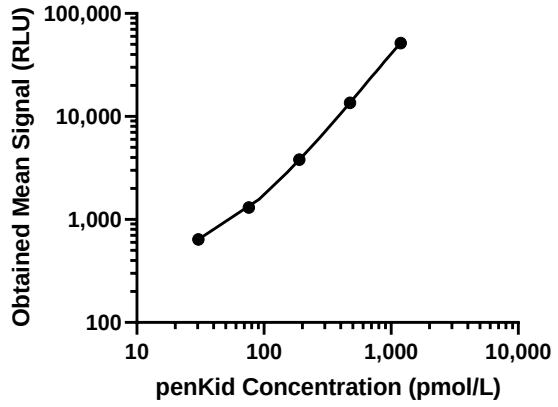


Figure 1: Exemplary calibration curve

Analytical performance characteristics

Calibration and measuring range

The calibrators contain synthetic human penKid and are supplied with lot-specific penKid concentrations. The concentration ranges of the calibrators are targeted from 30 pmol/L to 1,172pmol/L (see quality report for assigned lot-specific concentrations). The concentrations of the calibrators have been validated using a stock calibration series prepared with synthetic human penKid.

Accuracy of measurement

Precision of measurement

a. Repeatability and Within Laboratory Precision

Precision for repeatability and within-laboratory precision was established with plasma samples with analyte concentration covering the low, mid and high concentration range. The samples were analysed for 20 days in two runs with duplicate measurements with two lots respectively and according to the CLSI EP05 Ed3. The sphingotest® penKid® indicates repeatability of below ±10% for penKid concentrations from 50 to 1,000 pmol/L.

Sample ID	Lot	Mean penKid (pmol/L)	Repeatability CV	Within-laboratory CV
LOD-6	1	53.0	4.0%	7.2%
	2	52.5	6. 1%	9.9%
LOQ-1	1	69.4	3.3%	5.7%
	2	68.1	6.3%	10.3%
LOQ-2	1	103.7	3.1%	5.3%
	2	103.4	3.7%	7.2%
LOQ-3	1	243.5	1.8%	4.7%
	2	243.9	3.5%	5.5%
LOQ-4	1	423.0	2.5%	3.9%
	2	422.7	3.0%	5.4%
LOQ-5	1	1018.3	2.1%	3.3%
	2	986.3	2.8%	5.1%

b. Reproducibility

Reproducibility data were created using human specimens in the concentration ranges 30 to 300 pmol/L. The samples were analysed as five times replicate measurements over five days at three different measurement sites following CLSI EP05 Ed3. The sphingotest®

penKid® indicates a reproducibility of below ±10%.

Sample ID	Mean penKid (pmol/L)	Reproducibility CV
1	34.8	8.3%
2	90.0	6.5%
3	334.8	3.9%

Analytical specificity

Endogenous Interfering substances

The plasma constituents listed in the table below were tested for interference in the sphingotest® penKid®, according to CLSI EP7 Ed3 (Interference Testing in Clinical Chemistry). The listed substance concentrations were found to have no effect on the penKid result at a ±10% interference level.

Tested substance	Tested concentration	Obtained concentration at max. ±10% interference
Bilirubin, unconjugated	40 mg/dL (475 µmol/L)	40 mg/dL (475 µmol/L)
Bilirubin, conjugated	40 mg/dL (684 µmol/L)	40 mg/dL (684 µmol/L)
D-glucose	1000 mg/dL (55 mmol/L)	1000 mg/dL (55 mmol/L)
Haemoglobin	1000 mg/dL	455 mg/dL
Rheumatoid factor	1000 IU/mL	106.9 IU/mL
Total protein	15 g/dL (9 g/dL spike)	15 g/dL (9 g/dL spike)
Triglycerides	2000 mg/dL	2000 mg/dL

Cross-reacting substances

Tested substance	Tested concentration	Obtained concentration at max. ±10% interference
Human anti-mouse antibody (HAMA)	613.1 ng/dL	196.1 ng/mL

Despite preventive measures in assay design, it cannot be entirely ruled out that, in the case of high concentrations of HAMA, unspecific interactions with the tracer antibody may occur. This may lead to false positive results (HAMA effect).

Exogenous interfering substances

The potential interference of drugs in the sphingotest® penKid® was tested following CLSI EP7 Ed3. The concentrations of drugs listed below were found to have no effect on the test result at a ±10% interference level.

Tested substance	Tested concentration	Obtained concentration at max. ±10% interference
Acetyl salicylic acid	3 mg/dL (167 µmol/L)	1.2 mg/dL (66.8 µmol/L)
Captopril	0.264 mg/dL (12.1 µmol/L)	0.264 mg/dL (12.1 µmol/L)
Cephalosporin 3rd Gen (Cefotaxime)	52.8 mg/dL (1,160 µmol/L)	52.8 mg/dL (1,160 µmol/L)
Citrate trisodium	820.6 mg/dL (31,9 mmol/L)	177.8 mg/dL (6.9 mmol/L)
Dexamethasone	1.2 mg/dL (30.6 µmol/L)	1.2 mg/dL (30.6 µmol/L)
Dextro-methorphan	1.56 µg/dL (57.5 nmol/L)	1.56 µg/dL (57.5 nmol/L)
Dobutamine	0.121 mg/dL (4.0 µmol/L)	0.121 mg/dL (4.0 µmol/L)
Epinephrine	0.06 mg/dL (3.3 µmol/L)	0.06 mg/dL (3.3 µmol/L)

Tested substance	Tested concentration	Obtained concentration at max. ±10% interference
Ethanol	600 mg/dL (130 mmol/L)	600 mg/dL (130 mmol/L)
Fentanyl	0.03 mg/dL (0.89 µmol/L)	0.03 mg/dL (0.89 µmol/L)
Furosemide	1.59 mg/dL (48,1 µmol/L)	0.7 mg/dL (21.2 µmol/L)
Gentamycin sulfate	3 mg/dL (62.8 µmol/L)	3 mg/dL (62.8 µmol/L)
Heparin (NMH)	330 IU/dL	330 IU/dL
Heparin (UFH)	1250 IU/dL	1250 IU/dL
Ibuprofen	21.9 mg/dL (1.06 mmol/L)	7.6 mg/dL (367.9 µmol/L)
Iohexol	100 mg/dL (121.8 µmol/L)	100 mg/dL (121.8 µmol/L)
L-ascorbic acid	5.25 mg/dL (299 µmol/L)	5.25 mg/dL (299 µmol/L)
Loratadine	8.7 µg/dL (0.27 µmol/L)	8.7 µg/dL (0.27 µmol/L)
Nicardipine HCL	46.5 µg/dL (0.97 µmol/L)	46.5 µg/dL (0.97 µmol/L)
Paracetamol (Acetaminophen)	15.6 mg/dL (1.03 mmol/L)	3.4 mg/dL (224.5 µmol/L)
Phenylephrine	3.0 µg/dL (0.18 µmol/L)	14.88 µg/dL (0.89 µmol/L)
Sacubitril	0.915 mg/dL (22.2 µmol/L)	0.8 mg/dL (19.4 µmol/L)
Sacubitrilat	0.915 mg/dL (22.2 µmol/L)	0.7 mg/dL (17.0 µmol/L)
Salicylic acid	2,86 mg/dL (207 µmol/L)	1,3 mg/dL (94.1 µmol/L)
Tiotropium	0.0048 ng/dL (0,1 nmol/L)	0.0057 ng/dL (0,12 nmol/L)
Valsartan	1.17 mg/dL (26.9 µmol/L)	1.17 mg/dL (26.9 µmol/L)
Vancomycin	10 mg/dL (69 µmol/L)	8.7 mg/dL (60.0 µmol/L)

Limit of detection (LoD)

The limit of detection (LoD) for the sphingotest® penKid® has been determined as 29.9 pmol/L. Samples were analysed for 20 days in a single site study using two lots following CLSI EP17-A2.

Limit of quantification (LoQ)

The limit of quantitation (LoQ) of the sphingotest® penKid® has been determined to be 29.9 pmol/L and is defined as the lowest measurement result detectable with a precision of 20% intra-laboratory variance (coefficient of variation, CV). It was determined with samples according to CLSI EP17 A2. The samples were analysed for 20 days in a single site study using two lots.

Upper limit of quantification

The upper limit of quantitation is given by the highest calibrator (CAL5) and is targeted at 1,172 pmol/L (see quality report for assigned lot-specific concentrations).

High dose hook effect (HDH)

The sphingotest® penKid® shows no observational signal loss due to high penKid concentrations up to 100,000 pmol/L, which is about 85 times the upper measuring range of the assay.

Linearity (Measuring range)

The sphingotest® penKid® shows linearity throughout the measuring range, with deviations from linearity below ±10%. To establish the linearity data, 11 concentrations were analysed in triplicate measurement by mixing two samples spanning 16 pmol/L to 1217 pmol/L. Following CLSI EP06 Ed2, linear regression analysis was used for the calculated mean of the triplicate measurement results versus the expected penKid concentration of the prepared samples.

Notice to the user

For getting the appropriate Safety Data Sheets according to EC directive 1907/2006 (REACH) or technical assistance and more information please contact our distribution partner or Sphingotec GmbH (see contact information on the kit label).

Literature

1. Ernst A, Kohrle J, Bergmann A. Proenkephalin A 119-159, a stable proenkephalin A precursor fragment identified in human circulation. Peptides. 2006;27(7):1835-40.
2. Beunders R, Struck J, Wu AH, Zarbock A, Di Somma S, Mehta RL, et al. Proenkephalin (PENK) as a novel biomarker for kidney function. J Appl Lab Med. 2017;DOI: 10.1373/jalm.2017.023598 400-12.
3. Donato LJ, Meeusen JW, Lieske JC, Bergmann D, Sparwasser A, Jaffe AS. Analytical performance of an immunoassay to measure proenkephalin. Clinical biochemistry. 2018;58:72-7.
4. Denning GM, Ackermann LW, Barna TJ, Armstrong JG, Stoll LL, Weintraub NL, et al. Proenkephalin expression and enkephalin release are widely observed in non-neuronal tissues. Peptides. 2008;29(1):83-92.

Symbols

Symbol	Application	Symbol	Application	Symbol	Application
	Consult instructions for use		Article Number		Do not re-use
	For Research use only. Not for diagnostic procedures.		Contents sufficient for (number of) tests		Use by date
	Temperature limit		Batch code		Green dot according to German legislation
	Distributor		Reconstitution		Manufacturer
	Lyophilized				

sphingotest® is a registered trademark. Other product names used in this document serve for identification purposes and may be brands and / or trademarks of their respective companies.

Document Revision History

Revision No.	Date	Changes
01	September 2022	Initial release