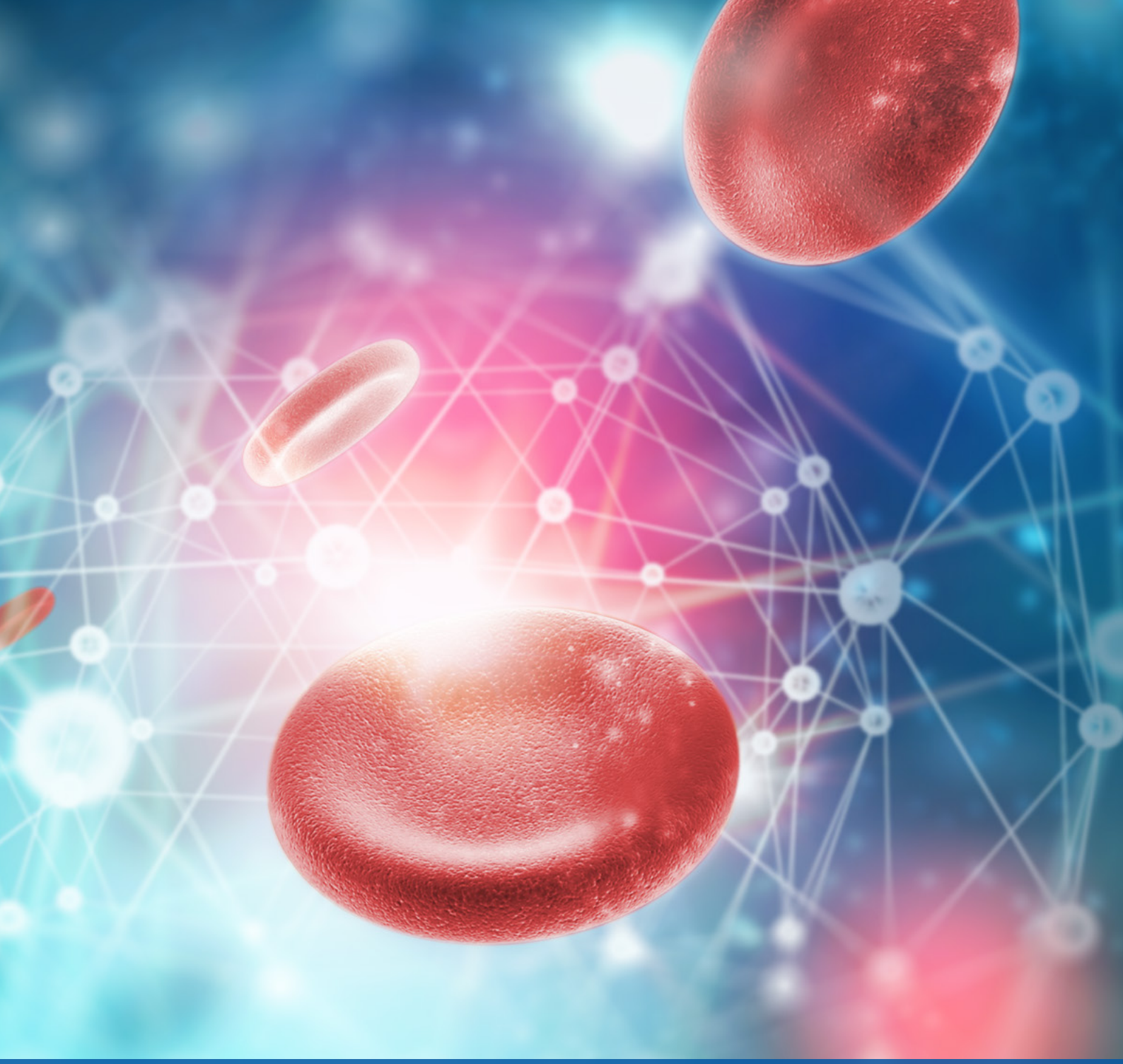


IB10 sphingotest®
product catalog

sphingotec
The Biomarker Company

Our Mission

To improve patient outcomes with innovative diagnostic solutions for acute care in real-time.

SphingoTec develops and markets innovative in vitro diagnostic (CE-IVD) tests for novel and proprietary blood-based protein biomarkers for critical care settings.

SphingoTec's first-in-class biomarker tests are made available on its proprietary whole-blood point-of-care Nexus IB10 platform for convenient and rapid testing in near-patient and laboratory settings alongside a broad standard-of-care test portfolio for acute care.

Our Products

Point of Care Instrument

Novel Tests

Standard of Care Tests

Work With Us

Nexus IB10

NEXUS IB10 Principle

The Nexus IB10 immunochemistry system combines chemistry with microfluidics and centrifugal flow to rapidly prepare a cell free plasma from whole blood that can then be moved through a channel to rehydrate, solubilize and mix with freeze dried immunoconjugates. Using a combination of active flow and capillary action, the test sample is quantitatively measured in 20 minutes* with an optical signal level proportional to the analyte(s) concentration. After addition of the patient sample, the entire test is performed within the Nexus IB10 Analyzer, which provides control of the temperature of the disc, as well as the reaction sequence, centrifugal flow, mixing, incubation time, final signal measurement, quantitation and reporting of results.

Fast & Fully Automated Time to Result 20 Minutes*

Simple & Easy-to-Use

Whole Blood Use

Quantitative Test Results

Multiple Analytes in a Single Run

Connectable to LIMS

The disc products can be stored at 2-8°C for at least 12 months and are stable up to 30 days at room temperature.
For more information, please refer to the individual product IFU. All IB10 sphingotest® test discs are **CE-IVD marked**.
* For IB10 sphingotest® DPP3 the time to result is 22 minutes.

Specification

Feature	Description
Display	109 mm Touch LCD Screen
Method	One Step Sandwich Reaction
Sample Type	Whole Blood and Plasma
Sample Volume	500 µL
Printer	Built-in Thermal Printer
Options	Barcode Reader
Time to Result	20 minutes*
Interface	PC, LIMS
Dimension (mm)	177 (W) x 330 (D) x 177 (H)
Weight	2.4 kg

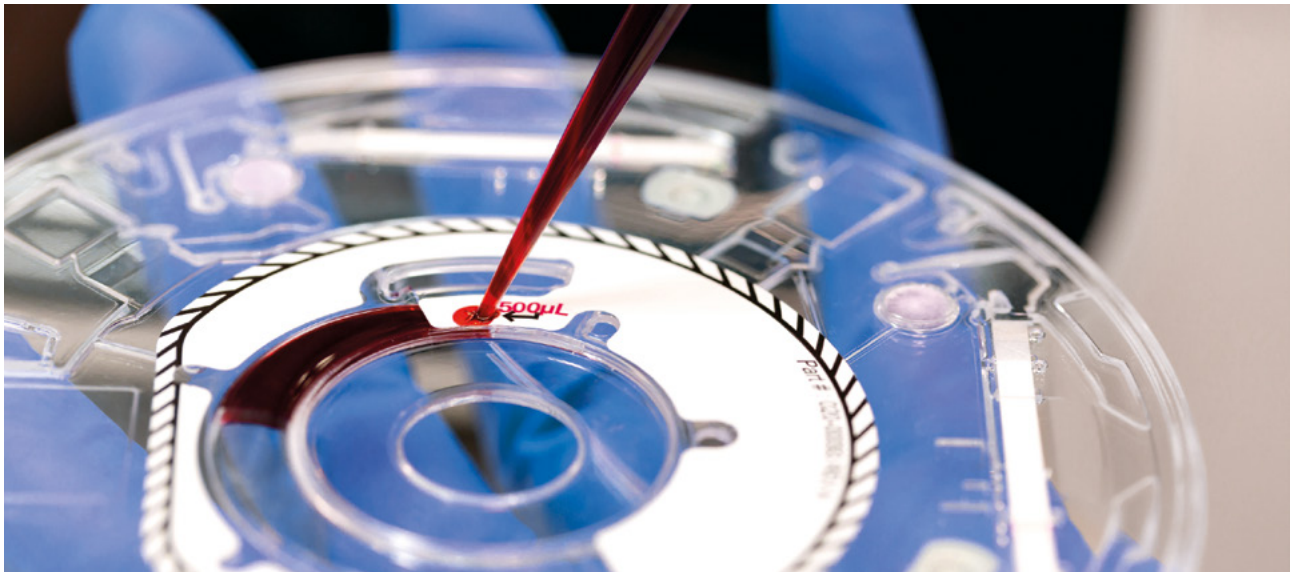
Products

Catalog Nr.	Description
IVR-IB65	**IB10 sphingotest® PCT** Procalcitonin (package of 10 discs)
IVR-IB62	**IB10 sphingotest® penKid®** Proenkephalin (package of 10 discs)
IVR-IB61	**IB10 sphingotest® bio-ADM®** bioactive Adrenomedullin (package of 10 discs)
IVR-IB58	**IB10 sphingotest® DPP3** Dipeptidyl Peptidase 3 (package of 10 discs)
IVR-IB56	**IB10 sphingotest® NT-proBNP** NT-proBNP (package of 10 discs)
IVR-IB55	**IB10 sphingotest® TSH** TSH (package of 10 discs)
IVR-IB54	**IB10 sphingotest® beta-hCG** beta-hCG (package of 10 discs)
IVR-IB53	**IB10 sphingotest® SOB** D-Dimer, NT-proBNP, Troponin I (package of 10 discs)
IVR-IB52	**IB10 sphingotest® D-Dimer** D-Dimer (package of 10 discs)
IVR-IB51	**IB10 sphingotest® 3-in-1 Cardiac** Troponin I, CK-MB, Myoglobin (package of 10 discs)
IVR-IB50	**IB10 sphingotest® Troponin-99** Troponin I (package of 10 discs)

Instrument & Accessories

Catalog Nr.	Description
IVR-IB59	**Nexus IB10 Analyzer** (1 unit)
IVR-IB60	**IB10 EQC** (1 disc)

Catalog Nr.	Description
IVR-IB90	**IB10 Demo Disc** (1 disc)
0105-001211	**Printer Paper** (1 roll)



* For IB10 sphingotest® DPP3 the time to result is 22 minutes.

IB10 sphingotest® penKid®

The assay for the kidney function biomarker Proenkephalin

IB10 sphingotest® penKid® is a rapid point-of-care (POC) immunoassay for the quantitative in vitro determination of Proenkephalin (penKid) in human EDTA whole blood and plasma. The test is designed for professional use only and may be used on sites where near-patient testing is practiced.

Whole Blood vs. Plasma Comparison

All our assays correlate with r=0.9. For more detailed information please read the IFUs or connect with our sales representatives.

Key Features

Easy Handling	
Sample Type	EDTA Whole Blood or Plasma Samples
Time to Result	20 minutes
Measuring Range	50 - 500 pmol/L
Limit of Detection	50 pmol/L
No High Dose Hook Effect	up to 250,000 pmol/L
Analyte Stability for IB10 Measurement	whole blood samples to be tested as soon as possible, but not later than 8 h after collection

Kidney function diagnostics with penKid

Acute kidney injury affects 1 in 3 patients in intensive care units (ICU). Timely information on kidney function is therefore of high importance to early initiate nephron-protective strategies. Existing creatinine-based estimations of the glomerular filtration rate (eGFR) routinely used in critical care settings are unspecific, error-prone and have a substantial time delay. An emerging body of evidence demonstrates that the biomarker Proenkephalin (penKid), detectable with the IB10 sphingotest® penKid® overcomes these limitations by indirectly measuring the levels of the kidney stimulating hormone enkephalin which reflects the true glomerular filtration rate (true GFR) (1,2,3).

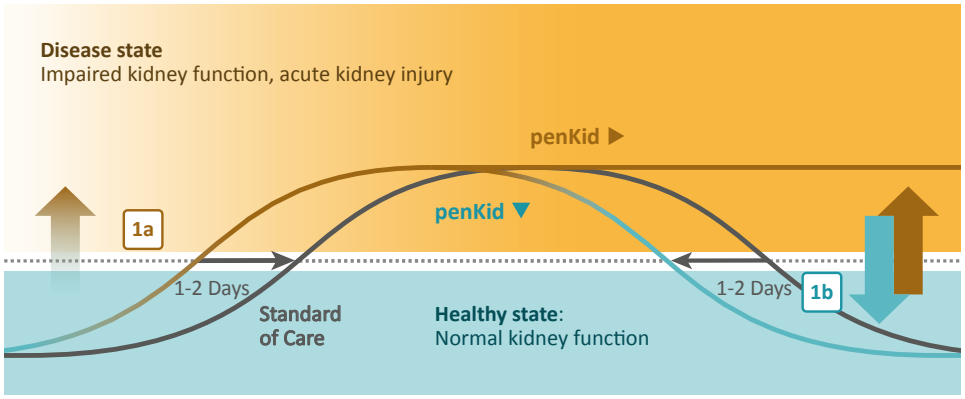


Figure 1

Measuring penKid levels reveals kidney function in real-time and offers a blood-based alternative for the in vivo measurement of true GFR. Rising penKid blood levels (Figure 1, 1a) predict acute kidney injury up to 48 hours earlier than today's standard of care and decreasing levels (Figure 1, 1b) show the normalization of kidney function (4).

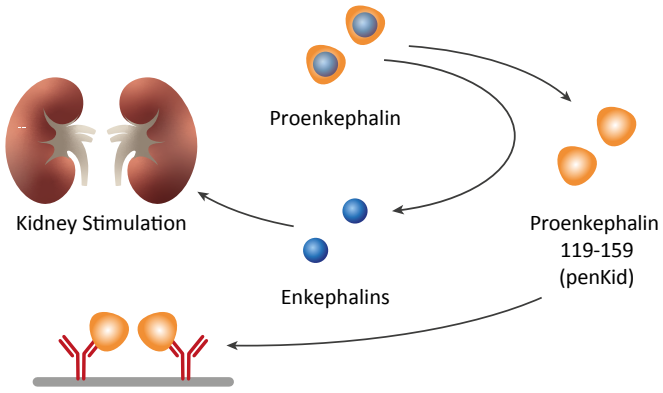


Figure 2

Diagnostic Principle

Kidney function is stimulated by the hormone enkephalin which remains hard to detect. penKid overcomes this limitation by measuring a stable fragment that results out of enkephalin processing (Figure 2).

The median penKid concentration of 4,643 healthy adults was 45 pmol/L; the 99th percentile was 80 pmol/L (5).

penKid

- Is a blood-based parameter that correlates with true GFR (6).
- Admission levels provide direct information about kidney function (1,2).
- Aids in the diagnosis of acute kidney injury (3).
- Is independent from inflammation (7, 8) and common comorbidities (e.g.: hypertension and diabetes) (4).
- Validated through clinical studies in more than 40,000 patients.

References

(1) Beunders R et al. Proenkephalin (PENK) as a Novel Biomarker for Kidney Function. *J Appl Lab Med*. 2017 Nov 1;2(3):400-412.

(2) Beunders R et al. Proenkephalin Compared to Conventional Methods to Assess Kidney Function in Critically Ill Sepsis Patients. *Shock*. 2020 Sep;54(3):308-314.

(3) Khorashadi et al. Proenkephalin: A New Biomarker for Glomerular Filtration Rate and Acute Kidney Injury. *Nephron* . 2020;144(12):655-661.

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(5) Marino R et al. Diagnostic and short-term prognostic utility of plasma pro-enkephalin (pro-ENK) for acute kidney injury in patients admitted with sepsis in the emergency department. *J Nephrol*. 2015 Dec;28(6):717-24.

(6) Donato LJ, et al. Analytical performance of an immunoassay to measure proenkephalin. Clin Biochem. 2018;58:72-7.

(7) Caironi et al. Circulating Proenkephalin, Acute Kidney Injury, and Its Improvement in Patients with Severe Sepsis or Shock. Clin Chem. 2018;64(9):1361-9.

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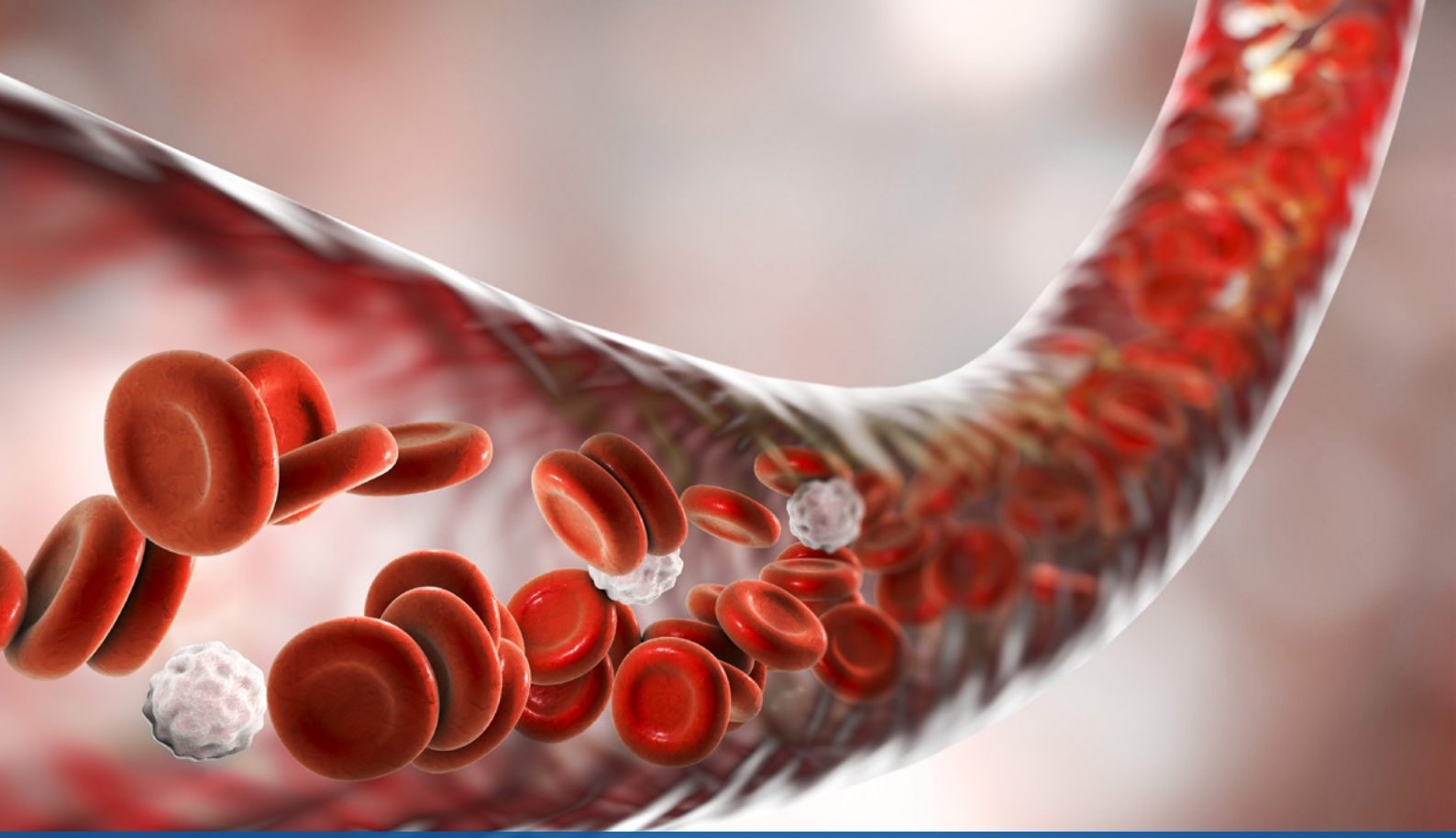

IB10 sphingotest® bio-ADM®

The assay for the endothelial function biomarker bioactive Adrenomedullin

IB10 sphingotest® bio-ADM® is a rapid point-of-care (POC) immunoassay for the quantitative in vitro determination of bioactive Adrenomedullin (bio-ADM) in human EDTA whole blood or plasma. The test is designed for professional use only and may be used on sites where near patient testing is practiced.

Whole Blood vs. Plasma Comparison

All our assays correlate with r=0.9. For more detailed information please read the IFUs or connect with our sales representatives.

Key Features

Easy Handling	
Sample Type	EDTA Whole Blood or Plasma Samples
Time to Result	20 minutes
Measuring Range	45 - 500 pg/mL
Limit of Detection	45 pg/mL
No High Dose Hook Effect	up to 100,000 pg/mL
Analyte Stability for IB10 Measurement	as soon as possible, but not later than 6 hours for whole blood

The relevance of endothelial function in critical care

In critical care settings, one of the main causes of organ failure and ultimately mortality is loss of endothelial function, which is associated with leakage of blood vessels. Although the symptoms of loss of endothelial functions are well-known, there are currently no simple, blood-based detection methods established for monitoring the worsening and improvement of endothelial function.

bio-ADM can easily be measured in the blood enabling the assessment of the endothelial function up to 48 hours before the symptoms become visible. Regular assessment of the bio-ADM levels allows for the monitoring of critically ill patients.

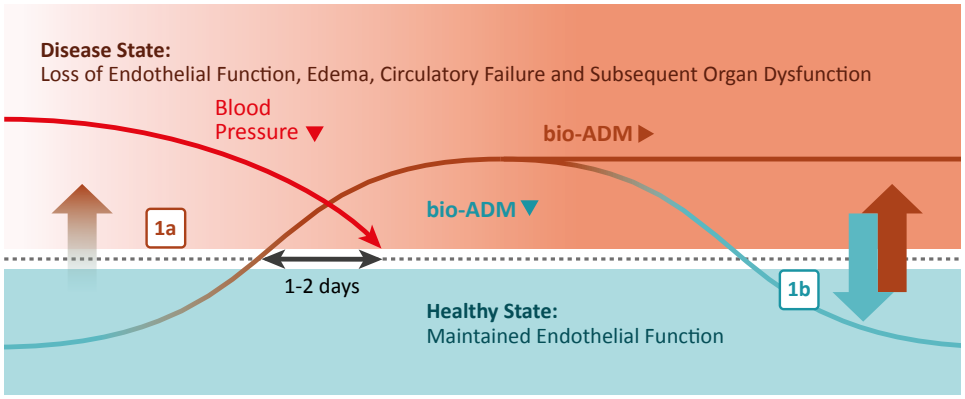

Figure 1

Elevated bio-ADM blood levels predict both blood pressure drop resulting in shock as well as leaky vessels leading to the formation of edema (Figure 1, 1a). Decreasing levels of bio-ADM reflect an improvement of the endothelial function, which is closely associated with the patient's clincal condition (Figure 1, 1b).

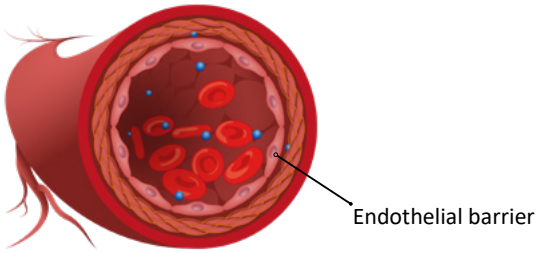

Figure 2a

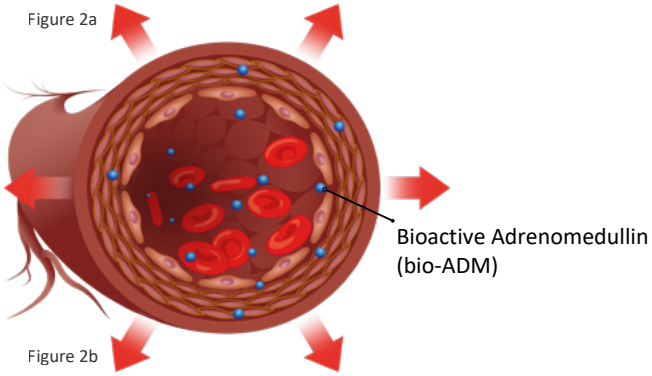

Figure 2b

Healthy State

Research has identified bioactive Adrenomedullin as a controlling hormone of the endothelial barrier, the interior wall protecting the blood vessels (Figure 2a) (1). The median bio-ADM concentration of 200 healthy subjects was 20.7 pg/mL; the 99th percentile was 43 pg/mL (2).

Disease State

In certain conditions such as septic shock (1), cardiogenic shock (3) or acute heart failure (4,5), the endothelial barrier becomes leaky, and additional bio-ADM is produced to reseal the barrier. However, bio-ADM has a second function. It also expands the blood vessels, resulting in a dangerous blood pressure drop, which leads to shock and may ultimately escalate into multiple organ failure (Figure 2b).

bio-ADM

- Is a blood-based parameter for quantifying the blood levels of bioactive Adrenomedullin (6).
- Aids in the early prediction of vasopressor demand in critically ill patients (2).
- Allows monitoring of the endothelial function (1).
- Is independent from common comorbidities (e.g.: hypertension and diabetes) (4).
- Aids in the diagnosis of residual congestion (5).
- Has been validated in more than 35,000 patients.

References

(1) Geven C et al. Vascular Effects of Adrenomedullin and the Anti-Adrenomedullin Antibody Adrecizumab in Sepsis. *Shock.* 2018 Aug;50(2):132-140.

(2) Marino R et al. Plasma adrenomedullin is associated with short-term mortality and vasopressor requirement in patients admitted with sepsis. *Crit Care.* 2014 Feb 17;18(1):R34.

(3) Tolppanen H et al. Adrenomedullin: a marker of impaired hemodynamics, organ dysfunction, and poor prognosis in cardiogenic shock. *Ann Intensive Care.* 2017 Dec;7(1):6.

(4) Ter Maaten JM et al. Bio-adrenomedullin as a marker of congestion in patients with new-onset and worsening heart failure. *Eur J Heart Fail.* 2019 Jun;21(6):732-743.

(5) Voors et al. Adrenomedullin in heart failure: pathophysiology and therapeutic application. *Eur J Heart Fail.* 2019 Feb;21(2):163-171.

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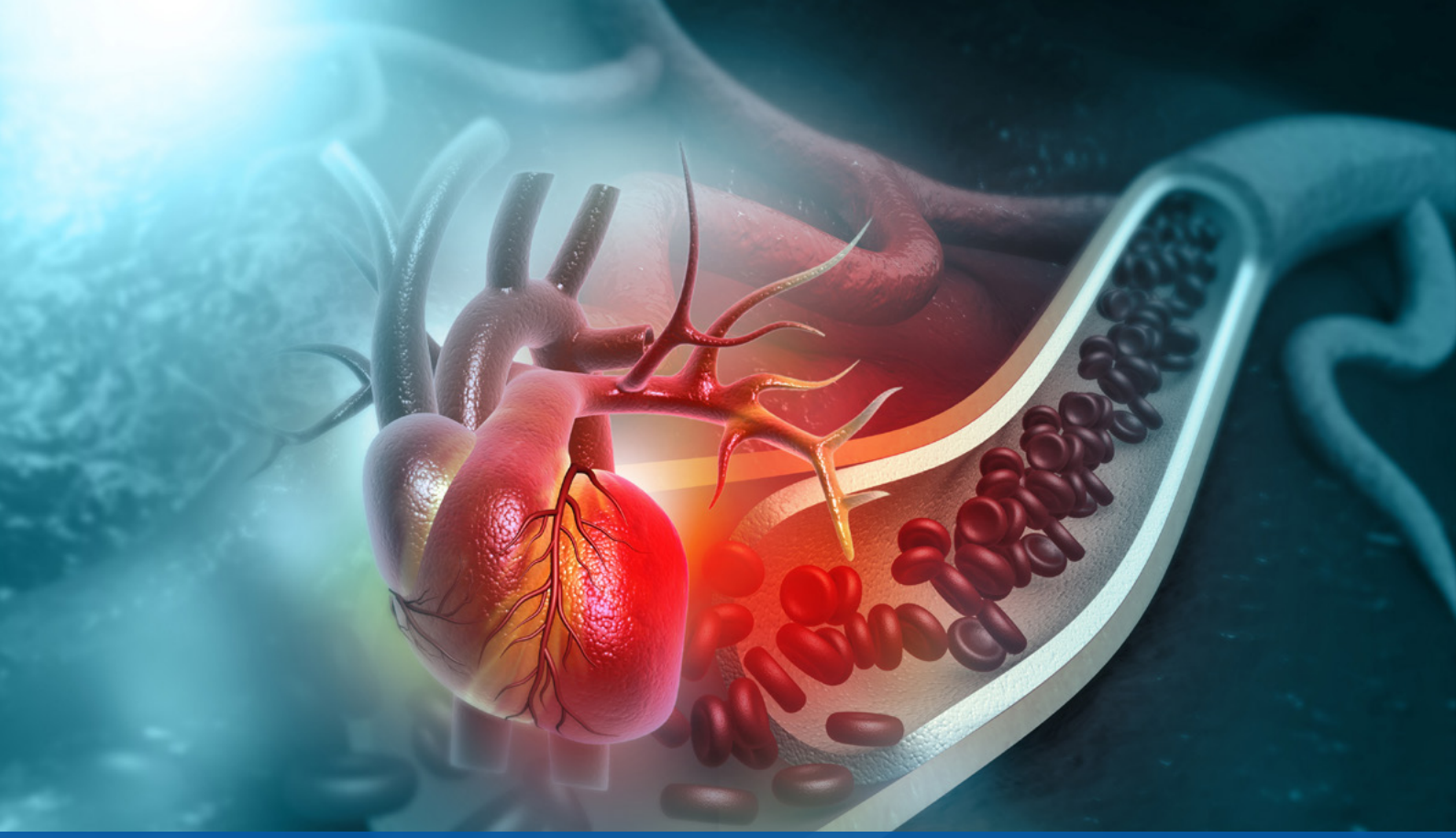

IB10 sphingotest® DPP3

The assay for measuring DPP3-release, a cause of cardiac depression

IB10 sphingotest® DPP3 is a rapid point-of-care (POC) immunoassay for the quantitative in vitro determination of Dipeptidyl Peptidase 3 (DPP3) in human EDTA whole blood and plasma. The test is designed for professional use only and may be used on sites where near patient testing is practiced.

Whole Blood vs. Plasma Comparison

All our assays correlate with r=0.9. For more detailed information please read the IFUs or connect with our sales representatives.

Key Features

Easy Handling	
Sample Type	EDTA whole blood or plasma samples
Time to Result	22 minutes
Measuring Range	5 - 150 ng/mL
Limit of Detection	5 ng/mL
No High Dose Hook Effect	up to 6,000 ng/mL
Analyte Stability for IB10 Measurement	2 hours for whole blood

The pathomechanism behind DPP3-release

Recently, a so far unknown disease mechanism leading to short-term organ failure was identified. According to the new findings, the release of the cardiac depressant factor DPP3 into the bloodstream plays a major role in sudden loss of heart function (1,2). DPP3 is a natural enzyme that plays a vital role in the recycling of cellular proteins. When massive, uncontrolled cell death occurs, for example, in major surgeries (3), burns (4), cardiogenic shock (1,5), or sepsis (6), DPP3 is released into the bloodstream, having a toxic-like effect on the human biology. This is because in the bloodstream, DPP3 inactivates angiotensin II, a hormone that is important for the heart function. This inactivation is leading to hemodynamic instability and consequently cardiac depression.

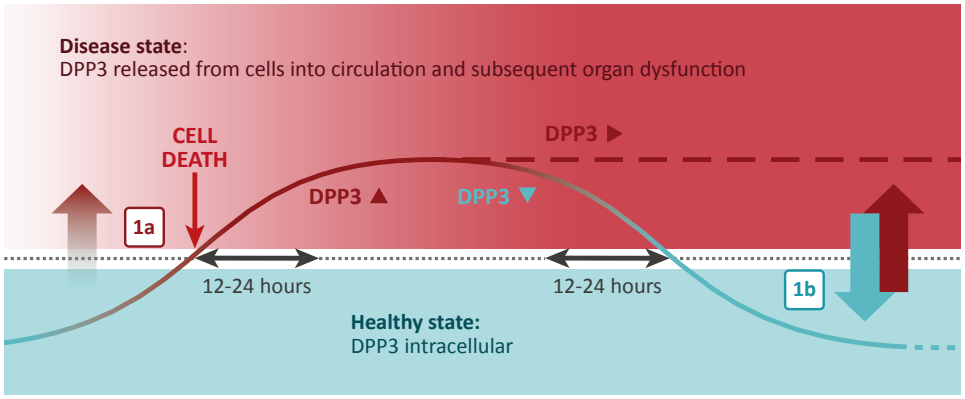

Figure 1

High or rising DPP3 blood levels (Figure 1, 1a), determined with the IB10 sphingotest® DPP3 indicate worsening of the patient's status that can lead to short term organ failure and death.

On the other hand, decreasing DPP3 levels (Figure 1, 1b) indicate a substantially reduced mortality risk (1).

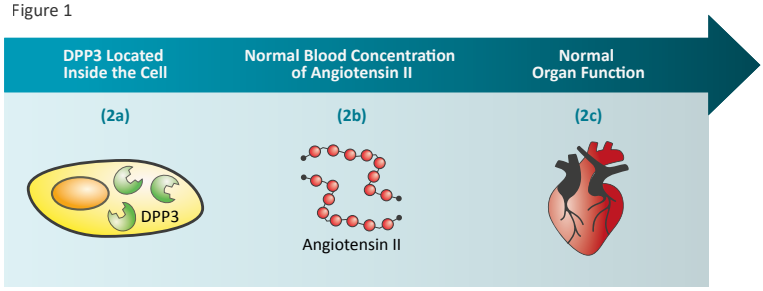

Figure 2

Healthy State

In healthy state, DPP3 is located intracellularly (Figure 2, 2a) and active angiotensin II (Figure 2, 2b) contributes to maintaining a normal heart function (Figure 2, 2c). The median DPP3 concentration of 5,021 healthy subjects was 15 ng/mL; the upper normal range (97.5th percentile) was 40 ng/mL.

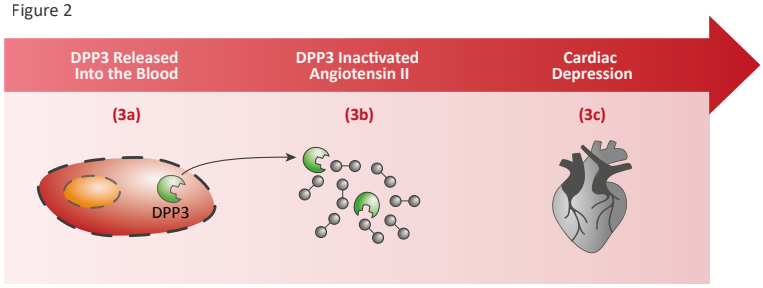

Figure 3

Disease State

In a disease state, uncontrolled cell death leads to the release of DPP3 (Figure 3, 3a).

Angiotensin II is inactivated by DPP3 (Figure 3, 3b), which leads to haemodynamic instability and cardiac depression (Figure 3, 3c).

DPP3

- Is a blood-based parameter for quantifying the DPP3 release into the blood stream (7).
- High DPP3 levels predict hemodynamic instability and need of cardiovascular support. (5,6).
- Aids in the stratification of patients at high risk to develop short-term organ dysfunction (3,5,6).
- Aids in the monitoring of treatment success (5,6).

References

(1) Deniau B et al. Circulating dipeptidyl peptidase 3 is a myocardial depressant factor: dipeptidyl peptidase 3 inhibition rapidly and sustainably improves haemodynamics. *Eur J Heart Fail.* 2020 Feb;22(2):290-299.

(2) Magliocca A et al. Dipeptidyl peptidase 3, a biomarker in cardiogenic shock and hopefully much more. *Eur J Heart Fail.* 2020 Feb;22(2):300-302.

(3) Gombert A et al. In-hospital mortality and organ failure after open and endovascular thoraco-abdominal aortic surgery can be predicted by increased levels of circulating dipeptidyl peptidase 3. Eur J Cardiothorac Surg. 2020 Nov 25:ezaa413.

(4) Dépret F et al. Circulating dipeptidyl peptidase-3 at admission is associated with circulatory failure, acute kidney injury and death in severely ill burn patients. *Crit Care.* 2020 Apr 22;24(1):168.

(5) Takagi K et al. Circulating dipeptidyl peptidase 3 and alteration in haemodynamics in cardiogenic shock: results from the OptimaCC trial. *Eur J Heart Fail.* 2020 Feb;22(2):279-286.

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(7) Kaufmann P, et al. (2019) A novel and highly efficient purification procedure for native human dipeptidyl peptidase 3 from human blood cell lysate. *PLoS ONE* 14(8): e0220866.

IB10 sphingotest® PCT

The assay for the in vitro quantitative determination of Procalcitonin

IB10 sphingotest® PCT is a rapid point-of-care (POC) immunoassay for the quantitative in vitro determination of Procalcitonin (PCT) in the concentration range of 0.3 µg/L to 10 µg/L in human EDTA whole blood or plasma. The test is designed for professional use only and may be used on sites where near patient testing is practiced.

Clinical Significance

Sepsis is the most common cause of death in intensive care units (ICU) with a mortality rate up to 50% depending on severity. The earlier sepsis is identified and treated, the better the prognosis (1,2). PCT levels in sepsis are often greater than 1 µg/L and reach values of 10 µg/L or even higher with severe sepsis and septic shock. As the septic infection resolves, the PCT levels also return to ranges < 0.5 µg/L, with a half-life of 24 hours. **The IB10 sphingotest® PCT** is only intended for the diagnosis of sepsis, the assessment of the degree of severity, and monitoring of the change of sepsis severity (3). This assay is neither suitable nor intended for other applications and/or uses.

Expected Values

All measurements with EDTA whole blood samples collected from 100 apparently healthy individuals were found as < 0.3 µg/L for the IB10 sphingotest® PCT.

Diagnosis of Sepsis (1,4)

PCT (µg/L)	Analysis
< 0.5	Local bacterial infection is possible. Systemic infection (sepsis) is not likely. Low risk for progression to severe systemic infection (severe sepsis).
	Levels below 0.5 µg/L do not exclude an infection, because localized infections (without systemic signs) may be associated with such low levels.
≥ 0.5 and ≤ 2	Systemic infection (sepsis) is possible, but various conditions are known to induce PCT as well.
	Moderate risk for progression to severe systemic infection (severe sepsis). The patient should be closely monitored both clinically and by re-assessing PCT within 6-24 hours.
> 2 and ≤ 10	Systemic infection (sepsis) is likely, unless other causes are known.
	High risk for progression to severe systemic infection (severe sepsis).
> 10	Important systemic inflammatory response, almost exclusively due to severe bacterial sepsis or septic shock.
	High likelihood of severe sepsis or septic shock.

Whole Blood vs. Plasma Comparison

All our assays correlate with r=0.9. For more detailed information please read the IFUs or connect with our sales representatives.

Key Features

Easy Handling	
Sample Type	EDTA whole blood or plasma samples
Time to Result	20 minutes
Measuring Range	0.3 - 10 µg/L
Limit of Detection	0.3 µg/L
No High Dose Hook Effect	up to 10,000 µg/L
Analyte Stability for IB10 Measurement	24 hours for whole blood

References

(1) Gregoriano C et al. Role of procalcitonin use in the management of sepsis. *J Thorac Dis.* 2020 Feb;12(Suppl 1):S5-S15.

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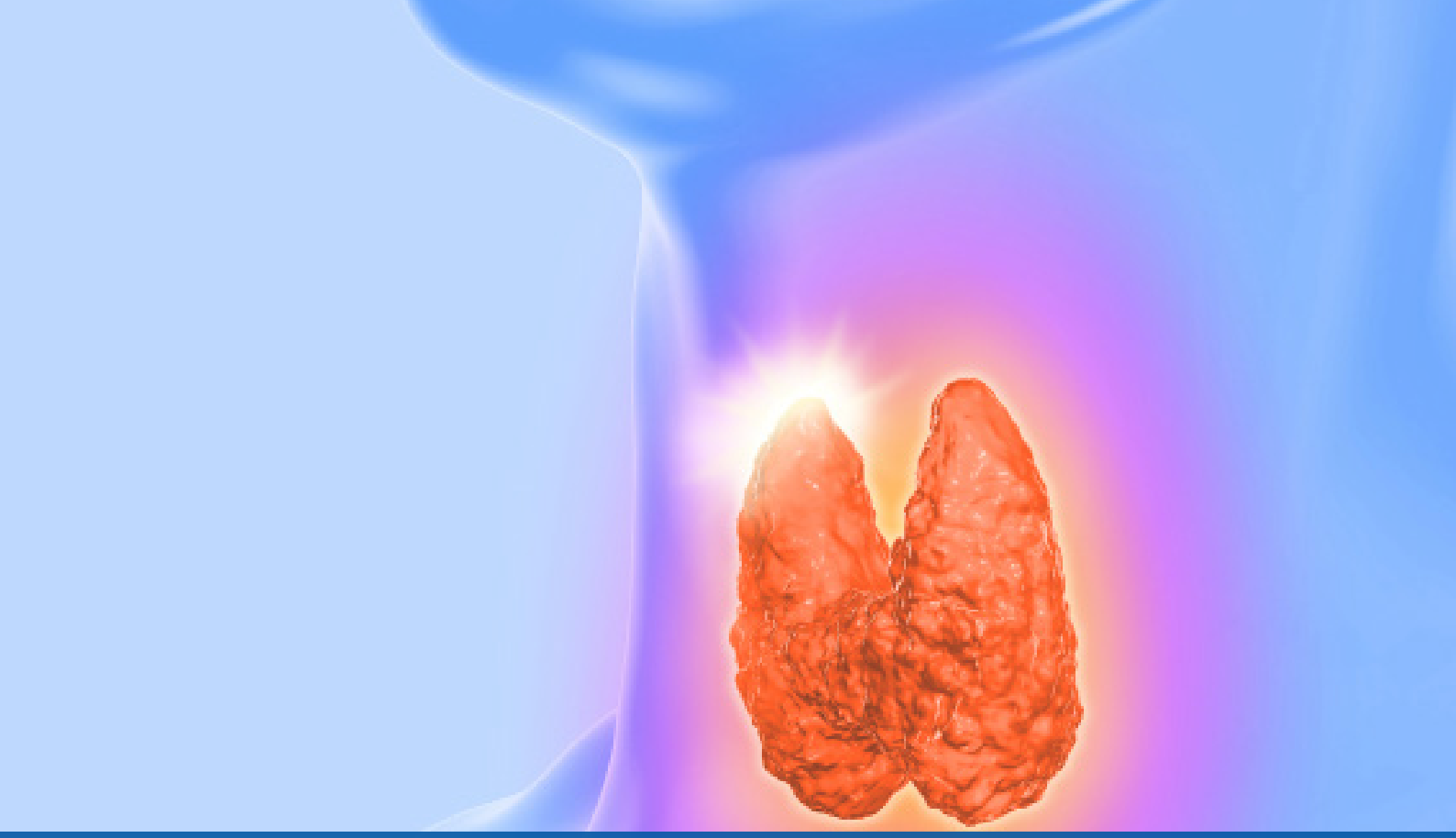

IB10 sphingotest® TSH

The assay for the in vitro quantitative determination of thyroid-stimulating hormone

The **IB10 sphingotest® TSH** is a rapid point-of-care (POC) immunoassay for the quantitative in vitro determination of thyroid stimulating hormone (TSH) in human lithium-heparin whole blood and plasma. The test is designed for professional use only and may be used on sites where near patient testing is practiced.

Clinical Significance

TSH is recognized as a sensitive indicator of thyroid status and thus the TSH assay has been widely adopted as the front-line thyroid function test (1,2,3). A normal TSH result excludes suspected thyroid disease in ambulatory patients with intact hypothalamic and pituitary function. Whereas elevated and suppressed TSH results are diagnostic of hypo- and hyperthyroidism (4). Functional sensitivity of 0.11 mIU/L and as such can be classified as a 2nd generation assay. It is able to differentiate between hyperthyroid and euthyroid conditions.

Expected Values

Reference Range(s)		
Premature Infants (28-36 weeks)		0.7 - 27.0 mIU/L
Term Infants (>37 weeks)	1-4 days	1.00 - 39.00 mIU/L
	2-20 weeks	1.70 - 9.10 mIU/L
	5 months - 20 years	0.70 - 6.40 mIU/L
Adults	21-54 years	0.40 - 4.20 mIU/L
	55-87 years	0.50 - 8.90 mIU/L
Pregnancy	First Trimester	0.30 - 4.50 mIU/L
	Second Trimester	0.50 - 4.60 mIU/L
	Third Trimester	0.80 - 5.20 mIU/L

As a guide, the following ranges were determined. The euthyroid reference interval for IB10 sphingotest® TSH was determined as the central 95% of the measurements with human plasma samples collected from 265 apparently healthy individuals.

2.5th Percentile (mIU/L)	97.5th Percentile (mIU/L)	Median (mIU/L)
0.25	3.85	1.43

Whole Blood vs. Plasma Comparison

All our assays correlate with r=0.9. For more detailed information please read the IFUs or connect with our sales representatives.

Key Features

Easy Handling	
Sample Type	Lithium-Heparin Whole Blood or Plasma Samples
Time to Result	20 minutes
Measuring Range	0.11 - 120 mIU/L
Limit of Detection	0.11 mIU/L
No High Dose Hook Effect	up to 8,000 mIU/L
Analyte Stability for IB10 Measurement	24 hours for whole blood

References

(1) Surks MI et al. American Thyroid Association guidelines for use of laboratory tests in thyroid disorders. *JAMA*. 1990 Mar 16;263(11):1529-32.

(2) Keffer JH. Preanalytical considerations in testing thyroid function. *Clin Chem*. 1996 Jan;42(1):125-34.

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IB10 sphingotest® Troponin-99

The assay for the in vitro quantitative determination of Cardiac Troponin I

IB10 sphingotest® Troponin-99 is a rapid point-of-care (POC) immunoassay for the quantitative in vitro determination of Cardiac Troponin I (cTnI) in human lithium-heparin whole blood and plasma. The test is designed for professional use only and may be used on sites where near patient testing is practiced.

Clinical Significance

cTnI determination aids in the diagnosis of myocardial infarction (MI) (1,2) and patients with non-ST-segment elevation (NSTEMI) acute coronary syndrome (ACS) (3,4). Elevated cTnI levels in the NSTEMI ACS sub-population correlate with the relative risk of mortality, MI or increased probability of ischemic events requiring urgent revascularization procedures. For patients with chronic or acute decompensated heart failure (HF), measurements of cTnI provide complementary information to assist in patient evaluation and management.

Expected Values

From a population of 224 individuals, the IB10 sphingotest® Troponin-99 test was used to determine the concentration upper reference limits of cTnI. This population included apparently healthy individuals.

Upper Reference Limit

The 99th percentile upper reference limit is 0.10 ng/mL. Each laboratory should establish a reference range that represents the patient population that is to be evaluated at their facility.

Whole Blood vs. Plasma Comparison

All our assays correlate with r=0.9. For more detailed information please read the IFUs or connect with our sales representatives.

Key Features

Easy Handling	
Sample Type	Lithium-Heparin Whole Blood or Plasma Samples
Time to Result	20 minutes
Measuring Range	0.05 - 30 ng/mL
Limit of Detection	0.05 ng/mL
No High Dose Hook Effect	up to 500 ng/mL
Analyte Stability for IB10 Measurement	48 hours for whole blood

References

(1) Reichlin T et al. Utility of absolute and relative changes in cardiac troponin concentrations in the early diagnosis of acute myocardial infarction. *Circulation*. 2011; 124:136–145.

(2) Thygesen K et al. Task Force for the Redefinition of Myocardial Infarction. Universal definition of myocardial infarction. *J Am Coll Cardiol*. 2007 Nov 27;50(22):2173-95.

(3) Babuin L et al. Troponin: the biomarker of choice for the detection of cardiac injury. *CMAJ.* 2005 Nov 8;173(10):1191-202.

(4) Larue C et al. Cardiac-specific immunoenzymometric assay of troponin I in the early phase of acute myocardial infarction. *Clin Chem.* 1993 Jun;39(6):972-9.

IB10 sphingotest® NT-proBNP

The assay for the in vitro quantitative determination of N-terminal pro-brain natriuretic peptide

IB10 sphingotest® NT-proBNP is a rapid point-of-care (POC) immunoassay for the quantitative in vitro determination of N-terminal pro-brain natriuretic peptide (NT-proBNP) in human whole blood or plasma using EDTA or lithium-heparin as the anticoagulant. The test is designed for professional use only and may be used on sites where near patient testing is practiced.

Clinical Significance

NT-proBNP (1) is a valuable diagnostic and prognostic marker for cardio-vascular diseases, especially in patients with a New York Heart Association (NYHA) Class I-IV Congestive Heart Failure (CHF) (2,3).
The measurement of NT-proBNP is an important tool for aiding in the diagnosis and the assessment of the severity of patients with CHF (4,5).

Expected Values

Recommended decision threshold values:

- Patients under 75 years of age: 125 pg/mL
- Patients 75 years of age and older: 450 pg/mL

Each laboratory should establish a reference range that represents the patient population that is to be evaluated.

Whole Blood vs. Plasma Comparison

All our assays correlate with r=0.9. For more detailed information please read the IFUs or connect with our sales representatives.

Key Features

Easy Handling	
Sample Type	EDTA or Lithium-Heparin Whole Blood or Plasma Samples
Time to Result	20 minutes
Measuring Range	30 - 5,000 pg/mL
Limit of Detection	30 pg/mL
No High Dose Hook Effect	up to 300,000 pg/mL
Analyte Stability for IB10 Measurement	24 hours for whole blood

References

(1) Hall C. NT-ProBNP: the mechanism behind the marker. *J Card Fail*. 2005 Jun;11(5 Suppl):S81-3.

(2) Costello-Boerrigter et al. The prognostic value of N-terminal proB-type natriuretic peptide. *Nat Clin Pract Cardiovasc Med.* 2005 Apr;2(4):194-201.

(3) Cowie et al. Clinical applications of B-type natriuretic peptide (BNP) testing. *Eur Heart J.* 2003 Oct;24(19):1710-8.

(4) Salah K et al. Prognosis and NT-proBNP in heart failure patients with preserved versus reduced ejection fraction. *Heart* 2019;105:1182-1189.

(5) McDonagh TA et al. NT-proBNP and the diagnosis of heart failure: a pooled analysis of three European epidemiological studies. *Eur J Heart Fail.* 2004 Mar 15;6(3):269-73.

IB10 sphingotest® D-Dimer

The assay for the in vitro quantitative determination of D-Dimer

IB10 sphingotest® D-Dimer is a rapid point-of-care (POC) immunoassay for the quantitative in vitro determination of cross-linked fibrin degradation products containing D-Dimer in lithium-heparin or citrate whole blood or plasma. The test is designed for professional use only and may be used on sites where near patient testing is practiced.

Clinical Significance

D-Dimer determinations aid in the quantitative assessment and evaluation of patients presenting with clinical symptoms of venous thromboembolism (VTE) including severely evolving disseminated intravascular coagulation, pulmonary embolism and deep vein thrombosis. Values at or below the upper limit of a healthy reference population are highly predictive of exclusion of VTE as a cause of symptoms (1,2,3,4).

Expected Values

From a population of 244 individuals, the IB10 sphingotest® D-Dimer test was used to determine the concentration upper reference limit of D-Dimer. This population included apparently healthy individuals. The 95th percentile upper reference limit, using lithium heparin as anticoagulant, is 446.8 FEU ng/mL. The IB10 sphingotest® D-Dimer reports results in FEU ng/mL. It is comonly accepted that 1 D-DU is equal to 2 FEU.
Each laboratory should establish a reference range that represents the patient population that is to be evaluated at their facility.

Whole Blood vs. Plasma Comparison

All our assays correlate with r=0.9. For more detailed information please read the IFUs or connect with our sales representatives.

Key Features

Easy Handling	
Sample Type	Lithium-Heparin or Citrate Whole Blood and Plasma Samples
Time to Result	20 minutes
Measuring Range	100 - 4,000 FEU ng/mL
Limit of Detection	100 FEU ng/mL
No High Dose Hook Effect	up to 40,000 FEU ng/mL
Analyte Stability for IB10 Measurement	24 hours for whole blood

References

(1) Riley RS et al. Widely Used Types and Clinical Applications of D-Dimer Assay. *Lab Med.* 2016 May;47(2):90-102.

(2) Song J et al. Analytical and clinical performance of a new point of care LABGEOIB D-dimer test for diagnosis of venous thromboembolism. *Ann Clin Lab Sci.* 2014 Summer;44(3):254-61.

(3) Price CP et al. Point-of-Care Testing for D-Dimer in the Diagnosis of Venous Thromboembolism in Primary Care: A Narrative Review. *Cardiol Ther* 2020.

(4) Kyrle PA et al. Deep vein thrombosis. *Lancet*. 2005 Mar 26-Apr 1;365(9465):1163-74.

IB10 sphingotest® SOB

The panel assay for the in vitro quantitative determination of Cardiac Troponin I, N-terminal pro-brain natriuretic peptide and D-Dimer

IB10 sphingotest® SOB is a rapid point-of-care (POC) immunoassay for the in vitro quantitative determination of Cardiac Troponin I (cTnI), N-terminal pro-brain natriuretic peptide (NT-proBNP) and D-Dimer in human lithium-heparin whole blood and plasma. The test is designed for professional use only and may be used on sites where near patient testing is practiced.

Clinical Significance

IB10 sphingotest® SOB is intended as an aid in the differential diagnosis and prognostic assessment of patients with symptoms of chest pain, typically accompanied by respiratory distress. Individually or in conjunction with each other, these markers: aid in the diagnosis of myocardial infarction (1,2), aid in the risk stratification of patients with acute coronary syndrome including prediction of the likelihood of developing heart failure (HF), aid in the diagnosis, assessment of severity and likelihood of survival in HF (3,4), and aid in determining the probability of rule-out of patients presenting with clinical symptoms of venous thromboembolism including pulmonary embolism and deep vein thrombosis (5).

Expected Values

Upper Reference Limit - cTnI

From a population of 224 individuals, IB10 sphingotest® SOB was used to determine the concentration upper reference limit of cTnI. This population included apparently healthy individuals. The 99th percentile upper reference limit is 0.10 ng/mL.

Recommended Decision Threshold Values - NT-proBNP

From calibration based on the reference Roche Elecsys® proBNP assay as measured on both the Roche Elecsys® and the Ortho VITROS® Immunodiagnostic Systems, the recommended Decision Threshold Values for the IB10 sphingotest® Shortness of Breath (NT-proBNP) are:

Patients under 75 years of age	125 pg/mL
Patients 75 years of age and older	450 pg/mL

Upper Reference Limit - D-Dimer

From a population of 244 individuals, the IB10 sphingotest® SOB was used to determine the concentration upper reference limit of D-Dimer. The 95th percentile upper reference limit, using lithium heparin as anti-coagulant, is 446.8 Fibrinogen Equivalent Units (FEU) ng/mL. It is comonly accepted that 1 D-DU is equal to 2 FEU.

Whole Blood vs. Plasma Comparison

All our assays correlate with r=0.9. For more detailed information please read the IFUs or connect with our sales representatives.

Key Features

Easy Handling	
Sample Type	Lithium-Heparin Whole Blood and Plasma Samples
Time to Result	20 minutes
Analyte Stability for IB10 Measurement	24 hours for whole blood
Measuring Range	
cTnI	0.05 – 30 ng/mL
NT-proBNP	30 – 5,000 pg/mL
D-Dimer	100 – 4,000 FEU ng/mL
Limit of Detection	
cTnI	0.05 ng/mL
NT-proBNP	30 pg/mL
D-Dimer	100 FEU ng/mL
No High Dose Hook Effect	
cTnI	up to 500 ng/mL
NT-proBNP	up to 300,000 pg/mL
D-Dimer	up to 40,000 FEU ng/mL

References

(1) Reichlin T et al. Utility of absolute and relative changes in cardiac troponin concentrations in the early diagnosis of acute myocardial infarction. *Circulation*. 2011 Jul 12;124(2):136-45.

(2) Fan J et al. Clinical Value of Combined Detection of CK-MB, MYO, cTnI and Plasma NT-proBNP in Diagnosis of Acute Myocardial Infarction. *Clin Lab.* 2017 Mar 1;63(3):427-433.

(3) Peacock et al. Cardiac troponin and outcome in acute heart failure. *N Engl J Med.* 2008 May 15;358(20):2117-26.

(4) Sakhuja et al. Amino-terminal pro-brain natriuretic peptide, brain natriuretic peptide, and troponin T for prediction of mortality in acute heart failure. *Clin Chem*. 2007 Mar;53(3):412-20.

(5) Kyrle et al. Deep vein thrombosis. *Lancet*. 2005 Mar 26-Apr 1;365(9465):1163-74.

IB10 sphingotest® 3-in-1 Cardiac

The panel assay for the in vitro quantitative determination of Cardiac Troponin I, CK-MB and Myoglobin

IB10 sphingotest® 3-in-1 Cardiac is a rapid point-of-care (POC) immunoassay for the quantitative in vitro determination of Cardiac Troponin I (cTnI), Creatine kinase-MB (CK-MB) and Myoglobin, in human lithium-heparin whole blood and plasma. The test is designed for professional use only and may be used on sites where near patient testing is practiced.

Clinical Significance

This panel of three cardiac markers enhances the reliability of earlier identification and risk stratification of patients presenting with chest pain compared to a single marker (1,2). Measurements of cardiac protein markers are essential for the accurate diagnosis of acute coronary syndrome in the absence of well-defined electrocardiographic ST-segment elevations (3,4).

Expected Values

From a population of 224 individuals, the IB10 sphingotest® 3-in-1 Cardiac was used to determine the concentration upper reference limits of cTnI, CK-MB and Myoglobin. This population included apparently healthy individuals.

cTnI	0.10 ng/mL (99th reference percentile)
CK-MB	8.58 ng/mL (95th reference percentile)
Myoglobin	99.84 ng/mL (95th reference percentile)

Each laboratory should establish a reference range that represents the patient population that is to be evaluated at their facility.

Whole Blood vs. Plasma Comparison

All our assays correlate with r=0.9. For more detailed information please read the IFUs or connect with our sales representatives.

Key Features

Easy Handling	
Sample Type	Lithium-Heparin Whole Blood and Plasma Samples
Time to Result	20 minutes
Analyte Stability for IB10 Measurement	48 hours for whole blood
Measuring Range	
cTnI	0.05 - 30 ng/mL
CK-MB	2.0 - 60 ng/mL
Myoglobin	30.0 - 500 ng/mL
Limit of Detection	
cTnI	0.05 ng/mL
CK-MB	2.0 ng/mL
Myoglobin	30.0 ng/mL
No High Dose Hook Effect	
cTnI	up to 500 ng/mL
CK-MB	up to 200 ng/mL
Myoglobin	up to 4,000 ng/mL

References

(1) Fan J et al. Clinical Value of Combined Detection of CK-MB, MYO, cTnI and Plasma NT-proBNP in Diagnosis of Acute Myocardial Infarction. *Clin Lab*. 2017 Mar 1;63(3):427-433.

(2) Newby LK et al. Bedside multimarker testing for risk stratification in chest pain units: The chest pain evaluation by creatine kinase-MB, myoglobin, and troponin I (CHECKMATE) study. *Circulation*. 2001 Apr 10;103(14):1832-7.

(3) Reichlin T et al. Utility of absolute and relative changes in cardiac troponin concentrations in the early diagnosis of acute myocardial infarction. *Circulation*. 2011 Jul 12;124(2):136-45.

(4) Thygesen K et al. Task Force for the Redefinition of Myocardial Infarction. Universal definition of myocardial infarction. *J Am Coll Cardiol.* 2007 Nov 27;50(22):2173-95.

IB10 sphingotest® beta-hCG

The assay for the in vitro quantitative determination of human chorionic gonadotropin

IB10 sphingotest® beta-hCG is a rapid point-of-care (POC) immunoassay for the quantitative in vitro determination of human chorionic gonadotropin (hCG) in human lithium-heparin whole blood and plasma. The assay detects total hCG, measuring both the intact hCG molecule and its free beta subunit. The quantitative measurement of hCG aids in the early detection of pregnancy. The test is designed for professional use only and may be used on sites where near patient testing is practiced.

Clinical Significance

hCG is the primary analyte used for pregnancy confirmation and monitoring due to its rapid rise in both blood and urine soon after conception (1). The detection of hCG within 3 - 4 weeks of the last menstrual period is the most reliable indicator for the confirmation of pregnancy. During a normal pregnancy, levels of hCG in the blood vary but are approximately 25 - 50 mIU/mL in the week after conception and rise exponentially doubling every 1.5 - 3 days during the first six weeks (2,3). hCG levels continue to rise through the end of the first trimester, followed by a slow decline as the pregnancy reaches full-term (~ 40 weeks).

Expected Values

Each laboratory should establish its own expected values that represents the population that is to be evaluated at their facility. As a guide, the following ranges were determined. The IB10 sphingotest® beta-hCG Test was used to determine the concentration upper reference limit of hCG in human plasma samples collected from apparently healthy, non-pregnant individuals. The 95th percentile upper reference limit as determined with the samples is 5.42 mIU/mL hCG.

Reference Group	N	Median (mIU/mL)	95th Percentile (mIU/mL)
Male	150	0.0	4.8
Non-preg. female	248	1.6	5.8
Female age ≤50 years	150	0.4	4.2
Female age >50 years	98	3.3	7.9
Total	398	0.5	5.4

Representative hCG ranges during normal pregnancy based on Last Menstrual Period (LMP) are summarized below. Other clinical reference citations may show different values.

After LMP (weeks)	hCG Range (mIU/mL)[2]
4	5 - 100
5	200 - 3,000
6	10,000 - 80,000
7-14	90,000 - 500,000
15-26	5,000 - 8,000
27-40	3,000 - 15,000

Whole Blood vs. Plasma Comparison

All our assays correlate with r=0.9. For more detailed information please read the IFUs or connect with our sales representatives.

Key Features

Easy Handling	
Sample Type	Lithium-Heparin Whole Blood or Plasma Samples
Time to Result	20 minutes
Measuring Range	4.0 - 400 mIU/mL
Limit of Detection	4.0 mIU/mL
No High Dose Hook Effect	up to 700,000 mIU/mL
Analyte Stability for IB10 Measurement	24 hours for whole blood

References

(1) Canfield RE et al. Development of an assay for a biomarker of pregnancy and early fetal loss. *Environ Health Perspect.* 1987 Oct;74:57-66.

(2) Vaitukaitis JL et al. Gonadotropins and their subunits: basic and clinical studies. *Recent Prog Horm Res.* 1976;32:289-331.

(3) Wu A. Tietz clinical guide to laboratory tests. 2006. *4th Ed. Philadelphia - Saunders-Elsevier* - pp. 252-259

Local Distributor

If you have any questions please contact your local distributor

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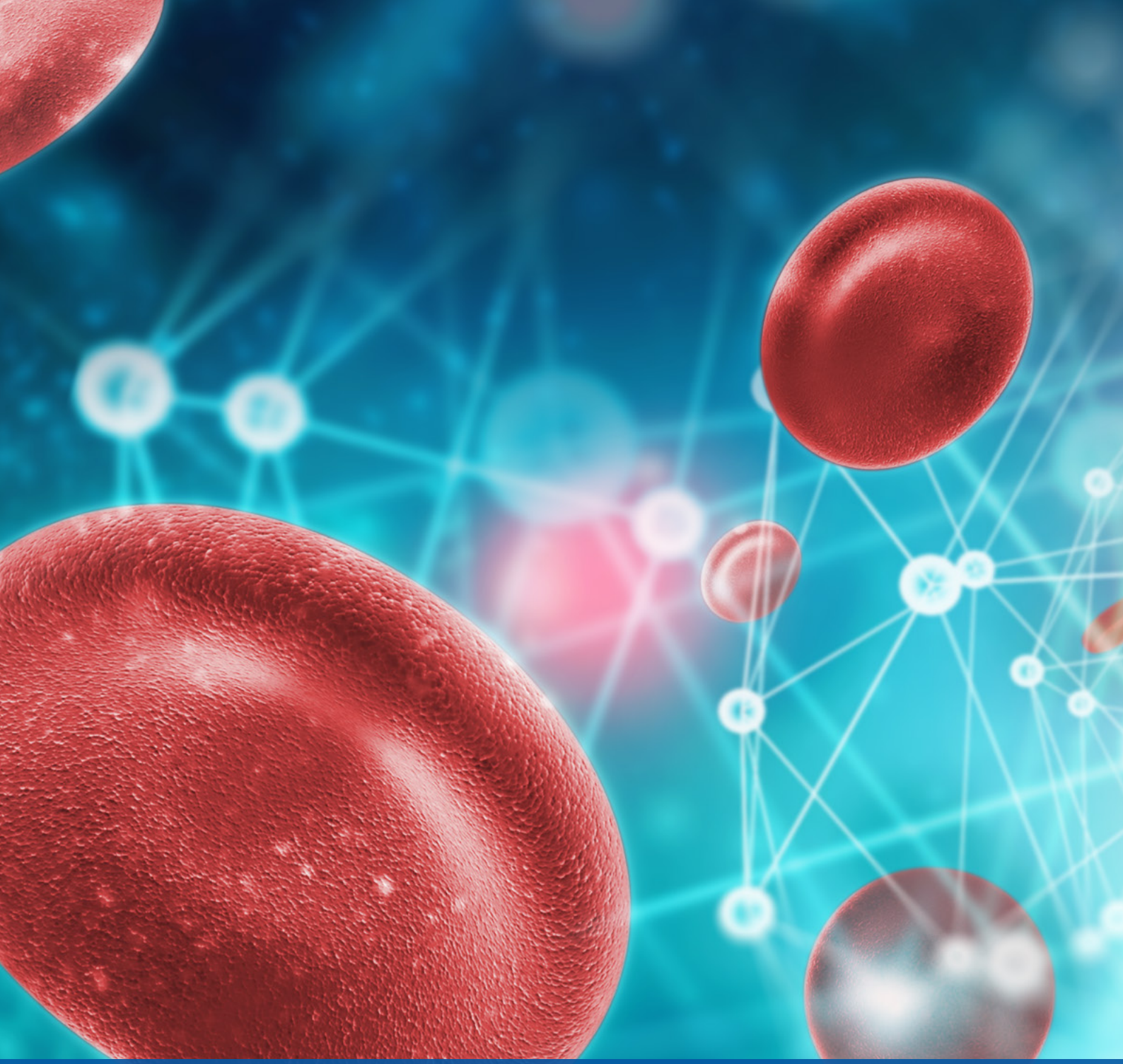

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