Instructions for Use

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Vaspin ELISA

Enzyme immunoassay for the quantitative determination of human Vaspin in human serum.

REF **30119800**

Σ **96**

For illustrative purposes only.
To perform the assay the instructions for use provided with the kit have to be used.

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Always there for you

ENGLISH - Instructions for use

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For Research Use Only. Not for use in diagnostic procedures.

ENGLISH - Instructions for use

VASPIN ELISA	96 Determinations
Principle of the test	Sandwich ELISA
Duration (incubation period)	2.5 h
Antibody-Conjugate	ready for use
Enzymkonjugat	ready for use
Buffer and Substrate	ready for use
Standards	5 single standards: 0.025 - 1 ng/mL, lyophilized, human Vaspin
Assay Range	4 pg/mL – 4000 pg/mL
Control	2 control sera, lyophilised
Sample	human serum
Required sample volume	75 µL
Sample dilution	1:4
Analytical sensitivity	4 pg/mL
average Intra- / Inter-Assay Variance	< 10 %

1 INTENDED USE

Measurement of human Vaspin in human serum. For Research Use Only. Not for Diagnostic Procedures.

2 INTRODUCTION

The ELISA for quantitative measurement of Vaspin is based on polyclonal rabbit antisera raised by genetic immunization of the rabbits (cDNA Vaspin SC306941).

Vaspin also known as SerpinA12 is a serine protease inhibitor and consists of 395 amino acids forming 3 β-sheets and 9 α-helices. Molecular weight of Vaspin is about 45.2 kDa. It does not form multimeric aggregates or intra-molecular disulfide bridges and no binding proteins in human serum are known. The Vaspin gene is not only expressed by subcutaneous and visceral adipose but also by liver tissue, in the pancreas[1] and in the human epidermis (granular keratinocytes / GK cells)[2].

“Serum Vaspin levels were **highest in the early morning** before breakfast and fell to trough levels within 2 h after breakfast. Serum Vaspin levels also showed a preprandial rise and postprandial fall at lunch and dinner, although at lesser degrees than at breakfast. Intermeal Vaspin concentrations reached a **nadir in the mid-afternoon** and showed a nocturnal rise, with peak nighttime Vaspin levels being approximately 250 % of nadir levels. Unscheduled food ingestion after a prolonged fast significantly reduced serum Vaspin levels, suggesting that energy intake itself has a suppressive effect on serum Vaspin levels. The diurnal patterns of serum Vaspin concentrations were exactly reciprocal to that of insulin and of glucose” [3].

A sexual dimorphism has been detected with higher Vaspin levels in girls increasing with age and pubertal stage[1,4]. A preliminary investigation (n = 81) of Vaspin levels in healthy adult blood donors revealed higher Vaspin levels in women decreasing with increasing age. In this context

it is important to reflect, that oral contraceptives significantly increase serum Vaspin concentration[4].

Serum Vaspin concentration is independent of BMI but negatively associated with insulin sensitivity and obesity, thus “Vaspin was increased with worsening insulin resistance” [1]. If glucose metabolism / insulin sensitivity is improved by therapeutic intervention e.g. rosiglitazone, plasma Vaspin concentration decreases significantly[5]. Interestingly lifestyle intervention results in increasing adiponectin concentrations as well as in improved insulin sensitivity but after a 10 month intervention Vaspin concentration remain unchanged[6]. Thus, the mechanism regulating the Vaspin concentration in circulation is still unclear. Vaspin concentration might be even more influenced by glucose uptake than by body fat at least in pre-pubertal children[7].
In insulin resistance, diabetes as well as atherosclerosis inflammatory processes are involved and Vaspin might be a link between the endocrine and the immune system. To elucidate the role of Vaspin in inflammation its influence on TNF-α-stimulated production of reactive oxygen species was investigated in smooth muscle cells. Vaspin significantly decreased the TNF-α-induced monocyte adhesion to SMCs as well as TNF-α induced intracellular signal cascade [8].

The diagnostic value of Vaspin remains unclear, conflicting results question its value as biomarker for visceral or total adipose tissue. As well as regarding insulin resistance while in children Vaspin might correlate with insulin sensitivity[1] but in adults no correlation was found[4].

The Vaspin ELISA is a tool for the further investigation and validation of Vaspin as a biomarker for the visceral adipose tissue, insulin sensitivity and glucose tolerance.

3 ASSAY PRINCIPLE

The enzyme immunoassay for Vaspin is a so-called Sandwich-Assay. It utilizes specific and high affinity polyclonal antibodies for this protein. The Vaspin in the samples binds to the immobilized first antibody on the microtiter plate. In the following step, the biotinylated antibody binds in turn to Vaspin. After washing, Streptavidin-Peroxidase-Enzyme conjugate will be added, which will bind highly specific to the biotin and will catalyse the enzymatic reaction, which turns the colour of the substrate, quantitatively depending on the Vaspin level of the samples.

4 WARNINGS AND PRECAUTIONS

For In Vitro Diagnostic Use only. For Professional use only.

The kit is suitable only for in vitro diagnostics and not for internal use in humans and animals. Follow strictly the test protocol. Use the valid version of the package insert provided with the kit. Be sure that everything has been understood. The manufacturer will not be held responsible for any loss or damage (except as required by statute) howsoever caused, arising out of noncompliance with the instructions provided.

Do not use obvious damaged or microbial contaminated or spilled material.

Caution: This kit contains material of human and/or animal origin. Therefore all components and patient´s specimens should be treated as potentially infectious.

Appropriate precautions and good laboratory practices must be used in the storage, handling and disposal of the kit reagents. The disposal of the kit components must be made according to the local regulations.

Human Serum

Following components contain human serum: **Control Sera KS1 / KS2, Standards A-E**

Source human serum for the control sera provided in this kit was tested and found non-reactive for Hepatitis-B surface antigen (HBsAg), Hepatitis C virus (HCV), and Human Immunodeficiency Virus 1 and 2 (HIV). No known methods can offer total security of the absence of infectious agents; therefore all components and patient´s specimens should be treated as potentially infectious.

Reagents AK, VP, WP

Contain as preservative **5-chloro-2-methyl-4-isothiazolin-3-one and 2-methyl-4-isothiazolin-3-one** (<0.015%)

H317	May cause an allergic skin reaction.
P280	Wear protective gloves/ protective clothing/ eye protection/ face protection.
P272	Contaminated work clothing should not be allowed out of the workplace.
P261	Avoid breathing dust/ fume/ gas/ mist/ vapours/ spray.
P333+P313	If skin irritation or rash occurs: Get medical advice/ attention.
P302+P352	IF ON SKIN: Wash with plenty of soap and water.
P501	Dispose of contents/ container in accordance with local/ regional/ national/ international regulations.

Substrate Solution (S)

The TMB-Substrate (S) contains 3,3´,5,5´ Tetramethylbencidine (<0.05%)

H315	Causes skin irritation.
H319	Causes serious eye irritation.
H335	May cause respiratory irritation.
P261	Avoid breathing dust/ fume/ gas/ mist/ vapours/ spray.
P305+P351+	IF IN EYES: Rinse cautiously with water for several minutes.
P338	Remove contact lenses, if present and easy to do. Continue rinsing.

Stopping Solution (SL)

The Stopping solution contains 0.2 M acid sulphur acid (H_2SO_4)

H290	May be corrosive to metals.
H314	Causes severe skin burns and eye damage.
P280	Wear protective gloves/ protective clothing/ eye protection/ face protection.
P301+P330+	IF SWALLOWED: rinse mouth.
P331	Do NOT induce vomiting.
P305+P351+	IF IN EYES: Rinse cautiously with water for several minutes.
P338	Remove contact lenses, if present and easy to do. Continue rinsing.
P309+P310	IF exposed or if you feel unwell: Immediately call a POISON CENTER or doctor/physician.

4.1 General first aid procedures:

Skin contact: Wash affected area rinse immediately with plenty of water at least 15 minutes. Remove contaminated cloths and shoes.

Eye contact: In case of contact with eyes, rinse immediately with plenty of water at least 15 minutes. In order to assure an effectual rinsing spread the eyelids.

Ingestion: After swallowing the product, if the affected person is conscious, rinse out the mouth with plenty of water: seek medical advice immediately.

5 SAMPLES

5.1 Sample type

Serum

5.2 Specimen collection

Use standard venipuncture for the blood sampling. Haemolytic reactions have to be avoided.

5.3 Required **sample volume:** 70 µL

5.4 Sample **stability**

Samples should be stored at - 20°C in firmly closable sample vials. Information of the long-term stability of Vaspin is not yet available. Freezing and thawing of samples should be minimized.

5.5 Interference

Triglyceride, bilirubin and hemoglobin in the sample do not interfere to a concentration of 100 mg/mL, 100 µg/mL or 5 mg/mL, respectively. However, the use of haemolytic, lipemic or icteric samples should be validated by the user.

5.6 Sample dilution

- Recommended Dilution: **1:4** with Dilution Buffer **VP**
- Pipette **210 µL Dilution Buffer VP** in PE-/PP-Tubes (application of a multi-stepper is recommended in larger series), add **70 µL Serum** (dilution factor 4). After mixing use **100 µL** of this 1:4 diluted solution **within 1 hour per determination** in the assay.
- The excellent linearity of the assay system allows dilutions of 1:2 - 1:32

6 MATERIALS

6.1 Materials provided

The reagents listed below are sufficient for 96 wells including the standard curve.

MTP	**Microtiter plate,** ready for use, coated with rabbit-anti-hVaspin-antibody. Wells are separately breakable.	**(8x12) wells**
A-E	**Standards**, lyophilized, (human Vaspin), concentrations are given on the QC-certificate.	**5 x 750 µL**
KS1	**Control Serum 1,** lyophilised, (human serum), concentration is given on the QC-certificate.	**1 x 250 µL**
KS2	**Control Serum 2,** lyophilised, (human serum), concentration is given on the QC-certificate.	**1 x 250 µL**
AK	**Antibody Conjugate,** ready for use, contains rabbit anti-hVaspin antibody, biotinylated	**1 x 12 mL**
EK	**Enzyme Conjugate,** ready for use, Contains horseradish-peroxidase conjugated to streptavidin.	**1 x 12 mL**
VP	**Dilution Buffer,** ready for use, **Please shake before use!**	**1x 120 mL**
WP	**Washing Buffer,** 20-fold concentrated solution	**1 x 50 mL**
S	**Substrate,** ready for use, horseradish-peroxidase-(HRP) substrate, stabilised H_2O_2 Tetramethylbencidine.	**1 x 12 mL**
SL	**Stopping Solution,** ready for use, 0.2 M sulphuric acid.	**1 x 12 mL**
-	**Sealing Tape,** for covering the **microtiter plate.**	**3 x**
	**Instructions for use**	**1 x**
--	**Quality Control Certificate**	**1 x**

6.2 Materials required, but not provided

- Distilled (Aqua destillata) or deionized water for dilution of the Washing Buffer **WP (A. dest.), 950 mL.**
- Precision pipettes and multichannel pipettes with disposable plastic tips
- Polyethylene PE/Polypropylene PP tubes for dilution of samples
- Vortex-mixer
- Microtiter plate shaker (350 rpm)
- Microtiter plate washer (recommended)
- Micro plate reader ("ELISA-Reader") with filter for 450 and ≥ 590 nm

7 TECHNICAL NOTES

Storage Conditions

Store the kit at 2 - 8°C after receipt until its expiry date. The lyophilized reagents should be stored at – 20°C after reconstitution. Avoid repeated thawing and freezing.

Storage Life

The shelf life of the components **after initial opening** is warranted for **4 weeks**, store the unused strips and microtiter wells **airtight** together with the desiccant at 2 - 8°C in the clip-lock bag, use in the frame provided. The **reconstituted components** standards **A-E** and Control Sera **KS1** and **KS2** must be stored at – 20°C (max. 4 weeks). For further use, thaw quickly but gently (avoid temperature increase above room temperature and avoid excessive vortexing). Up to 3 of the freeze-thaw cycles did not influence the assay. The 1:20 diluted Washing Buffer **WP** is 4 weeks stable at 2 - 8°C

Preparation of reagents

Bring all reagents to room temperature (20 - 25°C) before use. Possible precipitations in the buffers have to be resolved before usage by mixing and / or warming. Reagents with different lot numbers cannot be mixed.

Reconstitution

The Standards **A – E** and Controls **KS1 and KS2** are reconstituted with the Dilution Buffer **VP**. It is recommended to keep reconstituted reagents at room temperature for 15 minutes and then to mix them thoroughly but gently (no foam should result) with a Vortex mixer.

Dilution

After reconstitution dilute the Control Sera **KS1 and KS2** with the Dilution Buffer **VP** in the same ratio (1:505) as the sample.
The required volume of Washing Buffer **WP** is prepared by 1:20 dilution of the provided 20fold concentrate with Aqua dest.

Assay Procedure

When performing the assay, Blank, Standards **A-E**, Control Serum **KS1 and KS2** and the samples should be pipette as fast as possible (e.g. < 15 minutes). To avoid distortions due to differences in incubation times, Antibody-Conjugate **AK,** Enzymconjugate **EK** as well as the succeeding Substrate Solution **S** should be added to the plate in the same order and in the same time interval as the samples. Stopping Solution **SL** should be added to the plate in the same order as Substrate Solution **S**.
All determinations (Blank, Standards **A-E**, Control Sera **KS1 and KS2** and samples) should be assayed in duplicate. For optimal results, accurate pipetting and adherence to the protocol are recommended.

Incubation

Incubation at room temperature means: Incubation at 20 - 25°C. The Substrate Solution **S**, stabilised H_2O_2-Tetramethylbencidine, is photosensitive–store and incubation in the dark.

Shaking

The incubation steps should be performed at mean rotation frequency of a particularly suitable microtiter plate shaker. We are recommending 350 rpm. Due to certain technical differences deviations may occur, in case the rotation frequency must be adjusted. Insufficient shaking may lead to inadequate mixing of the solutions and thereby to low optical densities, high variations and/ or false values, excessive shaking may result in high optical densities and/ or false values.

Washing

Proper washing is of basic **importance** for a secure, reliable and precise performance of the test. Incomplete washing is common and will adversely affect the test outcome. Possible consequences may be uncontrolled unspecific variations of measured optical densities, potentially leading to false results calculations of the examined samples. Effects like high background values or high variations may indicate washing problems.

All washing must be performed with the provided Washing Buffer **WP** diluted to usage concentration. Washing volume per washing cycle and well must be 300 µL at least.

The danger of handling with potentially infectious material must be taken into account.

When using an **automatic microtiter** plate washer, the respective instructions fur use must be carefully followed. Device adjustments, e.g. for plate geometry and the provided washing parameters, must be performed. Dispensing and aspirating manifold must not scratch the inside well surface. Provisions must be made that the remaining fluid volume of every aspiration step is minimized. Following the last aspiration step of each washing cycle, this could be controlled, and possible remaining fluid could then be removed, by inverting the plate and repeatedly tapping it dry on non-fuzzy absorbent tissue.

Manual washing is an adequate alternative option. Washing Buffer may be dispensed via a multistepper device, a multichannel pipette, or a squirt bottle. The fluid may be removed by dynamical swinging out the microtiter plate over a basin. If aspirating devices are used, care has to be taken that the inside well surface is not scratched. Subsequent to every single washing step, the remaining fluid should be removed by inverting the plate and repeatedly tapping it dry on non-fuzzy absorbent tissue.

8 ASSAY PROCEDURE

Preparation of reagents		**Reconstitution:**	**Dilution**
A-E	**Standards**	in **750 µL** Dilution Buffer **VP**	-
KS1	**Control Serum 1**	in **250 µL** Dilution Buffer **VP**	**1:4** with **VP**
KS2	**Control Serum 2**	in **250 µL** Dilution Buffer **VP**	**1:4** with **VP**
WP	**Washing Buffer**	-	**1:20** with **Aqua dest.**
Sample dilution: with Dilution Buffer **VP 1:4**, mix directly and use within max. 60 min.			
Before assay procedure bring all reagents to room temperature **20 - 25°C**.			

Assay Procedure in Double Determination:

Pipette	**Reagents**	**Position**
100 µL	Dilution Buffer **VP**	A1/A2
100 µL	Standard **A** (**25 pg/mL**)	B1/B2
100 µL	Standard **B** (**75 pg/mL**)	C1/C2
100 µL	Standard **C** (**200 pg/mL**)	D1/D2
100 µL	Standard **D** (**500 pg/mL**)	E1/E2
100 µL	Standard **E** (**1000 pg/mL**)	F1/F2
100 µL	Control Serum **KS 1** (1:4 diluted)	G1/G2
100 µL	Control Serum **KS 2** (1:4 diluted)	H1/G2
100 µL	Sample (1:4 diluted)	in the rest of the wells according the requirements
Cover the wells with the sealing tape.		
Sample Incubation: 1 h at 20 - 25°C, 350 rpm		
5 x 300 µL	Aspirate the contents of the wells and **wash 5 x** with **300 µL** each Washing Buffer **WP/ well**	In each well
100 µL	Antibody Conjugate **AK**	In each well
Cover the wells with the sealing tape.		
Incubation: 1 hour at 20 - 25°C, 350 rpm		
5 x 300 µL	Aspirate the contents of the wells and **wash 5 x** with **300 µL** each Washing Buffer **WP/ well**	In each well
100 µL	Enzyme Conjugate **EK**	
Cover the wells with the sealing tape.		
Incubation: 1 hour at 20 - 25°C, 350 rpm		
5 x 300 µL	Aspirate the contents of the wells and **wash 5 x** with **300 µL** each Washing Buffer **WP/ well**	In each well
100 µL	Substrate Solution **S**	In each well
Incubation: 30 Minutes in the Dark at 20 - 25°C		
100 µL	Stopping Solution **SL**	In each well
Measure the absorbance within 30 min at **450 nm** with ≥ 590 nm as reference wavelength.		

9 QUALITY CONTROL

Good laboratory practice requires that controls are included in each assay. A statistically significant number of controls should be assayed to establish mean values and acceptable ranges to assure proper performance. The test results are only valid if the test has been performed following the instructions. Moreover the user must strictly adhere to the rules of GLP (Good Laboratory Practice) or other applicable federal, state or local standards / laws. All standards and kit controls must be found within the acceptable ranges as stated on the QC Certificate. If the criteria are not met, the run is not valid and should be repeated. Each laboratory should use known samples as further controls.

9.1 Quality criteria

For the evaluation of the assay it is required that the absorbance values of the blank should be below 0.25, and the absorbance of **Standard E** should be above 0.8.
Samples, which yield higher absorbance values than **Standard E**, should be re-tested with a higher dilution.

10 EVALUATION OF RESULTS

10.1 Establishing of the standard curve

The standards provided contain the following concentrations of human Vaspin

Standard	A	B	C	D	E
ng/mL	0,025	0,075	0,20	0,50	1,0
pg/mL	25	75	200	500	1000

1) Calculate the **mean absorbance** value for the blank from the duplicated determination (well A1/A2).
2) Subtract the mean absorbance of the blank from the mean absorbances of all other samples and standards.
3) Plot the standard concentrations on the x-axis versus the mean value of the absorbance of the standards on the y-axis.
4) Recommendation: Calculation of the standard curve should be done by using a computer program, because the curve is in general (without respective transformation) not ideally described by linear regression. **A higher-grade polynomial, or four parametric logistic (4-PL) curve fit** or **non-linear regression** are usually suitable for the evaluation (as might be spline or point-to-point alignment in individual cases).
5) The Vaspin concentration in ng/mL (or pg/mL, according the chosen unit for the standards) of the samples can be calculated by **multiplication** with the respective **dilution factor.**

10.2 Example of a typical standard curve

The following data is for demonstration only and cannot be used in place of data generation at the time of assay.

Standard	Blank	A	B	C	D	E
ng/mL	0,0	0,025	0,075	0,20	0,50	1,0
OD (450-620 nm)	0,027	0,096	0,241	0,608	1,456	2,729

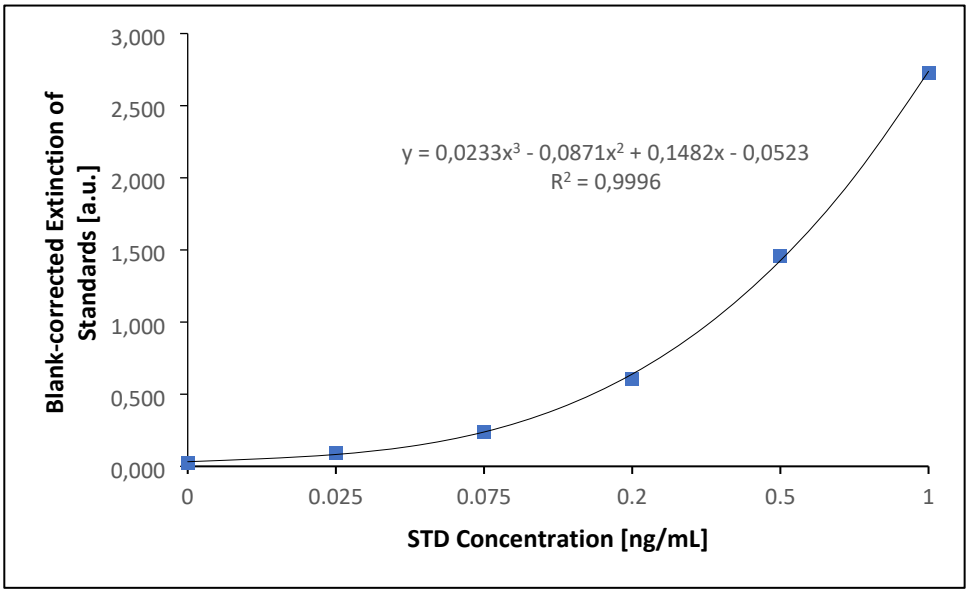

Figure 1: Exemplary standard curve using polynomial regression.

The exemplary shown standard curve in Figure 1 **cannot** be used for calculation of your test results. You have to establish a standard curve for each test you conduct!

10.3 Exemplary calculation of Vaspin concentrations

Sample dilution:

Measured extinction of your sample (OD_{450}-OD_{620}) 0.56
Measured extinction of the blank (OD_{450}-OD_{620}) 0.03

Your measurement program will calculate the Vaspin concentration of the diluted sample automatically by using the difference of sample and blank for the calculation.

In this exemplary case the following equation is solved by the program to calculate the Vaspin concentration in the sample:

$0,53 = 0,0233x^3 - 0,0871x^2 + 0,1482x - 0,0523$

$0,1735 = x$

If the dilution factor (**1:4**) is taken into account, the Vaspin concentration of the undiluted sample is

$0,1735 \times 4 = 0,694$ ng/mL

11 REFERENCE VALUES

Serum samples of a small group of healthy blood donors were used to assess the Vaspin concentration in healthy adults. No information regarding sampling time or contraceptive status was available. Samples were diluted 1:4.

Table 1: Exemplary Vaspin concentration in healthy adult humans (blood donors).

Age [years]	Mean Males [ng/mL]	SD [ng/mL]	Number	Mean Femals [ng/mL]	SD [ng/mL]	Number
19-25	0.208	0.12	13	2.277	1.8	9
26-30	0.241	0.23	11	1.130	0.88	5
34-44	0.241	0.15	8	0.999	0.78	10
45-54	0.253	0.18	8	0.708	0.69	9
55-68	0.2402	0.20	5	0.503	0.31	5

In females an age-dependent decline of Vaspin concentrations might be apparent, but it should be reflected that oral contraceptives result in an increase of Vaspin serum concentration. Thus, instead of age dependent changes decline of Vaspin concentration might reflect a changed behavior of women correlating with age.

Interpretation of results

The test results should not be the only base for therapeutic decisions. The results should be interpreted in regard to anamnesis, further clinical observations and results of other diagnostic investigations. Further, it is recommended to establish reference and cut-off values corresponding to the relevant group of patients for each laboratory.

12 PERFORMANCE CHARACTERISTICS

12.1 Sensitivity

We measured the blank (dilution buffer only) 16 times in one assay. The resulting standard deviation was used for calculating the concentration which can be differentiated from the blank. Thus, lowest amount of Vaspin detectable is 4 pg/mL.

Table 2: Limit of Detection and Quantification

Standard Deviation [a.u.]	1 SD Vaspin [ng/mL]	3 SD Vaspin [ng/mL]	10SD Vaspin [ng/mL]
0.015	0.004	0.012	0.037

12.2 Specificity

Specificity of the employed polyclonal antibodies was investigated by two different methods. Proteins of a native serum sample were separated by size exclusion chromatography, resulting fractions were tested a) by the ELISA and b) fractions positive in the ELISA were also tested by western blot. Figure 2 demonstrates that the ELISA detects a signal at about 37 kDa which is confirmed by western blot. Theoretically Vaspin has a molecular weight of 45.2 kDa. In comparison with recombinant Vaspin the signal of the SEC peak fraction is of the same size. Differences of the calculated molecular weight might result of the variability in column calibration as well as of the SEC conditions, like fraction size and flow velocity.

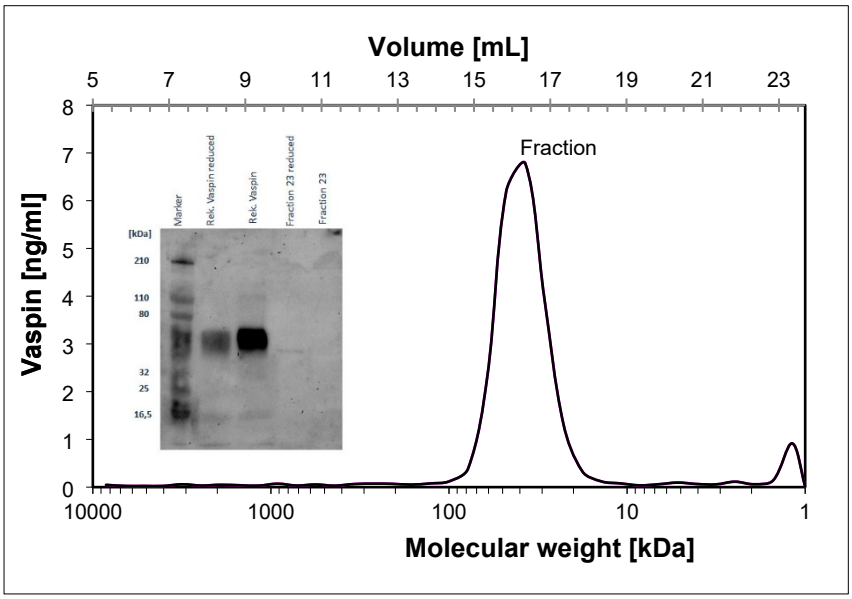

Figure 2: Specificity of Vaspin ELISA. Human Serum (250 µL) was separated by SEC Superdex 10/300GL, fraction size was 0.5 mL and flow velocity 0.5 mL/min. Samples were diluted 1:4 in dilution buffer. Inset shows results of western blotting, samples were separated by 10 % SDS-PAGE blotted and stained by biotinylated antibody (1:1000) and streptavidin-peroxidase conjugate (1:1500).

Table 3: Cross reactivity with related proteins. Proteins were diluted in dilution buffer and applied to the testsystem with the indicated analytic concentration.

Protein	Concentration used	Concentration measured	Relative Cross reactivity [%]
Alpha-1-antichymotrypsin Serpin A3	220 µg/mL	0.000055 µg/mL	0.000025
Alpha-1-antitrypsin Serpin A1	2 mg/mL	0.000000022 mg/mL	0.0000011
Thyroxine-binding globulin Serpin A7	30 µg/mL	0.00003 µg/mL	0.000206667
Adiponectin	20 µg/mL	0.00003 µg/mL	0.00015
Leptin	50 ng/mL	0.003 ng/mL	0.006

12.3 Precision

Intra-Assay-Variance

Table 4: Intra-Assay-Variation. Three exemplary serum samples were diluted and measured 20 times in one assay.

	Sample 1	Sample 2	Sample 3
Mean Value [ng/mL]	0.226	1.192	1.536
SD [ng/mL]	0.006	0.045	0.02
% VC	2.85	3.81	1.42
n	20	20	20

Inter-Assay-Variance

Table 5: Inter-Assay-Variation. Serum samples were diluted as recommended and Vaspin concentration was measured in various independent tests.

	Sample 1	Sample 2	Sample 3
Meanvalue [ng/mL]	0.189	0.823	2.885
SD [ng/mL]	0.016	0.037	0.137
% VC	8.55	4.52	4.75
n	9	9	9

12.4 Linearity

The linearity of serum dilutions is over a very wide range excellent. Two serum samples with high and low Vaspin content were serial diluted and dilution was measured by Vaspin ELISA. Results are shown in Figure 3. It was possible to quantify Vaspin down to 4 pg/mL. In both cases dilution resulted in linear decrease of concentration.

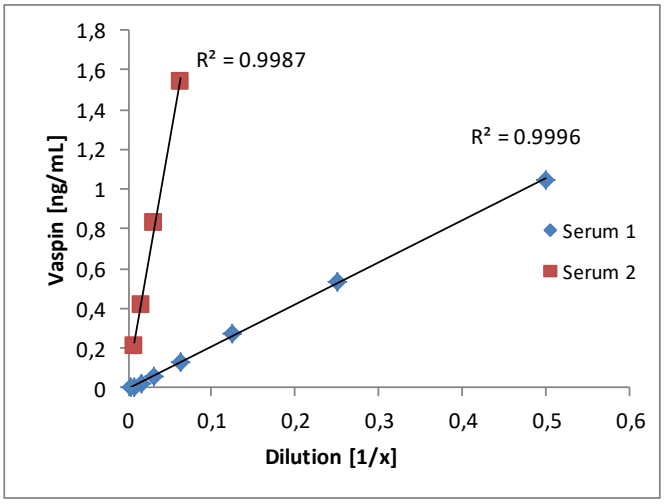

Figure 3: Linearity. Two serum samples were diluted and concentration of each dilution was measured. Here concentrations are shown.

12.5 Recovery

For evaluation of disturbing substances in serum samples as well as assessing correctness we enriched several human serum samples with two different amounts of recombinant Vaspin. For control purposes same amounts of Vaspin were added to buffer and relative recovery in serum samples was calculated based on the value found in buffer.

Table 6: Recovery of recombinant Vaspin in human serum samples.

	Endogenous Vaspin content [ng/mL]	**Serum enriched with 50 pg/mL** [ng/mL]	**Serum enriched with 500 pg/mL** [ng/mL]
Recombinant Vaspin in Buffe**r**		0.052	0.408
Sample 1	0.233	0.271	0.591
Recovery [%]		**95**	**87**
Sample 2	0.1055	0.139	0.455
Recovery [%]		**88**	**89**
Sample 8	0.2595	0.302	0.705
Recovery [%]		**97**	**99**
Sample 9	0.517	0.588	1.013
Recovery [%]		**103**	**102**
Sample 4	0.118	0.151	0.432
Recovery [%]		**89**	**77**
Sample 5	0.744	0.943	1.066
Recovery [%]		**118**	**79**
Sample 17	1.457	1.601	1.915
Recovery [%]		**106**	**95**
Sample 18	0.2895	0.345	0.695
Recovery [%]		**101**	**92**

Recovery range was 77 – 102 % for 500 pg/mL and 88 – 118 % for 50 pg/mL enrichment, on avarage **97 %** of the added recombinant material was found.

12.6 Interference

Interference of physiologically appearing substances with Vaspin was investigated. Serum samples have been enriched with different concentrations of possibly interfering substances and the amount of Vaspin was measured and compared with the Vaspin concentration in the sample without any enrichment. In table 7 the relative results are shown.
None of the tested substances interfered significantly with the Vaspin measurement.

Table 7: Recovery [%] in comparison to the native serum.

	Triglyceride 100 mg/mL	**Bilirubin 100 µg/mL**	**Hemoglobin 5 mg/mL**
Sample 1	106	112	114
Sample 2	93	107	91
Sample 3	96	123	91

13 COMPARISON WITH ANOTHER ASSAY

Vaspin ELISA was compared with an commercially available Vaspin ELISA. We found a very good correlation of measured values even absolute values differ by factor 2 because of differences in calibration (Figure 4).

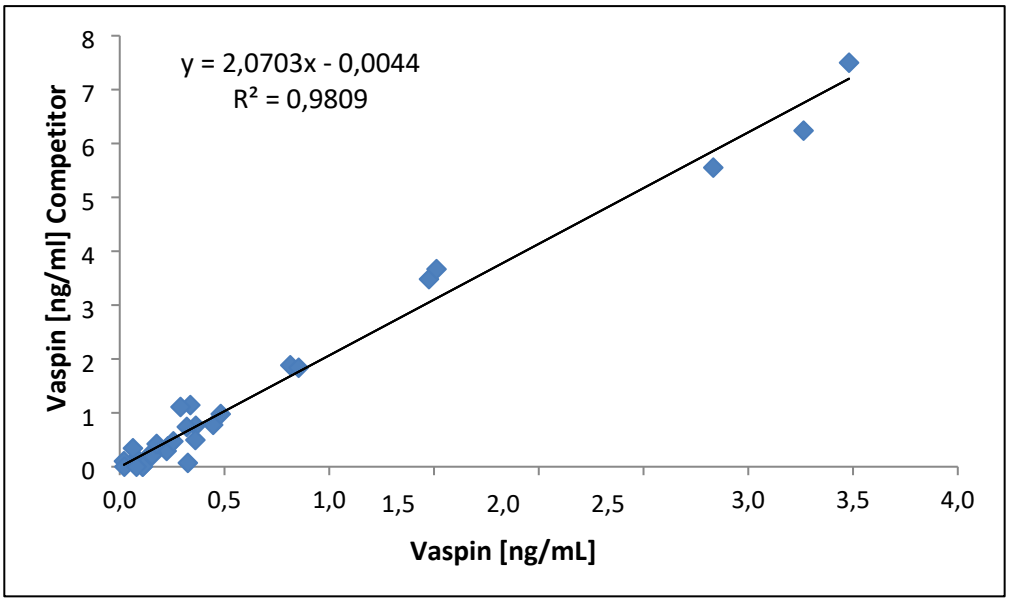

Figure 4: Assay Comparison with commercially available Testsystem

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Internationale Assay Description

A-E	STD	Rec in 750 µL BUF VP	-
KS1	Control	Rec in 250 µL BUF VP	1:4 DILU BUF VP
KS2	Control	Rec in 250 µL BUF VP	1:4 DILU BUF VP
WP	WASHBUF 20x	-	1:20 DILU A. dest.
-	SPE		1:4 DILU BUF VP
-	°C 20 - 25 °C		

100 µL	BUF VP	A1/A2
100 µL	STD A (25 pg/mL)	B1/B2
100 µL	STD B (75 pg/mL)	C1/C2
100 µL	STD C (200 pg/mL)	D1/D2
100 µL	STD D (500 pg/mL)	E1/E2
100 µL	STD E (1000 pg/mL)	F1/F2
100 µL	CONTROL KS1 1:4 DILU BUF VP	G1/G2
100 µL	CONTROL KS2 1:4 DILU BUF VP	H1/H2
100 µL	SPE 1:4 DILU BUF VP	
	TAPE	
	1 h °C 20 - 25 ↔ 350 rpm	
5x 300 µL	5x WASHBUF WP	
100 µL	Ab AK	
	TAPE	
	1 h °C 20 - 25 ↔ 350 rpm	
5x 300 µL	5x WASHBUF WP	
100 µL	CONJ EK	
	TAPE	
	1 h °C 20 - 25 ↔ 350 rpm	
5x 300 µL	5x WASHBUF WP	
100 µL	SUBST TMB S	
	0.5 h °C 20 - 25	
	H_2SO_4 SL	
	MEASURE	

EN/ DE/ FR/ IT/ ES/ PT/ NL/ DK/ SE/ PL/ HU/ SK/ CZ/ BG/ EE/ GR/ RO/ SI/ FI

Symbols/ Symbole /Symboles/ Simboli/ Símbolos/ Símbolos/ Symbolen/ Symboler/ Symboler/ Symbole/ Szimbólumok/ Symboly/ Symboly/ Символи/ Sümbolid/ Σύμβολα/ Simboluri/ Simboli/ Symbolit

DIN EN ISO 15223-1

	Expiry date/ Verfallsdatum/ Date de péremption/ Data di scadenza/ Fecha de caducidad/ Data de validade/ Uiterste gebruiksdatum/ Udløbsdato/ Bäst före-datum/ Termin ważności/ Lejárati idő/ Čas exspirácie/ Doba exspirace/ Срок на годност/ Aegumiskuupäev/ Ημερομηνία λήξης/ Data de expirare/ Rok uporabe/ Viimeinen käyttöpäivä
	Consider instructions for use/ Bitte Gebrauchsanweisung beachten/ Consultez la notice d'utilisation/ Consultare le istruzioni per l'uso/ Consulte las instrucciones de uso/ Respeitar as instruções de utilização/ A.u.b de gebruiksaanwijzing volgen/ Se brugsanvisningen/ Läs anvisningarna före användning/ Proszę przeczytać instrukcję obsługi/ Vegye figyelembe a használati utasításban foglaltakat/ Postupujte podľa pokynov na použitie/ Dodržujte návod k použití/ Моля, спазвайте инструкцията за употреба/ Palun järgige kasutusjuhendit/ Λάβετε υπόψη σας τις οδηγίες χρήσης/ Vă rugăm să respectaţi instrucţiunile de utilizare/ Upoštevajte navodila za uporabo!/ Lue käyttöohje huolellisesti!
	Lot-Batch Number/ Charge-Chargennummer/ Lot-Code du lot/ Lotto-Numero di lotto/ Lote-Código de lote/ Lote-Código do Lote/Lot-Patijnumme/ Lot-Batchkode/ Partisatskod/ Numer serii/ Tétel-sarzs szám/ Číslo šarže/ Číslo šarže/ Партиден номер/Partii number/ Παρτίδα-αριθμός παρτίδας/ Lot-număr lot/ Številka serije/ Erä
	Manufactured by/ Hergestellt von/ Fabriqué par/ Prodotto da/ Fabricado por/ Fabricado por/ Vervaardigd doo/ Fabrikation af/ Tillverkad av/ Wyprodukowane przez/ Gyártotta/ Vyrobené/ Vyrobeno v/ Производител/ Tootja/ Κατασκευάζεται από/ Produs de/ Proizvajalec/ Valmistaja
	Catalogue Number/ Bestellnummer/ Numéro de référence/ Numero di riferimento/ Número de referencia/ Número de Referência/ Referentienummer/ Referencenummer/ Beställningsnummer/ Numer katalogowy/ Rendelési szám/ Katalógové číslo/ Objednací číslo/ Каталожен номер/ Tellimisnumber/ Αρ. παραγγελίας/Număr comandă/ Številka naročila/ Viite tai tilausnumero
	Store at between/ Lagerung bei zwischen/ Conserver à entre/ Conservare a tra/ Conservar a temp. entre/ Armazenar entre/ Bewaar bij tussen/ Opbevares mellem/ Förvaras vid/ Przechowywać w/ Tárolási tartomány/ Skladujte v rozsahu / Skladujte v rozmezí/ Температурно ограничение/ Säilitada temperatuuridel/ Φύλαξη σε θερμοκρασία/ Depozitare între/ Skladiščenje med/ Säilytys x-y Celsiusasteen lämpötilassa
	Contains sufficient for x tests/ Inhalt ausreichend für x Tests/ Contient suffisant pour x tests/ Contenuto sufficiente per x test/ Contenido suficiente para x pruebas/ Conteúdo suficiente para x testes/ Bevat voldoende voor x bepalingen/ Indeholder tilstrækkeligt til x prøver/ Innehållet räcker till x analyser/ Zawartość na x testów/ Tartalma x teszt elvégzésére elegendő/ Obsahuje materiál pre x testov/ Obsah dostačuje pro x testů/ Съдържание достатъчно за x тестове/ Sisust jätkub x katse jaoks/ Το περιεχόμενο επαρκεί για x δοκιμές/ Conţinut suficient pentru x teste/ Vsebina zadostuje za x preizkusov/ Sisältö riittää x testille
	Incubation time/ Inkubationszeit/ Temps d'incubation/ Tempo d'incubazione/ Tiempo de incubación/ Tempo de incubação/ incubatietijd/ Inkubationstid/ inkubationstid/ Czas inkubacji/ Inkubációs idő/ Inkubačná lehota/ Inkubační doba/ Инкубационен период/ Inkubatsiooniaeg/ Χρόνος επώασης/ Timp de incubare/ Inkubacijska doba/ inkubaatioaika
	Incubate at/ Inkubation bei/ Incuber à/ Incubare a/ incubar a/ Incubar a/ incubatietemperatuur/ Inkubation ved/ inkubation vid/ Inkubacja przy/ Inkubáció hőmérséklete/ Inkubácia pri/ Inkubace při/ Инкубира се при/ Inkubatsioon temperatuuril/ Επώαση στους/ Incubare la/ Inkubacija pri/ Inkubaatiolämpötila
	Mix tubes with a Vortex mixer/ Mix Röhrchen mit Vortex Mixer/ Mélanger à l'aide d'un vortex/ Miscelare la provetta con agitatore Vortex/ Tubos de mezcla con mezclador de vórtex/ Misturar os tubos com um agitador Vortex/ buisjes mengen met een Vortex/ Blanderør med Vortex-mixer/ Blanda rören med en vortexblandare/ Miksowanie rurek w mikserze Vortex/ Csövecskék keverése örvénykeverővel/ Premiešať pomocou prístroja Vortex/ Promíchat pomocí přístroje Vortex/ Разбъркване на епруветките с миксер Vortex/ Segada torukesi Vortexi mikseriga/ Αναμίξτε τους σωληνίσκους με αναδευτήρα Vortex/ Amestecaţi eprubetele cu ajutorul unui agitator vortex/ Mešanje cevčic z mešalnikom Vortex/ Sekoita putket Vortex sekoittajalla
	Miktrotiterplate/ Mikrotiterplatte/ plaque de microtitrage/ Piastra di microtitolazione/ Placa de microtitulación/ Placa de Microtitulação/ Microtiterplaat/ Mikrotiterplade/ mikrotiterplatta/ microtiterplaat/ Płytka microtiter/ Mikrotiter lap/ Mikrotitračná podložka/ Mikrotitrační podložka/ Микротитърна плака/ Mikrotiiterplaat/ Τρυβλίο μικροτιτλοδότησης/ Microplacă/ Mikrotitrska plošča/ Mikrotitrauslevy
	Reconstitute in/ Rekonstituieren in/ Reconstituer dans/ Ricostituire nel/ Reconstituir en/ Reconstituir em/ Reconstitueren in/ Rekonstituér i/ Rekonstituera/ Rekonstytuować w/ Helyreállítás/ Znovu pripraviť za/ Znovu připravit za/ Разтваряне в/ Moodustada uuesti/ Ανασυστήστε σε/ Reconstituire în/ Predelava v/ Rekonstituoi
	Sample/ Probe/ Echantillon/ Campione/ Muestra/ Amostra/ Monster/ Prøve/ prov/ Próbka/ Minta/ Vzorka/ Vzorek/ Проба/ Proov/ Δείγμα/ Probă/ Vzorec/ Näyte
	Antibody and Enzyme Conjugate/ Antikörper und Enzym Konjugat/ Anticorps conjuguée et conjugué enzymatique/ Coniugato di anticorpo ed enzima/ Conjugado de anticuerpos y enzimas/ Conjugado Anticorpo-Enzima/ Antilichaam- en enzymconjugaat/ Antistoffer og enzym-konjugat/ Antikropps- och enzymkonjugat (antikropp och enzym, konjugat)/ Koniugat antyciał i enzymów/ Antitest és enzim páros/ Protilátkový a enzymatický konjugát/ Protilátkový a enzymatický konjugát/ Антитяло и ензим конюгат/ Antikehad ja ensüümi konjugaat/ Σύμπλοκο αντισώματος-ενζύμου/ Compuşi din anticorpi şi enzime/ Antitelesa in konjugat encima/ Vasta-aine ja entsymi konjugaatti
	Buffer/ Puffer/ Tampon/ Tampone/ Tampón/ Tampão/ Buffer/ Buffer/ Buffert/ Bufor/ Puffer/ Pufer/ Pufr/ Буфер/ Puhver/ Ρυθμιστικό διάλυμα/ Tampon/ Pufer/ Puskuri

DILU BUF X	Dilute in Buffer X/ Verdünnen in Puffer X/ Diluer dans le tampon X/ Diluire nel tampone X/ Diluir en tampón X/ Diluir no Tampão X/ Verdunnen in buffer X/ Fortyndes i buffer X/ Späd i buffert X/ Rozcieńczanie w buforze X/ Hígítás X pufferben/ Riediť v pufri X/Ředit v pufru X/ Разреждане в буфер X/ Lahjendada puhvris X/ Αραιώστε σε ρυθμιστικό διάλυμα X/ Diluaţi în tamponul X/ Razredčiti v pufru X/ Laimennetaan x puskuriin
STD	Standard X/ Standard X/ Etalon X/ Standard X/ Estándar X/ Standard X/ Standaard X/ Standard X/ standard X/ Standard X/ Standard X/ Štandard X/ Standard X/ Стандарт X/ Standard X/ Πρότυπο X/ Standard X/ Standardni X/ Standardi X
Control	Control Serum X/ Kontrollserum X/ Contôle sérique X/ Siero di controllo X/ Suero de control X/ Soro de Controlo X/ controleserum X/ Kontrolserum X/ Kontrollserum X/ Serum kontrolne X/ Ellenőrző szérum X/ Kontrolné serum X/ Kontrolní serum X/ Контролен серум X/ Kontrollseerum X/ Ορός ελέγχου X/ Ser de control X/ Kontrolni serum X/ Kontrolli seerumi X
WASHBUF 20x	Washing Buffer Concentrate/ Waschpufferkonzentrat/ Tampon de lavage conc./ Tampone di lavaggio concentrato/ Tampón de lavado concentrado/ Tampão de Lavagem Concentrado/ wasbuffer, geconcentreerd/ Vaskebufferkoncentrat/ Vaskebufferkoncentrat/ tvättbuffertkoncentrat/ Bufor płukania koncentrat/ Mosópuffer koncentrátum/ Koncentrát vymývacieho pufra/ Концентрат на промивен буфер/ Pesupuhvri kontsentraat/ Συμπύκνωμα ρυθμιστικού διαλύματος έκπλυσης/ Concentrat pentru tamponul de spălare/ Koncentrat izpiralnega pufra/ Pesuliuositiiviste
WASHBUF	Washing Buffer/ Waschpuffer/ Tampon de lavage/ Tampone di lavaggio/ Tampón de lavado/Tampão de Lavagem/ wasbuffer/ Vaskebuffer/ tvättbuffert/ Bufor płukania/ Mosópuffer/ Vymývací pufer/ Vymývací pufr/ Промивен буфер/ Pesupuhver/ Ρυθμιστικό διάλυμα έκπλυσης/ Tampon pentru spălare /Izpiralni pufer/ Pesuliuos
SUBST TMB	Substrate/ Substrat/ Substrat/ Substrato/ Substrato/ Substrato/ substraat/ Substrat/ Substrat/ Substrat/ Szubsztrátum/ Substrát/ Substrát/ Субстрат Substraat/ Υπόστρωμα/ Substrat/ Substrat/ Substraattiliuos
H_2SO_4	Stopping Solution/ Stopplösung/ Stop Solution/ Soluzione di stop/ Stop Solución/ Solução Stop/ stopoplossing/ Stopopløsning/ Stopplösning/ Stop roztwór/ Megállító oldat/ Roztok na ukončenie/ Roztok pro ukončení/ Стопиращ разтвор/ Stopp-lahus/ Διάλυμα διακοπής/ Soluţie de oprire/ Stop raztopina/ Pysäytysliuos
TAPE	Cover Plate with sealing tape/ Platte abkleben/ Recouvrir la microplaque avec bande adhésive/ Coprire la piastra con nastro adesivo/ Cubrir la placa con una cinta adhesiva/ Cobrir a Placa com fita adesiva/ plaatje met tape afdekken/ Afdækningsplade med tape/ maskera platta/ Odkleić płytkę/ Tányér leragasztása/ Oblepiť podložku lepiacou páskou/ Olepit podložku lepicí páskou/ Плака с лента за запечатване/ Katta plaat isoleerkleeplindiga/ Κολλήστε το πλακίδιο με κολλητική ταινία/ Aoperiţi placa cu o bandă adezivă/ Prelepiti ploščo/ Peitä mikrotitrauslevy oheisella teipillä
MEASURE	Measure plate within 30 min at 450 nm (Referencefilter ≥590 nm)/ Ausmessung innerhalb von 30 min bei 450 nm (Referenzfilter ≥ 590 nm)/ Mesure lábsorbance en léspace de 30 min à 450 nm avec ≥590 nm longueur dónde pour référence/ Misurazione entro 30 min. a 450 nm (filtro di riferimento ≥ 590 nm)/ Medición de la placa dentro de los siguientes 30 min a 450 nm (filtro de referencia ≥ 590nm)/ Medir a placa dentro de 30 min a 450 nm (Filtro de referência ≥ 590 nm)/ Binnen 30 minuten bij 450 nm meten (referentiefilter ≥ 590 nm)./ Mål plade i løbet af 30 min ved nm (referencefilter ≥590 nm)/ Mät inom 30 min vid 450 nm (referensfilter ≥ 590 nm)./ Pomiar w ciągu 30 min przy 450 nm (filtr odniesienia ≥ 590 nm)/ Ki mérés 30 percen belül 450 nm-nél (referenciaszűrő ≥ 590 nm)/ Merať 30 minút pri 450 nm (Referenčných filtrov ≥590 nm)/ Měřit 30 minut při 450 nm (Referenční filtr ≥ 590 nm)/ Отчитане в рамките на 30 min при 450 nm (референтен филтър ≥ 590 nm)/ Mõõtmine 30 min jooksul 450 nm korral (võrdlusfilter ≥ 590 nm)/ Μέτρηση εντός 30 min στα 450 nm (φίλτρο αναφοράς ≥ 590 nm)/ Măsurare în decurs de 30 min la 450 nm (filtru de referinţă ≥ 590 nm)/ Izmerite ploščico v 30 min pri 450 nm (referenčni filter ≥590nm)/ Mittaa 30 minuutin aikana 450 nm:ssä (referenssi suodatin ≥ 590 nm)
Literatur	Literature/ Literatur/ Bibliographie/ Letterario/ Bibliografía/ Literatura documentação/ literatuur/ Litteratur/ litteratur/ Literatura/ Irodalom/ Literatúra/ Literatura/ Литература// Kirjandus/ Βιβλιογραφία/ Bibliografie/ literatura/ Lähdeluettelo
International Test description	International test description/ internationale Testanleitung/ description internationale de test/ Istruzioni per il test internazionali/ Descripción de ensayo internacional/ Descrição internacional do teste/ internationale testbeschrijving/ internationell testbeskrivning/ Opis testu międzynarodowego/ nemzetközi teszt-útmutató/ Medzinárodný návod k testu/ Mezinárodní návod k testu/ rahvusvaheline katse kirjeldus/ Διεθνείς οδηγίες για εργαστηριακές δοκιμές/ instrucţiuni internaţionale pentru testare/ mednarodna navodila za preizkus/ Kansainvälinen käyttöohje
End	in all required wells/ in allen benötigten Vertiefungen/ dans tous les godets requis/ in tutti i pozzetti richiesti/ en todos los pozos requeridos/ em todos os tubos necessários/ in alle nodige putjes/ i alle nødvendige brønde/ i alla nödvändiga brunnar/ we wszystkich potrzebnych wgłębieniach/ minden szükséges forrásban/ vo všetkých potrebných miestach/ ve všech potřebných místech/ във всички необходими ямки/ kõigis vajalikes süvendites/ σε όλες τις απαραίτητες κοιλότητες/ în toate cavităţile necesare/ v vseh zahtevanih vdolbinah/ kaikkiin tarvittaviin mikrotitrauslevyn syvennyyksiin

Symbols / Symbole / Symboles / Símbolos / Simboli / Símbolos / Σύμβολα

REF	Cat.-No.: / Kat.-Nr.: / No.- Cat.: / Cat.-No.: / N.–Cat.: / N.º Cat.: / Αριθμός-Κατ.:
LOT	Lot-No.: / Chargen-Bez.: / No. Lot: / Lot-No.: / Lotto n.: / Lote N.º: / Αριθμός -Παραγωγή:
	Use by: / Verwendbar bis: / Utiliser à: / Usado por: / Da utilizzare entro:/ Usar até: / Χρησιμοποιείται από:
Σ	No. of Tests: / Kitgröße: / Nb. de Tests: / No. de Determ.: / Quantità dei tests: / N.º de Testes: / Αριθμός εξετάσεων:
CONC	Concentrate / Konzentrat / Concentré / Concentrar / Concentrato / Concentrado / Συμπύκνωμα
LYO	Lyophilized / Lyophilisat / Lyophilisé / Liofilizado / Liofilizzato / Liofilizado / Λυοφιλιασμένο
IVD	In Vitro Diagnostic Medical Device / In-vitro-Diagnostikum / Appareil Médical pour Diagnostics In Vitro / Dispositivo Médico para Diagnóstico In Vitro / Dispositivo Medico Diagnostico In vitro / Equipamento Médico de Diagnóstico In Vitro / Ιατρική συσκευή για In-Vitro Διάγνωση
BIO	Contains biological material of human origin / Enthält biologisches Material menschlichen Ursprungs / Contient une substance biologique d'origine humaine / Contiene material biológico de origen humano / Contiene materiale biologico di origine umana / Contém material biológico de origem humana / Περιέχει βιολογικό υλικό ανθρώπινης προέλευσης
BIO	Contains biological material of animal origin / Enthält biologisches Material tierischen Ursprungs / Contient une substance biologique d'origine animale / Contiene material biológico de origen animal / Contiene materiale biologico di origine animale / Contém material biológico de origem animal / Περιέχει βιολογικό υλικό ζωικής προέλευσης
UDI	Unique Device Identification / Eindeutige Gerätekennung / Identifiant de dispositif unique / Identificación única de producto / Identificatore univoco del dispositivo / Identificador de dispositivo único / Μοναδικός αναγνωριστικός κωδικός προϊόντος
	Read instructions before use / Arbeitsanleitung lesen / Lire la fiche technique avant emploi / Lea las instrucciones antes de usar / Leggere le istruzioni prima dell'uso / Ler as instruções antes de usar / Διαβάστε τις οδηγίες πριν την χρήση
	Keep away from heat or direct sun light / Vor Hitze und direkter Sonneneinstrahlung schützen / Garder à l'abri de la chaleur et de toute exposition lumineuse / Manténgase alejado del calor o la luz solar directa / Non esporre ai raggi solari / Manter longe do calor ou luz solar directa / Να φυλάσσεται μακριά από θερμότητα και άμεση επαφή με το φως του ηλίου
	Store at: / Lagern bei: / Stocker à: / Almacene a: / Armazenar a: / Conservare a: / Armazenar em: / Αποθήκευση στους:
2-8°C	Store at: 2 - 8°C / Lagern bei: 2 - 8°C / Stocker à: 2 - 8°C / Almacene a: 2 - 8°C / Armazenar a: 2 - 8°C / Conservare a: 2-8°C / Armazenar em: 2-8°C / Αποθήκευση στους: 2-8°C
	Manufacturer: / Hersteller: / Fabricant: / Productor: / Fabricante: / Fabbricante: / Παραγωγός:
	Distributor: / Distributor: / Distributeur: / Distributor: / Distributore: / Distribuidor: / Διανομέας:
	Caution! / Vorsicht! / Attention! / ¡Precaución! / Attenzione! / Cuidado! / Προσοχή!
	Symbols of the kit components see MATERIALS SUPPLIED. Die Symbole der Komponenten sind im Kapitel KOMPONENTEN DES KITS beschrieben. Voir MATERIEL FOURNI pour les symbôles des composants du kit. Símbolos de los componentes del juego de reactivos, vea MATERIALES SUMINISTRADOS. Per i simboli dei componenti del kit si veda COMPONENTI DEL KIT. Para símbolos dos componentes do kit ver MATERIAIS FORNECIDOS. Για τα σύμβολα των συστατικών του κιτ συμβουλευτείτε το ΠΑΡΕΧΟΜΕΝΑ ΥΛΙΚΑ.

Generic table, not all symbols are present in the product

COMPLAINTS: Complaints may be submitted initially written or vocal. Subsequently they need to be filed including the test performance and results in writing in case of analytical reasons.

WARRANTY: The product is warranted to be free from material defects within the specific shelf life and to comply with product specifications delivered with the product. The product must be used according to the Intended use, all instructions given in the instructions for use and within the product specific shelf life. Any modification of the test procedure or exchange or mixing of components of different lots could negatively affect the results. These cases invalidate any claim for replacement.

LIMITATION OF LIABILITY: IN ALL CIRCUMSTANCES THE EXTENT OF MANUFACTURER'S LIABILITY IS LIMITED TO THE PURCHASE PRICE OF THE KIT(S) IN QUESTION. IN NO EVENT SHALL MANUFACTURER BE LIABLE FOR ANY INCIDENTAL OR CONSEQUENTIAL DAMAGES, INCLUDING DAMAGES FOR LOST PROFITS, LOST SALES, INJURY TO PERSON OR PROPERTY OR ANY OTHER INCIDENTAL OR CONSEQUENTIAL LOSS.

The labelling of hazardous substances is according to European directive.
For further country-specific classifications, please refer to the corresponding safety data sheet.

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