Certificate of Analysis

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Analytical services

Grail Formula B.V.
Grail Formula B.V.
Hingenderstraat 39
6111 AB Sint Joost
Netherlands
info@24peptides.com

Liquilabs s.r.o.
Inovační 122
252 41 Zlatníky-Hodkovice
Czechia
www.liquilabs.cz

Verify Results Online

Sample Identification

Sample Name	Tri-Heal Max 45 mg
Batch Number	GF-THMAX-B241
Date Published	2026-06-11 14:31

Results for LYO-0199

Peptides	Result	Unit	Uncertainty	Acceptable Range
BPC-157 Assay Peptide Screening 0.1% TFA	13.51	*mg*	[± 0.07]	
KPV Assay Peptide Screening 0.1% TFA	10.01	*mg*	[± 0.05]	
BPC-157 Purity Peptide Screening 0.1% TFA	> 99.8	*%*		
KPV Purity Peptide Screening 0.1% TFA	> 99.8	*%*		
BPC-157 Identification by RT Peptide Screening 0.1% TFA	0.995		[± 0.005]	
KPV Identification by RT Peptide Screening 0.1% TFA	0.996		[± 0.005]	
Thymosin Beta 4 (TB-500) Assay Peptide Screening 0.1% TFA	34.9	*mg*	[± 0.2]	
Thymosin Beta 4 (TB-500) Purity Peptide Screening 0.1% TFA	> 99.8	*%*		
Thymosin Beta 4 (TB-500) Identification by RT Peptide Screening 0.1% TFA	0.995		[± 0.005]	

Microbiology	Result	Unit	Uncertainty	Acceptable Range
Total Aerobic Microbial Count USP <61>/Eur. Ph. 2.6.12. Plate Count Method	0	*CFU/g*	[±]	0 - 1000
Total Yeast and Mold Count USP <61>/Eur. Ph. 2.6.12. Plate Count Method	0	*CFU/g*	[±]	0 - 100
Bacterial Endotoxin Chromgenic USP<85>/ Eur. Ph. 2.6.14. Bacterial Endotoxin Chromgenic Test	< 0.001	*EU/mg*		0 - 0.5

Elemental Impurities	Result	Unit	Uncertainty	Acceptable Range
Arsenic Elemental Impurities screening USP ⟨232⟩ / Ph. Eur. 5.20 / 2.4.20	< 0.001	*ppm*		0 - 1.5
Cadmium Elemental Impurities screening USP ⟨232⟩ / Ph. Eur. 5.20 / 2.4.20	< 0.001	*ppm*		0 - 0.5
Quicksilver Elemental Impurities screening USP ⟨232⟩ / Ph. Eur. 5.20 / 2.4.20	< 0.001	*ppm*		0 - 1.5
Lead Elemental Impurities screening USP ⟨232⟩ / Ph. Eur. 5.20 / 2.4.20	< 0.001	*ppm*		0 - 1.5
Nickel Elemental Impurities screening USP ⟨232⟩ / Ph. Eur. 5.20 / 2.4.20	< 0.001	*ppm*		0 - 25
Vanadium Elemental Impurities screening USP ⟨232⟩ / Ph. Eur. 5.20 / 2.4.20	< 0.001	*ppm*		0 - 25
Cobalt Elemental Impurities screening USP ⟨232⟩ / Ph. Eur. 5.20 / 2.4.20	< 0.001	*ppm*		0 - 25

Mass Spectrometry	Result	Unit	Uncertainty	Acceptable Range
Molecular Ion Mass Identification (BPC-157) Mass Spectrometry Identity	1418	*Da*	[± 1]	
Molecular Ion Mass Identification (KPV) Mass Spectrometry Identity	343	*Da*	[± 1]	
Molecular Ion Mass Identification (TB-500) Mass Spectrometry Identity	4963	*Da*	[± 1]	

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Analysis Report

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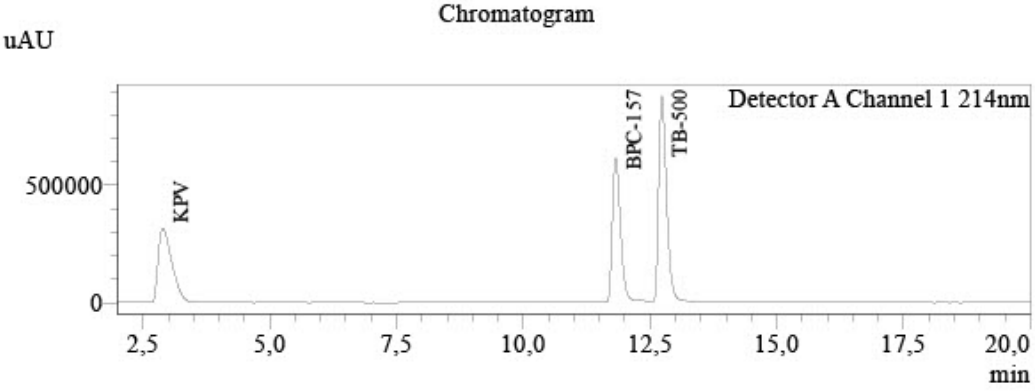
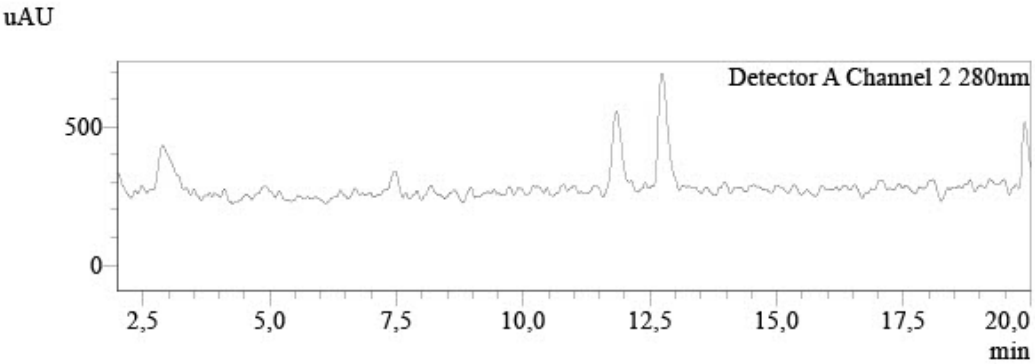
Sample Information

Injection Volume	: 0,5
Data File	: LYO-0199__005.lcd
Method File	: Peptide screening_202602_Polar_Blend A.lcm
Date Acquired	: 02.06.2026 18:17:11

Chromatogram





Peak Table

Detector A Channel 1 214nm

Peak#	Name	Ret. Time	Conc.	Unit	Area%
1	KPV	2,890	10,008	mg/L	26,305
2	BPC-157	11,825	13,512	mg/L	31,058
3		12,325	0,000		0,040
4	TB-500	12,735	34,902	mg/L	42,597
Total					100,000

Peak Table

Detector A Channel 2 280nm

Peak#	Name	Ret. Time	Conc.	Unit
Total				

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Qualitative Analysis Report

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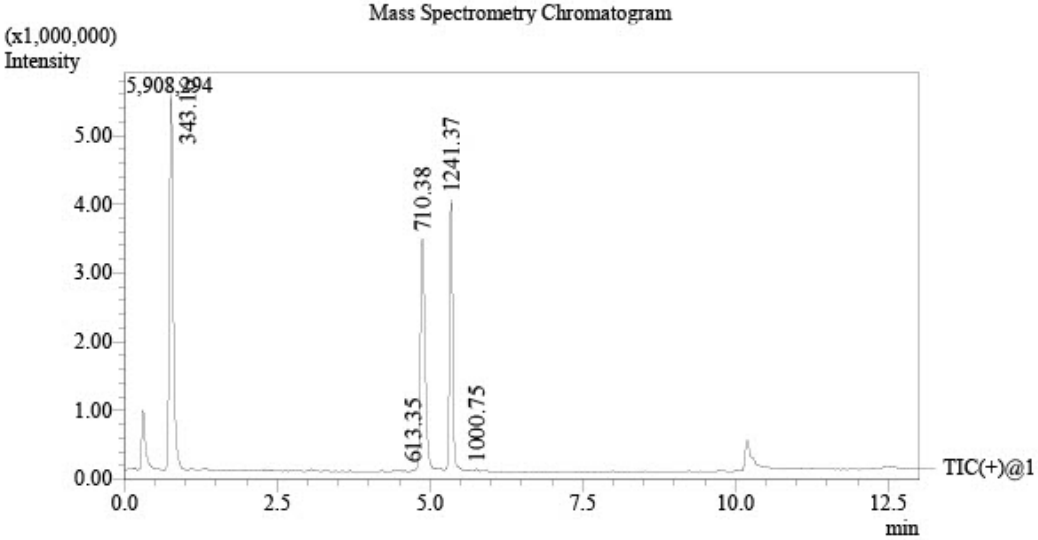
Sample Information

Injection Volume	: 2
Data File	: LYO-0199__002.lcd
Method File	: Peptide screening_V7.lcm
Date Acquired	: 6/11/2026 1:44:46 PM

Mass Spectrometry Chromatogram



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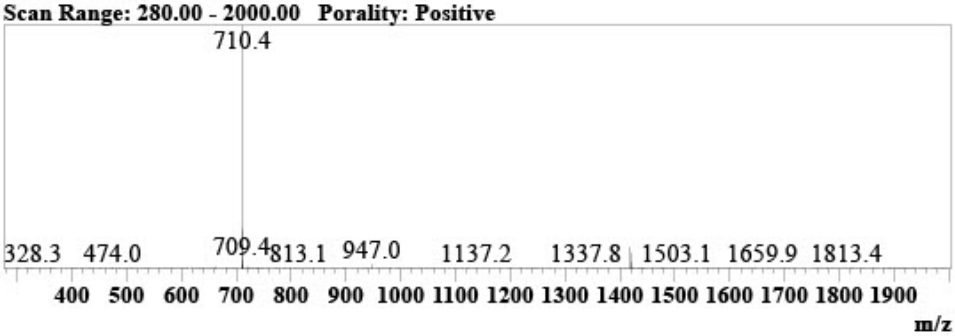
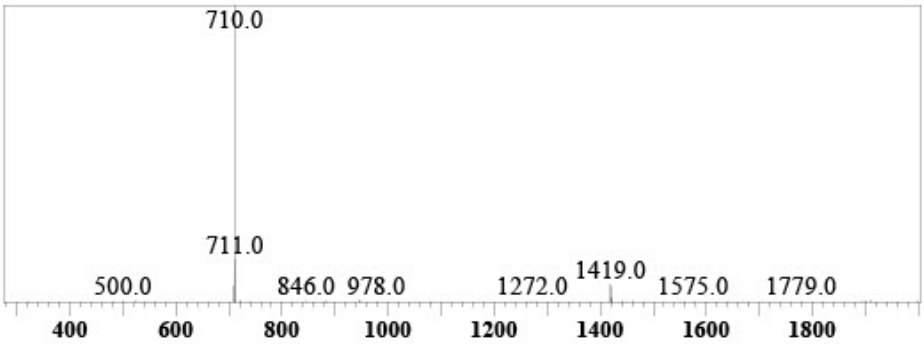
Detected substance

Ret.Time: 4.766
Base Peak: 710.4 Da
Scan Range: 280.00 - 2000.00 Porality: Positive



Identified Substance

Compound Name: BPC-157
Similarity: 95%
Formula: C62H98N16O22
CAS: 137525-51-0
Mol.Weight: 1418 Da



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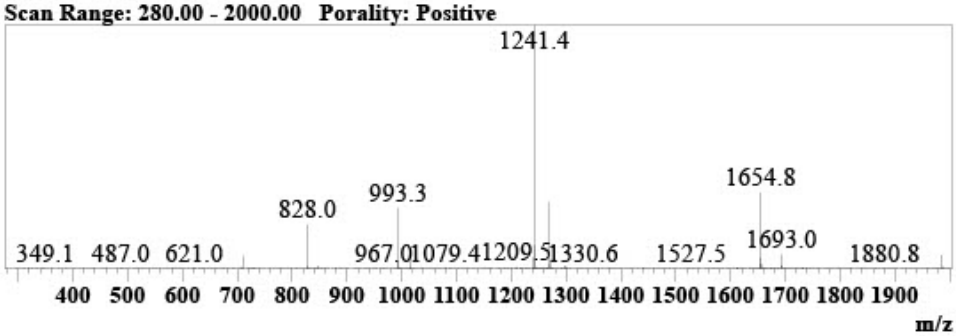
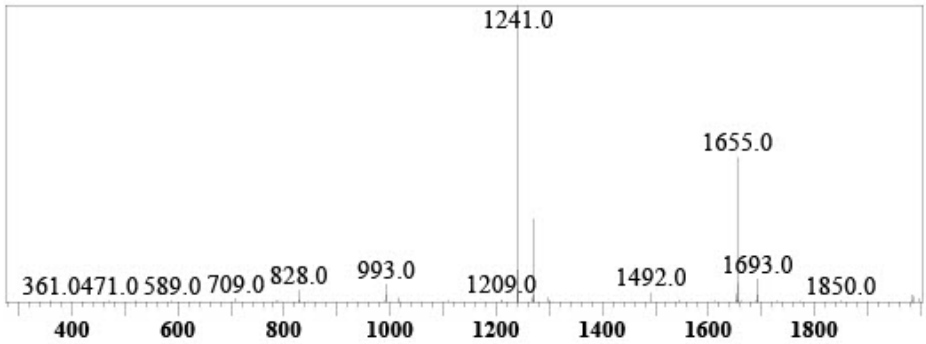
Detected substance

Ret.Time: 5.233
Base Peak: 1241.4 Da
Scan Range: 280.00 - 2000.00 Porality: Positive



Identified Substance

Compound Name: Thymosin Beta 4
Similarity: 88%
Formula: C212H350N56O78S
CAS: 77591-33-4
Mol.Weight: 4963 Da



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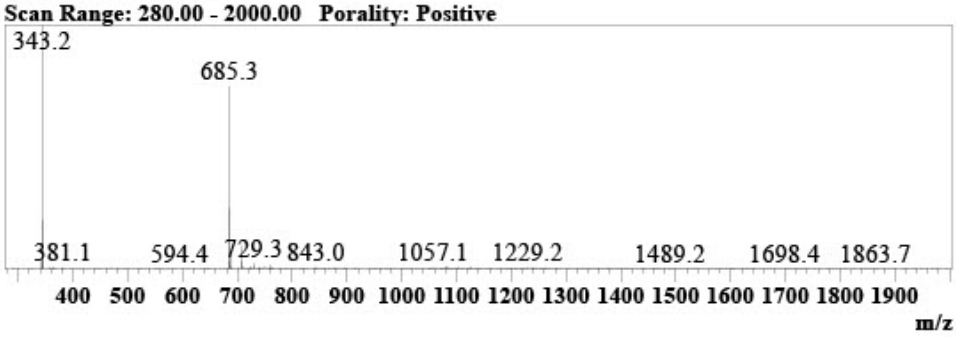
Substance Identification

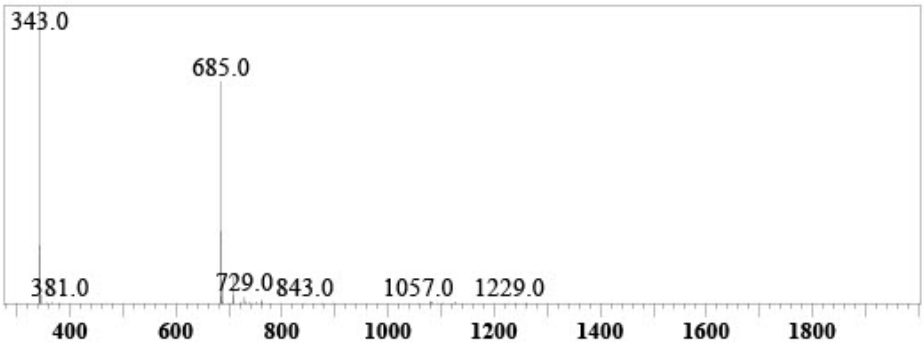
Detected substance

Ret.Time: 0.648
Base Peak: 343.2 Da
Scan Range: 280.00 - 2000.00 Porality: Positive



Identified Substance

Compound Name: KPV
Similarity: 99%
Formula: C16H30N4O4
CAS: 67727-97-3
Mol.Weight: 342 Da



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1. Chromgenic LAL Assay Determination of Bacterial Endotoxin content of sample

1.1. Instrumentation

- Pipette set 1-1000 µL
- Termostatically controlled water bath
- UV VIS spectrometer (Shimadzu UV-1601)
- GenScript ToxinSensor Chromgenic LAL Endotoxin Assay kit

1.2. Chemicals

- LAL Reagent water (endotoxin free)
- Limulus Amoebocyte Lysate
- LAL Substrate
- Color Stabilizer #1
- Color Stabilizer #2
- Color Stabilizer #3
- 35% HCl (p.a.)

1.3. Sample preparation

1. Sample container was weighed prior to dissolution and measured weight was marked.
2. Sample was completely dissolved in its container by 2 mL of LAL Reagent water.
3. 100 µL of the sample was aliquoted for analysis.
4. After analysis container was emptied and dried.
5. Dry mass of container was measured and exact weight of dissolved content was determined as:

$$m_{dc} = m_{sample} - m_{container}$$

1.4. Toxin sensor Chromgenic LAL Endotoxin Assay kit preparation

Procedures regarding preparation of reaction solutions possible to find in:
https://www.genscript.com/site2/document/5292_20080806231827.PDF

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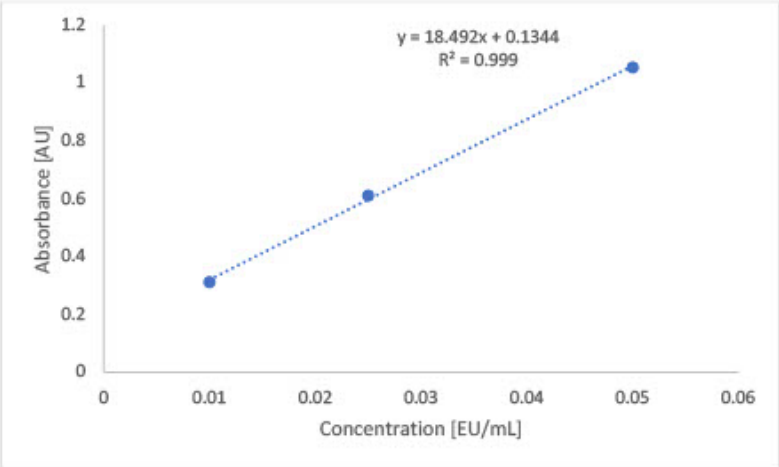
1.5. Measurement procedure

	Standards	Samples	Blank
Standards (mL)	0.1	-	-
Samples (mL)	-	0.1	-
LAL Reagent Water (mL)	-	-	0.1
LAL Solution (mL)	0.1	0.1	0.1
Mix well and incubate at 37°C for 27 min			
Substrate solution (mL)	0.1	0.1	0.1
Mix well and incubate at 37°C for 6 min			
Color Stabilizer #1 solution	0.5	0.5	0.5
Color Stabilizer #2 solution	0.5	0.5	0.5
Color Stabilizer #3 solution	0.5	0.5	0.5
Mix well and read the absorbance at 545nm			

1.6. Calibration curve



1.7. Calculation of endotoxin content

Endotoxin content of the sample was calculated from the calibration curve as:

$$Endotox\left[{}^{EU}/_{mg}\right] = \frac{\left(\frac{ABS_{sample}}{S_{calib}}\right) * 20}{m_{sample}}$$

ABS_{sample} = *Measured absorbance of sample*
S_{calib} = *Slope of calibration curve*
m_{sample} = *real measured mass of sample*
20 = *dilution factor of measured sample*

2

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LIQUILABS Analytical services	Method Specification	
Determination of bioburden of lyophilized samples		
Document number MIC_001_2025	*Superseded document* -	*Number of pages* 2

1. Instrumentation and chemicals

1.1. Instruments used

- Sterile Syringe 2mL Luer
- Sterile needles
- Ready made PCA Plate ROTI Aquatest
- Ready made Sab4 Plate ROTI Aquatest

1.2. Chemicals

Sterile physiological solution (0.9% NaCl)

2. Sample preparation and innoculation

2.1 Sample preparation

1. Fresh sterile needle and syringe was used for measuring exactly 2 mL of sterile physiological solution.
2. Needle was changed and by new needle rubber top of peptide containter was penetrated and 2 mL of sterile physiological solution was dispensed.
3. Content of container was completely dissolved and left for 5 minutes to settle potentially created bubbles.
4. This procedure is repeated for two vials.

2.2 Total Aerobic microbial count innoculation and cultivation

1. By sterile needle 1 mL of solution was filled into the sterile syringe.
2. Needle was placed above the flame for few seconds to sterilze.
3. Consequently 1 mL of solution was poured into the ready to use sterile petri dish filled with PCA agar and petri dish was closed.
4. Proces was repeated for two petri dishes.
5. With sterile needle, 1 mL of sterile physiological solution was filled into the sterile needle and was innoculated onto one sterile petri dish filled with PCA agar as negative control sample.
6. Samples and negative control sample were placed in incubator at temperature 37°C for 120h.

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2.3 Total Yeast and Mold count innoculation and cultivation

1. By sterile needle 1 mL of solution was filled into the sterile syringe.
2. Needle was placed above the flame for few seconds to sterilze.
3. Consequently 1 mL of solution was poured into the ready to use sterile petri dish filled with Sab4 agar and petri dish was closed.
4. Proces was repeated for two petri dishes.
5. With sterile needle, 1 mL of sterile physiological solution was filled into the sterile needle and was innoculated onto one sterile petri dish filled with Sab4 agar as negative control sample.
6. Samples and negative control sample were placed in incubator at temperature 25°C for 72h.

3. Evaluation of results

After incubation time, colonies are counted as cfu (colonies forming units) and result per 1g of sample is determined as:

$$CFU_{avg} = \frac{\sum CFU_n}{n}$$

$$CFU_{avg} = average\ CFU\ counted\ form\ n\ innoculations$$
$$CFU_n = CFU\ counted\ per\ innoculation$$
$$n = number\ of\ innoculations$$

$$CFU\ per\ gram = \frac{CFU_{avg}}{m_s} * DF$$

$$CFU_{avg} = Average\ CFU\ counted\ from\ n\ innoculations$$
$$m_s = mass\ of\ sample\ (mg)$$
$$DF = Dilution\ factor$$

If negative control sample is evaluated as positive, process have to be repeated due to possible contamination in the process of innoculation or incubation.

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Responsibles

Mr. Ján Galbavý
CEO

Analysis results relate only to the samples tested.
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