

Certificate Of Analysis



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Sample Identification

Sample Name	IllumiNeuro 48mg	Batch Number	GF102025051	Date Published	2026-01-27 16:33
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Results for Lyo-0239

Analysis of Peptide Identity, Content and Purity	Result	Unit	Uncertainty	Reporting Limit
N-Acetyl Selank Assay Peptide Screening	9.89	mg	[± 0.05]	
N-Acetyl Selank Identification by RT Peptide Screening	0.992		[± 0.005]	
N-Acetyl Semax Assay Peptide Screening	20.1	mg	[± 0.1]	
N-Acetyl Semax Identification by RT Peptide Screening	0.994		[± 0.005]	
PE-22-28 Assay Peptide Screening	9.99	mg	[± 0.05]	
PE-22-28 Identification by RT Peptide Screening	0.992		[± 0.005]	
Pinealon Assay Peptide Screening	12.92	mg	[± 0.06]	
Pinealon Identification by RT Peptide Screening	0.998		[± 0.005]	

Bioburden	Result	Unit	Uncertainty	Reporting Limit
Total Aerobic Microbial Count USP <61>/Eur. Ph. 2.6.12. Plate Count Method	Not detected	CFU/g		>= 1000
Total Yeast and Mold Count USP <61>/Eur. Ph. 2.6.12. Plate Count Method	Not detected	CFU/g		>= 100

Endotoxin Analysis	Result	Unit	Uncertainty	Reporting Limit	
Bacterial Endotoxin USP<85>/ Eur. Ph. 2.6.14. Bacterial Endotoxin Chromogenic Test	< 0.001	EU/mg		> 0.5	△
Heavy Metals	Result	Unit	Uncertainty	Reporting Limit	
Arsenic Elemental Impurities Screening	Not detected	ppm		>= 1.5	△
Cadmium Elemental Impurities Screening	Not detected	ppm		>= 0.5	△
Cobalt Elemental Impurities Screening	Not detected	ppm		>= 25	△
Lead Elemental Impurities Screening	Not detected	ppm		>= 1.5	△
Nickel Elemental Impurities Screening	Not detected	ppm		>= 25	△
Quicksilver Elemental Impurities Screening	Not detected	ppm		>= 1.5	△
Vanadium Elemental Impurities Screening	Not detected	ppm		>= 25	△

Attachments for Lyo-0239

Analysis Report

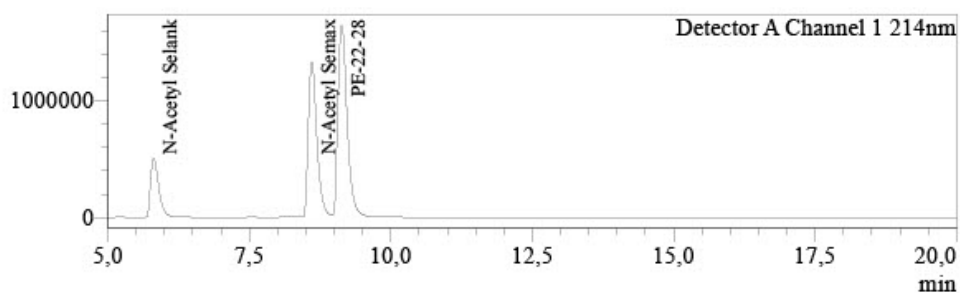


Sample Information

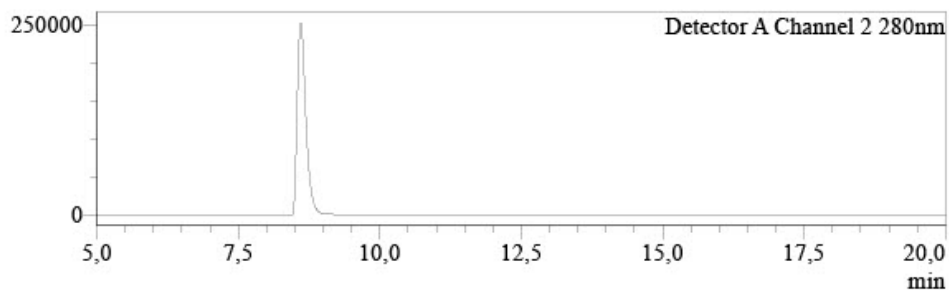
Injection Volume : 0.5
Data File : LYO-0239_021.lcd
Method File : Peptide screening_V10.1_Group F.lcm
Date Acquired : 18.01.2026 1:17:24

Chromatogram

uV



uV



Peak Table

Detector A Channel 1 214nm

Peak#	Name	Ret. Time	Conc.	Unit	Area%
1		1.206	0.000		0.090
2		1.416	0.000		4.356
3	N-Acetyl Selank	5.810	9.889	mg	12.756
4		8.157	0.000		0.131
5	N-Acetyl Semax	8.603	20.067	mg	35.434
6	PE-22-28	9.134	9.988	mg	47.234
Total					100.000

Peak Table

Detector A Channel 2 280nm

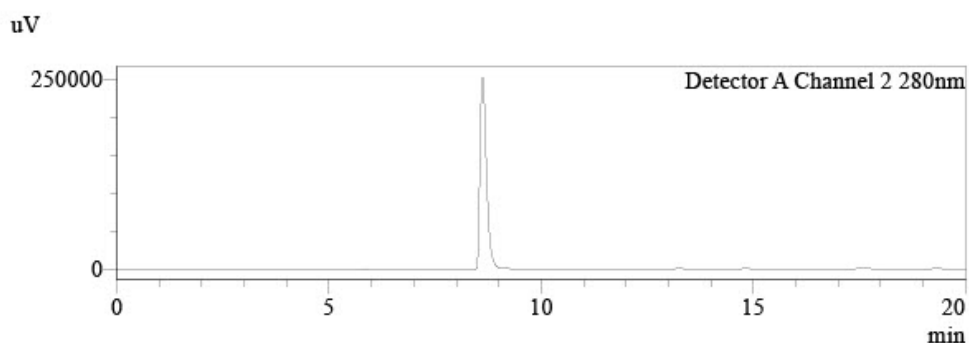
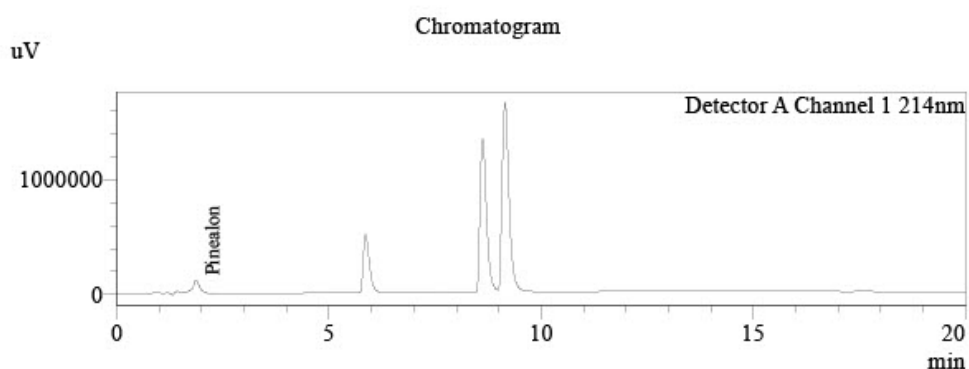
Peak#	Name	Ret. Time	Conc.	Unit
1		8.602	0.000	
Total				

Attachment for Lyo-0239
Filename: LYO-0239_Norm.jpg

Analysis Report



Sample Information
Injection Volume : 0,5
Data File : LYO-0239-polar_026.lcd
Method File : Peptide screening_V10.1_polar.lcm
Date Acquired : 18.01.2026 3:56:16



Peak Table

Detector A Channel 1 214nm


Peak#	Name	Ret. Time	Conc.	Unit	Area%
1	Pinealon	1.863	12.920	mg	4.224
2		5.861	0.000		12.708
3		8.619	0.000		35.654
4		9.146	0.000		47.414
Total					100.000

Peak Table

Detector A Channel 2 280nm

Peak#	Name	Ret. Time	Conc.	Unit
1		8.618	0.000	
2		23.473	0.000	
Total				

Attachment for Lyo-0239
Filename: LYO-0239_Polar.jpg

	Method Specification	
Determination of bioburden of lyophilized samples		
<i>Document number</i> MITC_001_2025	<i>Superseded document</i> -	<i>Number of pages</i> 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 inoculation

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 container 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 inoculation 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 sterilize.
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 inoculated 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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Attachment for Lyo-0239

Filename: 1765960204793-f3976882-f366-40fd-a8c1-7346eb4de6f2_1.jpg

2.3 Total Yeast and Mold count inoculation 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 sterilize.
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 inoculated 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 inoculations

CFU_n = CFU counted per inoculation

n = number of inoculations


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

CFU_{avg} = Average CFU counted from n inoculations

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 inoculation or incubation.

	Method Specification	
Determination of bacterial endotoxin content of lyophilized samples		
<i>Document number</i> ENDOTOX_012_2025_1	<i>Superseded document</i>	<i>Number of pages</i> 2

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

1.1. Instrumentation

- Pipette set 1-1000 µL
- Thermostatically 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

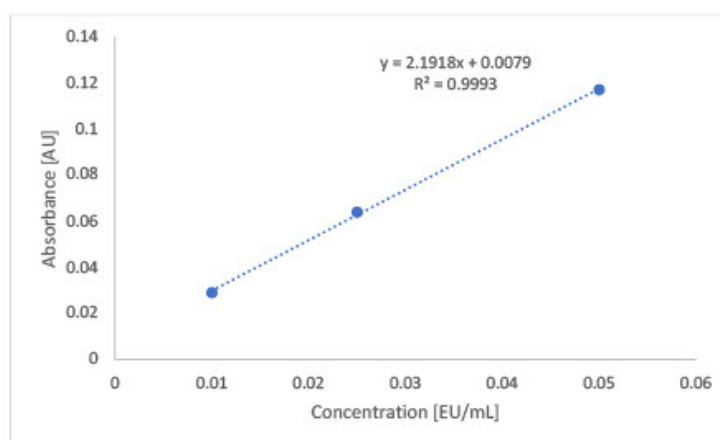
Procedures regarding preparation of reaction solutions possible to find in:

https://www.genscript.com/site2/document/5292_20080806231827.PDF

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:

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

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



Mr. Ján Galbavý
Founder/Manager

Analysis results relate only to the samples tested.

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