PrymaLab
PRYMALAB ANALYTICAL · IN-HOUSE LABORATORY
3705 Music Branch Rd, Ashland, KY 41102 · +1 (606) 465-9063 · prymalab.net

CERTIFICATE NO.
PL-26-00235
VERIFICATION KEY
VYTH2W25
Scan or enter both at prymalab.net/testing/verify

CERTIFICATE OF ANALYSIS · LOT RELEASE

Livagen 20 mg Pen

Lot PL-2610-121 · Solution · Label claim 20 mg/mL

TESTED IN-HOUSE BY PRYMALAB
In-house analytical result, not an independent third-party test

LOT / BATCH NUMBER	DATE MADE	DATE OF ANALYSIS	DATE ISSUED
PL-2610-121	2026-10-05	2026-10-06	2026-10-20
RETEST / EXPIRY	**UNITS IN LOT / SAMPLED**	**STORAGE**	**CERTIFICATE TYPE**
2028-10-05	190 / 3	—	Lot COA, 2 pages

COMPOUND	CAS NUMBER	MOLECULAR FORMULA	THEORETICAL MASS (AVG.)
Livagen Lys-Glu-Asp-Ala (KEDA)	433257-50-2	$C_{18}H_{31}N_5O_9$	461.47 Da

SEQUENCE
KEDA

PURITY · RP-HPLC, AREA %
99.70%
Specification ≥ 99.0 % • main peak at 9.81 min

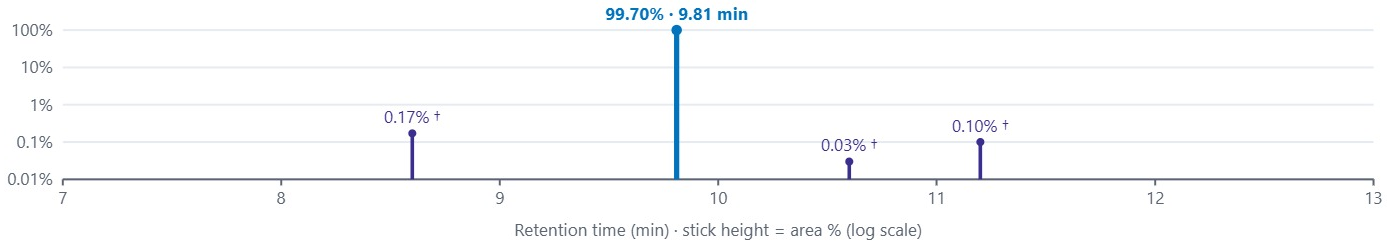
IDENTITY · OBSERVED MASS
461.46 Da
Theoretical 461.47 Da • −0.01 Da (22 ppm)

OVERALL CONCLUSION
PASS
Meets every specification for the tests performed

TEST	METHOD	SPECIFICATION	RESULT	CONCLUSION
Identity (mass)	LC-MS, ESI positive	Theoretical ± 1.0 Da	461.46 Da	PASS
Purity	RP-HPLC, UV 214 nm, area %	≥ 99.0 %	99.70 %	PASS
Largest impurity	RP-HPLC, area %	≤ 1.0%	0.17% (RT 8.60)	PASS
Assay (label claim)	Assay vs label claim	19–21 mg/mL	19.80 mg/mL	PASS
Bacterial endotoxin	LAL, kinetic	≤ 5.0 EU/mg	0.226 EU/mg	PASS
Sterility	USP <71>, 14-day	No growth	No growth	PASS

1 HPLC CHROMATOGRAM

Data file: PL-2610-121-HPLC.raw · Column C18, 150 × 4.6 mm · UV 214 nm



Peak plot drawn from the integrated peak table (area %, log scale); it is not the instrument trace, which is retained in PL-2610-121-HPLC.raw. † Nominal reference retention time for the assigned impurity; the main-peak RT is observed in this lot.

For laboratory research use only. Not for human or veterinary use.

2 HPLC METHOD · PL-2610-121-HPLC.RAW

INSTRUMENT
Waters Alliance e2695

DATA SYSTEM
Empower 3

DETECTOR
UV absorbance

DETECTION WAVELENGTH
214 nm

COLUMN
C18, 150 × 4.6 mm, 3.5 µm

MOBILE PHASE A
0.1 % TFA in water

MOBILE PHASE B
0.1 % TFA in MeCN

GRADIENT
5–95 % B over 25 min (linear)

FLOW RATE
1.0 mL/min

COLUMN TEMPERATURE
40 °C

INJECTION VOLUME
10 µL

3 GRADIENT PROGRAM

TIME (MIN)	% A	% B
0.0	95	5
25.0	5	95

4 PEAK TABLE

PEAK	RT (MIN)	AREA	AREA %
1	8.60 †	—	0.17
2	**9.81**	**—**	**99.70**
3	10.60 †	—	0.03
4	11.20 †	—	0.10
Total		—	100.00

Peaks: 1 deamidation product; 2 main peak (Livagen); 3 isoaspartate (isoasp) variant; 4 truncated sequence · Area % from the integrated peak table (absolute areas are not part of the lot-release export) · † nominal reference RT for the assigned impurity · Purity = main peak area ÷ total integrated area × 100, to two decimals; main peak shaded.

5 IDENTITY BY MASS SPECTROMETRY

INSTRUMENT
Waters SQD

IONIZATION / MODE
ESI, positive

REFERENCE M/Z (CHARGE)
462.48 (M+H)+

DECONVOLUTED MASS
461.46 Da

THEORETICAL MASS
461.47 Da

DIFFERENCE
−0.01 Da (22 ppm)

DATA FILE
PL-2610-121-MS.d

ACCEPTANCE
Within ± 1.0 Da

6 ADDITIONAL TESTS

TEST	PERFORMED BY	DATE	REPORT / FILE
Assay vs label claim	PrymaLab Analytical	2026-10-06	—
Endotoxin (LAL, kinetic)	PrymaLab Analytical	2026-10-06	—
Sterility (USP <71>, day-14 read-out)	PrymaLab Analytical	2026-10-20	—

A test with no row here was not performed on this lot. Outside-laboratory reports, when used, are attached and named below.

7 REVIEW AND APPROVAL

D. Reynolds
Analyst · performed the testing
Date: 2026-10-20

S. Calloway
Reviewer · checked against raw data
Date: 2026-10-20

M. Phelps
Lab Director · approved for release
Date: 2026-10-20

Raw data retained at: Empower 3, project PL-2610, archive PL-ARC-2026; 7 years. Outside laboratory reports attached: None

This certificate applies only to the lot named above and describes the units sampled from it; it is not a guarantee for any other lot. Results were obtained by PrymaLab LLC's own laboratory (PrymaLab Analytical) and are not an independent third-party test unless an outside report is attached. Reference values (CAS, formula, theoretical mass, sequence) are literature values for the named compound. Authenticity: scan the QR code or enter certificate number PL-26-00235 and key VYTH2W25 at prymalab.net/testing/verify; any copy that does not match the record shown there is not a PrymaLab certificate. PrymaLab LLC products are supplied for laboratory research use only and not for human or veterinary use.