



PrymaLab

PRYMALAB ANALYTICAL · IN-HOUSE LABORATORY

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CERTIFICATE NO.
PL-26-00031

VERIFICATION KEY
VGPQQ77C

Scan or enter both at
prymalab.net/testing/verify

CERTIFICATE OF ANALYSIS · LOT RELEASE

EPO (Erythropoietin) 3,000 IU

Lot PL-2609-031 · Lyophilized powder · Label claim 3000 IU/vial ($\approx 25 \mu\text{g}$ glycoprotein)

TESTED IN-HOUSE BY PRYMALAB

In-house analytical result,
not an independent third-party test

LOT / BATCH NUMBER PL-2609-031	DATE MADE 2026-09-18	DATE OF ANALYSIS 2026-09-19	DATE ISSUED 2026-10-03
RETEST / EXPIRY 2028-09-18	UNITS IN LOT / SAMPLED 250 / 2	STORAGE 2–8 °C, dark; do not freeze	CERTIFICATE TYPE Lot COA, 2 pages
COMPOUND Erythropoietin (rhEPO) Recombinant human erythropoietin, epoetin class	CAS NUMBER 11096-26-7	MOLECULAR FORMULA C₈₀₉H₁₃₀₁N₂₂₉O₂₄₀S₅ (165-residue protein core)	THEORETICAL MASS (AVG.) About 30.4 kDa glycoform average; 18.2 kDa protein core
STRUCTURE 165-residue mature human EPO (UniProt P01588 residues 28–192; C-terminal Arg166 removed), CHO-expressed; N-glycans at Asn24, Asn38 and Asn83, O-glycan at Ser126; disulfides Cys7–Cys161 and Cys29–Cys33.			

PURITY · RP-HPLC, AREA %

99.18%

Specification 99.0% • main peak (glycoform cluster) at 7.18 min

IDENTITY · OBSERVED MASS

30,412 Da

Deconvoluted glycoform centroid • theoretical 30.4 kDa average

OVERALL CONCLUSION

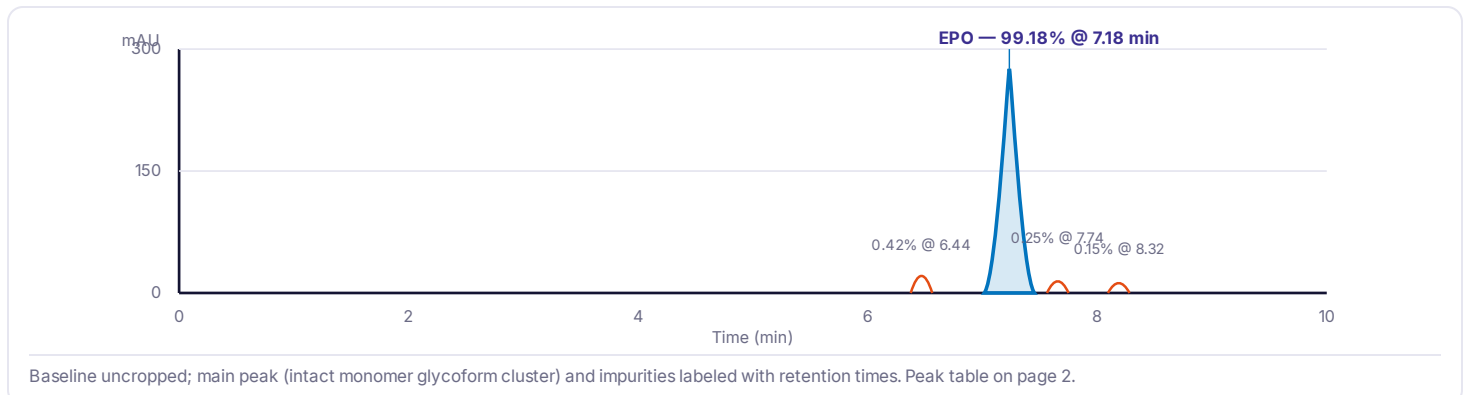
PASS

Meets every specification for the tests performed

TEST	METHOD	SPECIFICATION	RESULT	CONCLUSION
Appearance	Visual inspection	White lyophilized powder or cake	White lyophilized cake	PASS
Identity (mass)	LC-MS, ESI positive	Within glycoform envelope	30,412 Da centroid (CHO glycoforms 28–34 kDa)	PASS
Purity	RP-HPLC, UV 214 nm, area%	99.0%	99.18%	PASS
Largest impurity	RP-HPLC, area%	1.0%	0.42% at 6.44 min	PASS
Water content	Karl Fischer	5.0%	1.9%	PASS
Bacterial endotoxin	LAL, kinetic	≤ 5.0 EU/mg	0.27 EU/mg	PASS
Sterility / bioburden	USP <71>, membrane filtration	No growth after 14 days	No growth; conforms	PASS

1 HPLC CHROMATOGRAM

Data file: EPO_PL-2609-031_20260919_01 · Column C18 150 × 4.6 mm · UV 214 nm



**2 HPLC METHOD · EPO_PL-2609-031_20260919_01**

INSTRUMENT

Waters Alliance e2695, SN E2695B742

DETECTION WAVELENGTH

214 nm

MOBILE PHASE A

0.1% TFA in water

COLUMN TEMPERATURE

30 °C

SAMPLE DILUENT

Water, 0.1% TFA

REFERENCE STANDARD

In-house rhEPO reference, lot PL-RS-EPO-01, RT 7.16 min (glycoform cluster)

DATA SYSTEM

Empower 3, Build 3471

COLUMN

C18, 150 × 4.6 mm, 3.5 µm

MOBILE PHASE B

0.1% TFA in MeCN

INJECTION VOLUME

20 µL

SAMPLE CONCENTRATION

0.2 mg/mL (pooled composite)

DETECTOR

Waters 2998 PDA

COLUMN PART / SERIAL

186003326 / USHX18211

FLOW RATE

1.0 mL/min

RUN TIME

10 min

BLANK INJECTED

Yes

3 GRADIENT PROGRAM

TIME (MIN)	% A	% B
0.0	95	5
3.0	95	5
7.0	55	45
8.0	20	80
9.0	20	80
10.0	95	5

4 PEAK TABLE

PEAK	RT (MIN)	AREA	AREA %
1	6.44	18,060	0.42
2	7.18	4,264,740	99.18
3	7.74	10,750	0.25
4	8.32	6,450	0.15
Total		4,300,000	100.00

Threshold 0.05% area · Blank subtracted: Y · Purity = main peak area ÷ total integrated area × 100, to two decimals; main peak shaded.

5 IDENTITY BY MASS SPECTROMETRY

INSTRUMENT

Waters Acquity SQD

DECONVOLUTED MASS

30,412 Da (glycoform centroid)

DATA FILE

EPO_PL-2609-031_MS_20260919_01

IONIZATION / MODE

ESI, positive

THEORETICAL MASS

30,400 Da average glycoform (18.2 kDa protein core)

ACCEPTANCE

Within glycoform envelope

OBSERVED M/Z (CHARGE)

1521.6 (20+ [M+20H]) · 1217.5 (25+ [M+25H])

DIFFERENCE

Within CHO glycoform envelope (28–34 kDa)

6 ADDITIONAL TESTS

TEST	PERFORMED BY	DATE	REPORT / FILE
Water content	PrymaLab	2026-09-20	RPT-KF-PL-2609-031
Endotoxin	PrymaLab	2026-09-21	RPT-ET-PL-2609-031
Sterility	PrymaLab	2026-10-02	RPT-ST-PL-2609-031

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: 2026-09-19

S. Calloway

Reviewer · checked against raw data
Date: 2026-10-02

M. Phelps

Lab Director · approved for release
Date: 2026-10-03

Raw data retained at: Empower 3 (Build 3471), project PL-2609, 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-26-00031 and key VGPQ77C 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.