PrymaLab
PRYMALAB ANALYTICAL · IN-HOUSE LABORATORY
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CERTIFICATE NO.
PL-26-00047
VERIFICATION KEY
TE5TF38M
Scan or enter both at prymalab.net/testing/verify

CERTIFICATE OF ANALYSIS · LOT RELEASE

HCG 10,000 IU

Lot **PL-2609-047** · Lyophilized powder · Label claim **10,000 IU/vial (≈ 1 mg glycoprotein, standardized by bioassay)**

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-2609-047	2026-09-18	2026-09-19	2026-10-03
RETEST / EXPIRY	**UNITS IN LOT / SAMPLED**	**STORAGE**	**CERTIFICATE TYPE**
2028-09-18	250 / 2	2–8 °C, dark	Lot COA, 2 pages

COMPOUND	CAS NUMBER	MOLECULAR FORMULA	THEORETICAL MASS (AVG.)
HCG Human chorionic gonadotropin (urinary); potency assigned in IU by bioassay	9002-61-3	Not applicable (glycoprotein)	About 36–38 kDa glycoform average; 25.7 kDa protein core (about 30% carbohydrate)

STRUCTURE
Non-covalent heterodimer, 237 residues in total: common glycoprotein-hormone α-subunit (92 aa) paired with the hCG β-subunit (145 aa, including the 24-residue C-terminal peptide); 11 disulfides; N- and O-glycosylated.

PURITY · RP-HPLC, AREA %
99.24%
Specification 99.0% • main peak (glycoform cluster) at 7.28 min

IDENTITY · OBSERVED MASS
36,712 Da
Deconvoluted glycoform centroid • theoretical 36.7 kDa average

OVERALL CONCLUSION
PASS
Meets every specification for the tests performed

TEST	METHOD	SPECIFICATION	RESULT	CONCLUSION
Appearance	Visual inspection	White to off-white lyophilized powder or cake	White lyophilized cake	PASS
Identity (mass)	LC-MS, ESI positive	Within glycoform envelope	36,712 Da centroid (glycoforms 36–38 kDa)	PASS
Purity	RP-HPLC, UV 214 nm, area%	99.0%	99.24%	PASS
Largest impurity	RP-HPLC, area%	1.0%	0.30% at 6.52 min (free β-subunit)	PASS
Water content	Karl Fischer	5.0%	1.8%	PASS
Bacterial endotoxin	LAL, kinetic	≤ 5.0 EU/mg	0.24 EU/mg	PASS
Sterility / bioburden	USP <71>, membrane filtration	No growth after 14 days	No growth; conforms	PASS

1 HPLC CHROMATOGRAM

Data file: HCG_PL-2609-047_20260919_01 · Column C18 150 × 4.6 mm · UV 214 nm

Baseline uncropped; main peak (intact heterodimer glycoform cluster) and impurities labeled with retention times. Peak table on page 2.

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

2 HPLC METHOD · HCG_PL-2609-047_20260919_01

INSTRUMENT
Waters Alliance e2695, SN E2695B742

DATA SYSTEM
Empower 3, Build 3471

DETECTOR
Waters 2998 PDA

DETECTION WAVELENGTH
214 nm

COLUMN
C18, 150 × 4.6 mm, 3.5 µm

COLUMN PART / SERIAL
186003326 / USHX18211

MOBILE PHASE A
0.1% TFA in water

MOBILE PHASE B
0.1% TFA in MeCN

FLOW RATE
1.0 mL/min

COLUMN TEMPERATURE
30 °C

INJECTION VOLUME
20 µL

RUN TIME
10 min

SAMPLE DILUENT
Water, 0.1% TFA

SAMPLE CONCENTRATION
0.2 mg/mL (pooled composite)

BLANK INJECTED
Yes

REFERENCE STANDARD
In-house hCG reference, lot PL-RS-HCG-01, RT 7.26 min (glycoform cluster)

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 (free β-subunit)	6.52	12,900	0.30
2	**7.28**	**4,267,320**	**99.24**
3 (aggregates)	7.96	12,040	0.28
4 (CTP variants)	8.42	7,740	0.18
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

IONIZATION / MODE
ESI, positive

OBSERVED M/Z (CHARGE)
1836.6 (20+ [M+20H]) · 1597.2 (23+ [M+23H])

DECONVOLUTED MASS
36,712 Da (glycoform centroid)

THEORETICAL MASS
36,700 Da average glycoform (25.7 kDa protein core)

DIFFERENCE
Within urinary glycoform envelope (36–38 kDa)

DATA FILE
HCG_PL-2609-047_MS_20260919_01

ACCEPTANCE
Within glycoform envelope

6 ADDITIONAL TESTS

TEST	PERFORMED BY	DATE	REPORT / FILE
Water content	PrymaLab	2026-09-20	RPT-KF-PL-2609-047
Endotoxin	PrymaLab	2026-09-21	RPT-ET-PL-2609-047
Sterility	PrymaLab	2026-10-02	RPT-ST-PL-2609-047

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-26-00047 and key TE5TF38M 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.