



PrymaLab

PRYMALAB ANALYTICAL · IN-HOUSE LABORATORY

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CERTIFICATE NO.
PL-26-00046

VERIFICATION KEY
9WNXD2PS

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

CERTIFICATE OF ANALYSIS · LOT RELEASE

HCG 5,000 IU

Lot PL-2609-046 · Lyophilized powder · Label claim 5,000 IU/vial ($\approx$ 0.5 mg glycoprotein, standardized by bioassay)

TESTED IN-HOUSE BY PRYMALAB

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

LOT / BATCH NUMBER PL-2609-046	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	CERTIFICATE TYPE Lot COA, 2 pages
COMPOUND HCG Human chorionic gonadotropin (urinary); potency assigned in IU by bioassay	CAS NUMBER 9002-61-3	MOLECULAR FORMULA Not applicable (glycoprotein)	THEORETICAL MASS (AVG.) 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 %

99.20%

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

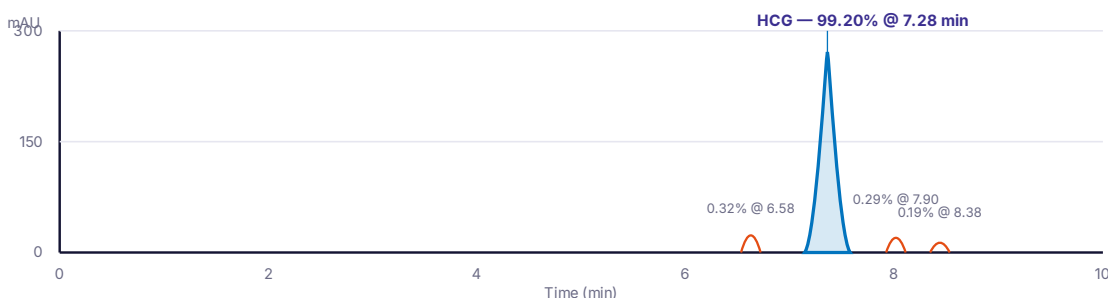
PASS

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%	99.20%	PASS
Largest impurity	RP-HPLC, area%	1.0%	0.32% at 6.58 min (free β -subunit)	PASS
Water content	Karl Fischer	5.0%	1.7%	PASS
Bacterial endotoxin	LAL, kinetic	$\leq$ 5.0 EU/mg	0.22 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-2609-046_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.

**2 HPLC METHOD · HCG_PL-2609-046_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 hCG reference, lot PL-RS-HCG-01, RT 7.26 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 (free β-subunit)	6.58	13,760	0.32
2	7.28	4,265,600	99.20
3 (aggregates)	7.90	12,470	0.29
4 (CTP variants)	8.38	8,170	0.19
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

36,712 Da (glycoform centroid)

DATA FILE

HCG_PL-2609-046_MS_20260919_01

IONIZATION / MODE

ESI, positive

THEORETICAL MASS

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

ACCEPTANCE

Within glycoform envelope

OBSERVED M/Z (CHARGE)

1836.6 (20+ [M+20H]) · 1597.2 (23+ [M+23H])

DIFFERENCE

Within urinary glycoform envelope (36–38 kDa)

6 ADDITIONAL TESTS

TEST	PERFORMED BY	DATE	REPORT / FILE
Water content	PrymaLab	2026-09-20	RPT-KF-PL-2609-046
Endotoxin	PrymaLab	2026-09-21	RPT-ET-PL-2609-046
Sterility	PrymaLab	2026-10-02	RPT-ST-PL-2609-046

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-26-00046 and key 9WNXD2PS 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.