



Alborz Innovation and Creative Industries Factory  
Karaj, Iran  
**Telephone:** +98 930 600 4641  
**Email:** [info@nozhanbiotech.com](mailto:info@nozhanbiotech.com)  
[www.nozhanbiotech.com](http://www.nozhanbiotech.com)

**Certificate of Analysis**

**Revision: 001**

**Revision Date: 01 DEC 2025**

**Trade Name: Human Chorionic Gonadotropin, Beta Subunit (b-HCG)**

## **Human Chorionic Gonadotropin (b-HCG) Certificate of Analysis (COA)**

| Specification              | Details                                                                                        |
|----------------------------|------------------------------------------------------------------------------------------------|
| Product Name               | Human Chorionic Gonadotropin, Beta Subunit (b-HCG)                                             |
| Source                     | Human Pregnancy Urine                                                                          |
| Catalog Number             | 325-11                                                                                         |
| Purity                     | ≥ 98% (confirmed by SDS-PAGE)                                                                  |
| Appearance                 | Clear to slightly opaque, colorless to pale yellow solution                                    |
| Protein Concentration      | ≥ 1 mg/ml                                                                                      |
| Molecular Weight           | ~22,200 Da (β-subunit)                                                                         |
| Physical Form              | Liquid solution in Tris buffer, neutral pH (7.0–7.4)                                           |
| Endotoxin Level            | ≤ 1 EU/mg                                                                                      |
| Storage Conditions         | -20 °C                                                                                         |
| Shelf Life                 | 2 years under recommended storage conditions                                                   |
| CAS Number                 | 9002-61-3                                                                                      |
| Infectious Disease Testing | Negative for anti-HIV-1, anti-HIV-2, anti-HCV, and HBsAg at donor level (FDA-approved methods) |
| Intended Use               | In Vitro Diagnostic (IVD) applications, immunoassay development, calibration, and research use |
| Use Limitations            | Not for therapeutic use, injection, or human/animal consumption                                |

**Description:**

Human Chorionic Gonadotropin (hCG) is a glycoprotein hormone composed of two non-covalently linked subunits, alpha and beta. The beta subunit (b-hCG) confers biological and immunological specificity and is widely recognized as the gold standard biomarker for:

Early detection of pregnancy (urine and serum-based tests)

Diagnosis and monitoring of trophoblastic diseases (hydatidiform mole, choriocarcinoma)

Tumor marker for certain germ cell cancers (testicular and ovarian cancers)

Prenatal screening programs

The b-hCG antigen produced by Nozhan Zist Fanavaran Co. is purified from human pregnancy urine using a proprietary, GMP-oriented native purification process developed in-house. This process ensures:

Preservation of the native conformational epitopes critical for high-affinity antibody binding

Superior batch-to-batch consistency and immunological reactivity

Removal of interfering contaminants and co-purified proteins

Full compatibility with monoclonal and polyclonal antibodies used in commercial immunoassays

The product is supplied as a high-purity, Liquid solution with defined protein content and long-term stability. It is negative for major blood-borne pathogens (HIV, HBV, HCV) at donor level, ensuring biosafety for diagnostic manufacturing.

**Applications:**

Immunoassay development: ELISA, CLIA, Rapid Test (lateral flow), and other IVD platforms

Calibration and quality control: Reference standard for in-house and commercial assay calibration

Assay standardization: Suitable for use as a primary or secondary reference material

Research use: Biochemical and immunological studies of hCG and related glycoproteins

**Quality Control & Assurance:**

Each batch is subjected to rigorous quality control testing, including:

Purity analysis by SDS-PAGE under reducing and non-reducing conditions

Protein quantification by ELISA and spectrophotometric methods

Endotoxin testing (LAL method)

Infectious disease screening at donor level

Immunoreactivity verification using validated anti-b-hCG antibody pairs

A Certificate of Analysis (COA) is issued for each production batch, ensuring full traceability and compliance with internal GMP guidelines and international diagnostic industry expectations.