

**DIAGNOSTIC AUTOMATION, INC.**

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onestep@rapidtest.comtechnicalsupport@rapidtest.comwww.rapidtest.com**MATERIAL SAFETY DATA SHEET****FREE BETA-HUMAN CHORIONIC
GONADOTROPIN (Free β -HCG) ELISA
TEST KIT****1. IDENTIFICATION OF THE PREPARATION AND COMPANY.****1.1. Identification of the product:**Product name: **FREE BETA-HUMAN CHORIONIC GONADOTROPIN
(Free β -HCG) ELISA TEST KIT**

Product classification: In-vitro diagnostics

Product number: 4221-16

1.2. Manufacturer identificationCompany Name: **Diagnostic Automation, Inc.**Address: 21250 Califa Street, Suite 102 and 116, Woodland Hills,
California 91367

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Emergency Telephone number: Please contact the local hospitals.

2. HAZARDS IDENTIFICATION

2.1 POTENTIAL BIOHAZARD:

The Calibrator and Controls are formulated with a buffer base, animal serum, and human serum. The human serums are tested by a United States Food and Drug Administration (USFDA) licensed method and found to be non-reactive for HIV-1, HIV-2, Hepatitis B surface antigen and HCV. Because no test method can offer absolute assurance that these agents are absent, reagents should be handled at the Biosafety Level 2, as recommended for any potentially infectious human blood product, in the United States Center for Disease Control (USCDC) and National Institute of Health (USNIH) manual "Biosafety in Microbiological Laboratories", 1988.

All bovine products and goat sera have been derived from animals of US origin and processed in USDA licensed facilities.

2.2 CHEMICAL HAZARD:

The TMB Chromogenic Substrate containing TMB, is formulated with DMSO, an irritant and mucous membranes. In case of contact with any of these reagents, wash thoroughly with water. TMB is a suspected carcinogen.

Stop Solution is an acidic and corrosive agent. Avoid contact with skin.

3. COMPOSITION OF THE KIT COMPONENTS

- 3.1 Microwell Strips, Microwell coated with beta hCG MAb, (96 wells)
- 3.2 Free Beta hCG Reference Standard set, hCG Calibrators, 12 vials (0.5 ml)
- 3.3 Sample Diluent, Chemical Buffers, 1 bottle, (20 ml)
- 3.4 Free Beta Enzyme Conjugate, 1 bottle (18 ml)
- 3.5 TMB Chromogenic Substrate, TMB Substrate, 1 bottle (12 ml)
- 3.6 Stop Solution, 2N HCl, 1 bottle (12 ml)
- 3.7 Wash Concentrate 50X, Detergent Concentrate, 1 bottle (15 ml)
- 3.8 Package Insert, paper, 1 piece.

4. FIRST-AID MEASURES

- 4.1 **Skin contact:** Remove contaminated clothing and wash the exposed skin area thoroughly with soap and water.
- 4.2 **Eye contact:** Flush with copious amounts of water for at least 15 minutes. Seek medical attention.
- 4.3 **Inhalation:** Remove to fresh air, give oxygen if breathing becomes difficult and seek medical attention.
- 4.4 **Ingestion:** Flush mouth with copious amounts of water, provided that the person is conscious and seek medical attention.

5. FIRE-FIGHTING MEASURES

- 5.1 **Suitable extinguishing media:** Chemical or water fire extinguisher.

- 5.2 **Extinguishing media not to be used:** None known.
- 5.3 **Special fire-fighting procedures:** None known.
- 5.4 **Unusual fire and explosion hazards:** Not available
- 5.5 **NFPA rating:** Health: 2, Flammability: 0, Reactivity: 1

6. ACCIDENTAL RELEASE MEASURES

- 6.1 **Body precautions:** Wear rubber gloves, impermeable shoe covers and long laboratory coat.
- 6.2 **Environmental precautions:** Contain the spill to the smallest area possible.
- 6.3 **Cleaning measures:** Take care not to contaminate body. Absorb the material with disposable towels. Soak area with a 10% bleach solution and wipe up with disposable towels. Dispose of all contaminated trash in accordance with local regulations.

7. HANDLING AND STORAGE

- 7.1 **Handling:** Wear suitable personal protective equipment. Take care not to splash spill or splatter reagents. Do not eat, drink, smoke or apply cosmetics in laboratory areas. Do not pipette samples or reagents by mouth.
- 7.2 **Storage:** Store the test kits in 2 - 8° C refrigerators designated and labeled to contain human blood products.

8. EXPOSURE CONTROLS/PERSONAL PROTECTION

- 8.1 **Body protection:** Wear long laboratory coat.
- 8.2 **Respiratory protection:** In case of fire, wear self-contained breathing apparatus.
- 8.3 **Hand protection:** Wear non-permeable rubber, neoprene, latex or nitrile disposable gloves. Change gloves when they become contaminated.
- 8.4 **Eye protection:** Wear safety glasses or goggles when a splash hazard exists.

9. PHYSICAL AND CHEMICAL PROPERTIES

- 9.1 **Physical state (at 20°C):** Microtiter plate is in solid form. All other reagents are in liquid form.
- 9.2 **Odor:** Odorless
- 9.3 **pH value:** All reagents 6.8 ~ 8.0
- 9.4 **Melting point/freezing Point:** Not determined
- 9.5 **Boiling point:** Not determined
- 9.6 **Evaporation rate:** Not determined
- 9.7 **Flammability (solid, gas):** Not flammable
- 9.8 **Upper/lower flammability or explosive limits:** Not applicable
- 9.9 **Vapor pressure:** Not determined
- 9.10 **Vapor density:** Not determined

- 9.11 **Relative density:** Not determined
- 9.12 **Solubility:** Water soluble
- 9.13 **Auto-ignition temperature:** Not applicable
- 9.14 **Decomposition temperature:** Not determined
- 9.15 **Viscosity:** Not determined
- 9.16 **Explosive properties:** None
- 9.17 **Oxidizing properties:** Not determined

10. STABILITY AND REACTIVITY

- 10.1 **Stability:** Stable under recommended storage conditions.
- 10.2 **Reactivity:** No known reactivity hazards associated with product.
- 10.3 **Possibility of hazardous reactions:** No hazardous polymerization
- 10.4 **Conditions to avoid:** Excessive heat and light
- 10.5 **Incompatible materials:** Acids

11. TOXICOLOGICAL INFORMATION

- 11.1 **Acute toxicity:** Not determined
- 11.2 **Skin corrosion/irritation:** Stop Solution is an acidic and corrosive agent, and may cause skin irritation with direct contact.
- 11.3 **Serious eye damage/irritation:** Not determined
- 11.4 **Respiratory or skin sensitization:** Not determined
- 11.5 **Germ cell mutagenicity:** Not determined
- 11.6 **Carcinogenicity:** None known
- 11.7 **Reproductive toxicity:** Not determined
- 11.8 **STOT-single exposure:** Not determined
- 11.9 **STOT-repeated exposure:** Not determined
- 11.10 **Aspiration hazard:** Not determined

12. ECOLOGICAL INFORMATION

None known.

13. DISPOSAL CONSIDERATIONS

- 13.1 **Disposal of reagents:** Dispose according to current regional and national regulations.
- 13.2 **Contaminated containers:** Dispose following current regional and national regulations.

14. TRANSPORT INFORMATION

- 14.1 **UN number:** Not available
- 14.2 **UN proper shipping name:** Not available

14.3 Transport hazard class(es): Not available

14.4 Packing group: Not available

14.5 Environmental hazards:

Overland transport (ADR/RID): None

Water transport (ADN/IMDG): None

Air transport (ICAO/IATA): None

14.6 Special precautions for user: None

15. REGULATORY INFORMATION

15.1 Classification: This preparation is classified and labeled in accordance with applicable national and international regulations.

15.2 Symbols of danger: N/A

15.3 "R" phrases indicating specific risks: Irritant R36/37/38, Irritating to the eyes, respiratory system and skin.

15.4 "S" phrases indicating caution: S26, In case of contact with any reagents rinse with copious amounts of water for at least 15 minutes. If irritation persists, seek medical attention. S36, Wear suitable protective clothing.

16. OTHER INFORMATION

Recommended Use: For research or clinical investigational use only. Not for use on or in human and animals. Information contained in this SDS relies upon our best knowledge of the product upon issue of this document to describe the use, storage, transport and disposal under safe and secure measures. Such information is not a guarantee of the characteristics and specific quality of the product. This SDS concerns the stated preparation and cannot apply to the product if used with other materials or in a process other than those specifically stated.

Date Adopted	2017-02-06
REF 4221-16	FREE BETA-HUMAN CHORIONIC GONADOTROPIN (Free β-HCG) ELISATEST KIT



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