

Material Safety Data Sheet

Free Testosterone ELISA

In-Vitro Diagnostic Use Only

SECTION 1.	Company Identification
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Product name: Free Testosterone ELISA
 Catalog No.: 2925-15
 Synonyms: N/A
 Product description: ELISA-based Diagnostic Kit
 Intended Use: Laboratory Use – Qualitative determination of free testosterone concentration in human serum or plasma by a microplate enzyme immunoassay, colorimetric.
 Kit Storage: 2-8°C

Company: Diagnostic Automation Inc.
 Address: 21250 Califa St, Suite 102 & 116,
 Woodland Hills, CA 91367, USA.

Website: www.rapidtest.com
 Phone: 818-591-3030
 Fax: 818-591-8383
 E-mail: onestep@rapidtest.com

Emergency phone: Contact your local Emergency Health Provider.

SECTION 2.	Hazards Identification
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2.1 Classification of the substance or mixture

Main hazards: None.

2.2 Label elements

Hazard Pictograms: None.

Signal Word: None.

Hazard Statement: None.

2.3 Other hazards

None.

SECTION 3.	Composition and Ingredients Information
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3.1 Mixtures

All concentrations of potentially hazardous substances or mixtures are below the specific concentration limits and M-factors for hazardous identification. As preparations, the product components are not classified as hazardous. The following substance exceeds the generic cut-off value and is listed with its concentration level. At this concentration level, the substance is not hazardous. See section 16 for definitions for all risk and hazards classifications.

Chemical Name	Index No.	CAS No.	EC No.	Hazard Code Risk phrase	Conc. (%w/w)	Classification
Hydrochloric acid			231-595-7	C; R34 Xi; R37	< 5%	Skin Corr. 1B: H314; STOT SE 3: H335



SECTION 4. First Aid Measures

4.1 Description of first aid measures

General instructions:	Immediately rinse with soap and plenty of water. Use personal protective working aids.
Inhalation:	Transport the affected person into the open air. If there are respiratory complaints, oxygen must be administered. If irritation persists, seek medical advice.
Eye contact:	Rinse with a stream of water for at least 15 minutes. Thorough rinsing must be ensured by opening the eyelids. If irritation occurs, seek medical advice.
Skin contact:	Wash contacted area with soap and water. Remove contaminated clothing. If irritation occurs, seek medical advice.
Ingestion:	Do NOT induce vomiting. If conscious, rinse the mouth and administer a large amount of water to dilute the substance. In the case of unconsciousness, never administer anything orally. If irritation occurs, seek medical advice.

SECTION 5. Firefighting measures

5.1 Extinguishing media

Use extinguishing media appropriate to the conditions. Dry powder. Carbon dioxide (CO₂). Foam. Water Spray.

5.2 Special hazards arising from the substance or mixture

None.

5.3 Advice for firefighters

Wear suitable respiratory equipment – self-contained breathing apparatus, if necessary.

SECTION 6. Accidental release measures

6.1 Personal precautions, protective equipment and emergency procedures

Avoid contact with skin and eyes.
Wear suitable protective equipment.

6.2 Environmental precautions

Do not allow product to enter sewerage systems, surface and ground water. Avoid soil pollution.

6.3 Methods and material for containment and cleaning up

Cover with suitable absorbing material. After removing the substance, rinse the spot of spilling thoroughly with water and soap. Dispose of waste according to all federal, state, and local regulations.

SECTION 7. Handling and Storage

7.1 Precautions for safe handling

Avoid spills. Avoid contact with eyes and skin. Use suitable protective means to work with the substance. Ensure adequate ventilation of the working area. Follow good manufacturing practices when using product. Do not drink, smoke, or eat in work areas.

7.2 Conditions for safe storage, including any incompatibilities

Kit and unopened components: Store at temperatures between +2 and +8 °C in a dry and dark place until expiration date.
Opened components: Opened reagents are stable for sixty days when stored at 2-8 °C.
For prepared reagents: Diluted wash buffer should be stored at room temperature (2-30 °C) for up to 60 days.
Working substrate solution should be stored at 2-8 °C and is stable for 1 year.

7.3 Specific end uses

Product procedures should be performed by a skilled or trained individual for in vitro diagnostic use only.



SECTION 8. Exposure controls/personal protection

8.1 Control parameters

No substances with occupational exposure limits.

8.2 Exposure controls

Eye/face protection Face shield, safety goggles.
 Skin protection Wear suitable gloves. Wash hands after properly removing and disposing of gloves. Lab coats recommended.
 Respiratory protection Use in a well-ventilated area. If local exhaustion is necessary, general (forced) exhaustion is recommended.
 Thermal hazards None.

SECTION 9. Physical and Chemical Properties

9.1 Information on basic physical and chemical properties

	Calibrators	Enzyme Reagent	Biotin Reagent	Wash Conc.	Substrate Solution	Stop Solution	Microtiter Strips
Appearance	Liquid						Solid
Color	Straw	Yellow	Blue	Clear			N/A
Odor	Odorless						
Odor threshold	Not applicable						
pH	6.8-7.4					< 3	N/A
Melting pt.	Not determined						
Boiling pt.	Not determined						
Flash pt.	Not applicable						
Evaporation rate:	Not determined						
Flammability:	Not determined						
Explosive limits:	Not applicable						
Vapor pressure:	Not determined						
Vapor density:	Not determined						
Relative density:	Not determined						
Solubility:	Water soluble						N/A
Partition coefficient: n-octanol/water	Not determined						
Auto-ignition temp.:	Not applicable						
Decomposition temp.:	Not determined						
Viscosity:	Not determined						
Explosive properties:	None						
Oxidizing properties:	Not determined						

SECTION 10. Stability and Reactivity

10.1 Reactivity

No known reactivity hazards associated with product.

10.2 Chemical stability

Stable under normal conditions.

10.3 Possibility of hazardous reactions

No hazardous polymerization.



10.4 Conditions to avoid

Excessive heat and light.

10.5 Incompatible materials

Acids

10.6 Hazardous decomposition products

Not determined.

SECTION 11. Toxicology Information

11.1 Toxicological information

Acute toxicity:	Not determined.
Skin corrosion/irritation:	Not determined.
Serious eye damage/irritation:	Not determined.
Respiratory or skin sensitization:	Not determined.
Germ cell mutagenicity:	Not determined.
Carcinogenicity:	No component of this product present at levels $\geq 0.1\%$ is identified as probable, possible or confirmed human carcinogen by NTP (National Toxicology Program), IARC (International Agency for Research on Cancer), or OSHA (Occupational Safety & Health Administration).
Reproductive toxicity:	Not determined.
STOT-single exposure:	Not determined.
STOT-repeated exposure:	Not determined.
Aspiration hazard:	Not determined.
Information on likely routes of exposure:	
If ingested:	Not determined.
If inhaled:	Not determined.
If contact with skin:	Not determined.
If contact with eyes:	Not determined.
Symptoms related to the physical, chemical, and toxicological characteristics:	None after short or long-term exposure.

SECTION 12. Ecological Information

12.1 Toxicity

Not determined.

12.2 Persistence and degradability

Not determined.

12.3 Bioaccumulative potential

Not determined.

12.4 Mobility in soil

Not determined.

12.5 Results of PBT and vPvB assessment

Not determined.

12.6 **Other adverse effects**

Not determined.

SECTION 13. Disposal Considerations

Waste treatment methods

All waste disposals must be carried out in accordance with federal, state, and local legislation and administrative regulations. A licensed professional waste disposal service should be utilized to dispose of material and packaging.

SECTION 14. Transport Information

The product is not classified as dangerous for carriage.

SECTION 15. Regulatory Information

15.1 **Safety, health and environmental regulations/legislation specific for the substance or mixture**

SARA: None.

TSCA: All components in product preparations are listed on the US Toxic Substances Control Act inventory of chemicals or are exempt from listing.

This safety data sheet has been prepared to comply with the requirements of Annex II, European Community Regulation No. 1907/2006 REACH (Registration, Evaluation, Authorisation and Restriction of Chemicals) and OSHA (Occupational Safety & Health Administration) 1910.1200, Appendix D.

Chemical safety assessment

None.

SECTION 16. Other information

Revision 2 (2015-May-05): Updated to comply with requirements of Annex II, European Community Regulation No. 1907/2006 (REACH) and OSHA 1910.1200, Appendix D

Revision 1 (2010-Dec-01): Updated to 16 point format

Revision 0 (2005-Dec-22): Initial Creation

<i>Hazard Statements</i>		<i>Hazard Class and Category Codes</i>	
H314	Causes severe skin burns and eye damage	Skin Corr.	Skin Corrosion/Irritation
H335	May cause respiratory irritation	STOT SE 3	Specific Target Organ toxicity – Single Exposure
<i>Hazard Codes</i>		<i>Risk Phrases</i>	
C	Corrosive	R34	Causes burns
Xi	Irritant	R37	Irritating to respiratory system

The material safety data sheet contains data necessary to ensure safety and health and environmental protection in working with chemical substances. This product is a chemical substance and can be solely used by persons with chemical education at their own risk. DAI kits are designed for biomedical research. The manufacturer has no responsibility for damage caused by unsuitable use and by disrespecting the enclosed working instructions. The above-stated information cannot be considered as complete and must be understood to be only a methodical instruction.



ISO 13485
ISO 9001



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