



## Material Safety Data Sheet

# Neo-natal TSH ELISA

In-Vitro Diagnostic Use Only

### SECTION 1. Company Identification

Product name: Neo-natal TSH ELISA  
Catalog No.: 3124-15  
Synonyms: N/A  
Product description: ELISA-based Diagnostic Kit  
Intended Use: Quantitative determination of Thyrotropin concentration in human (neonates) whole blood by a microplate enzyme immunoassay, colorimetric.  
For in vitro diagnostic use only. Not for internal or external use in humans or animals.  
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](http://www.rapidtest.com)  
Phone: 818-591-3030  
Fax: 818-591-8383  
E-mail: [onestep@rapidtest.com](mailto:onestep@rapidtest.com)  
Emergency phone: Contact your local Emergency Health Provider.

### SECTION 2. Hazards Identification

#### 2.1 Classification of the substance or mixture

None.

#### 2.2 Label elements

None.

#### 2.3 Other hazards

None.

### SECTION 3. Composition and Ingredients Information

#### 3.1 Substances and/or 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.

##### 3.1.1 N-TSH Calibrators (Dried blood spots)

N/A

##### 3.1.2 Whole Blood Controls (Dried blood spots)

N/A

3.1.3 N-TSH Enzyme Reagent  
N/A

3.1.4 N-TSH Biotin Reagent  
N/A

3.1.5 Streptavidin Coated Plate  
N/A

3.1.6 Substrate reagent  
N/A

3.1.7 Wash Solution Concentrate  
N/A

3.1.8 Stop Solution

| Chemical Name | CAS No.   | EC No.    | Hazard Code<br>Risk phrase | Hazard Class Category Code | Hazard<br>Statement | Conc.<br>(%w/w) |
|---------------|-----------|-----------|----------------------------|----------------------------|---------------------|-----------------|
| Sulfuric acid | 7664-93-9 | 231-639-5 | C; R35                     | Skin Corr. 1A              | H314                | < 4.5%          |

**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. |

**4.2 Most important symptoms and effects, both acute and delayed**

No data available

**4.3 Indication of any immediate medical attention and special treatment needed**

No data available

**SECTION 5. Firefighting measures**

**5.1 Extinguishing media**

Dry powder. Carbon dioxide (CO<sub>2</sub>). Foam. Water.

**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.

**6.4 Reference to other sections**

See Section 8 for personal protective equipment. See Section 13 for appropriate disposal methods.

**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 (60) 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.

**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: Safety glasses or goggles with side shields recommended.

Skin protection: Compatible protective gloves recommended. Wash hands after properly removing and disposing of gloves.

Other skin protection: Laboratory coats are recommended.

Respiratory protection: No respiratory protection is required. Use product in rooms enabling good ventilation. 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**

**9.1.1. Appearance:**

Physical state (at 20 °C)

Liquid: Enzyme Reagent, Biotin Reagent, Wash Solution Concentrate, Substrate Solution, Stop Solution

Solid: Calibrators and Controls (Dried blood spots on WHATMAN type 903 filter paper), Microtiter strips



- Color  
Yellow: Enzyme Reagent  
Green: Biotin Reagent  
Clear: Stop, Substrate, Wash
- 9.1.2. Odor: Odorless  
9.1.3. Odor threshold: Not applicable  
9.1.4. pH value: Stop Solution: <3  
Others: 6.8-7.4
- 9.1.5. Melting point/freezing point: Not determined  
9.1.6. Initial boiling point/range: Not determined  
9.1.7. Flash point: Not applicable  
9.1.8. Evaporation rate: Not determined  
9.1.9. Flammability (solid, gas): Not flammable  
9.1.10. Upper/lower flammability or explosive limits: Not applicable  
9.1.11. Vapor pressure: Not determined  
9.1.12. Vapor density: Not determined  
9.1.13. Relative density: Not determined  
9.1.14. Solubility: Water soluble  
9.1.15. Partition coefficient: n-octanol/water: Not determined  
9.1.16. Auto-ignition temperature: Not applicable  
9.1.17. Decomposition temperature: Not determined  
9.1.18. Viscosity: Not determined  
9.1.19. Explosive properties: None  
9.1.20. Oxidizing properties: Not determined

|                    |                                 |
|--------------------|---------------------------------|
| <b>SECTION 10.</b> | <b>Stability and Reactivity</b> |
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**10.1 Reactivity**

No known reactivity hazards associated with product.

**10.2 Chemical stability**

Stable under recommended storage 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**

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|--|--|
| 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:   | No known health effects.   |
| If inhaled:  | No known health effects.   |
| If contact with skin:  | No known health effects.   |
| If contact with eyes:  | No known health effects.   |
| 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**

**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 (AND/IMDG): None

Air transport (ICAO/IATA): None

**14.6 Special precautions for user**

None

**14.7 Transport in bulk according to Annex II of MARPOL73/78 and the IBC Code**

Not applicable

**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 |

| Hazard Codes |           | Risk Phrases |                     |
|--------------|-----------|--------------|---------------------|
| C            | Corrosive | R35          | Causes severe burns |

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.

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|---|--|
|  <p>ISO 13485<br/>ISO 9001</p>   |  |
|  <p><b>Diagnostic Automation/Cortez Diagnostics,<br/>Inc.</b><br/>21250 Califa Street, Suite 102 and 116,<br/>Woodland Hills, California 91367 USA</p> |  |
| <b>Date Adopted</b>   | <b>2017-4-6</b>                        |
| <b>REF</b> 3124-15  | <b>AccuDiag™ - Neo-natal TSH ELISA</b> |
| Revision #: 2 on 2015-05-05   |  |