

**HDL/LDL Direct Cholesterol Calibrator**

**SECTION 1 – PRODUCT AND COMPANY IDENTIFICATION**

Product Identification: HDL/LDL Direct Cholesterol Calibrator  
Ref No. 0595, 0595-003

Test kit contains HDL/LDL Cholesterol Calibrator.

Company Identification: Stanbio Laboratory  
1261 North Main Street  
Boerne, TX 78006

Telephone Number: (830) 249-0772  
Website: <http://www.stanbio.com>

**SECTION 2 – HAZARDS IDENTIFICATION**

**Routes of Exposure:** Only when used as directed.

**Classification system:** In compliance with OSHA's Hazard Communication Standard (29CFR 1910.1200), a chemical mixture is considered hazardous if it contains 1.0% or more of a hazardous compound or 0.1% or more of a carcinogen. The product does NOT contain hazardous material(s) in excess of these amounts; therefore, no SDS is required under the standard.

**National Fire Protection Association (NFPA) ratings (scale 0-4):**

Health=0  
Fire=0  
Reactivity=0

**Hazard Overview**

**Health:** Minimal risk if used as directed.

**Fire:** Not considered a fire hazard.

**Reactivity:** Reagents do not contain hazardous materials according to the standard. Minimal risk.

**Special Hazards:** Avoid ingestion of reagents, as toxicity has not been determined. Although no SDS is required by the standard, the following general guidelines are given should reagents be inhaled, ingested, or exposed to eyes or skin.

**Carcinogenicity information**

**OSHA (Occupational Safety and Health Administration):** None of the ingredients is listed.

**NTP (National Toxicology Program):** None of the ingredients is listed.

**IARC (International Agency for Research on Cancer):** None of the ingredients is listed.

**SECTION 3 – PRODUCT COMPOSITION**

The test kit is composed of HDL/LDL Cholesterol Calibrator.

HDL/LDL Cholesterol Calibrator/0595 (The reagent contains by percentage the following amounts of chemicals)

<u>Chemical Name</u>	<u>CAS No.</u>	<u>Concentration</u>
None determined to be hazardous.		

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### SECTION 4 – FIRST AID MEASURES

**After inhalation:** Provide fresh air. Restore or support breathing. Keep victim warm and quiet. Get medical attention.

**After skin contact:** Flush skin with water for 15 minutes. Wash affected area thoroughly with soap and water. Remove contaminated clothing and shoes. Get medical attention if irritation develops or persists.

**After eye contact:** Flush eyes including under the eyelids with water for 15 minutes. Get medical attention.

**After swallowing:** Wash out mouth with generous amounts of water. Do not give anything by mouth to an unconscious person. Get medical attention.

### SECTION 5 – FIRE FIGHTING MEASURES

**Suitable extinguishing agents:** Not considered a fire hazard.

**Protective equipment:** Wear a self-contained breathing apparatus and protective clothing.

### SECTION 6 – ACCIDENTAL RELEASE MEASURES

**Safe work practices:** Disposal should be made in accordance with existing disposal practices employed for infectious waste.

**Measures for environmental protection:** Prevent liquid and vapor from entering sewage system, storm drains, surface waters, and soil.

**Measures for cleaning/ collecting:** Wash spill area with appropriate cleaning materials. Dispose of in a manner consistent with federal, state and local regulation.

### SECTION 7 – HANDLING AND STORAGE

**Information for safe handling:** Refer to the package insert or product label for additional information on storage conditions.

**Information about protection against explosions and fires:** No special measures required.

**Requirements to be met by storerooms and receptacles:** Refer to the package insert or product label for additional information on storage conditions.

**Information about storage in one common storage facility:** Store product in original packaging.

**Further information about storage conditions:** Protect from heat and direct sunlight.

### SECTION 8 – EXPOSURE CONTROLS/PERSONAL PROTECTION

**Components with Occupational Exposure Limits:** The product does not contain any hazardous ingredients with occupational exposure limits established by OSHA, ACGIH, or NIOSH.

**General protective and hygienic measures:** Always maintain good housekeeping. Do not eat, drink or store food and beverages in areas where chemicals are used. Wash hands before breaks and at the end of the work shift.

**Breathing equipment:** Use adequate protection to prevent inhalation, as well as good ventilation.

**Hand protection:** Wear necessary gloves when handling.

**Eye protection:** Wear appropriate safety glasses or other protective eyewear.

**Body protection:** Wear apron, laboratory coat or appropriate protective clothing when handling.

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**General notes:** Human source material. Treat as potentially infectious. Each plasma donor unit used in the preparation of this product has been tested by an FDA approved method and found non-reactive for the presence of HBsAg, HCV, and antibodies to HIV 1/2. Because no known test method can offer complete assurance that hepatitis B virus, Human Immunodeficiency Virus (HIV) or other infectious agents are absent, all human-based products should be handled in accordance with good laboratory practices using appropriate precautions. All material used in this test should be considered potentially infectious. Universal precautions as they apply to your facility should be used for handling and disposal of materials during and after testing.

### **SECTION 9 – PHYSICAL AND CHEMICAL PROPERTIES**

**Form:** Lyophilized solid

**Color:** Not applicable

**Odor:** Not identified

**Boiling point/Boiling range:** NA/NA

**Flash point:** NA

**Auto igniting:** Not self-igniting

**Danger of explosion:** Not applicable

**Density at 20°C (68°F):** Not applicable

**Solubility in/Miscibility with Water:** Not applicable

**PH-value at 20°C (68°F):** Not applicable

**Water:** Not applicable

### **SECTION 10 – STABILITY AND REACTIVITY**

**Thermal decomposition / conditions to be avoided:** No decomposition if used according to specifications

**Dangerous reactions:** No dangerous reactions known.

Stability: Stable.

Incompatibility: None.

Hazardous Polymerization: Will not occur.

**Dangerous reactions:** No dangerous decomposition products known.

### **SECTION 11 – TOXICOLOGICAL INFORMATION**

**LD50/50LC values for hazardous ingredients per OSHA criteria:**

**Ingredients (100% pure substance/s)**

Not applicable.

**Primary toxicological effects of the final product**

**Skin irritation:** Not determined.

**Eye irritation:** Not determined.

**Sensitization:** No sensitizing effects known.

**Target organs/systems:** Not determined.

### **SECTION 12 – ECOLOGICAL INFORMATION**

**Toxicity:** Further details: no data available

**Persistence and degradability:** Further details: no data available

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**Bioaccumulative potential:** Partition coefficient: n-octanol/water: no data available

**Mobility in soil:** no data available

**Results of PBT and vPvB assessment:** no data available

**General information:** Do not allow to enter into ground-water, surface water or drains.

**SECTION 13 – DISPOSAL CONSIDERATIONS**

Dispose of in a manner consistent with federal, state, and local regulations.

**SECTION 14 – TRANSPORT INFORMATION**

**DOT Class** - Not restricted for transportation.

**IMDG Class - Marine pollutant:** No, not restricted for transportation.

**ICAO/IATA Class** - Not restricted for transportation.

**SECTION 15 – REGULATORY INFORMATION**

**SARA (Superfund Amendments and Reauthorization Act of 1986 – USA):**

**Section 302/304 (40CFR355.40):** The product does not contain listed substances.

**Section 313 (40CFR372.65):** The product does not contain listed substances.

**California Proposition 65 (USA)**

**Chemicals known to cause cancer:** The product does not contain listed substances.

**Chemicals known to cause female reproductive toxicity:** None of the ingredients is listed.

**Chemicals known to cause male reproductive toxicity:** None of the ingredients is listed.

**Chemicals known to cause developmental reproductive toxicity:** None of the ingredients is listed.

**Markings according to European guidelines:** observe the general safety regulations when handling chemicals. The product does not require any hazard warnings according the respective European Community (EC) Directives.

**SECTION 16 – OTHER INFORMATION**

The information contained in this SDS is believed to be accurate and represents the best information currently available. Stanbio Laboratory makes no warranty, express or implied, with respect to such information, and we assume no liability resulting from its use. Users should determine suitability of the information contained in SDS for their particular purpose.

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