Catalog No.: 502050

Reference No.: 502050 Revision Date: Oct 10, 2012

SECTION 1 – Product / Preparation and Company Identification

1.1 StrongStep® Procalcitonin TEST (For In Vitro Diagnostic Use Only)

1.2 The StrongStep® Procalcitonin Test is a rapid immune-chromatographic assay for the semi-quantitative detection of Procalcitonin in human serum or plasma. It is used for diagnosing and controlling the treatment of severe, bacterial infection and sepsis.

1.3 Manufacturer: Liming Bio-Products Co.,Ltd – No.12 Huayuan Road – Nanjing, Jiangsu, P.R.China 210042

Telephone No.: (0086)25 85476723 Fax No.: (0086)25 85476387

1.4 Emergency No.: (0086)25 85288500

SECTION 2 – Composition / Ingredients Information

2.1 Description of Components: Test Cassette (containing murine monoclonal anti-Procalcitonin antibody) and Disposable Pipette

2.2 Hazardous Ingredients: Dangerous solid or liquid substances present in >1% (or as required by applicable U.S., Canadian and E.U. regulations):

CAS#	EINECS	Chemical Name	Kit Component	% Weight	Classification:			
					US OSHA	WHMIS	EU	Risk Phrases
No hazardous substances greater than 1% are contained within this kit.								

** See Section 15 and Section 16 – Regulatory Information for additional information on hazard classifications.

SECTION 3 – Hazard Identification

Emergency Overview:

3.1 This kit may contain material of human and/or animal origin and should be considered as potentially capable of transmitting infectious diseases.

3.2 All patient samples, contaminated components, and fluids should be handled as potentially infectious. Follow Universal Precautions as necessary.

SECTION 4 – First Aid Measures

Special Instructions:

4.1 Inhalation Inhalation of any component in this kit is unlikely.

4.2 Eye Contact Contact with the test strip contained within the test cassette is unlikely.

4.3 Skin Contact Contact with the test strip contained within the test cassette is unlikely.

4.4 Ingestion If a component of this kit is ingested, wash mouth out with water. If irritation or discomfort occurs, obtain medical attention.

SECTION 5 – Fire Fighting Measures

5.1 Extinguishing Media: For small fires, use dry chemical, carbon dioxide, or alcohol-resistant foam.

5.2 Special Fire Fighting Procedures: This material will not significantly contribute to the intensity of a fire. Use extinguishing material suitable to the surrounding fire. Utilize proper personal protective equipment when responding to any fire. Incipient fire responders should wear eye protection. Structural firefighters must wear Self-Contained Breathing Apparatus and full protective equipment. Move containers from fire area if it can be done without risk to personnel. If possible, prevent runoff water from entering storm drains, bodies of water, or other environmentally sensitive areas.

5.3 Unusual Fire and Explosion Hazards: When involved in a fire, this material can decompose and produce irritating fumes and toxic gases (e.g., Carbon monoxide, Carbon dioxide).

Explosion Sensitivity to Mechanical Impact: Not sensitive under normal conditions.

Explosion Sensitivity to Static Discharge: Not sensitive under normal conditions.

5.4 Additional Considerations

5.4.1	Flash Point	Non-combustible
5.4.2	Auto-ignition Temperature	Not available
5.4.3	Upper / Lower Explosion Limit	Not available

5.5 NFPA Ratings (see 'Definition of Terms' for explanation of numerical ratings):

**Only trained and competent personnel shall attempt to extinguish a fire. Contact emergency response personnel as required. Be cautious of surrounding materials that may react with the extinguishing media.

SECTION 6 – Accidental Release Measures

6.1 Personal Precautions: This kit contains materials of biological origin. Avoid personal contact. Use Universal Precautions during clean-up procedures involving patient samples.

6.2 Environmental Precautions: No environmental hazard is anticipated provided that the material is handled and disposed of with due care.

6.3 Spill and Leak Procedures: Not Applicable

SECTION 7 – Handling and Storage

7.1 Handling: Avoid getting components within this kit ON YOU or IN YOU. Wash exposed areas thoroughly after using this kit. Do not eat or drink while using this kit. This kit should be handled only by qualified clinical or laboratory employees trained on the use of this kit and who are familiar with the potential hazards. This kit should be handled as though capable of transmitting infectious diseases. Universal Precautions should be followed when using this kit.

7.2 Storage: To maintain efficacy, store according to the package insert instructions.

7.3 Specific Use For In Vitro Diagnostic Use Only – Not for use by general public!

SECTION 8 – Exposure Controls and Personal Protection

8.1 Exposure Limits: Not available

8.2 Occupational Exposure Controls:

8.2.1 Engineering Controls:

No special engineering controls are required when working with this kit. Use with adequate ventilation to ensure exposure levels are maintained below the limits provided above.

8.2.2 Personal Protective Equipment (PPE):

Respiratory

Protection: None needed under normal conditions of use.

Eye Contact: Safety glasses are recommended to prevent eye contact.

Hand Contact: Impervious gloves (nitrile or equivalent) should be worn to prevent hand contact.

Skin Contact: Lab Coat or similar garment should be worn.

8.2.3 Environmental Controls: No special environmental controls are required.

SECTION 9 – Physical and Chemical Properties

Characteristic	**Test Cassette**
Boiling Point (°C)	Not available
Melting Point (°C)	Not available
Specific Gravity (H_2O = 1)	Not available
Vapor Pressure (mm Hg)	Not available
Vapor Density (AIR = 1)	Not available
Evaporation Rate (Ether = 1)	Not available
pH:	Not available
Solubility in Water:	Not applicable
Appearance and Odor:	Oblong white plastic test cassette with vents; no odor

SECTION 10 – Stability and Reactivity

Characteristic	**Test Cassette**
Stability	Stable
Conditions to Avoid	Incompatible materials
Materials to avoid (Incompatibilities)	None known
Hazardous Decomposition or Byproducts	Thermal decomposition may release toxic fumes of CO and CO_2
Hazardous Polymerization	Has not been reported

SECTION 11 – Toxicological Information

11.1 Toxicity Data for Hazardous Ingredients:

There are currently no toxicity data available for the components contained within this kit.

11.2 Primary Routes of Exposure:

Overexposures to components within this kit are not expected.

11.3 Potential Effects of Acute Overexposure, By Route Of Exposure:

This kit contains material of animal origin and should be considered as potentially capable of transmitting infectious diseases.

CONTACT WITH SKIN or EYES: Contact may cause eye or skin irritation.

INGESTION: If components of this kit are swallowed, irritation of the mouth, throat, and other tissues of the gastro-intestinal system may occur.

11.4 Potential Effects of Chronic Exposure: None known

11.5 Symptoms of Overexposure: None known

11.6 Medical Exposure Aggravated by Exposure: None known

11.7 Carcinogenicity:

To the best of our knowledge, this kit does not contain any substances that are listed by ACGIH, IARC, NTP or California Prop 65.

SECTION 12 – Ecological Information

12.1 Ecotoxicity: No adverse effects on the environment are expected from the components of this kit. There is no aquatic toxicity data for this kit at this time.

12.2 Mobility: Mobility data are not available for the components of this kit.

12.3 Persistence and Degradability: There is no persistence or degradation data for any component of this kit at this time.

12.4 Bioaccumulative Potential: There is limited potential for the components within this kit to accumulate in plant or animal systems.

SECTION 13 – Disposal Considerations

Dispose of waste materials, unused components and contaminated packaging in compliance with country (i.e., Canada, EU, etc.), federal, state and local regulations. If unsure of the applicable requirements, contact the authorities for information.

SECTION 14 – Transport Information

14.1 U.S. Transportation, Canadian Transportation, and International Air Transportation

This kit is not regulated for transport.

SECTION 15 – Regulatory Information

15.1 U.S. Federal and State Regulations

	QuickVue One-Step hCG Urine Test
40 CFR 355.30/355.40 - SECTION 302	Not Listed
40 CFR 302.4 – SECTION 304	Not Listed

40 CFR 372.65 – SECTION 313	Not Listed

U.S. SARA SECTION 311/312 FOR KIT: Not applicable

U.S. TSCA INVENTORY STATUS: Not applicable

OTHER U.S. FEDERAL REGULATIONS: Not applicable

15.2 Label Information – ANSI Z129.1: Not applicable

15.3 Canadian Regulations:

CANADIAN DSL/NDSL INVENTORY STATUS: The components of this kit are not listed on the DSL Inventory.

CANADIAN WHMIS SYMBOLS: Not applicable

15.4 HMIS Ratings: Not applicable

15.5 EU Labeling Classification: Not applicable

SECTION 16 – Other Information

This MSDS has been prepared in accordance with ANSI Z400.1 format. Every effort has been made to adhere to the hazard criteria and content requirements of the US OSHA Hazard Communication Standard, European Communities Safety Data Sheets Directive, Canadian Controlled Products Regulations, UK Chemical Hazard information and Packaging Regulations, and UN Globally Harmonized System of Classification and Labeling of Chemicals.

The hazard ratings on this MSDS are for appropriately trained workers using the Hazardous Materials Identification System (HMIS.) or a National Fire Protection Association (NFPA) 704 Program. The ratings are estimates and should be treated as such. The hazard rating scales range from (0) minimal hazards to (4) significant hazards or risks (Refer to Definitions of Terms at the end of this MSDS). Chronic (long-term) health effects are indicated in the HMIS by an asterisk (*). HMIS is a registered trade and service mark of the NPCA. For details on HMIS ratings visit www.paint.org/hmis. For details on NFPA 704 visit www.nfpa.org.

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DEFINITIONS OF TERMS

A large number of abbreviations and acronyms appear on a MSDS. Some of these, which are commonly used, include the following:

CAS #: This is the Chemical Abstract Service Number that uniquely identifies each compound.

ACGIH - American Conference of Governmental Industrial Hygienists, a professional association that establishes exposure limits.

TLV - Threshold Limit Value - an airborne concentration of a substance that represents conditions under which it is generally believed that nearly all workers can be repeatedly exposed without adverse effect. The duration must be considered, including the 8-hour Time Weighted Average (TWA), the 15-minute Short Term Exposure Limit, and the instantaneous Ceiling Level (C). Skin absorption effects must also be considered.

OSHA - U.S. Occupational Safety and Health Administration

PEL - Permissible Exposure Limit - This exposure value means exactly the same as a TLV, except that it is enforceable by OSHA. The OSHA Permissible Exposure Limits are based in the 1989 PELs and the June, 1993 Air Contaminants Rule (Federal Register: 58: 35338-35351 and 58: 40191). Both the current PELs and the vacated PELs are indicated. The phrase, “Vacated 1989 PEL,” is placed next to the PEL that was vacated by Court Order.

IDLH - Immediately Dangerous to Life and Health - This level represents a concentration from which one can escape within 30-minutes without suffering escape-preventing or permanent injury. The DFG - MAK is the Republic of Germany’s Maximum Exposure Level, similar to the U.S. PEL. NIOSH is the National Institute of Occupational Safety and Health, which is the research arm of the U.S. Occupational Safety and Health Administration (OSHA). NIOSH issues exposure guidelines called Recommended Exposure Levels (RELs). When no exposure guidelines are established, an entry of NE is made for reference. Protective Equipment – A: Safety Glasses. B: Safety glasses and gloves. C: Safety glasses, gloves and body protection. D: Splash goggles with face shield, gloves and body protection. E: Eye protection, gloves and dust mask respiratory protection. F: Eye protection, gloves, body protection and dust mask respiratory protection. G: Eye protection, gloves and air purifying respiratory protection.

HAZARD RATINGS:

HAZARDOUS MATERIALS IDENTIFICATION SYSTEM: Health Hazard: 0 (minimal acute or chronic exposure hazard); 1 (slight acute or chronic exposure hazard); 2 (moderate acute or significant chronic exposure hazard); 3 (severe acute exposure hazard; onetime overexposure can cause permanent injury and can be fatal); 4 (extreme acute exposure hazard; single overexposure can be fatal). * Indicates chronic hazard. Flammability Hazard: 0 (minimal hazard); 1 (materials that require substantial pre-heating before burning); 2 (combustible liquid or solids; liquids with a flash point of 38-93°C [100-200°F]); 3 (Class IB and IC flammable liquids with flash points below 38°C [100°F]); 4 (Class IA flammable liquids with flash points below 23°C [73°F] and boiling points below 38°C [100°F]. Reactivity Hazard: 0 (normally stable); 1 (material that can become unstable at elevated temperatures or which can react slightly with water); 2 (materials that are unstable but do not detonate or which can react violently with water); 3 (materials that can detonate when initiated or which can react explosively with water); 4 (materials that can detonate at normal temperatures or pressures).

NATIONAL FIRE PROTECTION ASSOCIATION: Health Hazard: 0 (material that on exposure under fire conditions would offer no hazard beyond that of ordinary combustible materials); 1

(materials that on exposure under fire conditions could cause irritation or minor residual injury); 2 (materials that on intense or continued exposure under fire conditions could cause temporary incapacitation or possible residual injury); 3 (materials that can on short exposure could cause serious temporary or residual injury); 4 (materials that under very short exposure could cause death or major residual injury). Flammability Hazard and Reactivity Hazard: Refer to definitions for "Hazardous Materials Identification System".

FLAMMABILITY LIMITS IN AIR: Much of the information related to fire and explosion is derived from the National Fire Protection Association (NFPA). Flash Point - Minimum temperature at which a liquid gives off sufficient vapors to form an ignitable mixture with air. Autoignition Temperature: The minimum temperature required to initiate combustion in air with no other source of ignition. LEL - the lowest percent of vapor in air, by volume, that will explode or ignite in the presence of an ignition source. UEL - the highest percent of vapor in air, by volume, that will explode or ignite in the presence of an ignition source.

TOXICOLOGICAL INFORMATION:

Possible health hazards as derived from human data, animal studies, or from the results of studies with similar compounds are presented. Definitions of some terms used in this section are: LD_{50} - Lethal Dose (solids & liquids) which kills 50% of the exposed animals; LC_{50} - Lethal Concentration (gases) which kills 50% of the exposed animals; ppm concentration expressed in parts of material per million parts of air or water; mg/m3 concentration expressed in weight of substance per volume of air; mg/kg quantity of material, by weight, administered to a test subject, based on their body weight in kg. Other measures of toxicity include TDLo, the lowest dose to cause a symptom and TCLo the lowest concentration to cause a symptom; TDo, LDLo, LDo, TC, TCo, LCLo, and LCo, the lowest dose (or concentration) to cause lethal or toxic effects. BEI - Biological Exposure Indices, represent the levels of determinants that are most likely to be observed in specimens collected from a healthy worker who has been exposed to chemicals to the same extent as a worker with inhalation exposure to the TLV. Ecological Information: EC is the effect concentration in water.

Data from several sources are used to evaluate the cancer-causing potential of the material. The sources and ratings are: IARC - the International Agency for Research on Cancer; 1 = Carcinogenic to humans, 2A, 2B = Probably carcinogenic to humans, 3 = Unclassifiable as to carcinogenicity in humans, and 4 = Probably not carcinogenic to humans. NTP - the National Toxicology Program; K =Known to be a human carcinogen, and R = Reasonably anticipated to be a human carcinogen. RTECS - the Registry of Toxic Effects of Chemical Substances. OSHA - Occupational Safety and Health Administration and CAL/OSHA - California's subunit of the Occupational Safety and Health Administration; Ca = Carcinogen defined with no further categorization. ACGIH – American Conference of Governmental Industrial Hygienists; A1 = Confirmed human carcinogen, A2 = Suspected human carcinogen, A3 = Confirmed animal carcinogen with unknown relevance to humans, A4 = Not classifiable as a human carcinogen, and A5 = Not suspected as a human carcinogen. NIOSH – U.S. National Institute for Occupational Safety and Health; Ca = Potential occupational carcinogen, with no further categorization. EPA – U.S. Environmental Protection Agency; A = Human carcinogen, B = Probable human carcinogen, C = Possible human carcinogen, D = Not classifiable as to human carcinogenicity, E = Evidence of Non-carcinogenicity for humans, K = Known human carcinogen, L = Likely to produce cancer

in humans, CBD = Cannot be determined, NL = Not likely to be carcinogenic in humans, and I = Data are inadequate for an assessment of human carcinogenic potential.

REGULATORY INFORMATION:

This section explains the impact of various laws and regulations on the material. EPA is the U.S. Environmental Protection Agency. WHMIS is the Canadian Workplace Hazardous Materials Information System. DOT and TC are the U.S. Department of Transportation and the Transport Canada, respectively.

Superfund Amendments and Reauthorization Act (SARA); the Canadian Domestic/Non-Domestic Substances List (DSL/NDSL); the U.S. Toxic Substance Control Act (TSCA); Marine Pollutant status according to the DOT; the Comprehensive Environmental Response, Compensation, and Liability Act (CERCLA or Superfund); and various state regulations. This section also includes information on the precautionary warnings that appear on a material’s industrial package label.