CYTYC	MSDS – Positive Control PTDCheck Enzyme Immunoassay Kit (PN 00122)

1. CHEMICAL AND COMPANY IDENTIFICATION

Product Identification: Positive Control, PTDCheck Enzyme Immunoassay Kit (PN 00122)

Trade Name/Chemical Family/Synonyms: Positive Control

Product Description: The PTDCheck Enzyme Immunoassay Kit consists of the following components: Negative Control and Positive Controls. The controls contain anti-proteases, detergents, proteins, and preservative agents in deionized water. The controls also contain small amounts of fetal fibronectin from human source material.

Product Use: The Positive Control is an aqueous solution to be used as an aid in assessing the risk of preterm delivery in 7 or 14 days from the time of vaginal sample collection in pregnant women with signs and symptoms of early preterm labor, intact amniotic membranes and minimal cervical dilatation (< 3 cm), sampled between 24 weeks, 0 days and 34 weeks, 6 days gestation.

Manufacturer:
Cytyc Corporation
250 Campus Drive
Marlborough, Massachusetts 01752
USA
Telephone: 800-442-9892

EMERGENCY TELEPHONE NUMBERS:
(24 hours a day and 7 days a week)

For Health/Transportation/Chemical Spills
(Multilingual capabilities and free calls accepted)
Continental United States: (800) 424-9300
Outside of continental United States: +(703) 527-3887

2. COMPOSITION / INFORMATION ON INGREDIENTS

Chemical	CAS Registry #	Wt. %
Fetal Fibronectin Purified**	N/A	<1
Sodium Azide	26628-22-8	<1
Aprotinin	9087-70-1	<10

** **Potentially Biohazardous Material**

3. HAZARDS IDENTIFICATION

EMERGENCY OVERVIEW: **Reagents marked with ** are considered Potentially Biohazardous Material. The positive control contains material of human origin. The donors were tested and found to be negative for HIV 1, HIV 2, and HCV antibody and hepatitis B surface antigen using established methods.**

The PTDCheck Positive Control contains human fetal fibronectin in a stable protein matrix with sodium azide as a preservative. Sodium azide is an irritant. Avoid contact with components containing azide.

Routes of exposure and Potential Health Effects:

Inhalation: May cause respiratory tract irritation.

Eye Contact: May irritate eyes.

Skin Contact: May irritate the skin.

Ingestion: May be harmful if swallowed. May cause stomach distress, nausea, or vomiting.

Target Organs: Eyes, skin, respiratory system, gastrointestinal tract.

Signs and Symptoms:	Signs may include discomfort or pain, excess blinking and tear production, with marked redness and swelling of the conjunctiva. Symptoms may include redness, edema, drying, defatting and cracking of the skin.
Medical Conditions Aggravated by Exposure:	Asthma, allergies.
Chronic:	Repeated exposure may cause skin dryness or cracking.

4. FIRST AID MEASURES

Inhalation:	Move person to fresh air. If symptoms persist, obtain immediate medical attention.
Eye Contact:	Immediately flush with clean water for at least 15 minutes. If irritation persists, obtain medical aid.
Skin Contact:	Remove contaminated clothing and shoes. Flush affected area with copious amounts of water. If irritation or other symptoms are present, obtain immediate medical attention.
Ingestion:	**Do Not Induce Vomiting.** Rinse out mouth with copious amounts of water (only if the person is conscious). Call a Poison Control Center or medical provider immediately.
Notes to Physician:	Symptoms may be delayed.

5. FIRE FIGHTING MEASURES

Flammability:	Not flammable by OSHA / WHMIS criteria.
Explosion Data:	Sensitivity of Mechanical impact: No data available. Sensitivity to Static Discharge: No data available.
General Hazard:	The controls contain a very small percentage (0.5%) of sodium azide. Azide reacts with many heavy metals (e.g., copper, lead) to form explosive compounds. If the controls are being disposed of through plumbing, flush with a large volume of water. Flammable material. Heated material may form toxic and/or explosive vapors.
Fire Fighting Instructions:	Wear full turnout gear with self-contained breathing apparatus. If material is not involved in fire, attempt to cool with water or remove from area.
Fire Fighting Equipment:	Wear full turnout gear with self-contained breathing apparatus.
Extinguishing Media:	Foam, water, carbon dioxide ($C0_2$), dry chemical.
Hazardous Combustion Products:	Oxides of carbon. Oxides of nitrogen.
Special Information:	None

6. ACCIDENTAL RELEASE MEASURES

Personal Precautions:	Use personal protection recommended in Section 8. Isolate area. Keep unnecessary personnel away.

Environmental Precautions:	The controls contain sodium azide which may form potentially explosive metal azides with lead and copper plumbing. For disposal, reagent should be flushed with large volumes of water to prevent azide build up. Prevent runoff from entering waterways, sewers, and confined spaces.
Methods for Containment:	Prevent further leakage or spillage if safe to do so. Absorb spills with sand, kitty litter, or vermiculite.
Methods for Clean-Up:	Sweep up or gather material and place in appropriate container for disposal. Disinfect with standard laboratory disinfectant or autoclave. Avoid skin contact.
Other Information:	Not available.

7. HANDLING AND STORAGE

Handling:	Follow universal precautions for handling potentially biohazardous material. Refer to the Directional Insert accompanying the PTDCheck Enzyme Immunoassay Kit for further details concerning material of human origin. Wear recommended personal protective equipment. Avoid contact with skin and eyes. Do not eat or drink while using this product.
Storage:	Store all reagents at 2-8° C. Keep out of reach of children. Keep away from food, drink, and animal feeding stuffs.

8. EXPOSURE CONTROLS / PERSONAL PROTECTIVE EQUIPMENT

Engineering Controls:	Provide adequate general exhaust ventilation to minimize worker exposure.
Personal Protective Equipment:	**Eye/Face Protection:** Wear safety glasses with side shields. **Hand Protection:** Wear suitable gloves. **Skin and Body Protection:** Wear suitable protective clothing. **Respiratory Protection:** In case of insufficient ventilation, wear suitable respiratory equipment.
General Hygiene Considerations:	Handle in accordance with good industrial hygiene and safety practices.

9. PHYSICAL AND CHEMICAL PROPERTIES

Appearance: Clear
Odor: Odorless
Specific Gravity (Water=1): Not available
Solubility in Water: Complete
Freezing Point (°F/°C): Not available
Evaporation Rate: Not available
Viscosity: Not available
Lower Flammability Limit: Not available
Coefficient of Water/Oil Distribution: Not available

Color: Light yellow
Physical State: Liquid
VOC Content, wt.%: Not available
Vapor Density (Air=1): Not available
Vapor Pressure mm/Hg: Not available
pH: 7.5
Boiling Point (°F/°C): Not available
Upper Flammability Limit: Not available
Auto-ignition Temperature: Not available

10. STABILITY AND REACTIVITY

General Stability:	Stable.
Incompatible Materials And Conditions To Avoid:	Metals, acids, oxidizers, and heat.

Hazardous Decomposition Products:	Nature of combustion products is unknown. The controls contain chemicals in dilute amounts which, in concentrated form, are known to produce toxic fumes under fire conditions.
Hazardous Polymerization:	No dangerous reactions known under conditions of normal use.

11. TOXICOLOGICAL INFORMATION

Effects of Acute Exposure:

Eyes:	May irritation eyes. Symptoms may include discomfort or pain, excess blinking and tear production, with marked redness and swelling of the conjunctiva.
Skin:	May irritate skin. Symptoms may include redness, edema, drying, defatting and cracking of the skin.
Ingestion:	May be harmful if swallowed. May cause stomach distress, nausea or vomiting.
Inhalation:	May cause respiratory tract irritation.

Effects of Chronic Exposure:

Target Organs:	No data available.
Chronic Effects:	Not hazardous by OSHA / WHMIS criteria.
Carcinogenicity:	Not hazardous by OSHA / WHMIS criteria.
Mutagenicity:	Controls contain a very small percentage (0.05%) of sodium azide. Concentrated sodium azide has been reported as a mutagen.
Reproductive Effects:	Not hazardous by OSHA / WHMIS criteria
Developmental Effects:	**Teratogenicity:** Not hazardous by OSHA / WHMIS criteria. **Embryotoxicity:** Not hazardous by OSHA / WHMIS criteria.
Respiratory Sensitization:	Not hazardous by OSHA / WHMIS criteria.
Skin Sensitization:	Not hazardous by OSHA / WHMIS criteria.
Toxicologically Synergistic Materials:	No data available.

12. ECOLOGICAL INFORMATION

Ecotoxicity:	This product is not expected to producer significant ecotoxicity upon exposure to aquatic organisms and aquatic systems.
Persistence / Degradability:	No data available
Bioaccumulation / Accumulation:	No data available
Mobility in Environment:	No data available

13. DISPOSAL CONSIDERATION

Disposal Instructions: Comply with all applicable state, local and federal laws. Follow universal precautions for handling biohazardous waste if spill contains material of human origin.

14. TRANSPORTATION INFORMATION

Not hazardous by DOT and TDG criteria.

15. REGULATORY INFORMATION

USA:	The MSDS was prepared pursuant to the Hazardous Communication Standard (29 CFR 1910.1200).
Canada:	This product has been classified in accordance with the hazard criteria of the Controlled Product Regulations.
WHMIS:	Not controlled.
State Issues:	Not listed for California Proposition 65
NFPA (National Fire Protection Association):	Health – 0 Fire – 0 Reactivity – 0 Hazard Ratings: 0 = minimal, 1 = slight, 2 = moderate, 3 = severe, 4 = extreme
Foreign Chemical Inventories:	All ingredients are listed on the chemical inventories of the following countries: Canada (DSL) Japan European Union Australia

16. OTHER INFORMATION

Current Issue Date:	March, 2009
Previous Issue Date:	Initial Cytyc
Other Information:	None

Information Note: Where no corresponding data was contained in manufacturer's MSDS, additional research is required and available upon request. THE INFORMATION RELATES TO THIS SPECIFIC MATERIAL. IT MAY NOT BE VALID FOR THIS MATERIAL IF USED IN COMBINATION WITH ANY OTHER MATERIALS OR IN ANY PROCESS. IT IS THE USER'S RESPONSIBILITY TO SATISFY ONESELF AS TO THE SUITABILITY AND COMPLETENESS OF THIS INFORMATION FOR HIS OR HER OWN PARTICULAR USE.