MATERIAL SAFETY DATA SHEET

1. IDENTIFICATION OF PRODUCT AND SUPPLIER

Product name: Rubella IgG EIA test kit (CATALOG No. T8003)
Supplier: POINTE SCIENTIFIC INC.
5449 Research Drive
Canton, Michigan 48188
Ph: 1-734-487-8300
Fax: 1-734-483-1592
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2. CHEMICAL CHARACTERIZATION / INFORMATION ON INGREDIENTS

1. COATED WELLS, COATED WITH SONICATED RUBELLA ANTIGEN (STRAIN HPV-77, PRODUCED IN VERO CELLS, AND PURIFIED BY PROPRIETARY CENTRIFUGATION STEPS). 12 EIGHT-WELL STRIPS.
2. DILUENT*, 25 ML (PINK COLOR). DILUENT FOR SPECIMENS.
3. PHOSPHATE-BUFFERED SALINE WITH A PROTEIN STABILIZER.
4. RUBELLA IGG CALIBRATOR 1*, 0.3 ML. HUMAN SERUM. STRONGLY REACTIVE FOR RUBELLA IGG ANTIBODIES. INDEX OR IU/ML VALUES SHOWN ON VIAL LABEL.
5. RUBELLA IGG CALIBRATOR 2*, 0.3 ML. HUMAN SERUM. MODERATELY REACTIVE FOR RUBELLA IGG ANTIBODIES. INDEX OR IU/ML VALUES SHOWN ON VIAL LABEL.
6. RUBELLA IGG HIGH POSITIVE CONTROL, 0.3 ML. HUMAN SERUM. REACTIVE FOR RUBELLA ANTIBODIES.
7. RUBELLA IGG LOW POSITIVE CONTROL, 0.3 ML. HUMAN SERUM. WEAKLY REACTIVE FOR RUBELLA ANTIBODIES.
8. RUBELLA IGG NEGATIVE CONTROL, 0.3 ML. HUMAN SERUM. NON-REACTIVE FOR RUBELLA ANTIBODIES.
9. RUBELLA IGG CONJUGATE, 12 ML (GREEN COLOR). GOAT ANTI-HUMAN IGG LABELED WITH ALKALINE PHOSPHATASE (CALF).
10. SUBSTRATE, 12 ML. P-NITROPHENYL PHOSPHATE.
11. WASH CONCENTRATE*, 30 ML. TRIS-BUFFERED SALINE WITH TWEEN 20, PH 8.0.
12. STOP REAGENT, 12 ML. TRISODIUM PHOSPHATE 0.5 M.

* CONTAINS 0.1% SODIUM AZIDE.

3. HAZARDS IDENTIFICATION

THIS TEST KIT SHOULD BE HANDLED ONLY BY QUALIFIED PERSONNEL, TRAINED IN LABORATORY PROCEDURES AND FAMILIAR WITH THEIR POTENTIAL HAZARDS. SPECIFIC WARNINGS ARE GIVEN IN THE INSTRUCTIONS FOR USE. THE ABSENCE OF A SPECIFIC WARNING SHOULD NOT BE INTERPRETED AS AN INDICATION OF SAFETY.

SOME OF THE COMPONENTS IN THIS TEST KIT WERE DERIVED FROM MATERIALS OF HUMAN ORIGIN. THE ABSENCE OF HEPATITIS B SURFACE ANTIGEN, HIV 1 AND 2 ANTIBODIES, AND HEPATITIS C ANTIBODIES, HAS BEEN CERTIFIED BY THE SUPPLIER OF THESE MATERIALS. SINCE NO TEST CAN OFFER COMPLETE ASSURANCE THAT HEPATITIS B VIRUS, HIV VIRUS OR OTHER INFECTIOUS AGENTS ARE ABSENT, THIS KIT SHOULD BE HANDLED AT BIOSAFETY LEVEL 2, AS RECOMMENDED FOR ANY POTENTIALLY INFECTIOUS SERUM OR BLOOD SPECIMEN IN THE CENTER FOR DISEASE CONTROL / NATIONAL INSTITUTE OF HEALTH MANUAL: BIOSAFETY IN MICROBIOLOGICAL AND BIOMEDICAL LABORATORIES, 1993 OR LATEST EDITION.

THE MICROWELLS IN THIS TEST KIT HAVE BEEN COATED WITH RUBELLA ANTIGEN WHICH HAS BEEN CERTIFIED BY THE SUPPLIER TO BE INACTIVATED. THE MICROWELLS SHOULD HOWEVER, BE HANDLED AS THOUGH CAPABLE OF TRANSMITTING INFECTION.

4. FIRST AID MEASURES

SKIN / EYES: THE STOP SOLUTION IN THIS TEST KIT IS CAUSTIC. IF IT COMES IN CONTACT WITH THE SKIN OR EYES, FLUSH THE EXPOSED AREA WITH WATER FOR THREE TO FIVE MINUTES.

5. FIRE-FIGHTING MEASURES

WITH THE EXCEPTION OF THE PLASTIC CONTAINERS AND MICROWELLS, THE MATERIALS IN THIS TEST KIT ARE NOT CAPABLE OF SUPPORTING COMBUSTION.

EXTINGUISHING MEDIA: AS APPROPRIATE FOR FIRE IN SURROUNDING MATERIALS.

WEAR SELF-CONTAINED BREATHING APPARATUS AND PROTECTIVE CLOTHING TO PREVENT EXPOSURE OF SKIN AND EYES.

6. ACCIDENTAL RELEASE MEASURES

CLEAN EXPOSED SURFACES WITH A SOLUTION OF 0.5% SODIUM HYPOCHLORITE (10% BLEACH).

7. HANDLING AND STORAGE

THE FDA RECOMMENDS AT LEAST A BIOSAFETY LEVEL 2 FOR HANDLING THE MATERIALS IN THIS TEST KIT. THE TEST KITS SHOULD BE STORED AT 2 TO 8°C.
## 8. EXPOSURE CONTROLS / PERSONNEL PROTECTION

CERTAIN COMPONENTS OF THIS TEST KIT ARE POTENTIALLY BIOHAZARDOUS MATERIALS. WEAR SUITABLE PROTECTIVE CLOTHING AND GLASSES WHEN WORKING WITH THE TEST KIT AND TEST SPECIMENS.

## 9. PHYSICAL AND CHEMICAL PROPERTIES

THE MATERIALS COMPRISING THIS TEST KIT ARE NOT CLASSIFIED AS HAZARDOUS CHEMICALS.

## 10. STABILITY AND REACTIVITY

THE MATERIALS COMPRISING THIS TEST KIT ARE STABLE INERT COMPOUNDS.

## 11. TOXICOLOGICAL INFORMATION

CERTAIN OF THE TEST REAGENTS CONTAINED IN THIS TEST KIT CONTAIN SODIUM AZIDE AT A CONCENTRATION OF 1 MG/ML OR LOWER. SODIUM AZIDE IS TOXIC AND CARE SHOULD BE TAKEN TO AVOID INGESTION.

## 12. ECOLOGICAL INFORMATION

WHEN THE MATERIALS IN THIS TEST KIT ARE PROPERLY DISPOSED OF (PLEASE SEE SECTION 13), THEY POSE NO ECOLOGICAL THREAT.

## 13. DISPOSAL CONSIDERATIONS

DISPOSAL SHOULD BE DONE IN ACCORDANCE WITH EXISTING DISPOSAL PRACTICES EMPLOYED FOR INFECTIOUS WASTE AT YOUR INSTITUTION. OBSERVE ALL FEDERAL, STATE AND LOCAL ENVIRONMENTAL REGULATIONS.

CERTAIN OF THE TEST REAGENTS IN THIS TEST KIT CONTAIN SODIUM AZIDE AT A CONCENTRATION OF 1 MG OR LOWER. AZIDES ARE REPORTED TO REACT WITH LEAD AND COPPER IN PLUMBING TO FORM COMPOUNDS THAT MAY DETONATE ON PERCUSSION. WHEN DISPOSING OF SOLUTIONS CONTAINING SODIUM AZIDE, FLUSH DRAINS WITH LARGE QUANTITIES OF WATER TO MINIMIZE THE BUILD-UP OF METAL AZIDE COMPOUNDS.

## 14. TRANSPORT INFORMATION

THE STOP SOLUTION IS THE ONLY COMPONENT IN THIS TEST KIT THAT IS POTENTIALLY CORROSIVE. THE STOP SOLUTION HAS BEEN EVALUATED WITH THE CORROSITEX® TEST METHOD TO DETERMINE ITS CORROSIVE POTENTIAL AND TO DESIGNATE ITS PACKING GROUP CLASSIFICATION. IT HAS BEEN CLASSIFIED NONCORROSIVE.

## 15. REGULATORY INFORMATION

RELEASED FOR SALE IN INTERSTATE COMMERCE BY FOOD AND DRUG ADMINISTRATION 510(K) PREMARKET NOTIFICATION EUROPEAN INFORMATION PENDING.

## 16. OTHER INFORMATION

THE ABOVE INFORMATION IS BELIEVED TO BE CORRECT BUT IS NOT ALL INCLUSIVE AND IS INTENDED ONLY AS A GUIDE.