

Poly stat<sup>®</sup> H. pylori Test

Section 1 Identification	
Product name	Poly stat <sup>®</sup> H. pylori Test
Catalog number	HP20
Recommended use	<i>In vitro</i> diagnostic test for antibodies to <i>Helicobacter pylori</i> in human whole blood, serum, or plasma specimens.
Manufactured for	Polymedco, Inc. 510 Furnace Dock Road Cortlandt Manor, NY 10567 <a href="http://www.polymedco.com">www.polymedco.com</a>
Emergency number	(800) 431-2123 or (914) 739-5400

Section 2 Hazards Identification	
Hazard classification	Does not present any particular physical, health, or environmental hazard at the concentrations present
Signal word	Not applicable
Pictogram	Not applicable
Hazard statements	Not applicable
Precautionary statements	Not applicable
Any hazards not otherwise classified	This product is derived from human source material that has been tested for HBsAg and antibodies to HIV. No test can offer complete assurance that infectious agents are absent, so handle this product as potentially biohazardous material.

Section 3 Composition and Information on Ingredients	
Chemical characterization	Ingredients are not hazardous at the concentrations present
Chemical name	Test Device, Developer Solution, Positive Control, Negative Control
Synonyms	Not applicable
CAS number	Not applicable
Concentration	Not applicable

Section 4 First Aid Measures	
IF IN EYES:	Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing. If eye irritation persists: Get medical advice / attention.
IF ON SKIN:	Wash with plenty of soap and water. If skin irritation occurs: Get medical advice / attention.
IF SWALLOWED:	Rinse mouth. Do NOT induce vomiting. Call a POISON CENTER or doctor / physician if you feel unwell.
IF INHALED:	If breathing is difficult, remove victim to fresh air and keep at rest in a position comfortable for breathing. If experiencing respiratory symptoms: Call a POISON CENTER or doctor / physician.

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<b>Section 5 Fire-Fighting Measures</b>	
Flash point	Not applicable
Flammable limits	Not applicable
Auto-ignition temperature	Not applicable
Extinguishing media	Use extinguishing media suitable for surrounding fire.
Special fire and explosion hazards	Fire may cause material to produce noxious fumes or gases.
Hazardous combustion products	No special hazards determined
Protective equipment for firefighters	Self-contained breathing apparatus is recommended for firefighters.

<b>Section 6 Accident Release Measures</b>	
Personal precautions	Wear protective clothing, gloves, and eye protection.
Emergency procedures	No special emergency procedures necessary.
Containment procedures	Contain spill to prevent migration.
Cleanup procedures	Use suitable absorbent material to soak up spill. Decontaminate spill area with bleach or other suitable disinfectant.

<b>Section 7 Handling and Storage</b>	
Handling and storage	Avoid inhaling, swallowing, and contact with eyes and skin.
Recommended storage conditions	Room temperature
Incompatibilities	Not determined

<b>Section 8 Exposure Controls and Personal Protection</b>	
Exposure limits:	
OSHA	Not determined
ACGIH	Not determined
Engineering controls	Normal room ventilation
Respiratory protection	Normal room ventilation
Eye protection	Safety glasses should be worn to prevent eye contact.
Skin protection	Appropriate gloves and clothing should be worn to prevent skin contact.

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<b>Section 9 Physical and Chemical Properties</b>				
	<b>Device</b>	<b>Developer solution</b>	<b>Positive Control</b>	<b>Negative Control</b>
Appearance	White strip in plastic housing	Clear colorless liquid	Clear colorless liquid	Clear colorless liquid
Odor	Odorless	Odorless	Odorless	Odorless
Odor threshold	Not determined	Not determined	Not determined	Not determined
pH	Not applicable	7.2	Not applicable	Not applicable
Melting point / Freezing point	Not applicable	Approx. 0°C	Approx. 0°C	Approx. 0°C
Initial boiling point and boiling range	Not applicable	Approx. 100°C	Approx. 100°C	Approx. 100°C
Flash point	Not determined	Not applicable	Not applicable	Not applicable
Evaporation rate	Not applicable	Not determined	Not determined	Not determined
Flammability (solid, gas)	Not determined	Not applicable	Not applicable	Not applicable
Upper/lower flammability or explosive limits	Not determined	Not applicable	Not applicable	Not applicable
Vapor pressure	Not applicable	Not determined	Not determined	Not determined
Vapor density	Not applicable	Not determined	Not determined	Not determined
Relative density	Not applicable	Not determined	Not determined	Not determined
Solubility	Not applicable	Soluble in water	Soluble in water	Soluble in water
Partition coefficient	Not determined	Not determined	Not determined	Not determined
Auto-ignition temperature	Not applicable	Not determined	Not determined	Not determined
Decomposition temperature	Not determined	Not determined	Not determined	Not determined
Viscosity	Not applicable	Not determined	Not determined	Not determined

<b>Section 10 Stability and Reactivity</b>	
Stability	Stable under normal ambient temperature and pressure.
Stabilizers needed	Not applicable
Safety issues with change in physical appearance	None identified
Hazardous reactions	None identified
Hazardous polymerization	Will not polymerize
Incompatibilities	None identified
Hazard decomposition products	Decomposition as a result of high heat/fire may result in noxious fumes, CO, and CO <sub>2</sub>
Conditions to avoid	None identified

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<b>Section 11 Toxicological Information</b>	
Information on likely routes and effects of exposure (short term / long term effects):	
Inhalation	May cause irritation of the respiratory tract.
Ingestion	May cause irritation of the mouth, throat, and gastrointestinal system.
Skin contact	May cause irritation of the skin.
Eye contact	May cause irritation of the eyes.
Toxicity (LD50/LC50)	Not available
Sensitization	Not available
Carcinogenicity	Not available
Reproductive Toxicity	Not available
Teratogenicity	Not available
Mutagenicity	Not available

<b>Section 12 Ecological Information</b>	
Ecotoxicity	Not determined
Persistence / degradability	Not determined
Bioaccumulation potential	Not determined
Mobility in soil (Adsorption / leaching)	Not determined
Environmental fate	Not determined
Ozone layer depletion potential	Not determined
Photochemical ozone creation potential	Not determined
Endocrine disrupting potential	Not determined
Global warming potential	Not determined

<b>Section 13 Disposal Considerations</b>	
Disposal containers	Controls: Leak-proof container marked with biohazard symbol.
Disposal methods	Dispose of human source materials in biohazardous or medical waste. Dispose in compliance with federal, state and local regulations. If unsure of the applicable requirements, contact the authorities for information.
Properties that may affect disposal	Potentially biohazardous material; dispose in biohazardous or medical waste
Sewage disposal	Do not dispose of product into drains or sewers
Precautions for landfills or incineration	Dispose in biohazardous or medical waste

<b>Section 14 Transport Information</b>	
UN Number	Not regulated
UN proper shipping name	Not regulated
Transport hazard class	Not regulated
Packing group	Not regulated
Environmental hazards	None identified
Guidance on transport in bulk	No special requirements
Special precautions on transport	None identified

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<b>Section 15 Regulatory Information</b>	
OSHA	This product does not meet the definition of a hazardous material under 29 CFR 1910.2000
TSCA	Not listed
SARA	
302	Not applicable
311/312	No hazards
313	Below threshold reporting levels
CA Prop 65	Not listed
Canada DSL/NDSL	Not listed
WHMIS Class	Not controlled
The above information is not intended to be a comprehensive listing of regulations pertinent to the product, and the regulations listed are subject to change. The user is responsible for observing all applicable local, state, and national/federal regulations in handling of the product.	

<b>Section 16 Other Information</b>			
NFPA Ratings:		HMIS Ratings:	
Health	0	Health	0
Flammability	0	Flammability	0
Reactivity	0	Reactivity	0
Physical Hazards	Potential biohazard	Protective Equipment	B
Date of preparation	12 September 2014		
Last revision date	25 February 2015		
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