1.0 COMPANY IDENTIFICATION

MANUFACTURER

Scimedx Corporation

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Monday – Friday, 8:00 AM – 5:00 PM EST

Product Name E. histolytica ELISA Kit

Product Code EH-96, EH-48

Generic Name NA

Product Type Enzyme-linked Immunosorbent Diagnostic Test Kit

Description For the qualitative screening of serum IgG antibodies to *E. histolytica* using an enzyme linked immunoabsorbant assay (ELISA) technique.

2.0 HAZARD IDENTIFICATION

Emergency Overview: Appearance: Seven different liquids. **Warning!** Stop Solution is a corrosive liquid. All liquids may be irritating to eyes, skin, digestive tract or respiratory tract. For *in vitro* use only.

HMIS HEALTH	1
HMIS FLAMMABILITY	0
HMIS REACTIVITY	0
PERSONAL PROTECTION	C

Regulatory Status: Only the Stop Solution is considered hazardous under the OSHA standard or WHMIS.

Potential Health Effects:

Inhalation: Inhalation of liquid or mist may be irritating to the respiratory tract.

Ingestion: May cause irritation of the digestive tract. Stop Solution may cause burns to the digestive tract

Skin Contact: May cause skin irritation. Stop Solution may cause burns.

Eye Contact: May cause eye irritation. Stop Solution may cause burns.

Chronic Exposure: Repeated or prolonged exposure may cause allergic reactions in sensitive individuals

Aggravation of Pre-existing Conditions: No information available

Target Organs: No information available

3.0 COMPOSITION/INFORMATION ON INGREDIENTS

Kit Component	Contains	CAS #	EINECS #	Weight %
Enzyme Conjugate	Thimerosal	54-64-8	200-210-4	0.5%
Positive Control	Thimerosal	54-64-8	200-210-4	0.2%
Negative Control	Thimerosal	54-64-8	200-210-4	0.2%
Chromogen	Tetramethylbenzidine	54827-17-7	259-364-6	<1%
Dilution Buffer	Thimerosal	54-64-8	200-210-4	0.2%
Wash Concentrate	Thimerosal	54-64-8	200-210-4	0.4%
Stop Solution	Phosphoric Acid	7664-38-2	231-633-2	5%

Non-hazardous components may or may not be listed. Carcinogens are listed when present at 0.1% or more; components which are otherwise hazardous according to OSHA are listed when present at 1.0% or more. This is not intended to be complete compositional disclosure. See section 15 for applicable states right to know and other regulatory information.

4.0 FIRST AID MEASURES

Eyes

Flush with copious amounts of water for at least 15 minutes. Assure adequate flushing by separating eyelids with fingers. Call a physician.

Skin

In case of contact, immediately flush skin with copious amounts of water for at least 15 minutes while removing contaminated clothing and shoes. Discard contaminated clothing and shoes.

Ingestion

Avoid ingestion of hazardous chemicals However, recognize that you can **accidentally** ingest toxic materials by eating/handling food in areas where toxic substances are used. Having a chemical on your hands and then eating or smoking are common ways that chemicals are accidentally ingested.

Be sure that all containers are properly labeled. **NEVER STORE CHEMICALS OF ANY SORT IN FOOD CONTAINERS**. Do not store food and chemicals in the same refrigerator.

Always have your poison control center phone number handy with your other emergency information. Always clean up chemical spills.

Drink several glasses of water or milk. Never give anything by mouth to an unconscious person. Get medical attention.

Inhalation

Remove to fresh air. If not breathing, give artificial respiration. If breathing is difficult, give oxygen. Get medical attention.

Note to Physicians

NA

5.0 FIRE-FIGHTING MEASURES

The following general measures apply to all components of the kit.

Fire	Flash point: Not flammable
Explosion	Not considered an explosion hazard
Extinguishing media:	Use appropriate media for the surrounding fire.
Specific methods of fire fighting	In the event of a fire, wear full protective clothing and NIOSH approved self-contained breathing apparatus with full face piece operated in the pressure demand or other positive pressure mode
NFPA Rating	Health – 1 Flammability – 0 Reactivity – 0 Other - NA

6.0 ACCIDENTAL RELEASE MEASURES

Ventilation	No special ventilation is necessary, however, a biosafety cabinet, as recommended in the CDC/NIH manual, may be necessary.
Personal precautions	Ventilate area of leak or spill. Wear appropriate personal protective equipment as specified in Section 8. Isolate hazard area. Keep unnecessary and unprotected personnel from entering.
Methods of cleaning up	Collect liquid or solid in an appropriate container or absorb with an inert material (e.g., vermiculite, dry sand, earth), and place in a chemical waste container. Wash contaminated area with plenty of water.

8.0 HANDLING AND STORAGE

Handling	Avoid contact with skin, eyes or clothing. Use adequate ventilation or minimize exposures to mists or aerosols. Wash thoroughly after handling. DO NOT permit contact with acids and other incompatible substances. Do not eat, drink, smoke or apply cosmetics in laboratory areas. Do not pipette reagents or samples by mouth. Use reagents according to the product insert. Avoid extreme temperatures during transport.
Storage	Keep all containers tightly closed. Store all components as directed in the package insert. Protect material from long-term exposures to light. Short periods of exposure to light are acceptable.

8.0 EXPOSURE CONTROLS, PERSONNEL PROTECTION

Compound	CAS#	OSHA PEL	ACGIH TLV	NIOSH TLV
Thimerosal	54-64-8	None Established	0.1mg/m^3 (TWA) (as Hg)	0.05 mg/m^3 (TWA) (vapor except organoalkyls, as Hg)
Tetramethylbenzidine	54827-17-7	None Established	None Established	None Established
Phosphoric acid	7664-38-2	1mg/m^3 (TWA)	1mg/m^3 (TWA) 3 mg/m^3 (STEL)	1mg/m^3 (TWA) 3 mg/m^3 (STEL)

Wear appropriate personal protective equipment when working with components or samples, including laboratory coats, disposable gloves and eye protection. Remove personal protective equipment when leaving work area.Avoid hand and mouth contact. Wash hands as soon as possible after handling components or samples.

Occupational Exposure Limits: There are no established exposure limits for this product.

Personal Protective Equipment

Eye and Face Protection: Wear safety glasses with side shield, or full-face shield where misting or splashing of solutions is possible. The choice of protection should be based on the job activity and potential for exposure to eyes and face. Maintain eye wash fountain and quick-drench facilities in work area.

Respiratory Protection Use NIOSH-approved vapor respirator if exposure is unknown or exceeds permissible limits. A respirator protection program that meets OSHA's 29 CFR 1910.134 or ANSI Z88.2 requirements must be followed whenever workplace conditions warrant respirator use. WARNING: Air-purifying respirators do not protect workers in oxygen deficient atmospheres.

Skin and Body Protection: Wear gloves, lab coat, or other impervious protective over-garment if skin contact is likely. Latex and nitrile are suitable glover material

Engineering Controls A system of local and/or general exhaust is recommended to keep employee exposures below the Airborne Exposure Limits. Local exhaust ventilation is generally preferred because it can control the emissions of the contaminant at its source, preventing dispersion of it into the general work area. Please refer to the ACGIH document, Industrial Ventilation, A Manual of Recommended Practices, most recent edition, for details.

Hygiene Measures Wash hands immediately after handling materials (especially before eating, drinking or smoking). Decontaminate or discard protective equipment after each use.

9.0 PHYSICAL & CHEMICAL PROPERTIES

	Enzyme Conjugate	Positive Control	Negative Control	
Appearance	Clear red liquid	Clear liquid	Clear colorless liquid	
Melting Point	0ºC	≈ 0ºC	≈ 0ºC	
Boiling Point	≥ 100ºC	≥ 100ºC	≥ 100ºC	
pH	About 6.6	About 6.7	About 6.7	
	Chromogen	**Dilution Buffer**	**Wash Concentrate**	**Stop Solution**
Appearance	Clear colorless liquid	Clear colorless liquid	Clear colorless liquid	Cl r colorless liquid
Melting Point	≈ 0ºC	≈ 0ºC	≈ 0ºC	≈ 0ºC
Boiling Point	≥ 100ºC	≥ 100ºC	≥ 100ºC	≥ 100ºC
pH	7.2	About 6.7	About 6.5	About 1.2

10.0 STABILITY AND REACTIVITY

The kit should only be used as instructed in the package insert. See package insert for further information of kit stability.

Chemical Stability	This product is stable in closed containers at room temperature
Hazardous Decomposition Products	Carbon oxides (CO, CO_2), nitrogen oxides (NO, NO_2, N_2O), sulfur oxides (SO_2, SO_3), phosphorus oxides (P_2O_5), hydrogen chloride
Incompatibilities	Strong oxidizers, heat, strong acids or bases
Conditions to avoid	Incompatible materials, combustible materials.

11.0 TOXICOLOGICAL INFORMATION

Acute Dose Effects	Acute Dose Effects: Eye: Phosphoric acid: Draize Rabbit: 119 mg Severe Skin: Phosphoric acid: Rat LD50: 2740 mg/kg Ingestion: Phosphoric acid: Rat LD50: 1530 mg/kg Inhalation: Rat LC50: >850 mg/m3/1H
Carcinogenicity:	NOT LISTED BY OSHA, NTP OR IARC.

12.0 ECOLOGICAL INFORMATION

Environmental Fate	This product is not expected to bioaccumulate. When released into water or air its expected halflife is 1 – 10 days.
Ecotoxicity	Dilute nature and small volumes of products makes any ecological effect highly unlikely.

13.0 DISPOSAL CONSIDERATIONS

As a waste, this material in its raw form IS NOT considered a HAZARDOUS WASTE under RCRA (29 CFR 261).

Whatever cannot be saved for recovery or recycling should be managed in an appropriate and approved waste disposal facility. Processing, use or contamination of this product may change the waste management options. State and local disposal regulations may differ from federal disposal regulations. Dispose of container and unused contents in accordance with federal, state and local requirements.

14.0 TRANSPORT INFORMATION

All the solutions are unregulated by DOT and IATA except for the Stop Solution.
The quantity of Stop Solution qualifies for excepted quantity rules and dangerous goods declarations are not necessary.
With proper packaging and labeling this kit can be transported by passenger and cargo aircraft.
This kit cannot be sent through the mail.

15.0 REGULATORY INFORMATION

TSCA Chemical Inventory: All of the chemicals in this product are listed on the TSCA Inventory.
TSCA Sec 4 Chemical Test Rule: None of the chemicals in this product are under a Chemical Test Rule.
TSCA Sec 8(d): None of the chemicals in this product are on the Health and Safety Reporting List.
TSCA Sec 12(b) Notices of Export: None of the chemicals in this product are on this list.

TSCA Significant New Use Rule (SNUR): None of the chemicals in this product are on this list.
SARA Sec 302 (EHS) TPQ: None of the chemicals in this product have a TPQ.
SARA Sec 302 (EHS) RQ: None of the chemicals in this product have a RQ.
SARA Sec 311/312: Acute – Phosphoric Acid; Chronic – NO; Fire – NO; Release of Pressure – NO; Reactivity – NO
SARA 313 List: No materials in this product are reportable under Section 313 Title III and 40 CFR Part 372.
CERCLA Hazardous Substances and corresponding RQs: Phosphoric Acid, 5000 lbs.
RCRA: None of the chemicals in this product are on this list.
Clean Air Act: **Hazardous Air Pollutants?** NO **Class 1 Ozone Depletors?** NO **Class 2 Ozone Depletors?** NO
Clean Water Act: **Hazardous Substance?** Phosphoric acid **Priority Pollutant?** NO **Toxic Pollutant?** NO
Chemical Weapons Convention: None of the chemicals in this product are on this list.
Drug Enforcement Agency (DEA) CDTA: None of the chemicals in this product are on this list.
OSHA: None of the chemicals in this product are considered Highly Hazardous by OSHA.
State Right-to-Know Lists: Phosphoric acid is found on the Right-to-Know lists of California, Florida, New Jersey, Pennsylvania, Massachusetts or Minnesota.
California Proposition 65: This product contains Thimerosal, a chemical known to the state to cause cancer or reproductive toxicity. A person in the course of doing business must warn others who may consume, come into contact with, or otherwise be exposed to this chemical.

Canadian DSL/NDSL Status: As an *in vitro* diagnostic product, this product is regulated by Health Canada (Medical Devices Regulations, SOR/98-282).
European Union
Hazard Symbols: C
Risk Phrases: R36/38- Irritating to eyes and skin.
R25- Toxic if swallowed.
R34- Causes burns.
Safety Phrases: S1/2- Keep locked up and out of the reach of children.
S26- In case of contact with eyes, rinse immediately with plenty of water and seek medical advice.
S28- After contact with skin, wash immediately with plenty of water.
S36/37- Wear suitable protective clothing and gloves.
S39- Wear eye/face protection.

S45- In case of accident or if you feel unwell, seek medical advice immediately (show the label where possible).

17.0 OTHER INFORMATION

Recommended use:	This product is an *in vitro diagnostic* testing kit and should only be used according to its package insert instructions.

Abbreviations and acronyms used:

ACGIH	American Conference of Governmental Industrial Hygienists	NA	not applicable, not available
ANSI	American National Standards Institute	NIOSH	National Institute for Occupational Safety and Health
atm	Atmosphere (pressure unit)	ND	not determined
BOD	biological oxygen demand	NFPA	National Fire Prevention Association
CAS	Chemical Abstracts Service	NTP	National Toxicology Program
CC	closed cup	OC	open cup
CDTA	Chemical Drug and Trafficking Act	OSHA	Occupational Safety and Health Administration
COC	Cleveland Open Cup	Part	partition
COD	chemical oxygen demand	PEL	permissible exposure limits
coeff.	coefficient	ppb	parts per billion
CFR	Code of Federal Regulations	PPE	personal protection equipment
CPR	cardio-pulmonary resuscitation	ppm	parts per million
DEA	Drug Enforcement Agency	psi	pounds per square inch
DOT	Department of Transportation	RCRA	Resource Conservation and Recovery Act
FDA	Food and Drug Administration	RQ	Reportable quantity
IARC	Internat'l Agency for Research on Cancer	RTK	Right to Know
IDLH	immediate danger to life and health	SARA	Superfund Amendments and Reauthorization Act
kg	kilogram	STEL	short-term exposure limit
L	liter	TCC	Tagliabue Closed Cup
LC50	median lethal concentration	TPQ	threshold planning quantity
LD50	median lethal dose	TQ	threshold quantity
LEL	lower explosive limit	TSCA	Toxic Substances Control Act
mg	milligram	TWA	time-weighted average
mL	milliliter	WHMIS	Workplace Hazardous Materials Information System

Other: The information contained in this Material Safety Data Sheet is believed to be accurate but it is the responsibility of the user to determine the applicability of the data to the formulation of necessary safety precautions. Scimedx Corporation shall not be held responsible for any damage resulting from the use of the above product or the information contained in this Material Safety Data Sheet. Since conditions and manner of use are outside our control, Scimedx can assume no liability in connection with any use of this information.