

Material Safety Data Sheet

EDI™ Novel Coronavirus COVID-19 IgG ELISA Kit

1. Company and Product Identification

Trade Name (As Labeled):	EDI™ Novel Coronavirus COVID-19 IgG ELISA Kit
Catalog Number:	KT-1032, KTR-1032
Product Description:	This kit is intended for the qualitative detection of human anti-COVID-19 IgG antibody in human serum.
Manufacturer's Name:	Epitope Diagnostics, Inc
Address:	7110 Carroll Road, San Diego, CA, 92121, USA
Telephone:	+ 1 (858) 693-7877
Emergency Telephone Number:	+ 1 (703) 527-3887 (CHEMTREC)
Date of Preparation:	March 6, 2020
Date of Last Revision:	April 21, 2020

2. Hazard Identification

Emergency Overview:

This kit is used as an aid for the detection of novel COVID-19 related pneumonia cases. Patients with suspected clustering cases require diagnosis or differential diagnosis of novel coronavirus infection.

Health Hazards:	Possible skin and eye irritant.
Flammability Hazards:	Non-Flammable solution.
Reactivity Hazards:	None known.
Environmental Hazards:	Not expected to have significant environmental effects.
Emergency Considerations:	Emergency responders must wear the proper personal protective equipments (and have appropriate fire-suppression equipment) suitable for the situation to which they are responding.

Hazard Communication

Hazard Determining Components of Labeling: ELISA Wash Concentrate (ProClin™)

GHS Pictogram:



Signal Words: Warning



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Hazard Statement:	H317: May cause an allergic skin reaction.
Precautionary Statement Prevention:	P261: Avoid breathing dust/fume/gas/mist/vapours/spray. P272: Contaminated work clothing should not be allowed out of the workplace. P280: Wear protective gloves/protective clothing/eye protection/face protection.
Precautionary Statement Response:	P302 + P352: IF ON SKIN: Wash with plenty of soap and water. P321: Specific treatment (See label). P333 + P313: If skin irritation or rash occurs: Get medical advice/attention. P363: Wash contaminated clothing before reuse.
Precautionary Statement Storage:	N/A.
Precautionary Statement Disposal:	P501: Dispose of contents/container.

Health Hazards or Risk from Exposure:

Prolonged contact with the components in this kit may irritate the skin. Contact with eyes may cause irritation or redness. This product is designed to be used in a laboratory environment.

Acute:	Individuals using this product should be wearing the proper personal protective equipment to prevent skin and eye contact.
Chronic:	None known.

3. Composition and Information on Ingredients

3.1 Substances

This substance is a mixture.

3.2 Mixture

Hazard Classification: ELISA Stop Solution	CAS #	EINECS #	Amount	EC 1272/2008 Annex VI, Part 3	Specific Concentration Limits
Sulfuric Acid	7664-93-9	231-639-5	< 4%	Skin Corr. 1A; H314	Skin Corr. 1A; H314: C ≥ 15 % Skin Irrit. 2; H315: 5 % ≤ C < 15 % Eye Irrit. 2; H319: 5 % ≤ C < 15 %
Hazard Classification: ELISA Wash Concentrate	CAS #	EINECS #	Amount	EC 1272/2008 Annex VI, Part 3	Specific Concentration Limits
ProClin™ 300*	55965-84-9	613-167-00-5	< 0.06%	Acute Tox. 3, H331 Acute Tox. 3, H311 Acute Tox. 3, H301 Skin Corr.1B, H314 Skin Sens. 1;H317 Aquatic Acute. 1; H400 Aquatic Chronic. A; H410	Skin Corr. 1B; H314: C ≥ 0.6 % Skin Irrit. 2; H315: 0.06 % ≤ C < 0.6 % Eye Irrit. 2; H319: 0.06 % ≤ C < 0.6 % Skin Sens. 1; H317: C ≥ 0.0015 %
Hazard Classification: COVID-19 Controls	CAS #	EINECS #	Amount	EC 1272/2008 Annex VI, Part 3	Specific Concentration Limits
ProClin™ 300*	55965-84-9	613-167-00-5	< 0.0015%	Acute Tox. 3, H331 Acute Tox. 3, H311	Skin Corr. 1B; H314: C ≥ 0.6 %



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Hazard Classification:	CAS #	EINECS #	Amount	EC 1272/2008 Annex VI, Part 3	Specific Concentration Limits
COVID-19 Antigen Coated Microplate				Acute Tox. 3, H301 Skin Corr.1B, H314 Skin Sens. 1;H317 Aquatic Acute. 1; H400 Aquatic Chronic. A; H410	Skin Irrit. 2; H315: 0.06 % ≤ C < 0.6 % Eye Irrit. 2; H319: 0.06 % ≤ C < 0.6 % Skin Sens. 1; H317: C ≥ 0.0015 %
ProClin™ 300*	55965-84-9	613-167-00-5	< 0.0015%	Acute Tox. 3, H331 Acute Tox. 3, H311 Acute Tox. 3, H301 Skin Corr.1B, H314 Skin Sens. 1;H317 Aquatic Acute. 1; H400 Aquatic Chronic. A; H410	Skin Corr. 1B; H314: C ≥ 0.6 % Skin Irrit. 2; H315: 0.06 % ≤ C < 0.6 % Eye Irrit. 2; H319: 0.06 % ≤ C < 0.6 % Skin Sens. 1; H317: C ≥ 0.0015 %

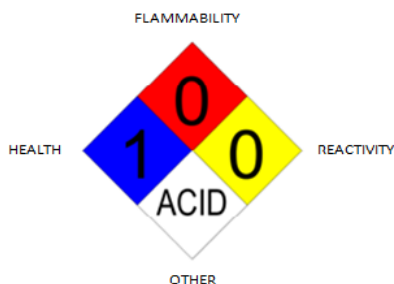
* ProClin™ 300 is used as a preservative in the listed reagents. The hazardous ingredient is the reaction mass of: 5-chloro-2-methyl-4-isothiazolin-3-one [EC no. 247-500-7] and 2-methyl-2H-isothiazol-3-one [ECno. 220-239-6] (3:1).

4. First-Aid Measures

Contaminated individuals of chemical exposure must be taken for medical attention if any adverse effect occurs. Rescuers should be taken for medical attention, if necessary. Take a copy of the label and MSDS to a health professional with the contaminated individual.

- Eye Contact:** If chemical contacts the eye, open victim's eyes while under gentle running water. Use sufficient force to open eyelids. Have victim "roll" eyes. Minimum flushing is for 15 minutes. Remove contact lenses, if worn. Seek medical attention if irritation persists.
- Skin Contact:** Wash contacted area with soap and water. Remove exposed or contaminated clothing, taking care not to contaminate eyes. Seek medical attention if irritation develops or persists.
- Inhalation:** Not a normal route of entry; however, if chemical is inhaled, or breathing becomes difficult, remove victim to fresh air. If necessary, use artificial respiration to support vital functions. Seek medical attention.
- Ingestion:** If chemical is swallowed, call physician or poison control center for most current information. If professional advice is not available, do not induce vomiting. Never induce vomiting or give diluents (milk or water) to someone who is unconscious, having convulsions, or who cannot swallow. Victims of chemical exposure must be taken for medical attention. Rescuers should be taken for medical attention, if necessary. Take a copy of the label and MSDS with the victim to the health professional.
- Medical Conditions Aggravated by Exposure:** None known.
- Recommendations to Physicals:** Treat symptoms and eliminate overexposure.

5. Fire-Fighting Measures



NFPA Rating Explanation Guide					
RATING NUMBER	HEALTH HAZARD	FLAMMABILITY HAZARD	INSTABILITY HAZARD	RATING SYMBOL	SPECIAL HAZARD
4	Can be lethal	Will vaporize and readily burn at normal temperatures	May explode at normal temperatures and pressures	ALK	Alkaline
3	Can cause serious or permanent injury	Can be ignited under almost all ambient temperatures	May explode at high temperature or shock	ACID	Acidic
2	Can cause temporary incapacitation or residual injury	Must be heated or high ambient temperature to burn	Violent chemical change at high temperatures or pressures	COR	Corrosive
1	Can cause significant irritation	Must be preheated before ignition can occur	Normally stable. High temperatures make unstable	OX	Oxidizing
0	No hazard	Will not burn	Stable	☸	Radioactive
				W	Reacts violently or explosively with water
				W OX	Reacts violently or explosively with water and oxidizing

This chart for reference only - For complete specifications consult the NFPA 704 Standard
NFPA Chart 1 www.complanet.com

Flash Point: Non-flammable.

Auto-ignition Temperature: Not applicable.

Flammable Limits (%): Lower and Upper N/A

Fire Extinguishing Materials: Use extinguishing materials appropriate for surrounding fire.

Unusual Fire and Explosive Hazards: The product is a water based mixture with no known fire or explosion hazards.

Explosion Sensitivity to Mechanical Impact: Not sensitive.

Explosion Sensitivity to Static Discharge: Not sensitive.

Special Fire-Fighting Procedures: Incipient fire responders should wear eye protection. Structural firefighters must wear Self-Contained Breathing Apparatus and full protective equipment. Isolate materials not yet involved in the fire and protect personnel. Move containers from fire area if this can be done without risk; otherwise, cool with carefully applied water spray. If possible, prevent runoff water from entering storm drains, bodies of water, or environmentally sensitive areas.

6. Accidental Release Measures

Spill and Leak Response: Proper protective equipment should be used. Personnel should be trained for spill response operations.

Spills: Trained personnel following pre-planned procedures should handle non-incident releases. Absorb spilled materials using polypads or other suitable absorbent material. Place all spill residue in an appropriate container and seal. Decontaminate the area thoroughly. Do not mix with wastes from other materials. Dispose of in accordance with applicable Federal, State, and local procedures.

7. Handling and Storage

Work and Hygiene Practices: As with all chemicals, avoid getting this product on you or in you. Wash thoroughly after



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handling this product. Do not eat, drink, smoke, or apply cosmetics while handling this product. Avoid breathing mists or sprays generated by this product. Use in a well-ventilated location. Remove contaminated clothing immediately.

Storage and Handling Practices:

Store product in properly labeled, closed containers at temperatures between 2-8°C. Protect from physical damage. Keep containers closed when not in use.

8. Exposure Controls – Personal Protection

Ventilation and Engineering Controls:

Use with adequate ventilation to ensure exposure levels are maintained below the established limits. Currently, International exposure limits are not established for all components of this product.

Please check with competent authority in each country for the most recent limits in place.

The following information on appropriate Personal Protective Equipment is provided to assist employers in complying with OSHA regulations found in 29 CFR Subpart I (beginning at 1910.132) or equivalent standards of Canada, or standards of EU member states (including EN 149 for respiratory PPE, and EN 166 for face/eye protection), and those of Japan. Please reference applicable standards for relevant details.

Respiratory Protection:

If exposure limits are exceeded, use only respiratory protection authorized in the US Federal OSHA Respiratory Protection Standard (29 CFR 1910.134), equivalent US State standards, Canadian CSA Standard Z94.4-93, the European Standard EN149, or EU member states.

Eye Protection:

Splash goggles or safety glasses with side shields recommended. If necessary, refer to US OSHA 29 CFR 1910.133, Canadian Standards, and the European Standard EN166, Australian Standards, or relevant Japanese Standards.

Hand Protection:

Compatible protective gloves recommended. Wash hands after removing gloves. If necessary refer to US OSHA 29 CFR 1910.133, Canadian Standards, and the European Standard EN166, Australian Standards, or relevant Japanese Standards.

Body Protection:

Use body protection appropriate for task. Coveralls, rubber aprons, or chemical protective clothing made from natural rubber are generally acceptable, depending upon the task. If necessary, refer to appropriate Standards of Canada, or appropriate Standards of the EU, Australian Standards, or relevant Japanese Standards. If a hazard of injury to the feet exists due to falling objects, rolling objects, where objects may pierce the soles of the feet or where employee's feet may be exposed to electrical hazards, use foot protection, as described in US OSHA 29 CFR 1910.139.

9. Physical and Chemical Properties

Vapor Density:

N/A.

Specific Gravity @ 20°C:

No data, (water = 1).

Vapor Pressure:

No data @ 20°C.

Appearance and Color:

This product is a clear to yellowish liquid.

Evaporation Rate (n –BaAC =1):

N/A

Solubility in Water:

Soluble.

pH:

Not established.



10. Stability and Reactivity

Stability:	Stable under ordinary conditions of use and storage.
Decomposition Products:	When stored as labeled, no known hazardous decomposition products are formed during the shelf-life of this product.
Materials with which Substance is Incompatible:	No information available.
Hazardous Depolymerization:	Will not occur.
Conditions to avoid:	Temperatures above or below the recommended storage range.

11. Toxicology Information

Toxicity Data:	No data available.
Suspected Cancer Agent:	The components of this product are not listed by agencies tracking the carcinogenic potential of chemical compounds as follows: <u>Carcinogenicity:</u> NTP Regulated: No IARC Regulated: No OSHA Regulated: No
Irritancy of the Product:	None known.
Sensitization of the Product:	This product is not known to cause human skin or respiratory sensitization.
Reproductive Toxicity Information:	Listed below is information concerning the effects of this product and its components on the human reproductive system. Mutagenicity: The components of this product are not reported to produce mutagenic effects in humans Embryotoxicity: The components of this product are not reported to produce embryotoxic effects in humans. Teratogenicity: The components of this product are not reported to produce teratogenic effects in humans. Reproductive Toxicity: The components of this product are not reported to produce reproductive effects in humans.

12. Ecological Information

All work practices must be aimed at eliminating environmental contamination.

Environmental Fate:	No data available.
Environmental Toxicity:	No data available.

13. Disposal Considerations

Preparing waste for disposal:	Waste disposal must be in accordance with appropriate US Federal, State, and local regulations, those of Canada, Australia, EU Member States, and Japan.
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14. Transportation Information



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DOT Classification:	Non-regulated material.
DOT Labeling Requirements:	None.
IATA Labeling Requirements:	None.
US Department of Transportation (DOT) Shipping Regulation:	This product is not classified as dangerous goods, per US DOT regulations, under 49 CFR 172.101.
Transport Canada, Transportation of Dangerous Goods Regulation:	This product is not classified as Dangerous Goods, per regulations of Transport Canada.
International Air Transport Association (IATA):	This product is not classified as Dangerous Goods, by rules of IATA.
International Maritime Organization (IMO) Designation:	This product is not classified as Dangerous Goods by the International Maritime Organization.
European Agreement Concerning the International Carriage of Dangerous Goods by Road (ADR)	This product is not classified by the United Nations Economic Commission for Europe to be dangerous goods.
UN Number:	None.

15. Regulatory Information

United States Regulations:

Sara Reporting Requirements:	None.
Marine Pollutant:	This product contains no components listed as a Marine Pollutant under 49 CFR 172.101, Appendix B.
TSCA:	All components in this product mixture are listed on the US Toxic Substances Control Act (TSCA) inventory of chemicals or are exempt from listing.
SARA 311/312:	None.
US CERCLA Reportable Quantity (RQ):	None.
US TSCA Inventory Status:	All of the components of this product are listed in the TSCA Inventory or exempt.
California Safe Drinking Water and Toxic Enforcement Act (Proposition 65):	This product does not contain any component above the 0.1% level which is listed as a California Proposition 65 chemical.

Note: the chemical identity of some or all components present is confidential business information (trade secret) and is being withheld as permitted by 29 CFR 1910.1200 (i).

Canadian Regulations:

Canadian DSL/INDSL Inventory Status:	All of the components of this product are on the DSL Inventory or exempt.
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Canadian Environmental Protection Act (CEPA) Priorities Substances Lists: No component of this product is on the CEPA First Priorities Substance Lists.

Canadian Whims Classification and Symbols: Not regulated.

European Economic Community Information:

European Representative: MDSS GmbH
Schiffgraben 4
30175 Hannover, Germany



16. Other Information

All chemicals may pose unknown hazards and should be used with cautions. This Material Safety Data Sheet (MSDS) applies only to the material as packaged. If this product is combined with other materials, deteriorates, or becomes contaminated, it may pose hazards not mentioned in this MSDS. It shall be the user's responsibility to develop proper methods of handling and personal protection based on the actual conditions of use. While this MSDS is based on technical data judged to be reliable, Epitope Diagnostics, Inc. assumes no responsibility for the completeness or accuracy of the information contained herein. Users should consider this data as only a supplement to other information gathered by them and must make independent determinations of suitability and completeness of information from all sources to assure proper use and disposal of these materials, as well as the safety and health of employees, customers, and protection of the environment.

Hazard Statements

H317: May cause an allergic skin reaction.

Precautionary Statements

P261: Avoid breathing dust/fume/gas/mist/vapours/spray.
P272: Contaminated work clothing should not be allowed out of the workplace.
P280: Wear protective gloves/protective clothing/eye protection/face protection.
P302 + P352: IF ON SKIN: Wash with plenty of soap and water.
P321: Specific treatment (see label).
P333 + P313: If skin irritation or rash occurs: Get medical advice/attention.
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