



Safety Data Sheet

Section 1 - Product and Company Information

1.1 Product Identifiers

Product Name: COVID-19 Trace™ IgG MICRO-ELISA (IVD)

Product Number: S1500

Components: Microplate 96-well strips (12 x 8 strips)
Positive Control (1X) (0.5 ml)
Negative Control (1X) (0.5 ml)
Cutoff Control (1X) (0.5 ml)
Sample Diluent (1X) (50 ml)
Enzyme Conjugate (100X) (150 µl)
Conjugate Diluent (1X) (12 ml)
Wash Buffer (20X) (25 ml)
Substrate Chromogen (1X) (12 ml)
Stop Solution (1X) (10 ml)
Adhesive Plate Sealers (2 x 1 each)

1.2 Relevant identified uses of the substance or mixture and advised against

The components within this product are available under Section IV.D notification for diagnostics within a CLIA certified lab authorized to run complex testing.

1.3 Company:

Leinco Technologies
410 Axminister Drive
St. Louis, Missouri 63026
Phone: 800-538-1145
Fax: 636-230-9477

Section 2 - Hazardous Identification

See pages 2-15.



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Section 1 - Product and Company Information

1.1 Product Identifiers:

Product Number and Name S1500-2: Positive Control (containing Proclin 300)
S1500-3: Negative Control (containing Proclin 300)
S1500-4: Cutoff Control (containing Proclin 300)
S1500-5: Sample Diluent (containing Proclin 300)
S1500-6: Enzyme Conjugate (containing Proclin 300)
S1500-7: Conjugate Diluent (containing Proclin 300)
S1500-8: Wash Buffer (containing Proclin 300)

1.2 Relevant identified uses of the substance or mixture and advised against

The components within this product are available under IVD notification for diagnostics within a CLIA certified lab authorized to run complex testing.

1.3 Company:

Leinco Technologies
410 Axminister Drive
St. Louis, Missouri 63026
Phone: 800-538-1145
Fax: 636-230-9477

Section 2 - Hazardous Identification

According to regulations OSHA Hazard Communication Standard 29CFR 1910:1200 and EC No 1271/2008 (GHS/CLP)

2.1 Hazard Category: Category 1: Sensitization, skin

2.2 Hazard Statement: May cause an allergic skin reaction

2.3 Precautionary Statements(s):

P261: Avoid breathing dust/fume/gas/mist/vapours/spray.

P280: Wear protective gloves/protective clothing/eye protection/face protection.

P302 + P352: IF ON SKIN: wash with plenty of soap and water

P333 + P313: If skin irritation or rash occurs, get medical advice/attention

P361 + P272: Remove/Take off immediately all contaminated clothing. Contaminated work clothing should not be allowed out of the workplace.



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Section 3 - Composition/Information on Ingredients

3.1 Substances

Not applicable

3.2 Mixture

Components	Component	CAS No.
<i>S1500-2: Positive Control (containing Proclin 300)</i>	Proclin 300	55965-84-9
<i>S1500-3: Negative Control (containing Proclin 300)</i>	Proclin 300	55965-84-9
<i>S1500-4: Cutoff Control (containing Proclin 300)</i>	Proclin 300	55965-84-9
<i>S1500-5: Sample Diluent (containing Proclin 300)</i>	Proclin 300	55965-84-9
<i>S1500-6: Enzyme Conjugate (containing Proclin 300)</i>	Proclin 300	55965-84-9
<i>S1500-7: Conjugate Diluent (containing Proclin 300)</i>	Proclin 300	55965-84-9
<i>S1500-8: Wash Buffer (containing Proclin 300)</i>	Proclin 300	55965-84-9

Section 4 - First Aid Measures

- 4.1 Oral Exposure:** If swallowed and the person is conscious, wash out mouth with water and immediately call a physician or dial emergency contact number.
- 4.2 Inhalation Exposure:** If inhaled, move to fresh air. If not breathing, administer CPR immediately. If breathing becomes difficult, give oxygen. If discomfort persists, seek immediate medical attention.
- 4.3 Dermal Exposure:** In case of contact, wash skin with soap and copious amounts of water.
- 4.4 Eye Exposure:** In case of contact with eyes, flush with copious amounts of water. Assure adequate flushing by separating the eyelids with fingers.

Section 5 - Fire Fighting Measures

- 5.1 Flash Point:** No data available
- 5.2 Auto Ignition Temp:** No data available



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- 5.3 Flammability:** No data available
- 5.4 Extinguishing Media:** *Suitable:* Noncombustible. Use extinguishing media appropriate to surrounding fire conditions.
- 5.5 Firefighting:** *Protective Equipment:* Wear self-contained breathing apparatus and protective clothing to prevent contact with skin and eyes. For fires involving this material, do not enter any enclosed or confined space without proper protective equipment.

Section 6 - Accidental Release Measures

- 6.1 Procedures and Personal Precautions:** Exercise appropriate precautions to minimize direct contact with skin or eyes and prevent inhalation of dust. See Section 8 of SDS.
- 6.2 Procedure to be Followed in Case of Leak or Spill:** Cover released or spilled material with absorbent and place in appropriate waste containers.
- 6.3 Methods for Cleaning Up:** Sweep up, place in a plastic bag and hold for waste disposal. Avoid raising dust. Ventilate area and wash spill site after material pickup is complete.
- 6.4 Environmental Precautions:** Dispose of containers and unused contents in accordance with Federal, State, and Local regulatory requirements.

Section 7 - Handling and Storage

- 7.1 Overall Kit and Specimen Handling:** This product requires the handling of human specimens. All patient specimens should be considered potentially infectious and handled in accordance with the OSHA Standard on Blood borne Pathogens and good laboratory procedure. Sample collection and handling procedures require specific training and guidance and should only be performed by properly trained healthcare professionals. Wear suitable protective attire, gloves, eye/face protection when handling any of the components of this kit. Avoid inhalation of vapors. Avoid contact with eyes, skin and clothing. Avoid prolonged or repeated exposure. Do not use if skin is cut or scratched. Wash thoroughly after handling.
- 7.1 Reagent Handling:** Avoid inhalation of vapors. Avoid contact with eyes, skin and clothing. Avoid prolonged or repeated exposure. Do not use if skin is cut or scratched. Wash thoroughly after handling.

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- 7.2 Storage and Stability:**
- Unopened:* This test kit must be stored at 2 – 8°C upon receipt. For the expiration date of the kit refer to the label on the kit box. All components are stable until this expiration date
- Opened:* Once opened, the kit reagents are stable when stored at 2 – 8°C. Refer to label on the kit box for expiration date
- Indication of instability or deterioration:* Deterioration of kit reagents may be indicated when a quality control value is out of the specified range. Associated test results are invalid, and samples must be retested with a new kit where the control values are within the specified ranges.

Section 8 - Exposure Control/Personal Protection

- 8.1 Control Parameters** **Components with workplace control parameters:** no substances occupational exposure limit values
- 8.2 Exposure Control** **Appropriate Engineering Controls:** Ensure all handling measures described under section 7 of SDS are in place. In addition, ensuring the laboratory is equipped with a safety shower and eyewash station. If applicable, use fume hood with handling of reagents.
- Personal Protective Equipment:** Ensure all handling measures described under section 7 of SDS are in place. For eye protection, wear chemical safety goggles or a face shield. For skin and body protection, wear suitable protective clothing. For respiratory protection and if risk assessment indicates necessary, use a suitable respirator.

Section 9 - Physical and Chemical Properties

9.1 Information on physical and chemical properties

Form:	Solution
Appearance/Color:	Clear
Odor:	Little to none
Boiling Point:	No data available
Freezing Point:	No data available
Melting Point:	No data available
Vapor Pressure (mm Hg):	No data available
Vapor Density:	No data available



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Specific Gravity:	No data available
Solubility in Water:	No data available
Evaporation Rate:	No data available
pH Range:	No data available

9.2 Other Safety Information

No data available

Section 10 - Stability and Reactivity

10.1 Reactivity:	Stable under recommended storage conditions
10.2 Possibility of Hazardous Reactivity:	Hazardous reactivity will not occur under normal transport or storage conditions Decomposition may occur due to exposure of conditions listed in section 10.4 - 10.6
10.3 Chemical Stability:	Stable under recommended storage conditions
10.4 Hazardous Decomposition Products:	Nature of decomposition products not known
10.5 Hazardous Polymerization Products:	Hazardous polymerization products will not occur
10.6 Incompatible Materials:	Strong acids, strong oxidation/reducing agents
10.7 Conditions to Avoid	Heat, moisture

Section 11- Toxicological Information

11.1 Information on Toxicological Effects

Skin Contact:	May cause skin irritation.
Skin Absorption:	May be harmful if absorbed through the skin.
Eye Contact:	May cause eye irritation.
Inhalation:	Harmful if inhaled. Material may be irritating to mucous membranes and upper respiratory tract.

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Ingestion:	Harmful if swallowed.
Signs/Symptoms of Exposure:	To the best of our knowledge, the chemical, physical, and toxicological properties have not been thoroughly investigated.
Target Organs or Systems:	No data available

Section 12 - Ecological Information

No data available.

Section 13 - Disposal Considerations

13.1 Appropriate Method of Disposal for product and contaminated packaging:

Small amounts of kit reagents may be washed down the drain with excess water. Dispose of containers and unused contents in accordance with Federal, State, and Local regulatory requirements.

Section 14 - Transport Information

U.S Department of Transportation (DOT) and International Air Transport Association (IATA)

14.1 UN-Number:	None. Substance is considered to be non-hazardous for transport.
14.2 Proper Shipping Name:	None. Substance is considered to be non-hazardous for transport.
14.2 Transport Hazard:	Substance is considered to be non-hazardous for transport.
14.3 Environmental Hazards:	Substance is considered to be non-hazardous for transport.

Section 15 - Regulatory Information

15.1 Safety, health and environmental regulations or legislations for specific substance and/or mixture

TSCA (Toxic Substance Control):	Not Applicable
SARA 313:	Not Applicable
SARA 311/312:	Not Applicable



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Section 16 - Other Information

Warranty: The above information is believed to be correct but does not purport to be all inclusive and shall be used only as a guide. The information in this document is based on the present state of our knowledge and is applicable to the product with regard to appropriate safety precautions. It does not represent any guarantee of the properties of the product. Leinco Technologies Inc. shall not be held liable for any damage resulting from handling or from contact with the above product.

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Section 1 - Product and Company Information

1.1 Product Identifiers:

Product Number and Name S1500-9: Substrate-Chromogen

1.2 Relevant identified uses of the substance or mixture and advised against

The components within this product are available under Section IV.D notification for diagnostics within a CLIA certified lab authorized to run complex testing.

1.3 Company:

Leinco Technologies
410 Axminister Drive
St. Louis, Missouri 63026
Phone: 800-538-1145
Fax: 636-230-9477

Section 2 - Hazardous Identification

According to regulations OSHA Hazard Communication Standard 29CFR 1910.1200 and EC No 1271/2008 (GHS/CLP)

S2500-10: Substrate-Chromogen `(3,3',5,5'tetramethylbenzidine) contains a non-carcinogenic analog of Benzedine, a mild oxidizing agent. The product contains no substances which at their given concentration, are considered to be hazardous to health. There are no affected target organs. The toxicological properties have not been thoroughly investigated. Contains no hazardous ingredients at levels requiring disclosure by the OSHA Hazard Communication Standard (29 CFR 1910.1200)

Section 3 - 15

Not Applicable

Section 16 - Other Information

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Safety Data Sheet

Section 1 - Product and Company Information

1.1 Product Identifiers:

Product Number and Name *S1500-10: Stop Solution*

1.2 Relevant identified uses of the substance or mixture and advised against

The components within this product are available under Section IV.D notification for diagnostics within a CLIA certified lab authorized to run complex testing.

1.3 Company:

Leinco Technologies
410 Axminister Drive
St. Louis, Missouri 63026
Phone: 800-538-1145
Fax: 636-230-9477

Section 2 - Hazardous Identification

According to regulations OSHA Hazard Communication Standard 29CFR 1910:1200 and EC No 1271/2008 (GHS/CLP)

2.1 Hazard Category: Category 1B: Skin corrosion/irritation

2.2 Hazard Statement: *H314: Causes severe skin burns and eye damage*

H318: Causes serious eye damage

2.3 Precautionary Statements(s):

P261: Avoid breathing dust/fume/gas/mist/vapours/spray

P280: Wear protective gloves/protective clothing/eye protection/face protection

P302 + P352: IF ON SKIN: wash with plenty of soap and water

P333 + P313: If skin irritation or rash occurs, get medical advice/attention

P361 + P272: Remove/take off immediately all contaminated clothing. Contaminated work clothing should not be allowed out of the workplace.

Section 3 - Composition/Information on Ingredients

3.1 Substances

Not applicable



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3.3 Mixture

Components	Component	CAS No.
S2500-11: Stop Solution	Sulfuric Acid	7664-93-9

Section 4 - First Aid Measures

- 4.1 Oral Exposure:** If swallowed and the person is conscious, wash out mouth with water and immediately call a physician or dial emergency contact number.
- 4.2 Inhalation Exposure:** If inhaled, move to fresh air. If not breathing, administer CPR immediately. If breathing becomes difficult, give oxygen. If discomfort persists, seek immediate medical attention.
- 4.3 Dermal Exposure:** In case of contact, wash skin with soap and copious amounts of water for at least 15 minutes. Remove contaminated clothing and shoes. Call a physician or dial emergency contact number.
- 4.4 Eye Exposure:** In case of contact with eyes, flush with copious amounts of water for at least 15 minutes. Assure adequate flushing by separating the eyelids with fingers. Call a physician or dial emergency contact number.

Section 5 - Fire Fighting Measures

- 5.1 Flash Point:** No data available
- 5.2 Auto Ignition Temp:** No data available
- 5.3 Flammability:** No data available
- 5.4 Extinguishing Media:** *Suitable:* Noncombustible. Use extinguishing media appropriate to surrounding fire conditions.
- 5.5 Firefighting:** *Protective Equipment:* Wear self-contained breathing apparatus and protective clothing to prevent contact with skin and eyes. For fires involving this material, do not enter any enclosed or confined space without proper protective equipment.



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Section 6 - Accidental Release Measures

6.1 Procedures and Personal Precautions:	Wear a mask, gloves and lab coat. Exercise appropriate precautions to minimize direct contact with skin or eyes and prevent inhalation of dust. See Section 8 of SDS.
6.2 Procedure to be Followed in Case of Leak or Spill	Cover released or spilled material with absorbent and place in appropriate waste containers.
6.3 Methods for Cleaning Up:	Sweep up, place in a plastic bag and hold for waste disposal. Avoid raising dust. Ventilate area and wash spill site after material pickup is complete.
6.4 Environmental Precautions:	Dispose of containers and unused contents in accordance with Federal, State, and Local regulatory requirements.

Section 7 - Handling and Storage

7.1 Overall Kit and Specimen Handling:	This product requires the handling of human specimens. All patient specimens should be considered potentially infectious and handled in accordance with the OSHA Standard on Blood borne Pathogens and good laboratory procedure. Sample collection and handling procedures require specific training and guidance and should only be performed by properly trained healthcare professionals. Wear suitable protective attire, gloves, eye/face protection when handling any of the components of this kit.
7.1 Reagent Handling:	Avoid inhalation of vapors. Avoid contact with eyes, skin and clothing. Avoid prolonged or repeated exposure. Do not use if skin is cut or scratched. Wash thoroughly after handling.
7.2 Storage and Stability:	<p><i>Unopened:</i> This test kit must be stored at 2 – 8°C upon receipt. For the expiration date of the kit refer to the label on the kit box. All components are stable until this expiration date</p> <p><i>Opened:</i> Once opened, the kit reagents are stable when stored at 2 – 8°C. Refer to label on the kit box for expiration date</p> <p><i>Indication of instability or deterioration:</i> Deterioration of kit reagents may be indicated when a quality control value is out of the specified range. Associated test results are invalid, and samples must be retested with a new kit where the control values are within the specified ranges.</p>

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Section 8 - Exposure Control/Personal Protection

8.1 Control Parameters: **Components with workplace control parameters:** no substances occupational exposure limit values

8.2 Exposure Control: **Appropriate Engineering Controls:** Ensure all handling measures described under section 7 of SDS are in place. In addition, ensuring the laboratory is equipped with a safety shower and eyewash station. If applicable, use fume hood with handling with reagents.

Personal Protective Equipment: Ensure all handling measures described under section 7 of SDS are in place. For hand protection, wear protective gloves. For eye protection, wear chemical safety goggles or a face shield. For skin and body protection, wear suitable protective clothing. For respiratory protection and if risk assessment indicates necessary, use a suitable respirator.

Section 9 - Physical/Chemical Properties

9.1 Information on physical and chemical properties

Form:	Solution
Appearance/Color:	Clear
Odor:	Little to none
Boiling Point:	No data available
Freezing Point:	No data available
Melting Point:	No data available
Vapor Pressure (mm Hg):	No data available
Vapor Density:	No data available
Specific Gravity:	No data available
Solubility in Water:	No data available
Evaporation Rate:	No data available
pH Range:	No data available

9.2 Other Safety Information

No data available



Safety Data Sheet

Section 10 - Stability and Reactivity

10.1 Reactivity:	Stable under recommended storage conditions
10.2 Possibility of Hazardous Reactivity:	Hazardous reactivity will not occur under normal transport or storage conditions Decomposition may occur due to exposure of conditions listed in section 10.4 - 10.6
10.3 Chemical Stability:	Stable under recommended storage conditions
10.4 Hazardous Decomposition Products:	Hazardous decomposition products will not occur
10.5 Hazardous Polymerization Products:	Hazardous polymerization products will not occur
10.6 Incompatible Materials:	Bases, strong oxidation/reducing agents
10.7 Conditions to Avoid	Heat, moisture

Section 11 - Toxicological Information

11.1 Information on Toxicological Effects

Skin Contact:	May cause severe skin burns
Skin Absorption:	Harmful if absorbed through the skin
Eye Contact:	May cause serious eye damage.
Inhalation:	Not classified
Ingestion:	Harmful and toxic if swallowed.
Signs/Symptoms of Exposure:	Dizziness. Gastrointestinal disturbances. Nausea, headache and vomiting. Ingestion can cause: To the best of our knowledge, the chemical, physical and toxicological properties have not been thoroughly investigated. Unconsciousness. Drowsiness. Confusion. Weakness. Cannot be made non-poisonous.
Target Organs or Systems:	Eyes, skin, respiratory system, teeth

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Section 12 - Ecological Information

No data available.

Section 13 - Disposal Considerations

13.1 Appropriate Method of Disposal for product and contaminated packaging:

Dispose in a safe manner in accordance with Federal, State, and Local regulatory requirements.

Section 14 - Transport Information

U.S Department of Transportation (DOT) and International Air Transport Association (IATA)

- 14.1 UN-Number:** None. Substance is considered to be non-hazardous for transport.
14.2 Proper Shipping Name: None. Substance is considered to be non-hazardous for transport.
14.2 Transport Hazard: Substance is considered to be non-hazardous for transport.
14.3 Environmental Hazards: Substance is considered to be non-hazardous for transport.

Section 15 Regulatory Information

15.1 Safety, health and environmental regulations or legislations for specific substance and/or mixture

- TSCA (Toxic Substance Control): Not Applicable
SARA 313: Not Applicable
SARA 311/312: Not Applicable

Section 16 - Other Information

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