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Safety Data Sheet

Section 1: Identification

Product Name: Clarity HCG Combo Cassette

Synonyms: DTG-Combo

CAS Number: N/A

Manufacturer: Clarity Diagnostics LLC

Address: 1060 Holland Dr. Suite A Boca Raton, FL 33487

Contact: 1(877) 722-6339

Recommended use: It is a qualitative immunoassay for the early detection of pregnancy in urine and serum.

Section 2: Hazard(s) Identification

GHS Classification:

Health	Environmental	Physical
N/A	N/A	N/A

GHS Label:

Symbols	
Hazard Statements Very toxic if swallowed Lead and other heavy metals not used in/on device. Sodium Azide: Poisonous. Human Plasma: Non-infectious to HIV, HCV, and HBV.	Precautionary Statements Wear protective eye and face protection Wear gloves. Do not inhale or swallow.

Section 3: Composition/Information on Ingredients

Component	CAS Number	Weight
N/A	N/A	N/A
Human Plasma		
See Section 8 For Exposure Limits		

Section 4: First-Aid Measures

Eyes: Rinse eyes if contacted by desiccant granules

Ingestion: If ingested, contact physician for further care.

Inhalation: Remove to fresh air.

Skin Exposure: Flush area with water for 15 minutes.

Section 5: Fire-Fighting Measures

Suitable Extinguishing Media: Use Media appropriate for surrounded materials

Fire Fighting Procedures: Water, CO₂, Dry Chemical, or foam.

Unusual Fire and Explosion Hazards: None Known

Combustion Products: None

Section 6: Accidental Release Measures

Accidental release measures: N/A

Section 7: Handling and Storage

Handling: Room temperature storage for product longevity – more extreme conditions do not present safety hazard

Section 8: Exposure Controls/Personal Protection

Exposure Limits

Primary Route of Entry: Antibody reagents contain Sodium Azide as an antibacterial agent.

Components: None

Engineering Controls: Not Applicable

Personal Protective Equipment (PPE): Refer to product insert for appropriate PPE during use. Applicable PPE for use environment.

Eye Protection: Wear Safety Glasses or full face shield

Skin Protection: Wear protective clothing and gloves, remove all clothing if contaminated

Respiratory Protection: None required

Section 9: Physical and Chemical Properties

Flashpoint: N.A

Auto Ignition Temperature: N.A.

Boiling Point: N.A

Melting Point: <0.1

Vapor Pressure: <0.1

Vapor Density (Air=1):

% Solubility in Water: N.A.

Pour Point: N.A

Molecular Formula: N.A

Odor/Appearance: Odorless solid/ Plastic Cassette Sealed in foil pouch.

Lower Flammability Limit: N.A.

Upper Flammability Limit: N.A

Specific Gravity: <0.1

% Volatile: N.A.

Evaporation Rate (Water=1): N.A.

Viscosity: N.A.

Octanol/Water Partition Coefficient: N.A

pH: N.A.

Molecular Weight: N.A

Section 10: Stability and Reactivity

Stability and reactivity: Stable. No dangerous reactions known for device. See insert or Certificate of Analysis for use of individual product.

Hazardous Reactions/Decomposition Products: Will not occur/Products and incompatibility are not known

Section 11: Toxicological Information

Signs and Symptoms of Overexposure: No effects of overexposure

Acute Effects: N/A

Eye Contact: May cause conjunctival irritation.

Skin Contact: May cause irritant skin reaction.

Inhalation: Granules within desiccant packet are considered nontoxic.

Ingestion: May cause irritant conditions if swallowed.

Target Organ Effects: None

Chronic Effects: None

Medical Conditions Aggravated by Exposure: N/A

Acute Toxicity Values: N/A

Section 12: Ecological Information* (non-mandatory)

- No ecological information available

Section 13: Disposal Considerations* (non-mandatory)

Appropriate Methods of Disposal	Device itself may be disposed as solid waste. Devices tested with patient samples should be handled as potentially biohazardous materials in accordance with Federal, State, and Local Requirements.
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Section 14: Transport Information* (non-mandatory)

Transport Precautions	Consult applicable regulation when transporting this product
Additional Information	Follow the instructed guidelines listed in package for proper transportation.

Section 15: Regulatory Information* (non-mandatory)

Not restricted for safety reasons

Section 16: Other Information

Other Precautions: No other precautions needed. Clarity Diagnostics provides the information contained herein in good faith but makes no representation as to its comprehensiveness or accuracy. This document is intended only as a guide to the appropriate precautionary handling of the materials contained in this kit by a properly trained person using this product. Clarity Diagnostics shall not be held liable for any damage resulting from handling or use.

- This product is for in vitro diagnostic use only.**

*Note: Since other Agencies regulate this information, OSHA will not be enforcing Sections 12 through 15(29 CFR 1910.1200(g)(2)).