

AccuDiag™
Rheumatoid Factor IgM (RF)
ELISA Kit

Cat#2550-1

SECTION 1 – PRODUCT AND COMPANY IDENTIFICATION

PRODUCT NAME: RF IgM

PRODUCT USE: Enzyme-linked immunosorbent assay (ELISA) for the qualitative and semi-quantitative detection of antibodies in the diagnosis of autoimmune diseases.

SUPPLIER: Diagnostic Automation/Cortez Diagnostics, Inc.
 21250 Califa St. Suite 102 and 116, Woodland Hills, CA 91367 USA
 Phone: 818-591-3030
 Fax: 818-591-8383

SECTION 2 – HAZARDS IDENTIFICATION

OSHA Hazards


No known OSHA hazards
 This product is classified as not dangerous according to directive 1999/45/EC.

GHS Classification

Classification: Regulation (EC) No. 1272/2008[CLP/GHS]

Skin Corrosion/Irritation Category 1

Eye Irritation Category 1

Pictogram: 

Signal Wording: Danger

Hazard statements:

H314 Causes severe skin burns and eye damage.

Precautionary statements:

P260 Do not breathe mist, vapors, or spray

P264 Wash exposed skin thoroughly after handling

P280 Wear protective gloves, protective clothing, eye protection, face protection

P301+P330+P331 IF SWALLOWED: Rinse mouth. Do NOT induce vomiting

P303+P361+P353 IF ON SKIN (or hair): Remove/Take off immediately all contaminated clothing. Rinse skin with water/shower

P304+P340 IF INHALED: Remove person to fresh air and keep comfortable for breathing

P305+P351+P338 If in eyes: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do.

Continue rinsing

P310 Immediately call a POISON CENTER or Doctor

P363 Wash contaminated clothing before reuse

P405 Store locked up

P501 Dispose of contents/container to comply with local, state and federal regulations

Other hazards: None

SECTION 3 – INFORMATION ON INGREDIENTS

Description: DACD

Contains	CAS No.	EC-No.	Index-No.	Content	Applies to the following products
Sodium Azide	26628-22-8	247-852-1	011-004-00-7	<0.1%	Positive control
Human Serum	N/A	N/A	N/A	N/A	Positive control
Triton® X-100	9002-93-1	N/A	N/A	≤ 10%	2308-1 Wash buffer
TMB (3, 3', 5, 5'-tetramethylbenzidine)	54827-17-7	259-364-6	N/A	≤0.2%	Enzyme Substrate
Sulfuric acid (H2SO4)	7664-93-9	231-639-5	016-020-00-8	2.7%	Stop solution
Proprietary formulation: no other hazardous components above 1% or carcinogens above 0.1%	Proprietary	Proprietary	N/A	N/A	All components

SECTION 4 – FIRST AID MEASURES

IF IN EYES: Flush with copious amounts of water for 15 minutes; contact a physician.

IF ON SKIN (or hair): Wash well with mild soap and water. Remove contaminated clothing. Flush skin surface with additional water.

IF INHALED: Remove victim to fresh air. Seek medical attention if victim is feeling unwell.

IF SWALLOWED: Flush mouth with plenty of water (do not swallow rinse water). Give plenty of water to drink. Obtain medical attention.

Potential Acute/delayed health effects:

Eye Contact: May cause temporary eye irritation.

Skin Contact: Prolonged skin contact may cause redness and irritation.

Inhalation: May cause coughing or mild irritation.

Ingestion: May cause discomfort if swallowed.

Notes to physician: Consult a physician. Show this safety data sheet to the doctor in attendance.

SECTION 5 – FIRE FIGHTING MEASURES

Non-flammable preparation.

Extinguishing media: Use media in adaption to materials stored in the immediate neighborhood, such as dry chemical.

Special firefighting procedures: Wear self-contained breathing apparatus and protective clothing to prevent contact with skin and eyes..

SECTION 6 – ACCIDENTAL RELEASE MEASURES

Person-related safety precautions: Use appropriate personnel protective equipment to prevent contamination of skin, eyes, and personal clothing.

Measures for environmental protection: Keep away from drains.

Measures for containment and cleaning: Absorb spill with inert material (ex. vermiculite, sand or earth), then place in suitable container.

Provide ventilation. Do not expose spill to water. Do not let enter the environment.

SECTION 7 – HANDLING and STORAGE

Precautions for safe handling: Do not ingest. Do not breathe gas/fumes/vapor/spray. Never add water to this product. In case of insufficient ventilation, wear suitable respiratory equipment. If ingested, seek medical advice immediately and show the container or the label. Avoid contact with skin and eyes. Keep away from incompatibles, such as

oxidizing agents, reducing agents, combustible materials, organic materials, metals, acids, alkalis, moisture. May corrode metallic surfaces. Conditions for safe storage: Keep container tightly closed and dry. Keep refrigerated at 2°-8° C

Other information: All human derived components have been tested and found to be negative for HBsAg and for antibodies to HIV by FDA required tests. However, all human serum specimens and human derived products should be treated as potentially hazardous, regardless of their origin. Follow good laboratory practices in storing, dispensing and disposing of these materials as per Biosafety in Microbiological and Biomedical Laboratories. Centers for Disease Control, National Institutes of Health, 1993 (HHS Pub. No. [CDC] 93-8395).

SECTION 8 – EXPOSURE CONTROLS and PERSONAL PROTECTION

Control parameters: Contains no substances with occupational control limit values

Appropriate engineering controls: Use with adequate ventilation including local extraction. Ensure that eyewash stations and safety showers are close to the workstation location.

Individual protection measures: Wash hands thoroughly after handling chemical products and before eating, smoking or using the toilet.

Appropriate techniques should be used to remove potentially contaminated clothing. Wash contaminated clothing before using.

Eye/face protection: Wear approved safety goggles

Skin/hand protection: Handle with protective gloves, rubber or plastic.

Use proper glove removal technique (without touching glove's outer surface) to avoid skin contact with this product. Dispose of contaminated gloves after use in accordance with applicable laws and good laboratory practices. Wash and dry hands.

Body protection: Wear suitable protective clothing as protection against splashing or contamination.

Other skin protection: Appropriate footwear and any additional skin protection measures should be selected based on the task being performed and the risks involved.

Respiratory protection: In case of adequate ventilation, use a suitable respirator. If the respirator is the sole means of protection, use a full-face supplied respirator. Use respirators and components tested and approved under appropriate government standards such as NIOSH (US) or CEN (EU).

SECTION 9 – PHYSICAL and CHEMICAL PROPERTIES

Appearance:

Sample diluent: Clear liquid (may be one of various colors depending on specific product)

Calibrator: Clear liquid (may be one of various colors depending on specific product)

Positive control: Clear liquid (may be one of various colors depending on specific product)

Negative control: Clear liquid (may be one of various colors depending on specific product)

Conjugate: Clear liquid (may be one of various colors depending on specific product)

Wash buffer: White powder

Enzyme Substrate: Clear liquid (may be slightly yellow in color)

Stop Solution: Clear

Odor: No odor

Odor threshold: Not available

pH: Not available

Melting point/freezing point: Not available

Boiling point/ Boiling range: Not available

Flash point: Not available

Evaporation rate: Not available

Flammability (solid/gas): Not available

Upper/lower flammability or explosive limits: Not available

Vapor density: Not available

Vapor pressure: Not available

Relative density: Not available

Solubility in/Miscibility with Water: Not available

Partition coefficient: noctanol/water: Not available

Auto igniting: Not available

Decomposition temperature: Not available

Viscosity: Not available

SECTION 10 – STABILITY and REACTIVITY

Reactivity: Reacts with protic solvents (water, alcohols, amines, etc.) to release hazardous acid.

Chemical Stability: Stable under recommended storage conditions.

Possibility of hazardous reactions: Under normal conditions of storage and use, hazardous reactions will not occur.

Conditions to avoid: Sodium azide may react with lead and copper plumbing to form highly explosive metal azides; flush with copious water when pouring dilute solutions down the drain to prevent azide buildup.

Incompatible materials: Sensitive to heat (do not heat over 270° C), strong acids, strong oxidizing agents, strong bases, heavy metals.

Hazardous decomposition products: Nitrogen Oxides; Reacts with protic solvents (water, alcohols, amines, etc.) to release toxic hydrazoic acid.

Hazardous polymerization: Will not occur.

SECTION 11 – TOXICOLOGICAL INFORMATION

Acute toxicity: May cause nausea, headache, and vomiting

Skin corrosion/irritation: May cause skin irritation

Serious eye damage/irritation: May cause eye irritation

Respiratory or skin sensitization: May be irritating to mucous membranes and upper respiratory tract with sore throat, coughing, shortness of breath and delayed lung edema.

Germ Cell mutagenicity: No data available

Carcinogenicity: No data available

Reproductive toxicity: No data available

Specific target organ toxicity (STOT)- single exposure: No data available

Specific target organ toxicity (STOT)- repeated exposure: Nerves, heart, brain

Information on likely routes of exposure: Routes of entry anticipated; oral, dermal, inhalation

Symptoms related to the physical, chemical and toxicological characteristics:

Inhalation: May be harmful if inhaled. Material is extremely destructive to the tissue of the mucous membranes and upper respiratory tract.

Ingestion: May be harmful if swallowed.

Skin contact: May be harmful if absorbed through skin.

Eye contact: May cause eye irritation

Delayed and immediate effects and also chronic effects from short and long term exposure:
 Short term exposure: Potential immediate effects: Not available. Potential long term effects: Not available
 Long term exposure: Potential immediate effects: Not available. Potential long term effects: Not available.
 Effects of chronic exposure: Repeated skin contact with this product may lead to dermatitis while repeated inhalation may cause damage to the mucous membranes and upper respiratory tract, nerves, and brain.
 Numerical measures of toxicity: Not available
 Other information: Not available

SECTION 12 – ECOLOGICAL INFORMATION

Ecotoxicity: No data available
 Bioaccumulative potential: No data available
 Mobility in soil: No data available
 Other adverse effects: No data available

SECTION 13 – DISPOSAL CONSIDERATIONS

Disposal methods: Dispose of waste in accordance to applicable national, regional, or local regulations
 Contaminated packaging: Dispose in the same manner as unused product
 Special precautions: Dispose of small amounts of spilled material as described in section 6. Large spills must be dealt with separately by qualified disposal personnel. Avoid dispersal of spill material to soil, waterways, drains and sewers.

SECTION 14 – TRANSPORT INFORMATION

DOT (US): Not dangerous goods.
 IMDG: Not dangerous goods
 IATA: Not dangerous goods.
 Transport/Additional Information: Transport in accordance with local, state, and federal regulations.

SECTION 15 – REGULATIONS



EU Regulation (EC) No. 1907/2006 (REACH) Annex XIV:
 List of substances subject to authorization Substances of very high concern: None of the components are listed
 Annex XVII - Restrictions on the manufacture, placing on the market and use of certain dangerous substances, mixtures are articles:
 Not applicable
 US Toxic Substances Control Act: On TSCA Inventory
 SARA 313 Components: Not listed
 SARA 311/312 Hazards: Not available
 CERCLA Reportable Quantity: Not available
 California Prop. 65: Not listed

SECTION 16 – OTHER INFORMATION

Symbols and indication of danger:



Notice to reader: To the best of our knowledge, the information contained herein is accurate. However, neither the above named supplier, nor any of its subsidiaries, assumes any liability whatsoever for the accuracy or completeness of the information contained herein. Final determination of suitability of any material is the sole responsibility of the user. All material may present unknown hazards and should be used with caution. Although certain hazards are described herein, we cannot guarantee that these are the only hazards that exist.

 ISO 13485 ISO 9001			
 Diagnostic Automation/Cortez Diagnostics, Inc. 21250 Califa Street, Suite 102 and 116, Woodland Hills, California 91367 USA			
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<table border="1"> <tr> <td>EC</td> <td>REP</td> </tr> </table>	EC	REP	CEpartner4U, Esdoornlaan 13, 3951DB Maarn. The Netherlands. www.cepartner4u.eu
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