

**Section 1 – Product and Company Identification**

**Manufacturer Information**

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**Product Information**

**Product Name:** QuickVue+ Mononucleosis Test (Catalog #: 20121)

**Recommended Use:** The QuickVue+ Mononucleosis test is a rapid Color ImmunoChromatographic Assay (CICA) for the detection of Infectious Mononucleosis IgM heterophile antibodies in serum, plasma or whole blood. This test is intended for use as an aid in the diagnosis of Infectious Mononucleosis for use by healthcare professionals.

**Components:** Kit is composed of individually pouched reaction units, Developer, Mono Negative Control, Mono Positive Control, sample pipettes and capillary tubes.


**Section 2 – Hazards Identification**

**Emergency Overview**

Significant health effects are not anticipated from routine use of this kit when following the precautions listed within this SDS and the kit specific Package Insert. The Developer, Mono Positive and Mono Negative Controls (0.2% Sodium Azide) within this kit are considered hazardous as defined by the Occupational Safety and Health Administration (OSHA), the Canadian Workplace Materials Information System (WHMIS), or the European Union (EU) Directives 1999/45/EC, 67/548/EEC and/or 1272/2008.

OSHA Hazards	Target Organs	GHS Classification
None	No data available	Acute Toxicity, Oral (Category 4) Acute Toxicity, Dermal (Category 5) Chronic Aquatic, Toxicity (Category 3)

**GHS Classification and Label Elements**

Component(s)	Pictogram	Signal Word	Hazard Statements	Precautionary Statements
Developer, Positive Control, and Negative Control		Warning	H303 May be harmful if swallowed.  H313 May be harmful in contact with skin.  H412 Harmful to aquatic life with long lasting effects	P264 Wash hands thoroughly after handling  P273 Avoid release to the environment.  P281 Use personal protective equipment, as required
<b>Supplemental Hazard Statements</b>			1. Avoid release to the environment. 2. Follow Universal Precautions when handling the Developer, Mono Positive and Mono Negative Controls.	

### Section 3 – Composition / Information on Ingredients

Component	Chemical Name	CAS #	EINECS #	Concentration (%)	Volume
Developer	Sodium Azide	26628-22-8	247-852-1	0.2	5 mL
	PEG-8000	25322-68-3	500-038-2	2.0	
Mono Positive Control	Sodium Azide	26628-22-8	247-852-1	0.2	1 mL
	Plasma, Mono Positive	--	--	3.86	
Mono Negative Control	Sodium Azide	26628-22-8	247-852-1	0.2	1 mL
	Plasma, Human	--	--	2.8	

### Section 4 – First Aid Measures

#### General Advice

Move out of the exposure area. Show this safety data sheet to the doctor in attendance, as necessary.

- If inhaled:* Move the person to fresh air and support breathing as required.
- In case of skin contact:* Wash affected area with soap and water. Seek medical advice if irritation develops.
- In case of eye contact:* Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing. If eye irritation persists get medical attention.
- If swallowed:* Never give anything by mouth to an unconscious person. Rinse mouth with water. Seek medical advice if irritation develops.

#### Most important symptoms and effects, both acute and delayed

To the best of our knowledge, the chemical, physical, and toxicological properties have not been thoroughly investigated.

#### Indication of any immediate medical attention and special treatment needed

No data available.

### Section 5 – Fire Fighting Measures

#### General Advice

Only individuals properly trained and issued appropriate personal protective equipment should respond and attempt to extinguish a fire.

- Suitable Extinguishing Media:* For small fires, use dry chemical, carbon dioxide or alcohol-resistant foam.
- General Fire Hazards:* The components within this kit will not significantly contribute to the intensity of a fire.
- Hazardous Combustion Products:* No data available.
- Fire Fighting Equipment:* Firefighters should wear full protective gear when responding to fires.

### Section 6 – Accidental Release Measures

#### General Advice

Only individuals properly trained and issued appropriate personal protective equipment should respond and attempt to clean up a spill or release. Large spills of the solutions, controls or reagents contained within this kit are unlikely.

- Personal Precautions:* Use personal protective equipment, including protective gloves and safety glasses when cleaning up small spills. Avoid breathing vapors, mist or gas. Ensure adequate ventilation. Keep all unnecessary personnel away from the spill area.

## Section 6 – Accidental Release Measures (cont'd)

### Materials and Methods

#### for Clean-Up:

Wipe up with appropriate absorbent (e.g., paper towel, etc.). Thoroughly wash the area with soap and water.

#### Recovery and Neutralization:

Collect spilled material and clean-up supplies and place in sealed container for disposal. Refer to Section 13 for disposal guidance.

#### Environmental Precautions:

Contain spill to prevent migration to public industrial / sanitary sewers or open water sources.

## Section 7 – Handling and Storage

**Specific Use:** For *in vitro* diagnostic use only – Not for use by the general public.

### Precautions for Safe Handling

As with all chemical and biological substances, avoid getting the components within this kit on you or in you. Wash exposed areas thoroughly after using this kit. Do not eat or drink while using this kit. This kit should be handled only by qualified clinical or laboratory employees trained on the use of this kit and who are familiar with the potential hazards. Universal Precautions should be followed when handling and working with this kit. Keep out of reach of the general public.

**Conditions for Safe Storage:** To maintain efficacy, store according to the instructions in the kit specific Package Insert.

**Incompatibilities:** None.

## Section 8 – Exposure Controls and Personal Protection

**Exposure Limits:** Contains no components with occupational exposure limit values.

### Exposure Controls:

#### Engineering Measures

Use with adequate ventilation to maintain worker exposure below limits listed above.

#### Personal Protective Equipment

##### Respiratory Protection:

None needed under normal conditions of use.

##### Hand Protection:

Handle with appropriately rated chemical resistant gloves (nitrile or equivalent). Gloves should be inspected prior to use. Use proper glove technique to remove gloves to avoid contact with skin. Wash hands after handling the components within this kit.

##### Eye Protection:

Wear safety glasses with side shields or goggles to prevent eye contact.

##### Skin and Body Protection:

Use body protection appropriate for the task. A laboratory coat is recommended.

##### Hygiene Measures:

Handle in accordance with good industrial hygiene and safety practice. Wash hands before and after use and at the end of the workday.

### Environmental Exposure Controls

No special environmental controls are required.

**Section 9 – Physical and Chemical Properties**

Characteristic	Developer	Mono Positive Control	Mono Negative Control
Boiling Point (°C)	No data available	No data available	No data available
Melting Point (°C)	No data available	No data available	No data available
Specific Gravity (H <sub>2</sub> O = 1)	No data available	No data available	No data available
Vapor Pressure (mm Hg)	No data available	No data available	No data available
Vapor Density (Air = 1)	No data available	No data available	No data available
Evaporation Rate (Ether = 1)	No data available	No data available	No data available
pH	Neutral	Neutral	Neutral
Solubility in Water	Soluble	Soluble	Soluble
Appearance and Odor	Clear to slightly yellow; odorless	Clear to slightly yellow; odorless	Clear to slightly yellow; odorless

**Section 10 – Stability and Reactivity**

Characteristic	Developer	Mono Positive Control	Mono Negative Control
Component Stability	Stable	Stable	Stable
Hazard Reaction Potential	Will not occur	Will not occur	Will not occur
Conditions to Avoid	None	None	None
Materials to Avoid	None	None	None
Hazardous Decomposition Products	No data available	No data available	No data available

**Additional Information:**

Sodium azide is present in the Developer, Mono Positive and Mono Negative Controls (as a preservative). Contact with acidic solutions or metal compounds over time may form potentially explosive metal azides. Avoid disposal into a sanitary sewer system.

**Section 11 – Toxicological Information**
**Acute Toxicity**
**Component Analysis – LD50 / LC50**

Chemical Name	CAS #	RTECS #	Information
Sodium Azide	26628-22-8	VY8050000	Oral LD <sub>50</sub> Rabbit 10 mg/kg
			Inhalation LC <sub>50</sub> Rat 37 mg/m <sup>3</sup>
			Dermal LD <sub>50</sub> Rabbit 20 mg/kg
Polyethylene Glycol	25322-68-3	TQ1000000	Oral LD <sub>50</sub> Rat 28,000 mg/kg
			Inhalation LC <sub>50</sub> -- No data
			Dermal LD <sub>50</sub> Rabbit 20,000 mg/kg

**Potential Health Effects**

<i>Skin Corrosion/ Irritation:</i>	No data available.	<i>Inhalation:</i>	May cause respiratory tract irritation.
<i>Serious Eye Damage / Irritation:</i>	No data available.	<i>Skin:</i>	May cause skin irritation upon contact.
<i>Respiratory or Skin Sensitization:</i>	No data available.	<i>Eyes:</i>	May cause eye irritation.
<i>Generative Cell Mutagenicity:</i>	No data available.	<i>Ingestion:</i>	May be harmful if swallowed.

### Section 11 – Toxicological Information (cont'd)

**Carcinogenicity**

The chemicals in the Positive and Negative Controls are not listed as carcinogens by any of the following: ACGIH, IARC, NTP or OSHA.

<b>Reproductive Toxicity</b>	No data available.	<b>Teratogenicity</b>	No data available.
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**Specified Target Organ General Toxicity**

<i>Single Exposure (GHS):</i>	No data available.	<i>Repeated Exposure (GHS):</i>	No data available.
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**Aspiration Respiratory Organs Hazard**

None anticipated under product use conditions.

**Signs and Symptoms of Exposure**

To the best of our knowledge, the chemical, physical, and toxicological properties have not been thoroughly investigated for the components contained within this kit.

**Synergistic Effects** No data available.

**Additional Information** No data available.

### Section 12 – Ecological Information

<b>Ecotoxicity</b>	No data available.	<b>Mobility in Soil</b>	No data available.
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<b>Persistence / Degradability</b>	No data available.	<b>PBT and vPvB Assessment</b>	No data available.
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**Bioaccumulation** No data available.

**Other Adverse Effects** An environmental hazard cannot be excluded in the event of unprofessional handling or disposal. The sodium azide (0.2%) within the Developer, Mono Positive and Mono Negative Controls may be harmful to aquatic life with long lasting effects.

### Section 13 – Disposal Considerations

**Waste Disposal Instructions**

Utilize appropriate personal protective equipment and spill control when handling wastes generated from using this kit. Do not discharge the Developer, Mono Positive or Mono Negative Controls into drains, water courses or onto the ground.

**Disposal of Product and Contaminated Packaging**

Dispose of waste materials, unused components and contaminated packaging in compliance with country (e.g., Canada, EU, Japan, etc.), federal, state and local regulations. If unsure of the applicable regulatory requirements, contact the authorities for information.

### Section 14 – Transportation Information

<b>U.S. Department of Transportation (DOT)</b>	Not regulated as a hazardous material.
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<b>International Air Transportation (IATA)</b>	Not regulated as a dangerous good.
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<b>International Maritime Dangerous Goods (IMDG)</b>	Not regulated as a dangerous good.
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### Section 15 – Regulatory Information

**Regulatory Information**
**U.S. Federal Regulations**

- OSHA Hazards** No known OSHA hazards.
- SARA 302** No chemicals in this kit are subject to the reporting requirements of SARA Title III, Section 302.
- SARA 313** This material does not contain any chemical components with known CAS numbers that exceed the threshold (De Minimis) reporting levels established by SARA Title III, Section 313.
- SARA 311/312** No SARA Hazards.

**State Regulations**

The following chemicals appear on one or more of the following state hazardous substances lists:

Chemical Name	CAS #	CA	MA	MN	NJ	PA
Sodium Azide	26628-22-8	Yes	Yes	Yes	Yes	Yes
Polyethylene Glycol	25322-68-3	No	No	Yes	No	No

**California Proposition 65**


This product does not contain any chemicals known to the State of California to cause cancer, birth, or any other reproductive defects.

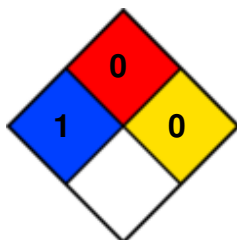
**Canadian - WHMIS IDL**

Chemical Name	CAS #	Minimum Concentration
Sodium Azide	26628-22-8	Not WHMIS Controlled below 1%
Polyethylene Glycol	25322-68-3	Not WHMIS Controlled

**Additional Regulatory Information**

- Safety, Health and Environmental regulations/legislation specific for the mixture** No data available.
- Chemical Safety Assessment** No data available.
- European Directive 67/548/EEC as amended**

Danger Symbol	Risk Phrases	Safety Phrases
Developer, Mono Positive and Mono Negative Controls   Xi Irritant	R32: Contact with acids liberates very toxic gas.	S24/25: Avoid contact with skin and eyes.  S29/35: Do not empty into drains; dispose of this material and its container in a safe way.

**NFPA 704 Rating**

**HMIS Classification**


**Section 16 – Other Information**

**PREPARED BY:** Quidel Corporation  
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**SUPERCEDES:** May 12, 2010

**REVISIONS:** Updated to GHS format and new brand.

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