

## Section 1 – Product and Company Identification

### Manufacturer Information

Quidel Corporation	Phone: 1.800.874.1517	Web: <a href="http://quidel.com">quidel.com</a>
2005 East State Street, Suite 100	Fax: 1.740.592.9820	E-mail: <a href="mailto:gehs@quidel.com">gehs@quidel.com</a>
Athens, OH 45701	Emergency #: 1.866.519.4752	

### Product Information

Product Name: D<sup>3</sup> Ultra DFA “Family” Screening and Identification Kit (Catalog #: 01-010000.v2, 01-010001.v2, 01-010002.v2, 01-010003.v2, 01-010004.v2, 01-010005.v2, 01-010006.v2, 01-010007.v2)

Intended Use: Identification kit intended for use in the qualitative detection and identification of influenza A virus, influenza B virus, respiratory syncytial virus (RSV), adenovirus, and parainfluenza virus types 1, 2 and 3 in respiratory specimens, by either direct detection or cell culture method, by immunofluorescence using fluoresceinated monoclonal antibodies (MAbs).


Components: Respiratory Virus DFA Screening Reagent (01-013010.v2), Influenza A DFA Reagent (01-013102.v2), Influenza B DFA Reagent (01-013202.v2), RSV Reagent (01-013302.v2), Adenovirus Reagent (01-013402.v2), Parainfluenza 1 Reagent (01-013502.v2), Parainfluenza 2 Reagent (01-013602.v2), Parainfluenza 3 Reagent (01-013702.v2), Normal Mouse Gamma Globulin DFA Reagent (01-015010), Respiratory Virus Antigen Control Slide (01-014005), 40X Wash Solution Concentrate (01-001025), and Mounting Fluid (01-002015).

## Section 2 – Hazards Identification

### Emergency Overview

Kit Component	OSHA Hazards	Target Organs	GHS Classification
<b>40X Wash Solution Concentrate</b> (Sodium Azide, 4%)	Toxic, Irritant	Eyes, Skin	Acute toxicity, Oral (Category 4) Acute aquatic toxicity (Category 3) Skin Irritation (Category 2) Eye Irritation (Category 2A) Chronic aquatic toxicity (Category 3)

### GHS Classification and Label Elements

Component	Pictogram	Hazard Statements	Precautionary Statements
<b>40X Wash Solution Concentrate</b> (Sodium Azide, 4%)		H302 Harmful if swallowed. H315 Causes skin irritation. H320 Causes eye irritation.	P264 Wash hands thoroughly after handling. P273 Avoid release to the environment. P280 Wear protective gloves and safety glasses.
	<b>Signal Word</b>	H412 Harmful to aquatic life with long lasting effects.	P308+P313: If exposed or concerned – get medical advice/attention.
	<b>Warning</b>		P305+P351+P338: IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing.
<b>Supplemental Hazard Statements</b>		1. Follow Universal Precautions when working with this kit. Refer to additional information in Section 7, Handling and Storage. 2. Sodium azide is used as a preservative (<0.1%) in the D <sup>3</sup> Ultra DFA Reagents, Normal Mouse Gamma Globulin DFA Reagent and Mounting Fluid. 3. Sodium azide may react with lead and copper plumbing to form highly explosive metal azides. Avoid disposal of this material down sanitary or industrial plumbing systems.	

## Section 2 – Hazards Identification (cont'd)

**Supplemental Hazard Statements**

4. Sodium azide – contact with acids liberates very toxic gas.
5. Sodium azide may readily be absorbed through the skin.
6. Evans Blue is used in the D<sup>3</sup> Ultra DFA Reagents and Normal Mouse Gamma Globulin DFA Reagent at a concentration of <0.01%. Evans Blue is a possible carcinogen and may cause cancer (IARC Group 3).
7. D3 Ultra DFA Reagents contain various combinations of adenovirus, influenza A, influenza B, respiratory syncytial virus, parainfluenza virus types 1, 2, and 3 and Normal Mouse Gamma Globulin.
8. Respiratory Viruses Antigen Control Slides are microscope slides onto which cultured cells infected with adenovirus, influenza A, influenza B, respiratory syncytial virus, and parainfluenza virus types 1, 2 and 3, have been grown then fixed (killed) with acetone; a drying agent is included in the foil envelope to preserve antigen integrity; there is no residual acetone present.
9. N-Propylgallate is used in the Mounting Fluid at a concentration of 0.11%. May act as a skin or respiratory sensitizer to some individuals.
10. 40X Wash Solution Concentrate is provided at a concentration of 4% sodium azide (0.1% sodium azide after dilution to 1X using de-mineralized water by the end-user).

## Section 3 – Composition / Information on Ingredients

Component	Chemical Name	CAS #	EINECS #	Conc. (%)	Component Volume
<b>40X Wash Solution Concentrate</b>	Sodium Chloride	7647-14-5	231-598-3	<36	25 mL
	Sodium Azide	26628-22-8	247-852-1	4	
<b>Mounting Fluid</b>	Glycerol	56-81-5	200-289-5	60	7 mL

**NOTE:** All of the above reagents, buffers, solutions or fluids are considered 'Mixtures'.

## Section 4 – First Aid Measures

**General Advice**

Move out of exposure area. Consult a physician. 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 (do not swallow). Seek medical advice if irritation develops.
- Note to Physicians:* Treat symptomatically.

## 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, water spray, 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.

<i>Personal Precautions:</i>	Use personal protective equipment, including protective gloves and safety glasses when cleaning up small spills of the solutions, controls or reagents within this kit. Avoid breathing vapors, mist or gas. Ensure adequate ventilation. Keep all unnecessary personnel away from the spill area.
<i>Materials and Methods for Clean-Up:</i>	Wipe up with inert absorbent material (e.g., paper towel, etc.). Thoroughly wash the area with soap and water after a spill or release clean-up.
<i>Recovery and Neutralization:</i>	Collect spilled material and clean-up supplies and place in sealed container for disposal. Refer to Section 13 for disposal guidance.
<i>Environmental Precautions:</i>	Contain spill to prevent migration to drains, sewers or open water sources. Discharge into the environment must be avoided.

## Section 7 – Handling and Storage

**Specific Use:** Refer to product specific Package Insert. 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. Keep out of reach of the general public.

### Universal Precautions

No known test method can offer complete assurance that product(s) derived from human blood, serum or plasma used in components of this kit will not transmit infectious agents. All blood products should be treated as potentially infectious; use universal precautions. Users should ensure the use of proper personal protective equipment (PPE), covering of any cuts or abrasions on the skin (hands), and follow standard protocols for the decontamination of work surfaces when testing has been completed. Always wash hands thoroughly after handling the components within this kit.

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

**Incompatibilities** To maintain efficacy, store according to the kit specific Package Insert instructions.

## Section 8 – Exposure Controls and Personal Protection

**Exposure Limits:** No data available for the specific components within this kit.

### Exposure Controls:

<b>Engineering Measures</b>	Use with adequate ventilation. <u>40X Wash Solution Concentrate:</u> Avoid contact with skin, eyes, and clothing.
-----------------------------	--

### Personal Protective Equipment

<i>Respiratory Protection:</i>	None needed under normal conditions of use.
<i>Hand Protection:</i>	Handle with appropriately rated chemical resistant gloves. 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.
<i>Eye Protection:</i>	Wear safety glasses with side shields or goggles to prevent eye contact.

## Section 8 – Exposure Controls and Personal Protection (cont'd)

*Skin and Body Protection:* Use body protection appropriate for the task. A laboratory coat is recommended.

*Hygiene Measures:* 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	40X Wash Solution Concentrate
Boiling Point (°C)	No data available
Melting Point (°C)	No data available
Specific Gravity (H <sub>2</sub> O = 1)	No data available
Vapor Pressure (mm Hg)	No data available
Vapor Density (Air = 1)	No data available
Evaporation Rate (Ether = 1)	No data available
pH	7.0 - 7.6
Solubility in Water	Soluble
Appearance and Odor	Clear liquid, mild odor

## Section 10 – Stability and Reactivity

Characteristic	40X Wash Solution Concentrate
Component Stability	Stable
Hazard Reaction Potential	No data available
Conditions to Avoid	No data available
Materials to Avoid	No data available
Hazardous Decomposition Products	No data available

## Section 11 – Toxicological Information

### Acute Toxicity

**Component Analysis – LD<sub>50</sub> / LC<sub>50</sub> / Irritation** (No data available for specific kit components)

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

**Potential Health Effects:** 40X Wash Solution Concentrate: Toxic, Irritant

*Skin Corrosion/ Irritation:* No data available

*Inhalation:* May cause respiratory tract irritation.

*Serious Eye Damage / Irritation:* No data available

*Skin:* May cause skin irritation upon contact.

*Respiratory or Skin Sensitization:* No data available

*Eyes:* May cause serious eye irritation.

*Generative Cell Mutagenicity:* No data available

*Ingestion:* May be harmful if swallowed.

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

### Carcinogenicity

D<sup>3</sup> Ultra DFA Reagents and Normal Mouse Gamma Globulin DFA Reagent:

Evans Blue IARC Group 3: Not classifiable as to its carcinogenicity to humans.

### Reproductive Toxicity

No data available

### Teratogenicity

No data available

### Specified Target Organ General Toxicity (GHS)

*Single Exposure (GHS):* No data available

*Repeated Exposure (GHS):* No data available

### Aspiration Respiratory Organs Hazard

None anticipated under product use conditions.

### Synergistic Effects

No data available

### Additional Information

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

40X Wash Solution Concentrate: Liver – irregularities – Based on Human Evidence (Sodium Azide)

## Section 12 – Ecological Information

### Ecotoxicity

No data available

### Mobility in Soil

No data available

### Persistence / Degradability

No data available

### PBT and vPvB Assessment

No data available

### Bioaccumulation

No data available

### Other Adverse Effects

An environmental hazard cannot be excluded in the event of unprofessional handling or disposal.

40X Wash Solution Concentrate: Sodium azide – very toxic to aquatic life with long lasting effects.

Avoid the release of any of the reagents, buffers or solutions contained in this kit to the environment.

## 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 any of the solutions, reagents, controls, cultures or media 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, federal, state and local regulations. If unsure of the applicable regulatory requirements, contact a licensed professional waste disposal service to dispose of this material.



**Section 16 – Other Information**

**PREPARED BY:** Quidel Corporation  
12544 High Bluff Drive, Suite 200  
San Diego, CA 92130

**SUPERCEDES:** May 10, 2016

**REVISIONS:** Update Section 2, Added comments to Supplemental Hazar Statements; Section 3, removed ‘Chemical Classification’ column; Section 7, added Universal Precautions statement; Section 10, updated ‘Materials to Avoid’ information; Section 12, added sodium azide statement; Section 15, updated Canadian WHMIS information, added EU regulatory reference, and removed HMIS information; Section 16, removed Text of H-Codes; and general formatting updates.

The information above is provided in good faith. It is believed to be accurate and represents the best information currently available to us. However, we make no warranty of merchantability, fitness for a particular purpose or of any other type, expressed or implied, with respect to products described or data or information provided, and we assume no liability resulting from the use of such products, data or information. Users should make their own investigations to determine the suitability of the information for their particular purposes, and the user assumes all risk arising from their use of the material. The user is required to comply with all laws and regulations relating to the purchase, use, storage and disposal of the material, and must be familiar with and follow generally accepted safe handling procedures. In no event shall Quidel be liable for any claims, losses, or damages of any individual or for lost profits or any special, indirect, incidental, consequential or exemplary damages of any kind, howsoever arising, even if Quidel has been advised of the possibility of such damages.

SD1670002EN00 (09/18)