

Product Code: 01-01#### (where # equals the individual D³ Ultra™ DFA product designation)
Product Name: D³ Ultra™ DFA “Family” Screening and Identification Kits/Sets

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1. Information on the Substance/Preparation and Company

1.1	<u>Catalog #</u>	<u>Product name</u>
	01-010000.v2	D ³ Ultra™ DFA Respiratory Virus Screening & ID Kit
	01-010001.v2	D ³ Ultra™ DFA Respiratory Virus Direct Specimen Screening Set
	01-010002.v2	D ³ Ultra™ DFA Respiratory Virus Shell Vial Screening Set
	01-010003.v2	D ³ Ultra™ DFA RSV Screening Set
	01-010004.v2	D ³ Ultra™ DFA Influenza A / Influenza B Reagent Set, 2-mL
	01-010005.v2	D ³ Ultra™ DFA Influenza A / Influenza B Reagent Set, 10-mL
	01-010006.v2	D ³ Ultra™ DFA Parainfluenza Reagent Set
	01-010007.v2	D ³ Ultra™ DFA Respiratory Virus ID Kit
		<u>Kit components</u>
	01-013010.v2	D ³ Ultra™ DFA Respiratory Virus Screening Reagent
	01-013102.v2	D ³ Ultra™ DFA Influenza A Reagent
	01-013202.v2	D ³ Ultra™ DFA Influenza B Reagent
	01-013302.v2	D ³ Ultra™ DFA RSV Reagent
	01-013402.v2	D ³ Ultra™ DFA Adenovirus Reagent
	01-013502.v2	D ³ Ultra™ DFA Parainfluenza 1 Reagent
	01-013602.v2	D ³ Ultra™ DFA Parainfluenza 2 Reagent
	01-013702.v2	D ³ Ultra™ DFA Parainfluenza 3 Reagent
	01-014005	Respiratory Virus Antigen Control Slide
	01-015010	Normal Mouse Gamma Globulin DFA Reagent
	01-001025	40X Wash Solution Concentrate
	01-002015	Mounting Fluid
1.2	<u>Company</u>	Diagnostic HYBRIDS, Inc. 1055 East State Street, Suite 100 Athens, OH 45701, USA (740) 589-3300 or (866) 344-3477
1.3	<u>In emergencies</u>	Call your local emergency center

2. Components and Hazardous Ingredients

<u>Kit Component</u>	<u>Hazardous Ingredients</u>	<u>Classification Substance</u>	<u>EINECS Nr.</u>
DFA Reagents*	0.1% Sodium azide (NaN ₃)	T+, N, R28-32-50/53	247-852-1
	0.007% Evans Blue	T, R23/24, 33, 40	206-242-5
	Fluorescein Isothiocyanate (FITC)	Xi, R36/37/38	222-042-0
	Contains bovine and murine proteins		
40X Wash Solution Concentrate	4% Sodium azide (NaN ₃)	T+, N, R28-32-50/53	247-852-1
	0.04% Tween 20	(none listed)	(unlisted)
	36% NaCl	Xi, O, R36/37/38	231-598-3
Mounting Fluid	60% Glycerol	Xi, R36/37/38	200-289-5
	0.1% Sodium azide (NaN ₃)	T+, N, R28-32-50/53	247-852-1
	0.1% n-Propylgallate	Xn, R20/21/22, 43	204-498-2
Antigen Control Slide†	Glass		

Classification key: Toxic (T); Very toxic (T+); Harmful (Xn); Irritant (Xi); Dangerous for the environment (N); Oxidizing agent (O); Explosive (E); Flammable (F)

* Respiratory Virus DFA Screening Reagent and the individual DFA Reagents [for Adenovirus, Influenza A, Influenza B, Respiratory Syncytial Virus, Parainfluenza 1, Parainfluenza 2, Parainfluenza 3] and Normal Mouse Gamma Globulin.

† Respiratory Viruses Antigen Control Slides are microscope slides onto which cultured cells infected with Adenovirus, Influenza A, Influenza B, Respiratory Syncytial Virus, Parainfluenza 1, Parainfluenza 2, Parainfluenza 3, have been grown then fixed

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(killed) with acetone; a drying agent is included in the foil envelope to preserve antigen integrity; there is no residual acetone present.

3. Hazards Identification

DFA Reagents

Solution Toxic if swallowed

Irritating to eyes, respiratory system and skin

Harmful to aquatic organisms, may cause long-term adverse effects in the aquatic environment

Contains animal proteins. Allergy or hypersensitivity to proteins (e.g., antibodies).

Wash Solution Concentrate (40X) and the diluted Wash Solution (1X)

Solution very Toxic if swallowed

Irritating to eyes, respiratory system and skin

Harmful to aquatic organisms, may cause long-term adverse effects in the aquatic environment

Mounting Fluid

Solution Toxic if swallowed

Irritating to eyes, respiratory system and skin

Harmful to aquatic organisms, may cause long-term adverse effects in the aquatic environment

Antigen Control Slide

If glass slide is broken, may pose a cut-skin hazard.

4. First Aid Measures

Eye contact:

- Flush eyes immediately with water for 15 minutes, occasionally lifting the upper and lower eyelids
- Consult a doctor/medical service if irritation persists

Skin contact:

- Rinse with plenty of water
- Remove clothing before washing
- Consult a doctor/medical service if irritation persists

After inhalation:

- Remove the victim into fresh air
- Consult a doctor/medical service if breathing problems develop

After ingestion:

- Consult a doctor/medical service if you feel unwell

5. Fire Fighting Measures

Suitable extinguishing media:

- All non combustible extinguishing media allowed

Unsuitable extinguishing media:

- No data available

Special exposure hazards:

- Aqueous solutions of sodium azide, when mixed with acids, may liberate a toxic gas (hydrazoic acid).
- Sodium azide may react with lead and copper plumbing to form highly explosive metal azides.

Instructions:

- Take account of toxic fire fighting water
- Use fire fighting water moderately and contain it

Special protective equipment for firefighters:

- Heat/fire exposure: compressed air/oxygen apparatus
- Heat/fire exposure: gas-tight suit

6. Accidental Release Measures

Personal protection:

- See 8, below

Environmental precautions:

- Prevent soil and water pollution
- Discharge according to local regulations

Clean-up:

- Take up liquid spill into absorbent material
- Discharge of absorbed material according to local regulations

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- Clean contaminated surfaces with an excess of water
- Wash clothing and equipment after handling

7. Handling and Storage

- Handling:*
- Product should be handled using Good Laboratory Practices.
 - Observe strict hygiene standards
 - Discharge according to local regulations
 - Remove and clean contaminated clothing
 - Handle and open the container with care
- Storage:*
- Keep away from: heat sources, acids, metals
 - 2° to 8°C; store in the dark

8. Exposure Controls/Personal Protection

8.1 Exposure Limits

Chemical/Component	TLV/NIOSH REL	OSHA PEL	CAS No.
Sodium azide (as NaN ₃)	0.3 mg/m ³ ACGIH TLV-VL	Not listed	2628-22-8
Sodium azide (as HN ₃)	0.1 ppm	Not listed	7782-79-8
Glycerol (C ₃ H ₈ O ₃)	10 mg/m ³ ACGIH TLV-TWA	Not listed	56-81-5
n-Propylgallate	Not determined	Not listed	121-79-9
Tween 20	Not determined	Not listed	9005-64-5
Evans Blue	Not determined	Not listed	314-13-6
Fluorescein Isothiocyanate (FITC)	Not determined	Not listed	3326-32-7

Information in above table from NIOSH Pocket Guide to Chemical Hazards, 2005.

n-Propylgallate: Propyl 3,4,5-trihydroxybenzoate; C₁₀H₁₂O₅

Tween® 20: Polysorbate 20, Sorbitan, monododecanoate, poly(oxy-1,2-ethanediyl) derivatives; 1,2-di-(dimethylamino) ethane; (C₂H₄O)_n - C₁₄H₂₂O, n=9-10.

Evans Blue (C₂₄H₂₄N₆O₁₄S₄•4Na): 1,3 - Naphthalenedisulfonic acid, 6,6' - ((3,3' - dimethyl-4,4' - biphenylene) bis (azo)) bis (4-amino-5-hydroxy- , tetrasodium salt)

5-Fluorescein Isothiocyanate (C₂₁H₁₁NO₅S): Spiro[isobenzofuran-1(3H),9'-[9H]xanthen]-3-one, 3',6'-dihydroxy-5-isothiocyanato-

8.2 Control of Exposure

- Eye protection:*
- Safety glasses or Face shield
- Hand protection:*
- Gloves
 - Suitable materials: Butyl rubber, natural rubber, neoprene, nitrile rubber, polyethylene, PVC
 - Hands should be washed after working with this product.
- Skin protection:*
- Corrosion proof clothing
 - Protective clothing
- Respiratory protection:*
- Area ventilation is generally adequate; avoid generation of dusts, mists or other airborne forms when working with the product
 - Insufficient ventilation: wear respiratory protection

9. Physical and Chemical Properties

DFA Reagents*	: clear blue solutions; odorless
Wash Solution Concentrate	: a clear solution; odorless
Mounting Fluid	: a clear colorless, slightly viscous, solution
Antigen Control Slide	: glass microscope slides, coated with a white pigment except for eight clear areas; the clear areas are coated with acetone-fixed cellular material.

* Respiratory Virus DFA Screening Reagent and the individual DFA Reagents [for Adenovirus, Influenza A, Influenza B, Respiratory Syncytial Virus, Parainfluenza 1, Parainfluenza 2, Parainfluenza 3] and Normal Mouse Gamma Globulin.

Note: Boiling and Freezing Points for all aqueous components are near those of pure water.

10. Stability and Reactivity

- *Stability:* All components are stable until expiry date if stored in specified conditions (see label)
- *Reactivity/Hazardous decomposition products:* No hazardous decomposition products are formed in high quantities

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- *Conditions/Materials to avoid:* Keep away from metals and acids (Azide containing components)

11. Toxicological Information

Acute toxicity:

<i>Sodium azide:</i>	LD ₅₀ oral rat	27 mg/kg
	LD ₅₀ dermal rabbit	20 mg/kg
<i>Evans Blue:</i>	LD ₅₀ intraperitoneal mouse	340 mg/kg
<i>Propylgallate:</i>	LD ₅₀ oral, mouse	1700 mg/kg
	LD ₅₀ oral, rat	2100 mg/kg
	LD ₅₀ oral, rabbit	2750 mg/kg
<i>NaCl:</i>	LD ₅₀ oral rat	3,000 mg/kg
	LD ₅₀ dermal rabbit	> 10,000 mg/kg
<i>Glycerol:</i>	LD ₅₀ oral, mouse	4090 mg/kg
	LD ₅₀ oral, rat	12,600 mg/kg
<i>Tween 20:</i>	LD ₅₀ oral, mouse	>33 gm/kg
	LD ₅₀ oral, rat	36,700 uL/kg
<i>FITC:</i>	LD ₅₀ : Not available	

Chronic toxicity:

<i>Sodium azide:</i>	<ul style="list-style-type: none"> ▪ Carcinogenicity (TLV-CL): A4 ▪ Target Organ(s): nerves, heart, brain; laboratory experiments have shown mutagenic effects
<i>Evans Blue:</i>	<ul style="list-style-type: none"> ▪ Carcinogen ▪ Target Organ(s): liver
<i>Propylgallate:</i>	Target Organ(s): gastrointestinal tract, lungs
<i>Glycerol:</i>	Target Organ(s): kidney
<i>Tween 20:</i>	Teratogen, Reproductive Hazard Target Organ(s): gastrointestinal tract, lungs
<i>NaCl:</i>	Target Organ(s): skin, eyes, stomach; mutagenic for bacteria and/or yeast
<i>FITC:</i>	Target Organ(s): lungs

Routes of exposure

- Ingestion, inhalation, eyes and skin
- Caution! Most components contain (a) substance(s) that are absorbed through the skin

Acute effects/symptoms

Sodium azide containing components: May be harmful or fatal by ingestion, inhalation or absorption through skin. Material may cause irritation to the skin and eyes. Exposure to material may cause the following: headache nausea, vomiting, diarrhea, dizziness, weakness, blurred vision, shortness of breath, drop in blood pressure, bradycardia, and restlessness. May be fatal due to swelling of the brain and lungs and/or degeneration of the liver. Experiments have shown animals to produce hypotensive effects, demyelination of myelinated nerve fibers in the CNS, testicular damage, blindness, attacks of rigidity, hepatic and cerebral effects.

Evans Blue containing components: Harmful if swallowed, inhaled, or absorbed through skin.

Chronic effects

Sodium azide containing components: Prolonged or repeated exposure to material may cause the following: Hypotension, demyelination of myelinated nerve fibers in the central nervous system, testicular damage, blindness, and attacks of rigidity. Material may cause brain and liver damage. There is limited evidence that Sodium Azide is tumorigenic in laboratory animals. There is also limited evidence that Sodium Azide is mutagenic in laboratory cell cultures. Until further testing has been done, it Sodium Azide should be treated as a possible mutagen and tumorigen in humans.

Evans Blue containing components: Overexposure may cause reproductive disorders based on tests with laboratory animals. Target Organ: liver (carcinogen).

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See also Chronic Toxicity (above). Other components do not contain substances with a known chronic effect (e.g. carcinogenicity, mutagenicity, toxicity to reproduction)

12. Ecological Information

Aquatic toxicity:

<i>Sodium azide:</i>	LD ₅₀ (96 h):	0.8 mg/L (<i>Salmo gairdneri</i> / <i>Oncorhynchus mykiss</i>)
	LD ₅₀ (96 h):	0.7 mg/L (<i>Lepomis macrochirus</i>)
	LD ₅₀ (48 h):	9 mg/L (<i>Gammarus sp.</i>)

Other Information:

- *Effect on the ozone layer:* Not dangerous for the ozone layer (1999/45/EC)
- *Greenhouse effect:* No data available
- *Effect on waste water purification:* No data available

13. Waste Disposal Considerations

Provisions relating to waste: Hazardous waste (91/689/EEC)

Packaging/container:

- Waste material code packaging (91/689/EEC, Council Decision 2001/118/EC, O.J. L47 of 16/2/2001): 15 01 10 (packaging containing residues of or contaminated by dangerous substances)

Disposal methods:

- All the kit components must be considered as hazardous waste. They should be disposed of following local regulations.
- Sodium azide reacts with lead and copper plumbing forming highly explosive metal azides. These azides may explode upon percussion, such as hammering. To prevent formation of lead or copper azide, flush drains thoroughly with water after disposing of solutions containing sodium azide. To remove contamination from old drains suspected of azide accumulation, the National Institute for Occupational Safety and Health recommends the following: (1) siphon liquid from trap using a rubber or plastic hose, (2) fill drain with 10% sodium hydroxide solution, (3) allow to stand for 16 hours, and (4) flush well with water.

14. Transport Information

No restrictions.

USA: Sodium azide, 4%: Department of Transportation, Office of Hazardous Materials Standards: 29 CFR part 1910.1200(g)(2)(i)(C)(1), Toxic and Hazardous Substances, Occupational Safety and Health Administration; and 49 CFR 173.4 – Small quantity exceptions





Canada: Sodium azide, 4%: Transport of Dangerous Goods Regulations: TDFR 1.31 Class 1, Explosives exception; and TDFR 1.17 Limited Quantity

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15. Regulatory Information

Classification according to directives 67/548/EEC and 1999/45/EC

Symbol	40X Wash Solution Concentrate (4% Sodium azide)
 T	R26/27/28: Very Toxic by inhalation, in contact with skin and if swallowed R32: Contact with acids liberates very toxic gas R36/37/38: Irritating to eyes, respiratory system and skin R50/53: Very Toxic to aquatic organisms, may cause long-term adverse effects in the aquatic environment R68: Possible risk of irreversible effects
 N	S28: After contact with skin, wash immediately with plenty of water S36: Wear suitable protective clothing S46: If swallowed, seek medical advice immediately and show this container or label S60: This material and its container must be disposed of as hazardous waste S61: Avoid release to the environment. Refer to special instructions safety data sheet
Symbol	DFA Reagents and Mounting Fluid (0.1% Sodium azide)
	R23/24/25: Toxic by inhalation, in contact with skin and if swallowed R32: Contact with acids liberates very toxic gas R36/37/38: Irritating to eyes, respiratory system and skin R50/53: Very Toxic to aquatic organisms, may cause long-term adverse effects in the aquatic environment R68: Possible risk of irreversible effects
 N	S35: This material and its container must be disposed of in a safe way S36: Wear suitable protective clothing S46: If swallowed, seek medical advice immediately and show this container or label S61: Avoid release to the environment. Refer to special instructions safety data sheet

16. Other Information

- Based on: US 29 CFR 1910:1200(g); Canadian Hazardous Product Act, Part II; Directive 911155/EEC et seq.
- This product is designed for use by professionals.
- The above information is believed to be accurate and represents the information available to date, but Diagnostic Hybrids does not purport it to be all-inclusive; this should be used only as a guide.
- Refer to the Product Insert for this Product for additional details on the proper storage, handling, use, and disposal of the reagents included in this Product.
- Contact Diagnostic Hybrids, Inc. if additional information is required.

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