

Product Code: 01-120000, 01-120001, 01-120002, 01-120003 and kit components
Product Name: D³ FastPoint™ L-DFA™ Respiratory Virus Identification Kit

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1. Information on the Substance/Preparation and Company

1.1	Catalog #	Product name
	01-120000	D ³ FastPoint™ L-DFA™ Respiratory Virus Identification Kit
	01-120001	D ³ FastPoint™ L-DFA™ Influenza A/Influenza B Virus Identification Kit
	01-120002	D ³ FastPoint™ L-DFA™ RSV/MPV Identification Kit
	01-120003	D ³ FastPoint™ L-DFA™ Parainfluenza Virus/Adenovirus Identification Kit
		<u>Kit components for "D³ FastPoint™ L-DFA™"</u>
	01-123104	Influenza A/Influenza B Reagent
	01-123304	RSV/MPV Reagent
	01-123504	PIV/Adenovirus Reagent (Parainfluenza Virus/Adenovirus)
	01-122006	Re-suspension Buffer
	01-124001	Respiratory Virus Antigen Control Slide (individuals, 6-wells)
	01-124005	Respiratory Virus Antigen Control Slide (5-slides)
	01-124010	Respiratory Virus Antigen Control Slide (10-slides)
	01-090025	40X PBS Concentrate
	99-01-120050	Specimen Slides and Coverslips
	99-01-121050	Influenza A/Influenza B Specimen Slides and Coverslips
	99-01-122050	RSV / MPV Specimen Slides and Coverslips
	99-01-123050	Parainfluenza / Adenovirus Specimen Slides and Coverslips
	01-124101	Influenza A/Influenza B Antigen Control Slide (individuals, 2-wells)
	01-124105	Influenza A/Influenza B Antigen Control Slide (5-slides)
	01-124110	Influenza A/Influenza B Antigen Control Slide (10-slides)
	01-124201	RSV/MPV Antigen Control Slide (individuals, 2-wells)
	01-124205	RSV/MPV Antigen Control Slide (5-slides)
	01-124110	RSV/MPV Antigen Control Slide (10-slides)
	01-124301	Parainfluenza Virus/Adenovirus Antigen Control Slide (individuals, 2-wells)
	01-124305	Parainfluenza Virus/Adenovirus Antigen Control Slide (5-slides)
	01-124310	Parainfluenza Virus/Adenovirus Antigen Control Slide (10-slides)
1.2	Company	Diagnostic HYBRIDS, Inc. 1055 East State Street, Suite 100 Athens, OH 45701, USA (740) 589-3300 or (866) 344-3477
1.3	In emergencies	Call your local emergency center

2. Components and Hazardous Ingredients

Kit Component	Hazardous Ingredients	Classification Substance*	EINECS Nr.
L-DFA Reagents	0.1% Sodium azide (NaN ₃)	T+, N, R:28-32,50/53, S:26/28,61	247-852-1
	Evans Blue	T, R:23/24, 33, 40	206-242-5
	Fluorescein Isothiocyanate (FITC)	Xi, R:36/37/38	222-042-0
	R-Phycoerythrin (R-PE)	Xn, R22	231-791-2
	Propidium Iodide (PI)	Muta. Cat. 2, Xi, R:46,36/37/38	247-081-0
	Proprietary ingredients** Contains bovine and murine proteins	Xn, R:20/21/22,36/37/38, S:26,36 (none listed)	(unlisted) (none listed)
40X PBS Concentrate	4% Sodium azide (NaN ₃)	T+, N, R28-32,50/53, S:26/28,61	247-852-1
	36% NaCl	Xi, O, R36/37/38	231-598-3
Re-suspension Buffer	0.1% Sodium azide (NaN ₃)	T+, N, R28-32,50/53, S:26/28,61	247-852-1

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<u>Kit Component</u>	<u>Hazardous Ingredients</u>	<u>Classification Substance*</u>	<u>EINECS Nr.</u>
	Glycerol	Xi, R36/37/38	200-289-5
	Proprietary ingredients**	Xi, R36/37/38	(unlisted)

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)

** Proprietary ingredients: "Trade secret", as defined according to US Code of Federal Regulations volume 29, section 1910.1200(i).

[†] Antigen Control Slides are glass microscope slides, coated with a colored pigment except for designated areas (wells) onto which tissue culture and Class B viruses have been fixed (killed).

3. Hazards Identification

L-DFA Reagents

Solutions 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).

Re-suspension Buffer

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

40X PBS Concentrate and the diluted 1X PBS solution

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

Antigen Control Slide

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

4. First Aid Measures

L-DFA Reagents, 40X PBS Concentrate, Re-suspension Buffer

- Eye contact:*
- Flush eyes immediately with water for 15 minutes, occasionally lifting the upper and lower eyelids
 - Consult a doctor/medical service

- Skin contact:*
- Wash with soap
 - Rinse with plenty of water
 - Consult a doctor/medical service

- After inhalation:*
- Remove the victim into fresh air
 - Consult a doctor/medical service

- After ingestion:*
- Consult a doctor/medical service

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:*
- No data available

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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
▪ Wash clothing and equipment after handling

7. Handling and Storage

- Handling:* ▪ If solution is spilled: take up with an absorbent material; if contact is possible, wear gloves as protection.
▪ 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
▪ 15° to 30°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
Evans Blue	Not determined	Not listed	314-13-6
Fluorescein Isothiocyanate (FITC)	Not determined	Not listed	3326-32-7
R-Phycoerythrin (R-PE)	Not determined	Not listed	11016-17-4
Propidium Iodide (PI)	Not determined	Not listed	25535-16-4

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

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:* ▪ 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

L-DFA Reagents	: clear blue solutions; odorless
40X PBS Concentrate	: a clear solution; odorless
Re-suspension Buffer	: a clear colorless to tea colored, slightly viscous, solution
Antigen Control Slides	: glass microscope slides, coated with a colored pigment except for circular clear areas

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)

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- **Reactivity/Hazardous decomposition products:** No hazardous decomposition products are formed in high quantities
- **Conditions/Materials to avoid:** Keep away from metals and acids (Azide containing components); Strong oxidizing agents (Propidium Iodide).

11. Toxicological Information

Acute toxicity:

Sodium azide:	LD ₅₀ oral, rat LD ₅₀ dermal, rabbit	: 27 mg/kg : 20 mg/kg
Evans Blue:	LD ₅₀ intraperitoneal mouse	: 340 mg/kg
Propidium Iodide:	LD ₅₀ subcutaneous, mouse	: 16 mg/kg
Glycerol:	LD ₅₀ oral, mouse LD ₅₀ oral, rat	: 4090 mg/kg : 12,600 mg/kg
Re-suspension Buffer Proprietary ingredients:	LD ₅₀ oral, rat LD ₅₀ dermal, mouse	: 5900 mg/kg : 1210 mg/kg
NaCl:	LD ₅₀ oral rat LD ₅₀ dermal, rat	: 3,000 mg/kg : > 10,000 mg/kg
FITC:	LD ₅₀ : Not available	
R-PE:	LD ₅₀ : oral, rat	: 27 mg/kg
L-DFA Reagent Proprietary ingredients:	LD ₅₀ : Not available	

Chronic toxicity:

Sodium azide:	<ul style="list-style-type: none"> ▪ Carcinogenicity (TLV-CL): A4 ▪ Target Organ(s): nerves, heart, brain; laboratory experiments have shown mutagenic effects
Evans Blue:	<ul style="list-style-type: none"> ▪ Carcinogen ▪ Target Organ(s): liver
Propidium Iodide:	<ul style="list-style-type: none"> ▪ Potential Mutagen ▪ Target Organs(s): reproductive system, lungs, eyes, skin, stomach
Glycerol:	Target Organ(s): kidney
Re-suspension Buffer Proprietary ingredients:	Target Organ(s): kidney, liver, gastrointestinal tract disturbances
NaCl:	Target Organ(s): skin, eyes, stomach
FITC:	Target Organ(s): lungs
R-PE:	Target Organ(s): kidney, central nervous system
L-DFA Reagent Proprietary ingredients:	Target Organ(s): blood, gastrointestinal system

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, de-myelination 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.

Propidium Iodide containing components: Harmful if swallowed, inhaled or absorbed through skin. May

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cause heritable genetic damage. Irritating to eyes, respiratory system and skin. Toxic to aquatic organisms.

Chronic effects:

Sodium azide containing components: Prolonged or repeated exposure to material may cause the following: Hypotension, de-myelination 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).

Propidium Iodide containing components: Prolonged or repeated exposure to material may cause harm.

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:

Sodium azide:
 LD₅₀ (96 h): 0.8 mg/L (*Salmo gairdneri/Oncorhynchus mykiss*)
 LD₅₀ (96 h): 0.7 mg/L (*Lepomis macrochirus*)
 LD₅₀ (48 h): 9 mg/L (*Gammarus sp.*)

Propidium Iodide: No data available

Proprietary ingredients: No data available

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

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,





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Explosives exception; and TDFR 1.17 Limited Quantity

15. Regulatory Information

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

Symbol	40X PBS 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	S26: In case of contact with eyes, rinse immediately with plenty of water and seek medical advice S28: After contact with skin, wash immediately with plenty of water 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 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	L-DFA Reagents and Re-suspension Buffer (0.1% Sodium azide)
 Xn – harmful Xi – irritant	R23/24/25: Toxic by inhalation, in contact with skin and if swallowed R32: Contact with acids liberates very toxic gas R33: Danger of cumulative effects R36/37/38: Irritating to eyes, respiratory system and skin R40: Limited evidence of a carcinogenic effect R46: May cause heritable genetic damage R50/53: Very Toxic to aquatic organisms, may cause long-term adverse effects in the aquatic environment
 N	S26: In case of contact with eyes, rinse immediately with plenty of water and seek medical advice S28: After contact with skin, wash immediately with plenty of water 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 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

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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