



Material Safety Data Sheet

Legionella IgG, IgM ELISA

SECTION 1. Company Identification

Product name: **Legionella IgG, IgM ELISA**
 Catalog No.: 1652-1
 Synonyms: N/A
 Product description: ELISA-based Diagnostic Kit
 Intended Use: Laboratory *in-vitro* diagnostic use.
 Kit Storage: 2-8°C

Company: Diagnostic Automation Inc.
 Address: 21250 Califa St, Suite 102 & 116,
 Woodland Hills, CA 91367, USA.

Website: www.rapidtest.com
 Phone: 818-591-3030
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 E-mail: onestep@rapidtest.com

Emergency phone: Contact your local Emergency Health Provider.

SECTION 2. Hazards Identification

2.1 Classification of the substance or mixture

Main hazards: HCV by FDA approved tests, no test method can offer complete assurance that the abovementioned or any other infectious agents are absent, this reagent should be handled as recommended for any potentially infectious human serum or blood specimen.

Stop Solution

Classification – EC Skin Irrit. 2: H315; Eye Irrit. 2: H319;
 1272/2008

2.2 Label elements

Hazard Pictograms:



Signal Word:	Warning
Hazard Statement:	Skin Irrit. 2: H315 – Causes skin irritation. Eye Irrit. 2: H319 – Causes serious eye irritation.
Precautionary Statement: <u>Prevention</u>	P264 – Wash thoroughly after handling. P280 - Wear protective gloves/protective clothing/eye protection/face protection
Precautionary Statement: <u>Response</u>	P302+P352 – IF ON SKIN: Wash with plenty of water. P305+P351+P338 – IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing. P321 – Specific treatment (see on this label). P332+P313 – If skin irritation occurs: Get medical advice/attention. P337+P313 – If eye irritation persists: Get medical advice/attention.

SECTION 3. Information on Ingredients
3.1 Components and/or Mixtures
3.1.1 Conjugate
EC 1272/2008

Chemical Name	Index No.	CAS No.	EC No.	REACH Registration No.	Conc. (%w/w)	Classification	M-factor
ProClin 300					0-0.5%		
Bromonitrodioxane					0-0.5%		
Gentamicin Sulfate		1405-41-0			0-0.5%		

3.1.2 High Positive Control
EC 1272/2008

Chemical Name	Index No.	CAS No.	EC No.	REACH Registration No.	Conc. (%w/w)	Classification	M-factor
Human Serum					70-80%		
Sodium azide (NaN ₃)	011-004-00-7	26628-22-8	247-852-1		0-0.5%	Acute Tox. 2: H300; Aquatic Acute 1: H400; Aquatic Chronic 1: H410;	

3.1.3 Calibrator
EC 1272/2008

Chemical Name	Index No.	CAS No.	EC No.	REACH Registration No.	Conc. (%w/w)	Classification	M-factor
Human Serum					70-80%		
Sodium azide (NaN ₃)	011-004-00-7	26628-22-8	247-852-1		0-0.5%	Acute Tox. 2: H300; Aquatic Acute 1: H400; Aquatic Chronic 1: H410;	

3.1.4 Negative Control
EC 1272/2008

Chemical Name	Index No.	CAS No.	EC No.	REACH Registration No.	Conc. (%w/w)	Classification	M-factor
Human Serum					70-80%		
Sodium azide (NaN ₃)	011-004-00-7	26628-22-8	247-852-1		0-0.5%	Acute Tox. 2: H300; Aquatic Acute 1: H400; Aquatic Chronic 1: H410;	

3.1.5 Low Positive Control
EC 1272/2008

Chemical Name	Index No.	CAS No.	EC No.	REACH Registration No.	Conc. (%w/w)	Classification	M-factor
Human Serum					70-80%		
Sodium azide (NaN ₃)	011-004-00-7	26628-22-8	247-852-1		0-0.5%	Acute Tox. 2: H300; Aquatic Acute 1: H400; Aquatic Chronic 1: H410;	

3.1.6 Serum Diluent Type I
EC 1272/2008

Chemical Name	Index No.	CAS No.	EC No.	REACH Registration No.	Conc. (%w/w)	Classification	M-factor
Bovine Serum Albumin 30%		9048-46-8			1-10%		
ProClin 300					0-0.5%		
Tween 20 CH016		9005-64-5	500-018-3		0-0.5%		
Trizma HCL		1185-53-1	214-684-5		0-0.5%		
TRIZMA BASE		77-86-1	201-06404		0-0.5%		

3.1.7 Wash Buffer Type I
EC 1272/2008

Chemical Name	Index No.	CAS No.	EC No.	REACH Registration No.	Conc. (%w/w)	Classification	M-factor
Trizma HCL		1185-53-1	214-584-5		1-10%		
Tween 20 CH016		9005-64-5	500-018-3		0-0.5%		

Tris Base	77-86-1	201-064-4	0-0.5%
ProClin 300			0-0.5%

3.1.8 Substrate Solution

EC 1272/2008

Chemical Name	Index No.	CAS No.	EC No.	REACH Registration No.	Conc. (%w/w)	Classification	M-factor
SureBlue TMB Microwell Peroxidase Substrate (1-Component)		Proprietary			10-20%		
Hydrogen peroxide		7722-84-1			0-0.5%		

3.1.9 Stop Solution

EC 1272/2008

Chemical Name	Index No.	CAS No.	EC No.	REACH Registration No.	Conc. (%w/w)	Classification	M-factor
Sulfuric acid...% (mist)	016-020-00-8	7664-93-9	231-639-5		1-10%	Skin Corr. 1A: H314;	

67/548/EEC / 1999/45/EC

Chemical Name	Index No.	CAS No.	EC No.	REACH Registration No.	Conc. (%w/w)	Classification	M-factor
Sulfuric acid...% (mist)	016-020-00-8	7664-93-9	231-639-5		1-10%	C; R35	

3.2 Hazardous Ingredients

Biohazardous Material

3.3 Further Information

No substance is present at a concentration level, specified by EC directive, which presents a health or environmental hazard.

SECTION 4. First Aid Measures

4.1 Description of first aid measures

Inhalation:	May cause irritation to mucous membranes. Inhalation may also cause coughing, tightness of the chest and irritation of the respiratory system. Move the exposed person to fresh air. Seek medical attention.
Eye contact:	May cause irritation to eyes. Rinse immediately with plenty of water for 15 minutes holding the eyelids open. Seek medical attention if irritation or symptoms persist.
Skin contact:	May cause irritation to skin. Wash off immediately with plenty of soap and water. Remove contaminated clothing. Seek medical attention if irritation or symptoms persist.
Ingestion:	Ingestion may cause nausea and vomiting. Flush mouth with water, without swallowing (DO NOT INDUCE VOMITING). Seek medical attention if irritation or symptoms persist.

If you feel unwell, seek medical advice.

First aid measures given apply to concentrated sulfuric acid solutions. Exposure to dilute solutions may not require these extensive first aid procedures.

SECTION 5. Firefighting measures

5.1 Extinguishing media

Use extinguishing media appropriate to the conditions. Dry chemical. Carbon dioxide (CO₂). Foam. Water Spray.

5.2 Special hazards arising from the substance or mixture

Burning produces irritating, toxic and obnoxious fumes.

5.3 Advice for firefighters

Wear suitable respiratory equipment – self-contained breathing apparatus.



SECTION 6. Accidental release measures

6.1 Personal precautions, protective equipment and emergency procedures

Ensure adequate ventilation of the working area.
 Wear suitable protective equipment.

6.2 Environmental precautions

Do not allow serum diluent, wash buffer, and stop solution to enter drains.

6.3 Methods and material for containment and cleaning up

Absorb with inert, absorbent material. Transfer to suitable, labelled containers for disposal. Clean spillage area thoroughly with plenty of water. Flush down the drain with plenty of water (DO NOT FLUSH: serum diluent, wash buffer, and stop solution).

SECTION 7. Handling and Storage

7.1 Precautions for safe handling

Avoid contact with eyes and skin. Ensure adequate ventilation of the working area. Adopt best Manual Handling considerations when handling, carrying and dispensing. Wear protective clothing. Handle as if capable of transmitting a disease.

7.2 Conditions for safe storage, including any incompatibilities

2-8 °C.
 Keep container tightly closed. Keep in a cool, dry, well ventilated area. Store in correctly labelled containers.

SECTION 8. Exposure Controls and Personal Protection

8.1 Control parameters – Exposure limit values

8.1.1 Stop Solution

Sulfuric acid...% (mist)	WEL 8-hr limit ppm: -	WEL 8-hr limit mg/m ³ : 0.05
	WEL 15 min limit ppm: -	WEL 15 min limit mg/m ³ : -
	WEL 8-hr mg/m ³ total inhalable dust: -	WEL 15 min limit mg/m ³ total inhalable dust: -
	WEL 8-hr mg/m ³ total respirable dust: -	WEL 15-min limit mg/m ³ total respirable dust: -

8.2 Exposure controls

Appropriate engineering controls	Ensure adequate ventilation of the working area.
Individual protection measures	Wear protective clothing. Handle as if potentially infectious.
Eye/face protection	Face shield, safety goggles.
Skin protection – hands	Wear suitable gloves.
Respiratory protection	Use in a well-ventilated area. Wear suitable respiratory equipment when necessary.
Environmental exposure controls	Do not eat, drink, or smoke in areas where this product is used or stored.

SECTION 9. Physical and Chemical Properties

9.1 Information on basic physical and chemical properties

	Conjugate	High pos. ctrl	Calibrator	Neg. ctrl	Low pos. ctrl	Serum diluent	Wash buffer	Substrate solution	Stop solution
Appearance	Liquid					Aqueous solution	Liquid	Aqueous solution	
Color	Off-white					Green	Blue	Clear	Colorless
Initial boiling point	N/A							100 °C	



SECTION 10. Stability and Reactivity

10.1 Reactivity

Stable under normal conditions.

10.2 Chemical stability

Stable under normal conditions.

10.3 Conditions to avoid

Heat, sparks, and open flames.

SECTION 11. Toxicology Information

11.1 Toxicological information

All available data for individual components are listed as below:

11.1.1 Conjugate

No known adverse health effects.

11.1.2 Substrate solution

When used and handled according to the specifications, the solution does not have a toxicological effect.

11.1.3 Stop solution

Sulfuric acid...%	Inhalation Rat LC50/2 h: 510	Oral Rat LD50: 2140
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11.2 Other information

To the best of our knowledge, the chemical, physical and toxicological properties of the following components have NOT been thoroughly investigated: Serum diluent type I, Wash buffer type I.

11.3 Notes

No data was available for unlisted components.

SECTION 12. Ecological Information

12.1 Toxicity

All available data for individual components are listed as below:

12.1.1 Wash buffer type I

No known adverse environmental effects.

12.1.2 Stop solution

Sulfuric acid...%	Fish LC50/96h: 42.000 mg/l
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12.2 Mobility in soil

When released into soil, sulfuric acid may leach into groundwater.

12.3 Notes

No data was available for unlisted components.

SECTION 13. Disposal Considerations

13.1 General information

Dispose of in compliance with all local and national regulations.



13.2 *Disposal methods*

Disposal should be made in accordance with existing procedures/protocols currently in place at facility for infectious waste. Serum diluent should be disposed of as special waste in compliance with all local and national regulations.

13.3 *Disposal of packaging*

Do NOT reuse empty containers.

SECTION 14. Transport Information

The product is not classified as dangerous for carriage.

SECTION 15. Regulatory Information

15.1 *Safety, health and environmental regulations/legislation specific for the substance or mixture*

COMMISSION REGULATION (EU) No 453/2010 of 20 May 2010 amending Regulation (EC) No 1907/2006 of the European Parliament and of the Council on the Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH), establishing a European Chemicals Agency, amending Directive 1999/45/EC and repealing Council Regulation (EEC) No 793/93 and Commission Regulation (EC) No 1488/94 as well as Council Directive 76/769/EEC and Commission Directives 91/155/EEC, 93/67/EEC, 93/105/EC and 2000/21/EC.

REGULATION (EC) No 1907/2006 OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL of 18 December 2006 concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH), establishing a European Chemicals Agency, amending Directive 1999/45/EC and repealing Council Regulation (EEC) No 793/93 and Commission Regulation (EC) No 1488/94 as well as Council Directive 76/769/EEC and Commission Directives 91/155/EEC, 93/67/EEC, 93/105/EC and 2000/21/EC.

Further information

This MSDS is prepared according to 29 CFR 1910.1200.

SECTION 16. Other information

Revision	This document differs from the previous version in the following areas: 2 – 2.1.2. Classification – EC 1272/2008. 2 – Hazard pictograms. 2 – Signal word. 2 – Precautionary Statement: Prevention. 2 – Precautionary Statement: Response. 3 – Further information. 8 – Skin protection – Hand protection. 12 – 12.1 Toxicity. 15 – 15.1 Safety, health and environmental regulations/legislation specific for the substance or mixture.
Text of risk phrases in Section 3	R35 – Causes severe burns.
Text of hazard statements in Section 3	EUH032 – Contact with acids liberates very toxic gas. Acute Tox. 2: H300 – Fatal if swallowed. Aquatic Acute 1: H400 – Very toxic to aquatic life. Aquatic Chronic 1: H410 – Very toxic to aquatic life with long lasting effects. Skin Corr. 1A: H314 – Causes severe skin burns and eye damage. STOT SE 3: H335 – May cause respiratory irritation.

Further information:

The information supplied in this Safety Data Sheet is designed only as guidance for the safe use, storage and handling of the product. This information is correct to the best of our knowledge and belief at the date of publication. However, no guarantee is made to its accuracy. This information relates only to the specific material designated and may not be valid for such material used in combination with any other materials or in any other processes.



ISO 13485
ISO 9001



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REF 1652-1

**AccuDiag™ - Legionella IgG, IgM
ELISA**

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