



# VALIDATE® Calibration Verification Test Kit

## Safety Data Sheet

according to Regulation (EC) No. 453/2010, EC 1272/2008, EC 1907/2006 and 29 CFR § 1910.1200

Revision date: Dec 2, 2024

### SECTION 1: Identification of the substance/mixture and of the company/undertaking

#### 1.1. Product identifier

Product form : Mixture  
Name : VALIDATE® Calibration Verification Test Kit  
Product code : 304, 504, 901, 1003

#### 1.2. Relevant identified uses of the substance or mixture and uses advised against

##### 1.2.1. Relevant identified uses

Use of the substance/preparation : Intended for *in vitro* diagnostic use in the determination of linearity, calibration verification and verification of reportable range in automated, semi-automated and manual instrument systems.

##### 1.2.2. Uses advised against

No additional information available

#### 1.3. Details of the supplier of the safety data sheet

LGC Clinical Diagnostics, Inc.  
221 US Route 1  
Cumberland Foreside, ME 04110 - USA  
800-377-9684; 207-892-1300 Hours: 8:30 AM to 5:00 PM, Eastern Time, Monday through Thursday. 8:30 AM to 4:00 PM on Friday.

#### 1.4. Emergency telephone number

Emergency number : Contact the CHEMTREC® Emergency Call Center for assistance with transportation or hazardous materials emergencies (24 hours/day, 7 days/week). Refer to LGC Clinical Diagnostics, Inc. customer number 798037.  
Within USA and Canada: 1-800-424-9300 or +1 703-527-3887 (collect calls accepted)

### SECTION 2: Hazards identification

#### 2.1. Classification of the substance or mixture

##### Classification according to Regulation (EC) No. 1272/2008 [CLP]

Not classified.

Full text of H-phrases: see section 16.

##### Classification according to 2012 29 CFR § 1910.1200 (OSHA-GHS)

Not classified.

##### Classification according to WHMIS (Controlled Products Regulations)

Not classified.

##### Adverse physicochemical, human health and environmental effects

None under normal conditions. However, product does contain material of human origin and should be considered potentially infectious.

#### 2.2. Label elements

##### Labelling according to Regulation (EC) No. 1272/2008 [CLP]

Hazard pictograms (CLP) : No symbol required  
Signal word (CLP) : Not Applicable  
Hazard statements (CLP) : Not Applicable  
Precautionary statements (CLP) : Not Applicable  
EUH phrases : Not Applicable

##### Labelling according to 2012 29 CFR § 1910.1200 [OSHA]

Hazard pictograms (OSHA) : No symbol required  
Signal word (OSHA) : Not Applicable  
Hazard statements (OSHA) : Not Applicable  
Precautionary statements (OSHA) : Not Applicable

#### 2.3. Other hazards

Human source material. Each human donor used in the preparation of the product was tested and found non-reactive for Anti-HIV I/II, Anti-HCV, and HbsAg, with kits approved by the United States FDA.

PBT: not relevant – no registration required

vPvB: not relevant – no registration required

### SECTION 3: Composition/information on ingredients

#### 3.1. Substances

Not applicable

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### 3.2. Mixtures

Name of Component	Product identifier	% in Mixture (see 2.1 for hazards for mixture)	Classification of Component according to Regulation (EC) No. 1272/2008 [CLP]
Ethanol	(CAS No.) 64-17-5 (EC no) 200-578-6	0.1-2	Flam. Liq.2 (H225)

Mixture of chemical and biological substances for *in vitro* diagnostic use.

Additional information: Contains human sourced plasma or serum and/or potentially infectious material.

Full text of R-, H- and EUH-phrases: see section 16.

## SECTION 4: First aid measures

### 4.1. Description of first aid measures

- First-aid measures after inhalation : If symptoms are experienced remove source of contamination or move victim to fresh air. Obtain medical advice.
- First-aid measures after skin contact : No health effects expected. If irritation does occur, flush with lukewarm, gently flowing water for 5 minutes or until chemical is removed.
- First-aid measures after eye contact : No effects expected. If irritation does occur, flush contaminated eye(s) with lukewarm, gently flowing water for 5 minutes or until the chemical is removed. If irritation persists, obtain medical advice.
- First-aid measures after ingestion : If irritation or discomfort occurs, obtain medical advice immediately.

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

- Symptoms/injuries after inhalation : Overexposure to mists or spray may produce slight irritation of the respiratory system.
- Symptoms/injuries after skin contact : May cause slight irritation to the skin.
- Symptoms/injuries after eye contact : May cause slight irritation to eyes.
- Symptoms/injuries after ingestion : May cause gastric irritation.

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

Treat symptomatically.

## SECTION 5: Firefighting measures

### 5.1. Extinguishing media

- Suitable extinguishing media : Powder, alcohol-resistant foam, water spray, carbon dioxide.
- Unsuitable extinguishing media : None known.

### 5.2. Special hazards arising from the substance or mixture

- Fire hazard : No particular fire or explosion hazard. In case of fire it can release carbon oxides, nitrogen oxides, hydrogen chloride and/or chlorine gases, disodium oxide and other toxic and irritating fumes.
- Reactivity : No dangerous reactions known under normal conditions of use.

### 5.3. Advice for firefighters

- Protective equipment for firefighters : In case of fire: Wear self-contained breathing apparatus. Wear recommended personal protective equipment.

## SECTION 6: Accidental release measures

### 6.1. Personal precautions, protective equipment and emergency procedures

#### 6.1.1. For non-emergency personnel

- Protective equipment : Wear suitable protective clothing, gloves and eye/face protection.

#### 6.1.2. For emergency responders

- Protective equipment : Wear suitable protective clothing, gloves and eye/face protection.
- Emergency procedures : Avoid all eye and skin contact and do not breathe spray and mist. Prevent product from entering drains.

### 6.2. Environmental precautions

Prevent product from entering drains.

### 6.3. Methods and material for containment and cleaning up

- For containment : Absorb with liquid-binding material (e.g. sand, diatomaceous earth, acid- or universal binding agents).
- Methods for cleaning up : Absorb with liquid-binding material (e.g. sand, diatomaceous earth, acid- or universal binding agents). Collect all waste in suitable and labelled containers and dispose according to local legislation.

### 6.4. Reference to other sections

Refer to sections 8 and 13.

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### SECTION 7: Handling and storage

#### 7.1. Precautions for safe handling

- Precautions for safe handling : Avoid all unnecessary exposure. Handle as if potentially infectious.  
Hygiene measures : Handle in accordance with good industrial hygiene and safety practice. Wash hands thoroughly after handling. Do not eat, drink or smoke when using this product. Contaminated work clothing must not be allowed out of the workplace.

#### 7.2. Conditions for safe storage, including any incompatibilities

- Technical measures: : Provide local exhaust or general room ventilation.  
Storage condition(s) : Keep container tightly closed and dry. Store in well ventilated area. Keep cool.  
Incompatible materials : None Known

#### 7.3. Specific end use(s)

Intended for *in vitro* diagnostic use in the determination of linearity, calibration verification and verification of reportable range in automated, semi-automated and manual instrument systems.

### SECTION 8: Exposure controls/personal protection

#### 8.1. Control parameters

Ethanol (64-17-5)		
Austria	MAK (mg/m <sup>3</sup> )	1900 mg/m <sup>3</sup>
Austria	MAK (ppm)	1000 ppm
Austria	MAK Short time value (mg/m <sup>3</sup> )	3800 mg/m <sup>3</sup>
Austria	MAK Short time value (ppm)	2000 ppm
Belgium	Limit value (mg/m <sup>3</sup> )	1907 mg/m <sup>3</sup>
Belgium	Limit value (ppm)	1000 ppm
France	VLE (mg/m <sup>3</sup> )	9500 mg/m <sup>3</sup>
France	VLE (ppm)	5000 ppm
France	VME (mg/m <sup>3</sup> )	1900 mg/m <sup>3</sup>
France	VME (ppm)	1000 ppm
Germany	TRGS 900 Occupational exposure limit value (mg/m <sup>3</sup> )	960 mg/m <sup>3</sup>
Germany	TRGS 900 Occupational exposure limit value (ppm)	500 ppm
Italy - Portugal - USA ACGIH	ACGIH TWA (mg/m <sup>3</sup> )	1884 mg/m <sup>3</sup>
Italy - Portugal - USA ACGIH	ACGIH TWA (ppm)	1000 ppm
Spain	VLA-ED (mg/m <sup>3</sup> )	1910 mg/m <sup>3</sup>
Spain	VLA-ED (ppm)	1000 ppm
Switzerland	VLE (mg/m <sup>3</sup> )	1920 mg/m <sup>3</sup>
Switzerland	VLE (ppm)	1000 ppm
Switzerland	VME (mg/m <sup>3</sup> )	960 mg/m <sup>3</sup>
Switzerland	VME (ppm)	500 ppm
Canada (Québec)	VEMP (mg/m <sup>3</sup> )	1880 mg/m <sup>3</sup>
Canada (Québec)	VEMP (ppm)	1000 ppm
Australia	TWA (mg/m <sup>3</sup> )	1920 mg/m <sup>3</sup>
Australia	TWA (ppm)	1000 ppm

#### 8.2. Exposure controls

- Appropriate engineering controls : Either local exhaust or general room ventilation is usually required.  
Personal protective equipment : Gloves. Safety glasses.



- Hand protection : If this material may come into contact with the hands during handling and use, we recommend wearing gloves of the following material(s): natural rubber latex, neoprene, nitrile, or polyvinyl chloride (PVC). Consult your PPE provider for breakthrough times and the specific glove that is best for you based on your use patterns.
- Eye protection : As a minimum, safety glasses with side shields should be worn when handling this material
- Skin and Body protection : If this material may come into contact with the body during handling and use, we recommend wearing appropriate protective clothing to prevent contact with the skin.
- Respiratory protection : With correct and proper use, and under normal conditions, breathing protection is not required

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Environmental exposure controls : None known.

### SECTION 9: Physical and chemical properties

#### 9.1. Information on basic physical and chemical properties

Physical state : Liquid  
Colour : Colourless to slightly yellow  
Odour : No data available  
Odour threshold : No data available  
pH : No data available  
Melting point : No data available  
Solidification point : No data available  
Boiling point : No data available  
Flash point : No data available  
Relative evaporation rate (butylacetate=1) : No data available  
Flammability (solid, gas) : Not applicable.  
Explosive limits : No data available  
Vapour pressure : No data available  
Relative vapour density at 20 °C : No data available  
Relative density : No data available  
Solubility : Water: Soluble in water  
Log Pow : No data available  
Log Kow : No data available  
Self ignition temperature : No data available  
Decomposition temperature : No data available  
Viscosity, kinematic : No data available  
Viscosity, dynamic : No data available  
Explosive properties : Not explosive.  
Oxidising properties : Not oxidizing.

#### 9.2. Other information

Upper flammable Limit : No Data Available  
Lower Flammable Limit : No Data Available  
Sensitivity to mechanical impact : No Data Available  
Sensitivity to static discharge : No Data Available

### SECTION 10: Stability and reactivity

#### 10.1. Reactivity

No dangerous reactions known under normal conditions of use.

#### 10.2. Chemical stability

Stable in use and storage conditions as recommended in item 7.

#### 10.3. Possibility of hazardous reactions

None under normal conditions.

#### 10.4. Conditions to avoid

Incompatible materials.

#### 10.5. Incompatible materials

None known.

#### 10.6. Hazardous decomposition products

No hazardous decomposition products known at room temperature.

### SECTION 11: Toxicological information

#### 11.1. Information on toxicological effects: Also see Sections 3 and 15 for specific chemical hazards present.

Routes of Entry : Skin, Eyes, Inhalation and Ingestion  
Acute toxicity : (Mixture not tested. Based on available data.)

Ethanol (64-17-5)	
LD50 oral mouse	3450 mg/kg
LD50 dermal rabbit	>15800 mg/kg
LD50 inhalation mouse (4h)	21000 ppm

Skin corrosion/irritation : Not classified (Mixture not tested. Based on available data, the classification criteria are not met)  
Serious eye damage/irritation : Not classified (Mixture not tested. Based on available data, the classification criteria are not met)

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Respiratory or skin sensitisation	: May cause an allergic skin reaction (Mixture not tested. Based on available data.)
Germ cell mutagenicity	: Not classified (Mixture not tested. Based on available data, the classification criteria are not met)
Carcinogenicity	: Not classified (Mixture not tested. Based on available data, the classification criteria are not met). No ingredient present at greater than 0.1% is listed in National Toxicology Program (NTP) Report on Carcinogens (12th Edition), the International Agency for Research on Cancer (IARC) Monographs (Volumes 1–105), or by OSHA.
Reproductive toxicity	: Not classified (Mixture not tested. Based on available data, the classification criteria are not met)
Teratogenicity/Embryotoxicity	: Not classified (Mixture not tested. Based on available data, the classification criteria are not met)
Specific target organ toxicity (single exposure)	: Not classified (Mixture not tested. Based on available data, the classification criteria are not met)
Specific target organ toxicity (repeated exposure)	: Not classified (Mixture not tested. Based on available data, the classification criteria are not met)
Aspiration hazard	: Not classified (Not applicable)
Potential Adverse human health effects and symptoms	: May cause slight temporary irritation.
Toxicologically Synergistic Materials	: None known
Endocrine-disrupting properties	: Not classified (Mixture not tested). Based on available data, the classification criteria are not met)

## SECTION 12: Ecological information

### 12.1. Toxicity

Ethanol (64-17-5)	
LC50 fish (24h)	>100 mg/L <i>Danio rerio</i>
EC50 Daphnia (48h)	11853-13248 mg/L <i>Daphnia magna</i>

### 12.2. Persistence and degradability

No additional information available

### 12.3. Bioaccumulative potential

Ethanol (64-17-5)	
Log P(oct)	= -0.31

### 12.4. Mobility in soil

No additional information available

### 12.5. Results of PBT and vPvB assessment

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PBT: not relevant – no registration required	
vPvB: not relevant – no registration required	

### 12.6. Other adverse effects

No additional information available

## SECTION 13: Disposal considerations

### 13.1. Waste treatment methods

Waste disposal recommendations	: Dispose of this material and its container at hazardous or special waste collection point. Can be deposited in landfills, sent to an incineration or other appropriate means of disposal, provided they meet the requirements of local laws. Comply with applicable local, national and international regulation.
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## SECTION 14: Transport information

Not regulated for transport.

## SECTION 15: Regulatory information

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

#### 15.1.1. EU-Regulations

No REACH restricted substances are present. No substances from the ECHA Candidate List of SVHC are present. No substances listed in REACH Annex XIV are present. See Section 3 for any hazardous materials if present.

#### 15.1.2. National regulations

Regional legislation	: Canada: This product has been classified in accordance with the hazard criteria of the <i>Controlled Products Regulations</i> and the SDS contains all the information required by the <i>Controlled Products Regulations</i> .
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USA: This product has been classified in accordance with the 2012 hazard criteria of the *Occupational Safety and Health Administration's (OSHA) Hazard Communication Standard (HCS)* and the SDS contains all the information required by the 29 CFR § 1910.1200.

### 15.2. Chemical safety assessment

CSA has not been established

## SECTION 16: Other information

Sources of Key data : Data arise from reference works and literature.  
Abbreviations and acronyms :  
CFR - Code of Federal Regulations  
CLP - Classification, Labelling and Packaging  
CSA – Chemical Safety Assessment  
DPD – Dangerous Products Directive  
EC - European Community  
EC No. - European Commission number  
EEC - European Economic Community  
EN - European Norm  
EU- European Union  
GHS – Globally Harmonized System  
h – hours  
H-phrases – Hazard phrases  
Log Pow – Log of the Octanol/Water Partition Coefficient  
MSDS – Material Safety Data Sheet  
No. – Number  
OSHA - Occupational Safety and Health Administration  
PBT - Persistent, Bioaccumulative and Toxic substance  
PPE – Personal Protective Equipment  
REACH - Registration, Evaluation, Authorisation and Restriction of Chemicals  
R-phrases – Risk phrases  
SDS – Safety Data Sheet  
vPvB - Very Persistent and Very Bioaccumulative  
WHMIS – Workplace Hazardous Material Information System

SDS EU (REACH Annex II)

*This information is based on our current knowledge and is intended to describe the product for the purposes of health, safety and environmental requirements only. It should not therefore be construed as guaranteeing any specific property of the product.*