

# SAFETY DATA SHEET

Revision date: 04.09.2020  
Revision 5.6  
according to 2015/830/EC

Safety Data Sheet RealFast™ Assay

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## Section 1. Identification of the substance/mixture and of the company/undertaking

### 1.1. Product identifier

Trade name: **RealFast™ Assay (see Section 16)**  
Catalogue Number: see Section 16  
REACH Reg. number: -----

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

Identified uses: Laboratory chemicals

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

Manufacturer: ViennaLab Diagnostics GmbH  
Gaudenzdorfer Guertel 43-45  
A-1120 Vienna, Austria  
tel: +43-1-8120156 0  
fax: +43-1-8120156 19  
email: [info@viennalab.com](mailto:info@viennalab.com)

### 1.4 Emergency telephone number

Call your local emergency center.

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## Section 2. Hazards identification

### 2.1 Classification of the substance/mixture

This mixture is classified as not hazardous or does not meet the criteria for classification according to the 1272/2008/EC.

### 2.2 Label elements

#### Hazard pictogram/s and signal word

This mixture is not subject to labeling according to the calculation methods of the regulation 1272/2008/EC.

### 2.3 Other hazards

Not known.

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## Section 3. Composition/information on ingredients

### 3.1 Mixtures

The ingredients of the components of the RealFast™ Assays are not dangerous or their concentrations do not exceed the limits specified in the regulation 1272/2008/EC.

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## Section 4. First Aid Measures

### 4.1. Description of first aid measures

**General information:** Immediately take off contaminated clothing. If unwell seek medical advice.  
**Following inhalation:** Provide fresh air. In case of irritation of the respiratory tract consult a physician.  
**Following skin contact:** Wash with plenty of water and soap.  
**Following eye contact:** Remove contact lenses. Flush immediately with plenty of flowing water for 15 minutes holding eyelids apart, protecting the uninjured eye. If necessary consult a physician.  
**Following ingestion:** Rinse mouth immediately and drink plenty of water (200-300 mL) in little sips (dilution effect). Avoid vomiting.

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

No symptoms known up to now.

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

First aid, symptomatic treatment.

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## Section 5. Firefighting measures

### 5.1. Extinguishing media

**Suitable extinguishing media:** Adapt extinguishing measures to suit the environment.

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

No information available.

### 5.3. Advice for fire-fighters

In case of fire: Use self-contained breathing apparatus.

### 5.4. Additional information

No data available.

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## Section 6. Accidental release measures

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

Avoid contact with mixture. Provide fresh air. Leave danger zone. Consult expert.

### 6.2. Environmental precautions

Do not allow to enter drainage system or water.

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

Absorb with liquid binding and neutralizing material and dispose of according to section 13.

### 6.4. Reference to other sections

Observe protective measures in sections 7, 8 and 13.

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## Section 7. Handling and storage

### 7.1. Precautions for safe handling

**Advice on safe handling:** General occupational hygiene measures. Do not eat, drink or smoke in the work area. Wash hands after use. Change contaminated clothing before entering eating areas. Use personal protective equipment

**Precautions against fire and explosion:** General measures of preventive fire protection.

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

**Requirements for storage rooms and vessels:** No special technical protective measures are necessary. Store only in original containers. Keep container tightly closed.

### 7.3 Specific end uses

Observe instructions for use.

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## Section 8. Exposure controls/personal protection

### 8.1 Control parameters

These mixtures do not contain substances above concentration limits fixing an occupational exposure limit.

### 8.2 Exposure controls/personal protection

**Appropriate engineering controls:** Technical measures and the design of appropriate work processes go before the use of protective equipment. See section 7.1.

**Hygiene measures:** Do not eat, drink or smoke at the workplace. Wash hands after working with the mixtures. Preventive skin protection. Immediately change contaminated clothing.

**Personal protective equipment:** Minimum standards for protective measures during handling of working materials listed in TRGS 500.

**Respiratory protection:** With proper use, and under normal conditions, breathing protection is not required.

**Hand protection:** Tested protective gloves are to be worn. Chemical resistance has to be clarified with the supplier.

**Eye protection:** Tightly sealed goggles.

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**Other protective measures:** Wear protective clothing to prevent contact with skin.  
**Limitation and monitoring environmental exposure:** see section 7. No further action is necessary.

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## Section 9. Physical and chemical properties

### 9.1 Information on basic physical and chemical properties

Physical state	liquid
Color	colorless
Odor	odorless
Odor threshold	no information available
Melting point	no data available
Boiling point	no data available
Ignition temperature	no data available
Flash point	no data available
Explosion limits lower/upper	no explosion hazard
Density (20°C)	no data available
Solubility in water (20°C)	soluble
Oxidizing properties	not corrosive

### 9.2. Other information

Not available.

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## Section 10. Stability and reactivity

### 10.1 Reactivity

No hazardous reaction known.

### 10.2 Chemical stability

No dangerous decompositions products known.

### 10.3 Possibility of hazardous reactions

There are expected no hazardous reactions for intended use.

### 10.4 Conditions to avoid

No information available.

### 10.5 Incompatible materials

None known.

### 10.6 Hazardous decomposition products

None known.

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## Section 11. Toxicological information

### 11.1 Information on toxicological effects

Toxicological data for the mixture are not available.

**Acute toxicity:** No information available.

**Skin corrosion/irritation:** No information available.

**Severe eye damage/irritation:** No information available.

**Sensitization to respiratory tract/skin:** No information available.

**Germ cell-mutagenicity:** No information available.

**Carcinogenicity:** No information available.

**Reproductive toxicity:** The mixture is not classified. The mixture does not contain any substances that are classified as toxic for reproduction.

**Specific target organ toxicity (repeated exposure):** No information available.

**Specific target organ toxicity (single exposure):** No information available.

**Aspiration hazard:** No information available.

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## Section 12. Ecological information

### 12.1 Toxicity

These mixtures do not contain any hazardous ingredients according to regulation 1272/2008/EC.

### 12.2 Persistence and degradability

These mixtures do not contain any hazardous ingredients according to regulation 1272/2008/EC.

### 12.3 Bioaccumulative potential

These mixtures do not contain any hazardous ingredients according to regulation 1272/2008/EC.

### 12.4 Mobility in soil

These mixtures do not contain any hazardous ingredients according to regulation 1272/2008/EC.

### 12.5 Results of PBT and vPvB assessment

These mixtures do not contain any hazardous ingredients according to regulation 1272/2008/EC.

### 12.6 Other adverse effects

No information available.

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## Section 13. Disposal consideration

### 13.1 Waste treatment methods

Disposal according to the Waste Framework Directive 2008/98/EC and in compliance with national and local rules and regulations.

Disposal in accordance with applicable national and local statutes and regulations.

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## Section 14. Transport Information

### 14.1 UN-Number

UN-No. ---

### 14.2 Proper UN-shipping name

ADR/RID: ---

No hazardous material with respect to these transport regulations.

IMDG-Code/ICAO-/IATA-DGR: ---

No hazardous material with respect to these transport regulations.

### 14.3 Transport hazard class(es)

ADR/RID/IMDG-Code/ICAO-/IATA-DGR: No hazardous material with respect to these transport regulations.

### 14.4. Packing group

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### 14.5 Environmental hazards

No hazardous material with respect to these transport regulations.

### 14.6 Special precautions for user

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### 14.7 Transport in bulk according to Annex II of MARPOL73/78 and the IBC Code

Not applicable.

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## Section 15. Regulatory information

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

#### EU regulations

REACH regulation (EC) No1907/2006 in its latest version

CLP regulation (EC) No 1272/2008 in its latest version

#### German regulations

Water pollution class 1 (slightly polluting)

#### National regulations

Refer to the national legal regulations!

### 15.2 Chemical safety assessment

For these mixtures no chemical safety assessment has been carried out.

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## Section 16. Other information

### Indication of changes compared to revision 5.5

Update of product list

### Catalogue number and Trade name (Section 1.1)

REF 7-110 / 7-113	FV Leiden RealFast™ Assay <sup>a)</sup>
REF 7-115 / 7-118	FV-PTH mpx RealFast™ Assay <sup>c)</sup>
REF 7-120 / 7-123	PTH 20210G>A RealFast™ Assay <sup>a)</sup>
REF 7-130 / 7-133	HFE C282Y RealFast™ Assay <sup>a)</sup>
REF 7-135 / 7-138	HFE mpx RealFast™ Assay <sup>c)</sup>
REF 7-140 / 7-143	HFE H63D RealFast™ Assay <sup>a)</sup>
REF 7-150 / 7-153	LCT -13910C>T RealFast™ Assay <sup>a)</sup>
REF 7-160 / 7-163	MTHFR 677C>T RealFast™ Assay <sup>a)</sup>
REF 7-165 / 7-168	MTHFR mpx RealFast™ Assay <sup>c)</sup>
REF 7-170 / 7-173	MTHFR 1298A>C RealFast™ Assay <sup>a)</sup>
REF 7-180 / 7-183	PAI-1 4G/5G RealFast™ Assay <sup>a)</sup>
REF 7-190 / 7-193	VKORC1 -1639G>A RealFast™ Assay <sup>a)</sup>
REF 7-200 / 7-203	IL28B RealFast™ Assay <sup>a)</sup>
REF 7-210 / 7-213	SLCO1B1 c.521T>C RealFast™ Assay <sup>a)</sup>
REF 7-225 / 7-228	CYP2C9 mpx RealFast™ Assay <sup>c)</sup>
REF 7-230 / 7-233	FGB -455G>A RealFast™ Assay <sup>a)</sup>
REF 7-240 / 7-243	FXII 46C>T RealFast™ Assay <sup>a)</sup>
REF 7-250 / 7-253	FXIII V34L RealFast™ Assay <sup>a)</sup>
REF 7-260 / 7-263	CF F508del RealFast™ Assay <sup>a)</sup>
REF 7-265 / 7-268	AAT mpx RealFast™ Assay <sup>c)</sup>
REF 7-275 / 7-278	NAFLD mpx RealFast™ Assay <sup>c)</sup>
REF 7-410	CAH RealFast™ CNV Assay <sup>b)</sup>
REF 7-420	CYP2D6 RealFast™ CNV Assay <sup>b)</sup>
REF 7-610 / 7-613	HLA-B5701 RealFast™ Assay <sup>a)</sup>
REF 7-620 / 7-623	HLA-B27 RealFast™ Assay <sup>a)</sup>
REF 7-630 / 7-633	HLA-B1502 RealFast™ Assay <sup>a)</sup>
REF 7-640 / 7-643	HLA-A3101 RealFast™ Assay <sup>a)</sup>
REF 7-650 / 7-653	HLA-A29 RealFast™ Assay <sup>a)</sup>
REF 8-110 / 8-113	EGFR T790M RealFast™ Assay <sup>d)</sup>
REF 8-410 / 8-412	SARS-CoV-2 RealFast™ Assay <sup>e)</sup>

Einzelkomponenten des entsprechenden RealFast™ Assay:

- <sup>a)</sup> 2x Genotyping Mix, Assay Mix, Controls
- <sup>b)</sup> 2x Probe Mix, Assay Mix, Calibrator
- <sup>c)</sup> 2x mpx Probe Mix, Assay Mix, Controls
- <sup>d)</sup> 2x Probe Mix, Assay Mix, Control

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e) RT-PCR Mix, Assay Mix, RTase

This information is based on our present knowledge and shall be used only as a guide. However, this shall not constitute a guarantee for any specific product features and shall not establish a legally valid contractual relationship. ViennaLab Diagnostics GmbH is not held liable for any damage resulting from handling or from contact with the above mentioned products.

The safety data sheet has been prepared in accordance with EC regulation 1907/2006/EC.