

# Quality Assurance Certificate

## Description

<b>Product Name:</b>	LactaZyme® LDHLt
<b>Article Code / Grade:</b>	LZ-LDH-Lt / Diagnostic Grade
<b>Batch No.:</b>	Add result.
<b>Quality Release Date:</b>	2024-02-21
<b>Description:</b>	Flavin dependent Lactate Dehydrogenase that catalyses the conversion of L-lactate to pyruvate.
<b>Formulation:</b>	Add formulation
<b>Recommended Retesting Date:</b>	In dry state as provided and stored at 4 to 8 °C: Add date After reconstitution: 14 days at 4 to 8 °C

## Intended Use

This material is intended for use in diagnostic tests for the determination of L-lactate.

## Results

Test Parameter <sup>[1]</sup>	Specification	Result
Appearance [color]	Yellow	Add result
Appearance [form]	Powder	Add result
Purity by SDS-PAGE [Band %]	≥ 90 %	Add result
Predominant band [kDa]	~ 42 kDa	Add result
Specific activity [U/mg powder]	249 - 411 U/mg powder	Add result
<b>Kinetic Parameters</b> Electrochemical performance testing with Ferricyanide as electron acceptor		
$J_{max}$ [ $\mu\text{A}/\text{mm}^2$ ]: Maximum current response	6.1 - 10.0 $\mu\text{A}/\text{mm}^2$	Add result
$K_{half}$ [mM]: Substrate concentration at which $J_{max}$ is at 50 %	8.1 - 13.3 mM	Add result
Thermal stability ( $T_{50}$ ) [°C]; after 30 min. storage at given temperature	60 ± 2 °C	Add result
<b>Accelerated Shelf-life</b> ; in formulation defined above for given time and temperature		
Treatment time [time], temperature [°C]	14 days, 40 °C	
Relative activity after treatment [%]	≥ 75 %	Add result

<sup>[1]</sup> Details on analytical methods available on request.

### DirectSens GmbH

Am Rosenbühel 38 3400, Klosterneuburg, Austria  
Phone: +43 699 18355188 Fax: +43 1 476546199  
[www.directsens.com](http://www.directsens.com)

### Board of Directors:

Dr. Christoph Sygmund (CEO)  
Dr. Roman Kittl (COO)

**Reg. No.:** Amtsgericht Wien FN 397944m

**VAT Reg. No.:** ATU 67985601

## Compliance Statement

Manufactured by DirectSens GmbH, Austria. DirectSens certifies that this batch has been tested and approved in accordance with internal Quality Management System. This batch fulfills our specifications at shipping time.

September 12, 2024

Sign. Dr. Dipl.-Ing. Alfons Felice (CTO)

Enzyme Production, DirectSens GmbH

*Remarks: Present QAC is printed electronically and therefore valid in absence of a signature.*

**DirectSens GmbH**

Am Rosenbühel 38 3400, Klosterneuburg, Austria

Phone: +43 699 18355188 Fax: +43 1 476546199

[www.directsens.com](http://www.directsens.com)

**Board of Directors:**

Dr. Christoph Sygmund (CEO)

Dr. Roman Kittl (COO)

**Reg. No.:** Amtsgericht Wien FN 397944m

**VAT Reg. No.:** ATU 67985601