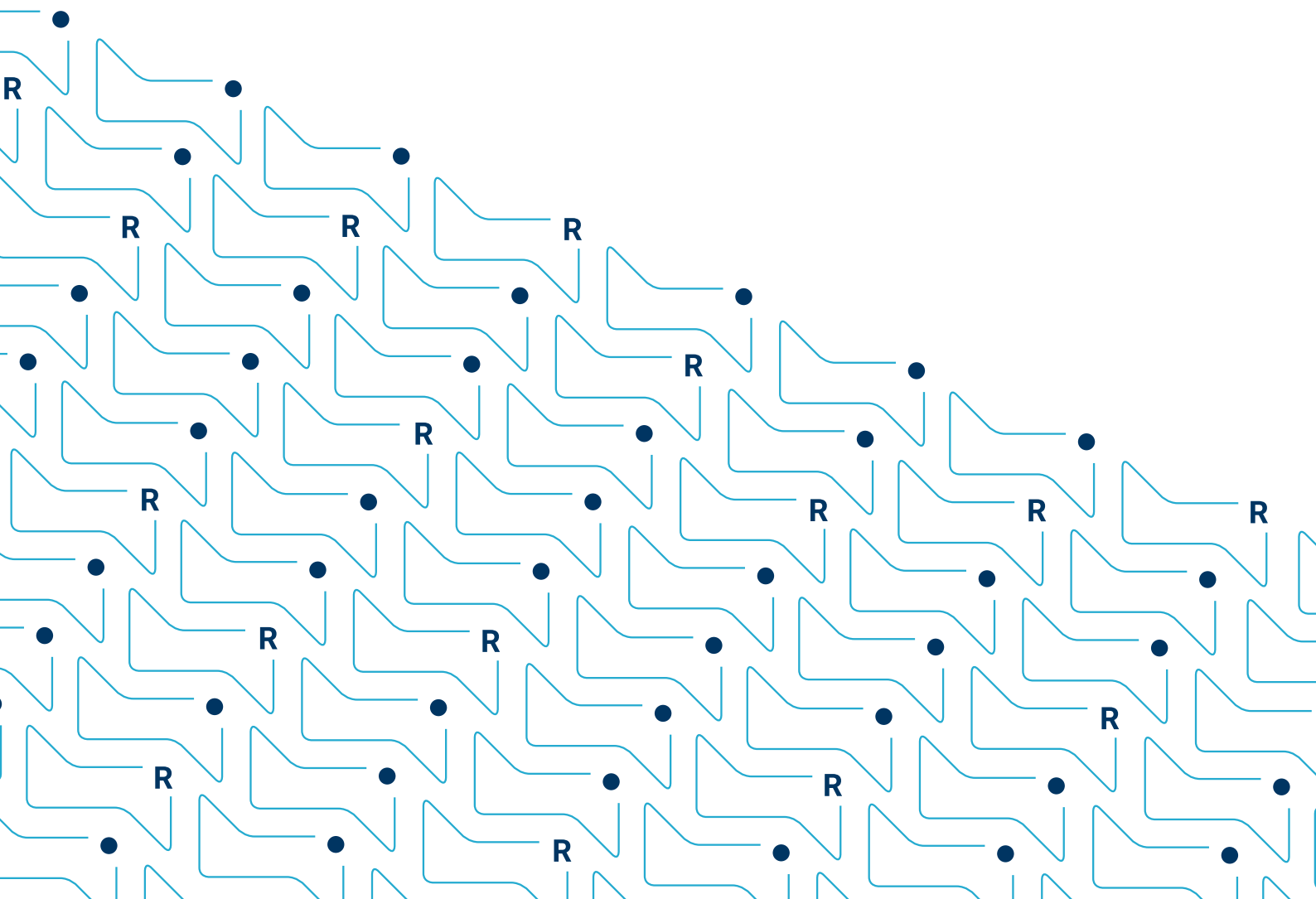


Manual

Reader Kit & Software Guide



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Introduction

The LactoSens®**R** Reader Kit provides hardware and software that will allow you to get precise lactose measurements when used with the LactoSens® biosensors. The LactoSens®**R** Reader utilizes electrochemical technologies to accurately measure the lactose concentration in lactose-free or low-lactose milk & dairy products. The LactoSens®**R** Reader Kit can produce traceability reports and full documentation to validate your “lactose-free” labeling claims. The software provides an intuitive set of menus which guides you, step by step through the assay process. The system is simple to use and rapidly produces results, allowing you to easily include this measurement in your production process. This makes LactoSens®**R** the ideal solution for product release, process optimization and product development.



Technical Specifications

Product Name	LactoSens®R Reader Kit
Product Code	LR10
Key Benefits	The LactoSens®R Reader Kit provides hardware and software that will allow you to get precise lactose measurements when used with the LactoSens® biosensors
Suitable for	Direct measurement of lactose levels in combination with LactoSens®R Biosensor Assay Kit range
Measurement type	Amperometric detection
Function Principle	The lactose-specific enzyme on the biosensor oxidizes the lactose molecules in the sample. The current generated (electrochemical principle) depends on the amount of lactose and can be detected directly and accurately using the LactoSens®R Reader
Dimensions Reader Case	L: 300 mm (11.8 in), W: 85 mm (3.35 in), H: 280 mm (11.02 in)
Dimensions Reader	L: 112 mm (4.41 in), W: 60 mm (2.36 in), H: 27 mm (1.06 in)
Housing Material Reader	Anodized aluminium with rubber sleeve, Color: Silver metallic
Weight	Reader: 220 g, Reader Kit total: 1321 g
Power Supply	USB; 5 V
Communication	Via USB
Components Reader Kit	LactoSens®R Reader with USB-cable • QR Code Scanner (LQ10) • LactoSens®R Adapter (LA10) • LactoSens® Calibration Device (LM10) • LactoSens® Software, Manuals and driver on USB Flash Drive (LU01)
Software	LactoSens® Software V. 2.1
System Requirements	Windows™ 7.0 or higher, min. free 25 MB hard disk space, 2 × USB, windows administrative rights to install software, display resolution min 1280 × 800 pixel
Language Capability	English, German, Portuguese, Spanish, Polish, Italian, Slovak, French, Swedish, Finnish, Chinese, Norwegian
Data Export	In .csv/.xls file: sample name, date, time, test type, parameter, result, unit (g/L, %, mg/100g, ppm), sensor batch, sensor ID, sensor expiry date, reader internal ID, software version
Validation of Method	Against reference method HPAEC-PAD by NordVal International and AOAC Official Method of Analysis First Action status

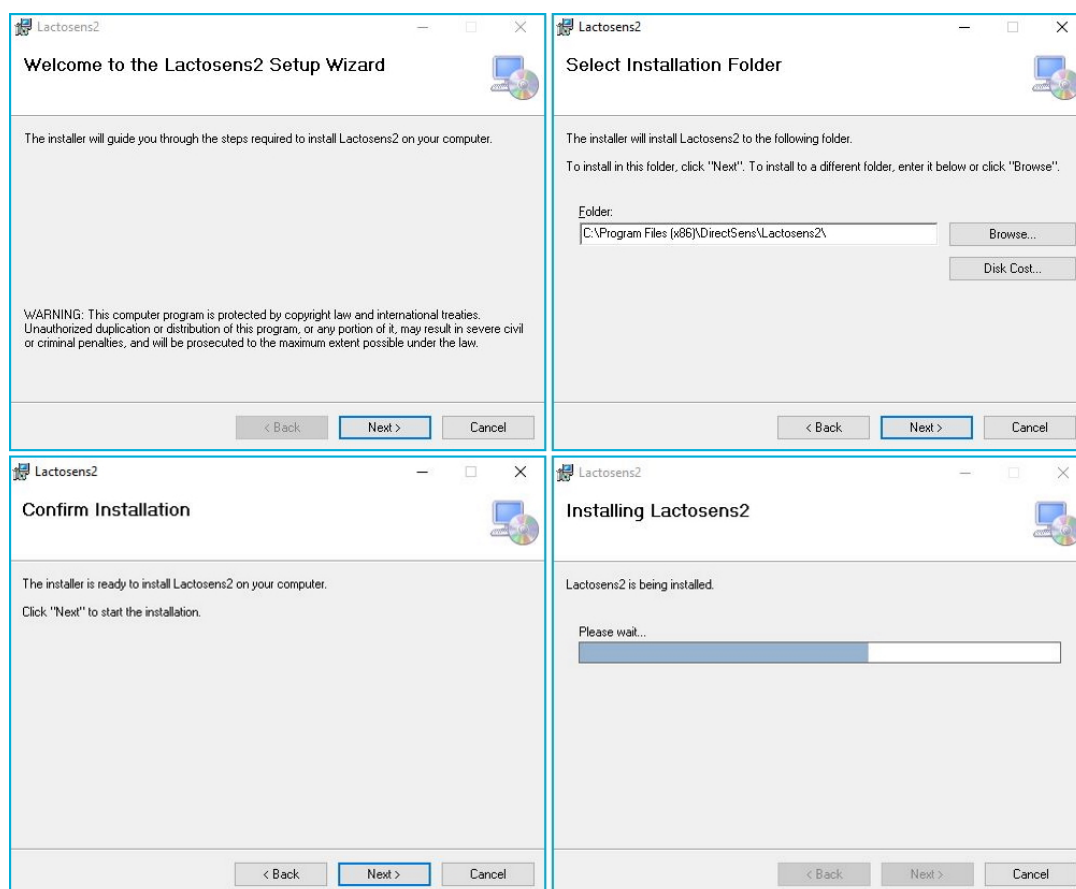
1. Software

1.1 Installing the software

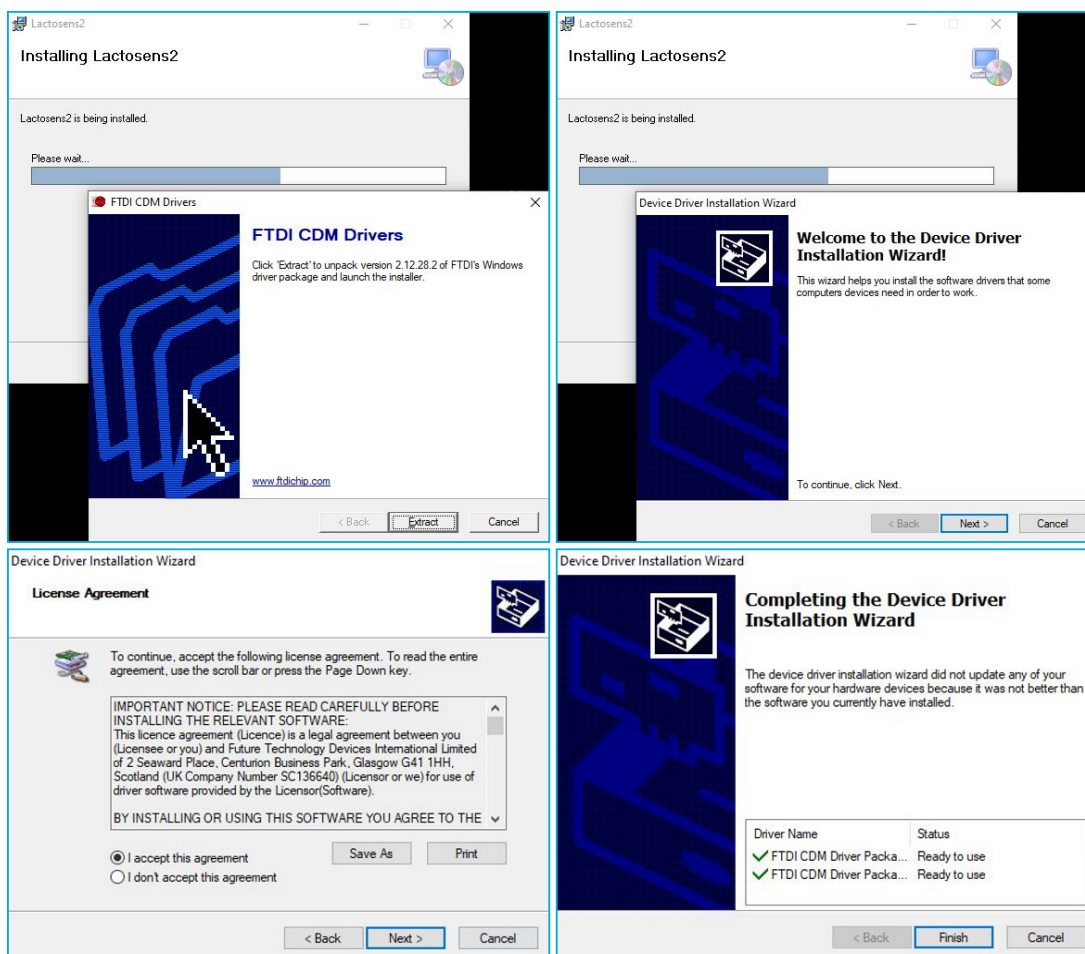


Start setup.exe from the USB Flash Drive.

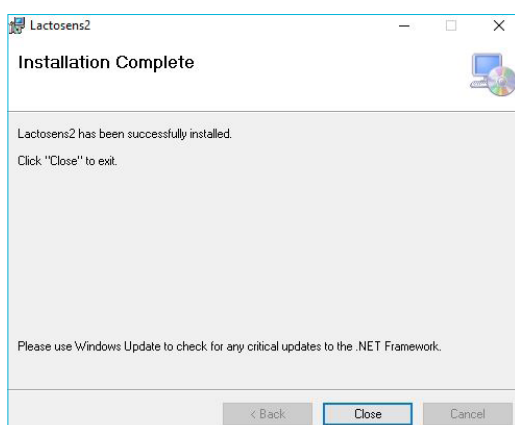
An installation-wizard will guide you through the setup where you can specify the installation path. At each step, after filling in the requested information, press "**Next**" to continue.



Depending on the security settings Windows might ask you now about access-rights on the hard-drive please allow and continue the installation.



During the installation of LactoSens® Software v. 2.1, also drivers for the used hardware will be installed. The setup will invite you to extract the required drivers. An additional wizard will pop up and guide you through the driver installation.



After the drivers are installed, a start button for LactoSens® Software v. 2.1 will be created on your computer desktop and in your start menu (folder DirectSens). The software installation is finished.

The software is now fully installed and ready-to-use.

1.2 Settings

After starting the LactoSens® Software click on the “Settings” button in the upper left corner of the start screen. It gives you the option to configure the following:

Language	Choose between 12 available language (default English)
Sounds	On/off (default on)
Output format	.xls or .CSV (default .xls)
QR code scanner used	QR Code Scanner or Webcam QR Scanner (default QR code scanner)
Automatic drop detection	On/off (default on)

1.3 Data storage and handling

Lactosens_v2.xls file

All measured results are stored as Excel file (.XLS file) by default. If needed the output format can be changed to comma separated value file (.CSV file; see section settings). The file is located at the default path C:\Users\[USERS]\Documents\Lactosens_v2.xls. If there is an existing Lactosens_v2.xls file, the software will automatically amend the values to the file. If no file called Lactosens_v2.xls exists, it will be created automatically. The information given in the results file is compatible with LIMS.

Test Report lactosens®

Test Date: 10/5/2020
Test Time: 2:42 PM

Sample Name	Test	Parameter	Result	Unit
Sample 1	LactoSens®R	Lactose	< 0.008	%

Measurement Details

Sensor Batch	LL1206A	Reader Internal ID	LR1610210
Sensor ID	2543	Software Version	v2.1.510.0
Sensor Expiry	4/28/2021		

This Report is electronically generated and has therefore not been signed.

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Biosensors
DirectSens GmbH | Am Rosenhügel 18 | 3420 Kirchdorf | Austria
lactosens@directsens.com | Tel: +43 699 1835 5188 | www.lactosens.com

Test Report

With each LactoSens® measurement the software automatically generates a specific Test Report document in pdf format. The location where the Test Report is saved can be selected individually. This feature can also be switched off at the results screen.

View last results

Individual results of the ongoing measurement session can be viewed by clicking on the button “View last results” in the upper left corner. This will open a window with the measurement specific data which can be easily exported to an excel file.

2. Hardware

2.1. Connecting the hardware

- Connect the LactoSens®R Reader and the QR Code Scanner with the computer using the provided USB cables
- Turn on the LactoSens®R Reader by pressing the start button until the white ring around the start button is illuminated
- When LactoSens®R Reader is connected for the first time, USB-to-serial drivers will be automatically installed (the number of the COM-port might vary between computers and is of no relevance)

2.2. QR code and scanner

Each individually packed sensor is labeled with a QR code containing the following information:

- Batch specific calibration data
- Sensor expiry date
- Sensor batch name
- Sensor identification number

Before you can start the actual lactose measurement this information has to be transferred to the software. This can either be done by scanning the QR code with the included QR Code Scanner or by typing in the 53-digit number (without spaces) printed below the QR code. We strongly recommend using the QR Code Scanner!

Scanning the QR code with the QR Code Scanner

Put the package with the QR code in front of you on the table. Point the laser at the QR code from a distance of approx. 20 cm. Once the code is recognized you will hear a beep and the software will guide you through the next steps.

Enter sensor information manually (in the case of problems)

Alternatively, the QR code can be entered by typing in the 53-digit number (without spaces) printed below the QR code. After pressing the button "Scan

sensor QR code" you can click the box "Enter QR code value manually". Please type in the 53-digit code which is printed below the QR code. Please enter all digits including "." and "-". Do not press space between the digits. Once the code is recognized you will hear a beep and the software will guide you through the next steps. DirectSens strongly recommends using the QR Code Scanner!

Sensor identification number

Please be aware that the sensors are for single use only. Consecutive measurements with the same sensor are not allowed and lead to strong underestimation of lactose concentration. After pressing the START button in the LactoSens® Software the sensor identification number will be blocked for further use.

2.3 LactoSens®R Adapter with automatic sample detection

Replacement of sensor connector

If the LactoSens®R Adapter is broken, you can easily exchange it by following these steps:

- Disconnect the LactoSens®R Reader and remove rubber sleeve
- Turn the reader on its back and open screw next to front panel
- Remove front panel with adjacent printed circuit board (PCB) by carefully sliding it out of the housing
- Take ESD bag with spare LactoSens®R Adapter, open and take out the Adapter
- Be careful to touch only the aluminium front panel

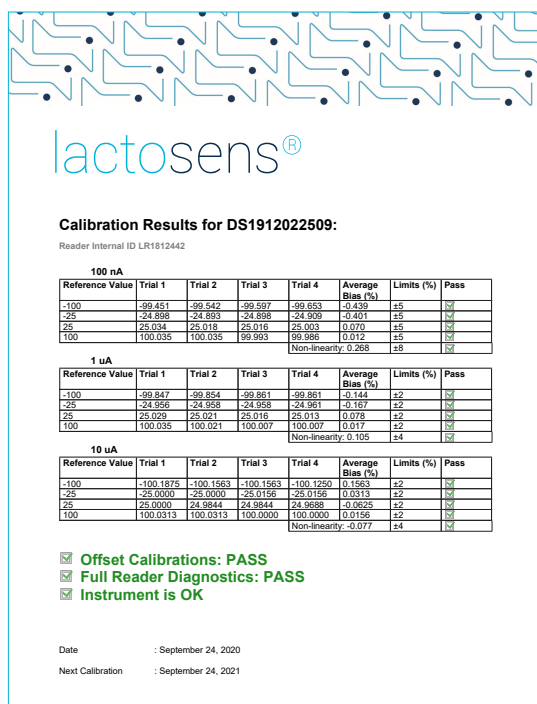
Avoid touching the PCB!

- Carefully slide the LactoSens®R Adapter into the housing using the rails on the side
- Firmly close the screw and pull the rubber sleeve over the LactoSens®R Reader

Automatic sample detection

Once the LactoSens®R Reader detects first contact of the sample with the sensitive area a 15 seconds countdown will start. The remaining time is visualized in a progress bar in the right lower corner in the software window and can be used to load the sample correctly. After 15 seconds the start of the measurement will be triggered automatically.

2.4 Calibration device



lactosens®

Calibration Results for DS1912022509:
Reader Internal ID LR1812442

100 nA

Reference Value	Trial 1	Trial 2	Trial 3	Trial 4	Average Bias (%)	Limits (%)	Pass
-100	-99.451	-99.542	-99.597	-99.653	-0.439	±5	✓
-25	-24.898	-24.993	-24.898	-24.909	-0.401	±5	✓
25	25.034	25.018	25.016	25.003	0.070	±5	✓
100	100.035	100.035	99.993	99.985	0.012	±5	✓
Non-linearity: 0.268						±5	✓

1 uA

Reference Value	Trial 1	Trial 2	Trial 3	Trial 4	Average Bias (%)	Limits (%)	Pass
-100	-99.847	-99.854	-99.861	-99.881	-0.144	±2	✓
-25	-24.956	-24.958	-24.958	-24.961	-0.167	±2	✓
25	25.029	25.021	25.016	25.013	0.075	±2	✓
100	100.035	100.021	100.007	100.007	0.017	±2	✓
Non-linearity: 0.105						±2	✓

10 uA

Reference Value	Trial 1	Trial 2	Trial 3	Trial 4	Average Bias (%)	Limits (%)	Pass
-100	-100.1875	-100.1563	-100.1563	-100.1250	0.1563	±2	✓
-25	-25.0000	-25.0000	-25.0156	-25.0156	0.0313	±2	✓
25	25.0000	24.9844	24.9844	24.9688	-0.0625	±2	✓
100	100.0313	100.0313	100.0000	100.0000	0.0156	±2	✓
Non-linearity: -0.077						±2	✓

☒ **Offset Calibrations: PASS**
☒ **Full Reader Diagnostics: PASS**
☒ **Instrument is OK**

Date : September 24, 2020
Next Calibration : September 24, 2021

The LactoSens®R Reader kit provides a calibration device, allowing the user to check if the instrument works within its specifications. At the end of the calibration process a PDF calibration report is generated certifying that tested parameters are within the limits.

- The LactoSens®R Software will guide you through the whole calibration process with step-by-step instructions
- Start the LactoSens®R Software on your computer
- Connect and turn on the LactoSens®R Reader

- Press the button "Calibration" in the upper left corner of the software start screen
- Enter the LactoSens®R Reader serial number found on the bottom of the reader and confirm
- The LactoSens®R Software will prompt you to insert the calibration device into the reader
- Take out the LactoSens® Calibration Device from your LactoSens®R Reader Kit
- Insert the LactoSens® Calibration Device into the reader by pushing the side with the golden contacts into the reader slot. The LactoSens® logo must face upwards
- Confirm by pressing "START"
- A progress bar will appear and indicate the time to result (approx. 150 seconds)
- After successfully finishing the calibration, a calibration report will be generated

Determination of lactose in lactose-free and low lactose dairy products

lactosens®R

Biosensor Assay Kit for
determination of lactose
in lactose-free and low-
lactose dairy products

Manual

LactoSens®R is a resilient and robust biosensor assay kit providing reliable results within a minute. The method is applicable for a vast range of milk products, from milk to mozzarella (complete list see www.lactosens.com) and gives accurate results even in the presence of fruit preps or added flavors (e.g. cocoa, coffee).

The method convinces with its simplicity and accuracy. Already factory calibrated, a simple 1 plus 1 sample dilution is enough to enable results equivalent to the reference method HPAEC-PAD¹. LactoSens®R has received AOAC Official Method of Analysis First Action status and external certification by NordVal. This makes LactoSens®R the perfect choice for product release, process optimization and product development.

LactoSens®R Biosensor Assay Kit specifications

- **Product number** (assays per kit): LK1225 (25 sensors)
- **Key benefits** fast and precise detection of lactose, easy-to-use, universally applicable
- **Suitable for** direct measurement of lactose levels in lactose-free or low-lactose milk, (fruit) yoghurt, sour cream, curd, cream and many more milk products (to learn more visit www.lactosens.com)
- **Limit of quantitation** 0.008 % lactose, equivalent to 0.08 g/L
- **Quantitation range** 0.008 % - 0.2 % lactose in dairy products
- **Measuring time** < 1 minute
- **Sample preparation** 1 plus 1 dilution with buffer
- **Sample volume** 100 µL
- **Storage** 2 – 8 °C (36 – 46 °F)
- **Certified by external body** validated against reference method HPAEC-PAD by NordVal International and AOAC Official Method of Analysis First Action status



¹ High Performance Anion Exchange Chromatography with Pulsed Amperometric Detection

directsens Biosensors LactoSens®R manual V 3.0 www.lactosens.com

1. What you need

LactoSens®R Biosensor Assay Kit

25 single packed LactoSens®R Biosensors

2 bottles (125 mL) of LactoSens®R Buffer, ready-to-use

1 vial (2 mL) of LactoSens®R Positive Control, ready-to-use (specifications see QAC)

Manual

Quality Assurance Certificate

Additionally required materials

LactoSens®R Reader Kit

LactoSens® Software V.2.0 or higher

Vials, pipettes, tips for product dilution and sample application

Vortex device for mixing samples

Laptop or PC for connection with LactoSens®R Reader

NOTE: LactoSens®R Biosensor Assay Kit is only compatible with **LactoSens® Software V. 2.0** or higher!

2. Sample preparation



- Bring milk product, buffer and required quantity of sensors to room temperature: $22 \pm 2^\circ\text{C}$ ($72 \pm 3^\circ\text{F}$)
- Dilute milk product with equal amount of LactoSens®R Buffer (e.g. 1 mL or 1 g milk product plus 1 mL or 1 g buffer)
- Mix diluted milk product (e.g. by shaking or vortexing)



For information regarding additional sample preparation steps for solid products (mozzarella, curd, fresh cheese) or products with a fat content above 20 % please visit www.lactosens.com.

3. Measurement

3.1 Connect and turn on LactoSens®R Reader



LactoSens®R manual V 3.0

3.2 Start the LactoSens®R Software

A green icon in the lower left corner of the LactoSens®R Software window indicates a connected reader!

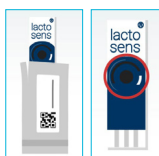
3.3 Insert sample name and scan QR code



- Click on "Scan sensor QR code"
- Optimal scanning distance is 10 – 20 cm
- Point the red light directly on the QR code
- Acoustic signal if sensor is scanned correctly



3.4 Insert sensor



3.4.1 Open sensor package

Do not touch the sensitive area on the sensor!

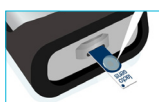
3.4.2 Insert sensor

- The LactoSens® logo must face upwards
- Push side with silver contacts into the reader
- Sensor must be inserted to the very end



3.4.3 Confirm by pressing "Next"

3.5 Sample application



Add 100 µL sample

- Distribute sample equally on the sensitive area
- Use the pipette tip to position the drop correctly
- Make sure that the sensor area is completely covered!



A correct sample application is crucial for an accurate measurement!

www.lactosens.com

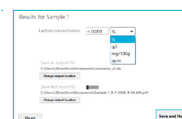
3.6 Analysis

LactoSens®R Reader will automatically detect sample and start measurement.

You have 15 seconds to finish sample application!

3.7 Save results

- Select unit (% or g/L or mg/100g or ppm)
- Click "Save and Next" to return to the start screen



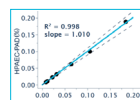
For detailed information please refer to the LactoSens®R Reader and Software Guide or watch the training video available at www.lactosens.com.

4. LactoSens®R assay performance



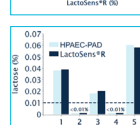
Precision and Accuracy

A reference milk sample containing 0.031 % lactose (HPAEC-PAD, ●) was measured with LactoSens®R biosensors (+) on three consecutive days by three different operators. All 18 measurements give the correct lactose concentration with a deviation of below 10 % (---) with an overall RSD of 4 %.



Recovery and measurement range

Milk samples with lactose concentrations covering the whole measurement range (0.008 – 0.2 %) show an exceptional correlation (slope of 0.997) to HPAEC-PAD with deviations of below 10 %.



Robustness

LactoSens®R biosensor can be used in white mass or finished products. It gives accurate results even in the presence of fruit preps and added flavors. During validation a wide variety of samples were successfully tested: fruit yoghurt (1), milk coffee (2), chocolate milk (3), high protein milk drink (4) and flavored dairy drink (5).

directsens Biosensors

DirectSens GmbH | Am Rosenbühl 38 | 3400 Klosterneuburg | Austria
lactosens@directsens.com | Tel. +43 699 1835 5188 | www.lactosens.com

LactoSens® to order

LactoSens®R Biosensor Assay Kit	LK1225	GIN 719766
LactoSens®R Reader Kit	LR10	GIN 719604
LactoSens®R Biosensor Assay Kit for NOLA™ Fit	LK1325	GIN 719602
LactoSens®R Adapter	LA10	-
LactoSens® 0.02% Biosensor Test Kit	LK0125	GIN 714978
LactoSens® Calibration Device	LM10	GIN 720031
QR Code Scanner	LQ01	-

Training video

for the correct use of the LactoSens®R Biosensor Assay Kit

available at www.lactosens.com. For technical support please contact DirectSens® or your local distribution partner

Contact

DirectSens GmbH

Am Rosenbüchel 38
3400 Klosterneuburg | Austria
lactosens@directsens.com
Tel. +43 699 1835 5188
www.lactosens.com