EN Product information about the Lactate Scout sensors for single, disposable use with the Lactate Scout and Lactate Scout+ analyzer to determine lactate in whole blood. Please read carefully before using!

INTENDED USE

CE 0123 MD

Lactate Scout sensors are only to be used with the Lactate Scout analyzer to determine the lactate concentration in capillary blood. For in-vitro-application only! The Lactate Scout sensors and the Lactate Scout analyzer can be used by individuals for self-testing and by health personnel.

WARNING NOTICES

Read the instruction manual and package insert before using the Lactate Scout. Avoid any risk of sensors being swallowed! Keep away from children! Always wear gloves when you are carrying out a measurement on another person! The handling of blood generally carries the risk of infections. Please make sure items containing or contacted by blood (such as sensors, lancets and tissues) are safely disposed and make sure that all items and devices that have been in contact with blood are desinfected properly.

STORAGE

-18 °C +8 °C

Keep the sensors protected from moisture and direct sun light! Keep refrigerated! Store the sensors only in the original container and within the specified temperature range of -18 °C to +8 °C. The expiration date of the sensors on the label of the sensor container must be observed. Once the sensor vial is opened the sensors are stable for 90 days or until the specified expiry date if it is sooner. Without refrigeration store below 25 °C / 77 °F for maximal 30 days. Transport and store the sensors only in the original vial! Take out the required sensors for immediate use only and close the vial again, to keep the other sensors protected continually. Before using refrigerated sensors, keep the closed vial at ambient temperature for at least 20 min. When used, analyzer and sensors should be at same temperature.

WRONG TEST RESULTS / INTERFERENCES

Impurities like sweat, alcohol or disinfectant on the skin may cause problems with the sample uptake or falsify the result. Ensure that the puncture site is cleaned carefully with water and dried before every sampling. Use only fresh blood samples for measurement! The intake of drugs like i.e. Paracetamol or diseases, infections, diets, carbonhydrate-rich food, physical or mental stress can influence the test result individually.

HANDLING (FOR SINGLE, DISPOSABLE USE)

After cleaning and puncturing of the sampling area, a new, non-used Lactate Scout sensor has to be inserted into the Lactate Scout analyzer. Therefore, hold the sensor in the middle and do not touch the tip! The hands should be clean and dry. By inserting the sensor, the calibration code will be displayed briefly. Ensure that it is identical to the code as printed on the used sensor vial. Also check the expiry date! Blot away the first drop of blood and use the second drop for the measurement. Lower the Lactate Scout analyzer with the tip of the inserted sensor from top down to the fresh drop of blood do not touch the skin! The required sample volume (0.2 µl) will be uptaken automatically. When the display shows LAC, the measurement proceeds and the result will be displayed after 10 s. By removing the sensor, the result will be stored automatically (incl. date, time and other data), and the Lactate Scout analyzer switches off.

Error messages: For readings above 25.0 mmol/L, „HI“ appears, and „LO“ for readings lower than 0.5 mmol/L. In case of handling problems or malfunctions, an error message will appear (Er 1 - 6“, as described in the manual).

Health note: There are no known health risks when using Lactate Scout sensors according to the instructions. If even so discomfort is felt after usage a physician should be contacted immediately. Persons prone to excessive bleeding or infection, should consult a doctor generally before puncturing and sampling.

PERFORMANCE DATA

Measurement method: Enzymatic-amperometric detection of lactate
Reagent per sensor: Lactate oxidase, electron mediator, additives
Precision:
± 3 % (minimal standard deviation: ± 0.2 mmol/L) for Hct range 35 – 50%
± 4 % (minimal standard deviation: ± 0.3 mmol/L) for extended Hct range
Sample volume: 0.2 µl
Measuring range: 0.5 - 25.0 mmol/L