51416 - 02/20

Symbols

	Manufacturer
	Caution, read instructions for use
REF	Catalogue number
LOT	Batch code
	Temperature limitation
	Use by
CE	CE marking
IVD	*In vitro* Diagnostic Medical Device
	Significant additions or changes from previous instructions for use revision
	Recyclable package

The test strips comply with the requirements of directive 2011/65/EU on the restriction of use of certain hazardous substances in electrical and electronic equipment and with the requirements of directive 98/79/EC on *in vitro* diagnostic medical devices.

Availability

REF **51342** - 10 GLUCOFIX® TECH Sensor: 1 vial x 10 test strip
REF **51343** - 50 GLUCOFIX® TECH Sensor: 1 vial x 50 test strip

Date of issue: June 2018

A. MENARINI DIAGNOSTICS Srl
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Made in Taiwan

If you have any question about GLUCOFIX® TECH Sensor, please contact:

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GLUCOFIX® TECH Sensor

- GLUCOSE TEST STRIPS
  Instructions for use

CE 0123 IVD

A.MENARINI diagnostics

ENGLISH

Before using the test strips carefully read these instructions for use and the User Manual of your meter. If you have any questions, please contact the A. Menarini Diagnostics Customer Service.

Intended use

The GLUCOFIX® TECH Sensor test strips are only for use with the GLUCOFIX® TECH blood glucose meter or the GLUCOFIX® TECH 2K blood glucose and β-ketone meter for the quantitative measurement of glucose levels in fresh capillary whole blood.
GLUCOFIX® TECH Sensor is an *in vitro* diagnostic medical device.
GLUCOFIX® TECH Sensor test strips are intended for self-testing to monitor and control blood glucose levels by people with diabetes mellitus; they can also be used in a clinical setting by healthcare professionals. They are not intended for diagnosis or screening of diabetes or for neonatal use. Do not alter your treatment on the basis of test results without previously consulting your doctor or healthcare professional.

Measurement Principle

The glucose present in the blood sample mixes with reagents on the test strip and this reaction produces a small electric current, the intensity of which is proportional to the concentration of glucose in the blood. The meter measures this current and calculates your blood glucose level.

Reagent system (per cm²)

- Glucose Oxidase (*Aspergillus niger* sourced), 3.5%
- Mediator: Hexacyanoferrate(III) ion, 17.5%
- Non-Reactive Substances, 79%

Storage and Usage Conditions

- Store the test strip vial in a dry place (RH 20-90%), at a temperature of 4-30 °C (39.2 – 86 °F). Do not freeze. Avoid heat and direct sunlight.
- Keep all unused test strips in the original vial and after having removed on, close the cap tightly to maintain their quality. Do not transfer them into any other container.
- Do not use the test strips after their expiry date.
- Do not use the test strips for more than 12 months after first opening the test strip vial. We recommend writing the discard date (opening date + 12 months) on the label.

Warning and safety information

- Keep the meter, test strips and other items out of the reach and sight of children. Small items may represent choking hazards.
- Handle the vial and test strips with clean, dry hands.
- Dispose of the vial and used test strips according to local regulations.
- HANDLING BLOOD CAN BE DANGEROUS. You or other individuals could be infected by pathogenic microorganisms due to incorrect or imprecise procedures. USE EXTREME CAUTION when handling blood, test strips, lancets and meter.

Sample

This meter can test the glucose level of blood from your fingertip, palm, and forearm. However, test results from sites other than the fingertip (Alternative Site Testing, AST) may give different measurements. Consult your doctor or healthcare professional before performing AST.

Test procedure

Materials provided. GLUCOFIX® TECH Sensor test strips.
Materials required but not provided. Meter, Lancing device, Lancets.

See the user manual of your meter for more details.

- For accurate test results, allow the test strips and meter to adjust to their surroundings for at least 30 minutes before testing your blood glucose. Operating conditions are: temperature 5-45 °C (41-113 °F); relative humidity 20-90%.

1. Remove 1 test strip from the vial with clean, dry hands.
  • The test strips are for single-use only. **Do not** use test strips if wet, damaged, or stored in a damaged vial.
  • Tightly close the bottle immediately after taking out a test strip.
  • Use the test strip immediately.
2. Insert a new test strip into the test strip port. The drop icon will start blinking on the screen.
3. Collect blood using a lancing device and a new lancet, according to the relative instructions for use.
4. Apply the drop of blood to the tip of the test strip until the check window is full.
  • Do not test blood that runs or spreads out from the puncture site.
  • Do not smear blood onto the test strip.
  • Do not forcefully press the test strip into your puncture site.
  • Do not touch the test strip once the meter starts the countdown.
5. The test result will appear on the screen once the test is completed.
6. Press the release button to remove the test strip.
  • Test strips and lancets qualify as biohazardous waste once used to test blood glucose. They must therefore be disposed according to local regulations on biohazardous waste.

- **If the test results do not match how you feel:**
  Make sure you performed the test correctly as explained in the user manual. Then conduct a control test to check that the system is working properly. If you tested blood from your palm or forearm, repeat the test **using a blood sample taken from a fingertip (do not use an alternative site)**. If the test results still do not match how you feel, contact your doctor or healthcare professional.

Control Test

If you need to perform a control test, read the user manual of your meter and the instructions for use of your GLUCOFIX® TECH Control solution.

Restrictions

- DO NOT use plasma or serum samples. DO NOT test venous or arterial blood samples.
- DO NOT test samples from newborn infants.
- Altitudes up to 3150 m (10335 feet) will not affect the test results.
- Allowed haematocrit range: 10 - 70% (EN ISO 15197:2015).
- Icodextrin and its metabolites (maltose, maltotriose and maltotetraose) do not significantly affect test results.
- The following drugs may affect test results: dopamine (>0.1 mg/dL), L-DOPA (>3 mg/dL), acetaminophen (>10 mg/dL).
- The glucose reading for GLUCOFIX® TECH is not affected by sample oxygen conditions (pO2) from 52-115 mmHg (6.9-15.3 kPa).
  Under 52 mmHg (6.9 kPa) the GLUCOFIX® TECH system overestimates the glucose values, whereas over 115 mmHg (15.3 kPa) the system underestimates the measurements.

Measurement range

The results are equivalent to the plasma glucose concentration. The measurement range of the GLUCOFIX® TECH Sensor is 1.1 – 33.3 mmol/L.

Calibration and traceability

The system is calibrated using reference plasma values determined with a YSI analyzer. The YSI analyzer is calibrated (as a secondary reference measurement procedure) using a series of YSI standards (primary calibrators) taken from the NIST (National Institute of Standards and Technology, USA).

Performance of GLUCOFIX® TECH Sensor

The performance of GLUCOFIX® TECH Sensor fully complies with EN ISO 15197:2015.

Precision. Repeatability and intermediate precision results are shown in *Fig. 1*.

	REPEATABILITY (Blood Samples, N=300 per level)					INTERMEDIATE PRECISION (Control Material, N=300 per level)		
Glucose Level mmol/L	1.7-2.8	2.8-6.1	6.2-8.3	8.4-13.9	13.9-22.2	1.7-2.8	5.3-8.0	15.5-23.3
Average mmol/L	3.1	4.5	6.8	12.3	20.4	2.2	6.7	21.2
SD mmol/L	0.1	0.1	0.2	0.3	0.4	0.2	0.2	0.6
CV%	NA	NA	2.7	2.3	1.9	NA	3.3	3.0

Fig. 1

Accuracy. A comparison of the results of the GLUCOFIX® TECH Sensor with those obtained using capillary plasma tested with the glucose oxidase method performed on a laboratory analyser (YSI Model 2300 STAT Plus), indicated a high level of accuracy. The results were obtained by testing samples from 100 diabetic subjects (*Fig. 2*). 100% of individual glucose measured values falls within zones A and B of the Consensus Error Grid for type 1 diabetes.

ACCURACY	
Glucose concentration < 5.6 mmol/L (N=186)	
Within ± 0.28 mmol/L	128/186 (68.8%)
Within ± 0.56 mmol/L	180/186 (96.8%)
Within ± 0.83 mmol/L	186/186 (100%)
Glucose concentration ≥ 5.6 mmol/L (N=414)	
Within ± 5%	329/414 (79.5%)
Within ± 10%	409/414 (98.8%)
Within ± 15%	414/414 (100%)
Combined results (N=600)	
Within ± 0.83 mmol/L or 15%	600/600 (100%)

Fig. 2

Interference Testing. The substances listed in *Fig. 3* have been tested for interference with the system. The table reports the maximum concentration with no interfering effect according to EN ISO 15197:2015.

Substance	Test Concentration	Substance	Test Concentration
Acetaminophen	10 mg/dL	Heparin	3000 U/L
Acetylsalicylic acid	40 mg/dL	Ibuprofen	40 mg/dL
Ascorbic acid	6 mg/dL	Icodextrin	1094 mg/dL
Bilirubin	20 mg/dL	L-DOPA	3 mg/dL
Cholesterol	500 mg/dL	Maltose	280 mg/dL
Creatinine	5 mg/dL	Methyl-Dopa	15 mg/dL
Dopamine	0.1 mg/dL	Pralidoxime Iodide (PAM)	50 mg/dL
EDTA	0.5 mg/dL	Tolazamide	23 mg/dL
Galactose	15 mg/dL	Tolbutamide	10 mg/dL
Gentisic acid	2 mg/dL	Triglycerides	1500 mg/dL
Glutathione	1.5 mmol/L	Uric Acid	15 mg/dL
Hemoglobin	200 mg/dL	Xylose	25 mg/dL

Fig. 3

User performance evaluation with GLUCOFIX® TECH meter. A study evaluating glucose values from fingertip capillary blood sample obtained by 105 lay persons showed the following results: 100% within ± 0.83 mmol/L of the reference values at glucose concentration < 5.6 mmol/L and 98.9% within ± 15% of the reference values at glucose concentration ≥ 5.6 mmol/L.

User performance evaluation with GLUCOFIX® TECH 2K meter. A study evaluating the glucose values in fingertip capillary whole blood samples obtained by 100 lay persons showed the following results: 100% within ± 0.83 mmol/L of the reference values at glucose concentrations < 5.6 mmol/L and 100% within ± 15% of the reference values at glucose concentrations ≥ 5.6 mmol/L.

References

- Definition and diagnosis of diabetes mellitus and intermediate hyperglycaemia. Report of a WHO/IDF, World Health Organization, 2006.
- American Diabetes Association, Standards of Medical Care in Diabetes-2014. Diabetes Care, 37, Suppl 1, 2014.
- Oliver N. S., Toumazou C., Cass A. E. G., Johnston D. G., Glucose sensors: a review of current and emerging technology. Diabetic Medicine, 26, 197–210, 2009.

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Description	GLUCOFIX® TECH Sensor - Insert - UK		**Colours Used**
Code	51416	■	I - BLACK C
Rev	02/20		
Size (mm)	220 (w) x 390 (h)		

Edition	1	2	3	4	5	6	7	8
Date preparation								

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