# EASYMAX® Blood Glucose Test Strip Instructions

## Intended Use

The EASYMAX® Series test strip is intended for the quantitative determination of glucose in whole blood. The test strip is intended for use with EASYMAX® Series glucose monitors. The test strip is suitable for use in venous blood or fresh capillary blood. It is not intended for use in urine or expired breath samples.

## Important Information

1. Before you use this product, make sure that the EASYMAX® Series Manual is included in the test strip package.
2. Do not test neonate blood sample.

## Principle

The EASYMAX® test strip is a solid phase enzyme immunoassay (EIA) based on competitive inhibition. The enzyme is gluco-oxidase bound to polystyrene beads. In this reaction, gluco-oxidase catalyzes the oxidation of glucose in the presence of oxygen to gluconic acid and hydrogen peroxide. The amount of hydrogen peroxide generated is measured by the enzyme HPOD which catalyze the conversion of a fluorophore (aminophenazone) to a fluorescent compound (fluorescein). The amount of the fluorescent compound is measured in the meter and is proportional to the blood glucose concentration. The test strip contains, in addition to the enzyme gluco-oxidase, two other enzymes, PO and HPOD, which catalyze the conversion of the aminophenazone fluorophore to a fluorescent compound (fluorescein). The amount of the fluorescent compound is measured in the meter and is proportional to the blood glucose concentration.

## Reagent Composition

EASYMAX® Test Strips: 6 strips/pack.

- Glucose oxidase
- Peroxidase
- Aminophenazone
- Fluorescein

## Storage and Handling

1. Store the Test Strips and Control Solution at room temperature (20°C to 30°C (68°F to 86°F)) for at least 6 months before opening the foil wrapping.
2. Do not store the test strip outside the foil wrapper.
3. Do not store the test strip beyond its expiration date.
4. Make sure that the test strip is not exposed to moisture or high humidity.

## Precautions

1. Do not use the test strip after the expiration date.
2. Do not store the test strip beyond its expiration date.
3. Do not use the test strip if it is not in its original package.
4. Do not use the test strip if it is expired.
5. Avoid using the test strip if it is damaged.

## Supplies For Testing Your Blood

- EASYMAX® Test Strips
- Lancets
- Alcohol swab
- Glucose Control Solution

## EASYMAX® Series User’s Manual

- For use with EASYMAX® Series glucose monitors.

## Collection and Preparation

1. **Blood Collection**
   - Use the blood collection area at the tip of the strip.
   - Apply a blood sample to the blood collection area at the tip of the strip.
   - The blood sample volume requires at least 0.6 mL.

## Antigen Control

1. If the antigen control is low, your meter and test strips are not working properly. Contact your local dealer.
2. If the antigen control is high, your meter and test strips are working properly.
3. Do not test grossly lipemic patient samples with EASYMAX® Series test strips.

## Expected Results

1. Your result will appear on the screen after 5 seconds and be stored in the meter.
2. The test range is between 20 to 630 mg/dL (1.1~35.0 mmol/L).

## Interpretation

1. If the control solution test results are outside the range, your meter and test strips are not working properly. Contact your local dealer.
2. If the control solution test results are within the range but not close to the expected results, your meter and test strips are working properly.

## References


## Limitations

1. Do not use the test strip if it is damaged.
2. Do not use the test strip if it is expired.

## Performance Characteristics

1. Labelled range: 20 to 630 mg/dL (1.1~35.0 mmol/L).

## Quality Assurance

1. EASYMAX® Series Self-Monitoring Blood Glucose System was measured with both venous blood and control solution in the laboratory.

## Accuracy

In comparison to the YSI ELAN 2123, the YSI EN ISO 15197:2013 standard, 95% of the blood glucose values measured were within the following ranges: (a) ≤10 mg/dL (≤0.56 mmol/L) and (b) ≤10 mg/dL (≤0.56 mmol/L) measured average values when using the reference measuring procedure for the calibration of the EASYMAX® Series Self-Monitoring Blood Glucose System.

## Interfering Substances

- The test strips performance in both laboratory and clinical tests.
- Use the anticoagulant EDTA or sodium Heparin or Lithium Heparin to prevent for venous and capillary blood samples.
- Use the anticoagulant EDTA or sodium Heparin or Lithium Heparin to confirm the SMBG system.
- The test strips performance in both laboratory and clinical tests.
- Use the anticoagulant EDTA or sodium Heparin or Lithium Heparin to diagnose the EASYMAX® Series SMBG System.

## Notes

- This product met the requirements of Directive 98/79/EC.
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## Acknowledgments

- EPS Biotechnology Corp.
- Hematocrit: the test strip result is not significantly affected by
- The reference range is for the EASYMAX® Series SMBG System.
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