

# AUVON DS-W

## Draw-In Blood Glucose

Test Strip

### Before You Begin

- Carefully read this entire instruction for use.
- If you have any question or need assistance, please contact our authorized dealer in your country.

### Summary

The Draw-In blood glucose test strip is designed to provide an easy and accurate method for the determination of blood glucose in capillary whole blood. When the method is applied to the edge of reaction zone, the blood is drawn into the reaction chamber and displays a reading on the meter. Only a small amount of blood is needed. The test strip for the quantitative measurement of blood glucose is within the range of 20-600mg/dL (1.1-33.3 mmol/L)

### Principles of the procedure

This analysis employs the enzyme glucose oxidase and is based on advanced biosensor technology that is specifically for  $\beta$ -D-glucose measurement. The test strips are designed in such a way that the blood sample is drawn into the test strip through capillary action. The glucose oxidase triggers the oxidation of glucose in the blood. The intensity of the electrons formed is measured by the meter which correlates well with the concentration of glucose in the blood sample.

### Reagents

35.6% w/w glucose oxidase  
41.0% w/w potassium ferricyanide  
23.4% w/w nonreactive ingredients

### Precautions and Warnings

- The device is intended for self-testing.
- Draw-In blood glucose test strips are for in vitro diagnostic use only (external use only).
- The Draw-In blood glucose test strips are only used with DS-Series Blood Glucose Meter. The use of any other brand of test strips may cause erroneous results. AUVON® Inc. does not warrant the use of the DS-Series Blood Glucose Meter with other brands of test strips.
- Used strips, lancets and alcohol pads may be infectious if users have been infected by contagious diseases. Therefore, it is important to treat the used materials as infectious or biologically hazardous waste.
- **Potential Biohazard:** Healthcare professionals or individuals using this system on multiple patients should be aware that all objects that come in contact with human blood, or after cleaning, should be handled well as it is capable of transmitting viral diseases.
- Draw-In test strips uses glucose oxidase (GO) as glucose-sensing material, The GO could be affected by the oxygen concentration in the sample. It is important to use finger prick capillary blood and to perform the test under 8,563ft.
- If you have symptoms which are not consistent with your blood test result and you have eliminated common procedural errors described in the user's guide, contact your healthcare professional immediately.
- If your reading is above or below your prescribed range of expected blood glucose values, repeat the test.
- Never make significant changes in your diabetes treatment program or ignore symptoms without consulting your physician.

### Storage and handling

- Do not use test strips after expiry date.
- Do not use test strips that are wet, bent, scratched, or damaged in any way.
- Do not re-use the strips.
- The Draw-In blood glucose test strips are packaged in the vial.
- Store at temperatures between 4°C~32°C (40°F~89°F), and below 85% relative humidity.
- Store away from direct sunlight and heat.
- Do not refrigerate or freeze.
- Perform blood glucose determinations at temperatures between 14°C~40°C (57°F~104°F), and below 85%relative humidity.
- When stored properly, the unopened test strips are stable until the expiry date printed on the vial label.
- The expiry date is printed on the box.
- Record the first opening date on the vial label, and use within 3 months after first opening.
- Always close the vial immediately after use. If the vial is left open for a long period of the time, the test strip will become unusable.
- Do not take the test strips with wet or dirty hands.

### Sample collection and preparation

The Draw-In blood glucose test strips are designed to measure the glucose concentration in capillary whole blood. To obtain accurate test results, it is recommended that the user should follow the exact test procedures:

- Clean and dry your hands especially on the same collection site. If you are using an alcohol pad, please make sure the sample collection site is dry out completely.
- Use the accompanied lancing device for finger pricking. Gently massage before sticking will help to collect enough blood sample. Do not over-press the pricked site.
- Venous blood, plasma, or serum samples are not to be used. Using venous blood will get higher glucose reading than capillary blood because of the difference in oxygen content.
- Testing must be performed immediately after the sample is obtained.
- Common anticoagulants and preservatives such as heparin and sodium EDTA may be used, but fluoride preservatives must be avoided.

#### Important:

There is still a minor difference of oxygen content in different capillaries of various body sites, it is important to use finger prick for comparison and constant monitoring.

### Testing your blood

Refer to information of "Measuring Your Blood Glucose Level" in the User's Guide of meter before testing.

## Quality Control (Optional Accessory)

It is recommended to run a quality control test:

- When your test results do not agree well with how you feel.
- At least once per week to verify that the meter and test strips are working properly together.
- Every time you open a new vial of test strips.
- If you drop your meter.
- To check performance of the meter and test your testing technique, run a monitor check test and/or a control solution test by following the instructions detailed in the User's Guide of the meter.

Use only the Draw-In series Control Solutions designed for use with the meter system. Other control solutions may provide incorrect result and therefore cannot be used. When control solutions are used, you should get test results within the expected ranges printed on the label of test strip vial. Test results within range indicate that your meter and test strips are working properly. If test results of control solution are not within the expected range, repeat the control solution test.

## Test Results

Blood glucose test results are shown on the monitor display as either mg/dL or mmol/L. The units are interchangeable.

To calculate the unit difference:  $(\text{mg/dL}) \div 18 = (\text{mmol/L})$ .

If you get an unusual test result, check the following items, then repeat the test:

- Check if the drop of blood completely fills the reaction zone.
- Check if the test strip in use is within the expiration date printed on the test strip box.
- Check if the code number of the test strip in use matches the number programmed in the meter.
- Check meter performance with the monitor checker.
- Check meter and test strip performance with control solutions.

When test results are still questionable or inconsistent, and your blood glucose results are less than 55 mg/dL (2.8mmol/L) or greater than 300 mg/dL (16.7mmol/L), consult your healthcare professional before making any changes to your diabetes medication program.

## Limitations

Draw-In test strips are designed for use with fresh capillary whole blood samples. **DO NOT** use serum or plasma samples.

- Hematocrit: Variation in sample hematocrit between 20% and 60% has no significant effect on test results. Very high (above 60%) and very low (20%) hematocrits can cause inaccurate results.
- Neonates: Do not use Draw-In test strips to test neonates. The performance of this system has not been validated with neonatal samples.
- Do not use fluoride or iodoacetic acid as a preservative for blood samples.
- Abnormal blood specimens (i.e., high ascorbic acid, high uric acid) may affect the results. Blood glucose readings from these cases should be interpreted with caution.
- Therapeutic levels of L-dopa or Dopamine may result in inaccurate (elevated) glucose readings with the system.

## Accuracy

To examine how Draw-In series test strips are similar to or different from other devices of comparable type, the YSI 2300 STAT Plus™ was used as the reference method. Using oxygenated Heparin-venous blood, properly reconstituted with exogenous glucose to a final concentration ranged from 20 to 600 mg/dL, parallel comparison was obtained as follows:

Number of sample	Slope	Intercept	Correlation coefficient
145	0.985	5.0	0.965














## Precision

To compare the precision of Draw-In series test strips and YSI 2300 STAT Plus™ glucose analyzer, oxygenated Heparin-venous blood, properly reconstituted with exogenous glucose to a final concentration of 40, 80, 160, 275 and 400 mg/dL, 20 tests of Draw-In series test strips were performed with each glucose concentration. The results obtained were as follows:

Glucose concentration (mg/dL)	40	80	160	275	400
Number of tests	20	20	20	20	20
Average (mg/dL)	45	83	173	277	381
S.D.	2.4	3.6	5.1	8.9	12.1
C.V.%	--	4.4	2.9	3.2	3.2

## Reference

1. N. Tietz, Fundamentals of Clinical Chemistry, W.B Sanders Co. 1987.
2. A.E.G. Cass, Biosensors: A practical approach, IRL Press, 1990.
3. D. Schade, "101 Tips for Improving Your Blood Sugar" P.4-5

 <b>LOT</b> Lot number	 Manufactured by
 <b>IVD</b> For in vitro diagnostic use	 Keep away from sunlight
 <b>REF</b> Catalogue number	 Keep dry
 Consult instructions for use	 Temperature limitation
 Use by	 Caution
 Do not re-use	 WEEE
 <b>CE</b> 0123 Fulfills the requirement of 98/79/EC	

## Distributor

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## Customer Service

-  24-Month Limited Warranty
-  Lifetime Technical Support
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