

# GLUCOLAB™ Auto-coding Test Strip

**Important:** Please read this information and your **GLUCOLAB™ Auto-coding** manual before using the **GLUCOLAB™ Auto-coding** blood glucose test strips.

**Intended Use:** The blood glucose test strips are used with the **GLUCOLAB™ Auto-coding** blood glucose test meter for the measurement of glucose in your blood. The **GLUCOLAB™ Auto-coding** blood glucose measuring system is plasma-calibrated to allow easy comparison of results with the laboratory method. The blood glucose test strips are for testing outside the body (in vitro diagnostic use only). **GLUCOLAB™ Auto-coding** blood glucose measuring system is for self-testing.

**General :**

**GLUCOLAB™ Auto-coding** blood glucose test strips adopts a new bio-sensor technology composed of electro-chemical components and requires a small 1µL volume of blood giving you less pain ( • 1 µL). **GLUCOLAB™ Auto-coding** can store 365 readings in memory with date & time and with the bio-sensor technology, you can easily store your readings on your PC (optional). This will provide an easier and better way to control your glucose levels.

**Storage and Handling :**

- Store the **GLUCOLAB™ Auto-coding** blood glucose test strip vials in a cool, dry place between 2-30°C (36-86°F). Keep out of direct sunlight. Do not freeze.
- Store blood glucose test strips in its original vial only. Do not mix the blood glucose test strips in new vials or in any other container.
- Immediately replace the vial cap and close tightly after removing an **GLUCOLAB™ Auto-coding** blood glucose test strip. This keeps the blood glucose test strips fully functional right up to the expiry date.
- Use test strip immediately after removing it from the vial.
- Do not use blood glucose test strips after the expiration date printed on the package or vial since it may cause inaccurate results.
- Make a notation of the discard date on the vial label when you first open it. Discard remaining **GLUCOLAB™ Auto-coding** Blood Glucose Test Strips 3 months after first opening the vial.
- Avoid getting dirt, food, and water on the blood glucose test strip. Do not handle blood glucose test strips with wet hands.
- Do not bend, cut, or alter any **GLUCOLAB™ Auto-coding** blood glucose test strip.
- **GLUCOLAB™ Auto-coding** blood glucose test strips are for single use only. Do not re-use.
- Do not perform blood glucose determinations at temperature below +10°C(50°F) or above +40 °C(104 °F), at humidity below 10 % or above 90 %.
- Discard the used blood glucose test strip carefully, to prevent any infection.



**Warning!**

To avoid false reading, use **GLUCOLAB™ Auto-coding** blood glucose test strips for **GLUCOLAB™ Auto-coding** blood glucose test meter or **GLUCOLAB™** blood glucose test meter to measure glucoses.

**Care Procedures :**

- Code the blood glucose test meter to match the code number printed on the blood glucose test strip vial.
- Do not reuse blood glucose test strips. Single use only.
- If you experience any symptoms that are not consistent with your test results, call your doctor.
- Do not make changes to your diabetes control program without consulting your physician.

**Test Principle :**

Glucose in the blood sample will react to the electrodes in the blood glucose test strip, generating an electrical current that will stimulate a chemical reaction. This reaction is measured by the blood glucose test meter and displayed as your result.

**Note:** Different levels of reactions will occur depending on the amount of glucose in the blood sample.

**Reagent Composition :**

Each **GLUCOLAB™ Auto-coding** blood glucose test strip contains :

Glucose Oxidase (Aspergillus niger) :	3 Units
Mediator (Hexaammineruthenium chloride) :	139 µg
Binder :	5.7 µg
Stabilizer :	86 µg






**The procedure for Blood Glucose Measurement :**

Materials provided : **GLUCOLAB™ Auto-coding** blood glucose test strips

**Obtaining Blood Sample :**

The blood glucose test strips are designed to be used with fresh whole blood. The blood glucose test meter gives you the ability to obtain a blood sample for testing your glucoses from different areas of your body. You may obtain a blood drop from either a fingertip or an alternative site.

To obtain a drop of blood, follow these steps :

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- Step 1: Wash your hands and test site with warm soapy water. Dry thoroughly. You may also use an alcohol wipe to clean. Make sure it is completely dry before testing. (Dirt, oil, lotion, or sweat may affect the test result).
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- Step 2: Prepare the lancing device. Insert a lancet into the lancing device. The device holds, positions, and controls how deeply the lancet goes into the skin. (Refer to the owner's manual for more information).
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- Step 3: Remove blood glucose test strip from the vial. Recap the vial immediately to prevent moisture from affecting the other blood glucose test strips. Insert the blood glucose test strip, into the port of the blood glucose test meter, with "infopia" logo facing up. The meter will automatically turn on and display the code number. Make sure the code number matches the code number on the blood glucose test strip vial. The blood glucose test strip icon with a drop of blood will be flashing at the top of your screen. You are now ready for testing.
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- Step 4: Poke the test site. Only a small drop of blood is necessary for accurate test results. Touch the top edge of your blood glucose test strip. The meter will countdown from 5 to 1 and a result will be displayed.
- Note:** Poking the side of your fingertip is less painful. Do not squeeze or milk the puncture site. You may get an inaccurate result if the blood sample is not completely filled in a single action.
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- Step 5: The meter will automatically store your results in the memory to be retrieved at anytime. Push the ejector button forward to discard the blood glucose test strip.

**Important Information About Using Alternate Site Testing :**

- Alternate sites where you can test are dorsal hand, ventral palm, upper arm, forearm, calf, and thigh.
- Under certain conditions, blood glucose test results obtained using samples taken from your alternate sites may differ significantly from fingertip samples
- The conditions in which these differences are more likely to occur are when your blood glucose is changing rapidly such as following a meal, as insulin dose, or associated with physical exercise.
- When blood glucose is changing rapidly, fingertip samples show these changes more quickly than alternate sites samples.
- When your blood glucose is falling, testing with a fingertip sample may identify a hypoglycemic (low blood glucose) level sooner than a test with a alternate sites sample.
- Use alternate sites samples only for testing prior to or more than two hours after meal, insulin doses, or physical exercise.
- Testing performed within two hours after meals, insulin doses, or physical exercise or whenever you feel that your glucose levels may be changing rapidly should be done from the fingertip.
- You should also use fingertip testing whenever you have a concern about hypoglycemia (insulin reactions) such as when driving a car, particularly if you suffer from hypoglycemic unawareness (lack of symptom to indicate as insulin reaction), as forearm testing may fail to detect hypoglycemia.

**Test Results :**

The results are displayed on the blood glucose test meter as milligrams of glucose per deciliter of blood (mg/dL). The meter displays results between 10–600mg/dL.

If the test result is below 10mg/dL, "LO" will appear on the blood glucose test meter display. Consult with your doctor immediately in how to treat extremely low blood glucose (hypoglycemia).  
If the test result is above 600mg/dL, "HI" will appear on the meter display. This indicates extremely high blood glucose (hyperglycemia). Seek medical assistance immediately.

**IMPORTANT NOTE:** Blood glucoses may be altered by your food, physical activity, and/or stress.

**Range of Expected Values :**

Self-testing of blood glucose levels provides a way to control your diabetes. Consult with your physician to determine the best range of expected blood glucose values for you.

Expected blood glucose levels for people without diabetes\*:

Fasting and before meal:	< 100 mg/dL (5.6 mmol/L)
2 hours after meal:	< 140 mg/dL (7.8 mmol/L)

\*American Diabetes Association: Diagnosis and Classification of Diabetes Mellitus (Position Statement), Diabetes Care 34 (Supplement 1), 2011

**IMPORTANT:**

If you have a test result below 60mg/dL or over 240mg/dL contact your doctor immediately.  
If your blood glucose result is unusually low or high, repeat the test again with a new blood glucose test strip.  
If the results are still inconsistent, please consult your doctor.

**Quality Control (Blood glucose measuring system Maintenance) :**

Glucose Control Solution was designed to ensure that the blood glucose termeter and the blood glucose test strips are working together properly.

**Note:** The Glucose Control Solution is sold separately. The low, normal, and high level glucose control solutions can be obtained through local representative..

Glucose Control solution tests can only be used with the **Glucolab™ Auto-coding** blood glucose meter and blood glucose test strips.

Always perform a Glucose control solution test when :

- A new vial of blood glucose test strips is opened.
- Any suspicion that the blood glucose test meter or blood glucose test strips are not working properly.
- When your blood glucose test results are not consistent with your symptoms, or if you think they are not accurate.
- If you drop the meter.

When the Glucosecontrol solution is applied to the top edge of the blood glucose test strip, you should get results within the expected range printed on the label of the blood glucose test strip vial. If the glucose control solution test results fall outside the range, repeat the test. Results that fall out-side the range may be caused by :

- Error in performing the test.
- Failure to shake the control solution vial well enough (must shake vigorously).
- Failure to discard the first drop of glucose control solution.
- Expired or contaminated bglucose control solution.
- Test Strip deterioration.
- Meter malfunction.
- Control solution that is too warm or cold.

**IMPORTANT NOTE:** If the control solution test results continuously falls outside the range printed on the bottle, the **GLUCOLAB™ Auto-coding** blood glucose measuring system may not be functioning properly. DO NOT use the blood glucose measuring system to test your blood until you get a control solution test result that falls within the range. If you continue to have problems, contact your local representative immediately.

**Limitations of Blood glucose measuring system :**

The blood glucose test strips provide accurate results when the following constraints are observed :

- Use the **GLUCOLAB™ Auto-coding** blood glucose test strips with the **GLUCOLAB™ Auto-coding** blood glucose test meter or **GLUCOLAB™** blood glucose test meter .
- Use fresh capillary whole blood only.
- Do not use neonate samples.
- The blood glucose test strips are for single use only. Do not reuse.
- Dehydration may lower test results.
- Inaccurate results may occur when in shock, hypotensive, hyperglycemic, or hyperosmolar state, with or without ketosis.
- Blood glucose test strips used above altitudes of 10,000 feet will have an effect on test results.

**Doctors - Please note the following interferences that may affect test results :**

- Extremes in hematocrit may affect test results. Hematocrit levels less than 20 % may cause falsely high reading. Hematocrit levels greater than 60 % may cause falsely low readings. If you do not know your hematocrit level, consult your healthcare professionals.
- Interferences: Acetaminophen, Uric acid, Ascorbic acid (Vitamin C), and other reducing substances when occurring in normal blood or normal therapeutic concentrations do not significantly affect results. However, abnormally high concentrations in may cause inaccurately high results.
- Lipemic samples; Cholesterol up to 500 mg/dL or triglyceride up to 3000 mg/dl do not significantly affect the results. Values beyond these levels should be interpreted with caution.
- Blood samples that contain a high concentration of dissolved oxygen may lower the test result.
- EDTA containing tube is recommended as an anticoagulant tube.

**Performance Characteristics :**

The performance of the blood glucose test strips has been evaluated in laboratory and in clinical tests.

Measurement Range: The measurement range of the **GLUCOLAB™ Auto-coding** Blood glucose measuring system is 10 to 600 mg/dL.

**Accuracy:**

The accuracy results obtained with the **GLUCOLAB™ Auto-coding** Blood glucose measuring system were compared to glucose results obtained with the Hitachi Glucose Auto analyzer 747, a laboratory instrument. Glucose levels were measured on 160 fresh capillary specimens at three different clinical centers.

Blood glucose measuring system accuracy results for glucose concentration <75 mg/dL (4.2 mmol/L)

Within ± 5mg/dL (within ± 0.28 mmol/L)	Within ± 10 mg/dL (within ± 0.56 mmol/L)	Within ± 15mg/dL (within ± 0.83 mmol/L)
50/62 (81%)	62/62(100 %)	62/62(100%)

Blood glucose measuring system accuracy results for glucose concentration ≥ 75 mg/dL (4.2 mmol/L)

Within ±5%	Within ±10%	Within ±15%	Within ±20%
132/258(51%)	204/258(79%)	245/258(95%)	257/258(100%)

**Precision:**

Precision Results for venous blood samples.

Mean (mg/dL)	40.5	79.2	131.6	204.0	319.2
SD	1.3	1.6	2.6	4.2	7.8
CV (%)	3.5	2.2	1.6	1.3	0.9

Precision Results for control solutions.

Mean (mg/dL)	41	119	347
SD	1.1	2.3	3.8
CV (%)	2.5	1.9	1.2

**IMPORTANT:**

- Before using the **GLUCOLAB™ Auto-coding** blood glucose test meter and blood glucose test strips, read all of the operating instructions in the owner's manual.
- Consult with your doctor on daily management of your diabetes with the **GLUCOLAB™ Auto-coding** blood glucose measuring system.
- If you have any questions about use of the products, please contact your local representative or go to [www.infopia21.com](http://www.infopia21.com)

**References :**














- 1) National Committee for Clinical Laboratory Standards. Point-Care Blood Glucose Testing in Acute and Chronic care Facilities ; Approved Guideline, 2nd Edition. NCCLS Document C30-A2 (ISBN1-56238-471-6)
- 2) National Committee for Clinical Laboratory Standards. Statistical Quality Control for Quantitative Measurements ; Principle and Definitions; Approved Guideline, 2nd Edition. NCCLS Document C24-A2 (ISBN1-56238-371-X). 1999
- 3) National Committee for Clinical Laboratory Standards. User Demonstration of performance for Precision and Accuracy ; Approved Guideline. NCCLS Document EP15-A (ISBN1-56238-451-1)
- 4) National Committee for Clinical Laboratory Standards. Interference Testing in Clinical Chemistry ; Proposed Guideline. NCCLS Document EP7-P (ISSN 0273-3099)
- 5) Krall, L.P., and Beaser, R.S.: Joslin Diabetes Manua\I. Philadelphia: Lea and Febiger(1989), 138
- 6) Beaser, R.S. and Hill, Joan: The Joslin Guide to Diabetes. New York: Simon and Schuster (1995), P158

**OUR COMMITMENT TO YOU :**

We understand that self-testing your blood glucose levels provides a way to control your diabetes. As a result, the **Glucolab™ Auto-coding** blood glucose measuring system was developed to help you manage your diabetes by the most comfortable and convenient way possible. Our goal, at Infopia is to provide you the best quality products and superior customer service. If you have any questions or comments, please contact your local representative or visit our website at [www.infopia21.com](http://www.infopia21.com)

**NOTE :**

Please refer to the table below to identify symbol

	Consult operating instructions
	Used By
	This product fulfills the requirements of Directive 98/79/EC on in vitro diagnostic medical devices.
	Caution, consult accompanying documents
	For In Vitro Diagnostic Use
	Batch code
	Catalogue number
	Temperature limitation
	Do not re-use
	Date of Manufacture
	For Self-testing
	manufacturer
	Authorized Representative



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**U.K. Distributor: Neon Diagnostics Ltd.**  
Units 7 & 8  
Swanbridge Industrial Park  
Black Croft Road  
Witham  
Essex  
CM8 3YN

**REF INFS22A**

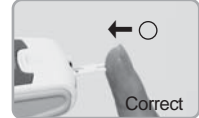
IMS07-077 Rev.2011-10-01

● **Correct**




Completely Filled

● **Applying Blood**




Correct

● **Incorrect**



Poorly filled

✗ **Incorrect**



Incorrect