

GLUCOSE SCREENING TEST

Instructions

EarlyDETECT™

The earlier, the better.

KIT CONTENTS

This **EarlyDETECT™** Glucose Kit contains:

- Sealed pouch containing the test card and a moisture absorbent packet to keep it fresh
- Safety lancet
- Bandage
- Alcohol swab
- Set of instructions

Materials required but not provided:

- Clock or timer
- Clean tissue

STORAGE & STABILITY

- Store this test kit in its sealed pouch at room temperature (15°–28°C, 59°–82°F).
- Do not use this kit after the expiration date printed on the package.

BEFORE YOU BEGIN

- You must FAST before you run the test. Do not eat or drink anything, other than water, for 9–12 hours before you test yourself. A good time to test yourself is in the morning before you eat breakfast.
- The **EarlyDETECT™** Glucose Test is intended for one time use only. Therefore, it is very important that you read these instructions and understand everything you have to do before you begin the test. You must follow the instructions exactly.
- Do not open the pouch containing the test card until you are ready to perform the test.

INTENDED USE

The **EarlyDETECT™** Glucose Test is a semi-quantitative test used to measure your fasting blood glucose (blood sugar) level so that you know if it is normal. The **EarlyDETECT™** Glucose Test measures your blood glucose level using a drop of blood from your finger. Since abnormal blood glucose levels can be a sign of medical problems, including diabetes, you should consult your doctor if you obtain abnormal results using the **EarlyDETECT™** Glucose Test. The **EarlyDETECT™** Glucose Test is not intended for use by people who have been diagnosed as diabetic.

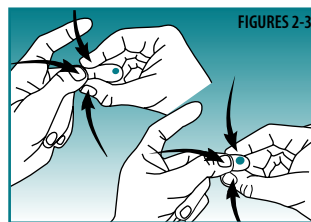
INSTRUCTIONS FOR USE

Perform the test in a well lit room, but away from direct sunlight. Each test is performed on a drop of fresh, whole blood that may be obtained from the finger tip.

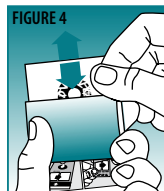
1. Remove the test card from the pouch and place it on a flat surface with the Test Area facing up. Do not peel off the overlay tab until instructed to do so.



2. Select a puncture site on a finger, wash your hands in warm water for at least 3 MINUTES. Dry your hands completely and cleanse the puncture site with the alcohol swab. Allow your arm to hang down at your side for 30 seconds to increase blood flow. If you are right handed, it is often best to draw blood from your left hand. The reverse is true if you are left handed. Select a hand that is not calloused near the tip.



3. Twist the blue stem back and forth until it becomes loose to easily remove the protective cap (as shown in Figure 1).
4. Position the lancet on the puncture site.
5. Press the blue top button to activate the safety lancet. Place the used lancet in the pouch the card was packed in, and discard it safely. It is important to get a "good" fingertick in order to run the test. WARNING: Do not share or reuse lancet and dispose of properly.
6. Gently massage the finger from the hand down toward the fingertip to obtain the required blood sample (as shown in Figure 2-3). Squeeze one large drop of blood onto the test area, making sure your finger does not come in contact with the test card. If you are unsure about the amount of blood, add another drop.
7. Begin timing immediately. The blood should remain on the test area for 3 minutes.
8. Wipe the puncture site with a clean tissue and apply a bandage.
9. After 3 minutes, grasp the overlay tab and carefully peel off the entire top layer (as shown in Figure 4).



INTERPRETING THE RESULTS

To determine your result, match the blue-green color of the Test Area with the FIVE different color blocks that appear in the windows as you slide the color chart up and down. You will have 30 seconds to decide which color block most closely matches your test result before the test area begins to fade.

Note: If the test area is unevenly colored, match the overall color area of the Test Area to the color blocks on the sliding chart.

After determining the nearest color match, turn the card over. Your total glucose reading appears in the clear window marked "mg/dL" and "mmo/L"

Abnormally Low: 50 mg/dL (2.8 mmol/L) or lighter than 50 color block. You should see your doctor without delay.

Normal: 75 or 100 mg/dL (4.2 or 5.6 mmol/L). This is a low risk area. You should maintain a healthy diet, exercise regularly, and monitor your glucose periodically.

Abnormally High: 125 or 150 mg/dL (6.9 or 8.3 mmol/L) or darker than 150 color block. This is a high risk area. You should contact your doctor for further tests and advice.

Many things can cause glucose readings to vary, including stress, recent diet, rest/exercise, and other biological factors. It is not unusual for results in some people to vary by as much as 10% to 20% over a period of time.

LIMITATIONS OF THIS TEST

- The directions must be followed exactly to provide accurate results.
- Do not open the foil packet containing the test card until you are ready to conduct the test.
- Do not alter your medication dosage or schedule based on the results of this test. Discuss any medication changes with your doctor first.
- Certain rare medical conditions (such as blood bilirubin or hematocrit levels outside the normal range) may cause your test results to be inaccurate. If you are unsure whether this applies to you, ask your doctor.
- Glucose testing should not be done within three months of a serious health problem (such as heart attack or major surgery) or within three weeks of a minor health problem (such as influenza or diarrhea). Pregnant women should wait until after delivery to test their glucose levels.
- Each test card may only be used once. Discard it after use.

FREQUENTLY ASKED QUESTIONS

Q: What is glucose?

A: Glucose is a form of sugar that your body uses for energy. It is found in your blood and comes from the food that you eat. It is commonly referred to as "blood sugar".

Q: Why should I be concerned about my glucose level?

A: Abnormal blood glucose levels are often a sign of a medical problem, such as diabetes, which affects how your body uses glucose (sugar). Over time, abnormal glucose levels can result in serious medical side effects. By identifying abnormal blood glucose levels early, the severity of these side effects can often be reduced or even prevented.

Q: What are common signs or symptoms of diabetes?

A: Frequent need to urinate, increased thirst, increased appetite, rapid unexplained weight loss or blurred vision are all common symptoms of diabetes.

Q: What will the **EarlyDETECT™** Glucose test tell me?

A: The **EarlyDETECT™** Glucose test will tell you if your fasting blood glucose level is normal or abnormal. If you obtain an abnormal result using the **EarlyDETECT™** Glucose test, it is important that you see your doctor for medical advice.

Q: Why can't I tell whether or not I have diabetes from my test results?

A: Diagnosis of diabetes or other medical problems involving abnormal blood glucose is a complicated process which is different for each person, glucose is only one of the signs. For this reason, diagnosis is best left to a trained medical professional.

Q: Should I fast before performing the test?

A: Yes. If you do not fast properly, your test results may not be accurate. You should not eat or drink anything other than water for at least 9 hours before performing the test. Most people find it easiest if they perform the test first thing in the morning before they eat breakfast.

Q: What can I do to make it easier to draw blood?

A: Wash your hands in warm water for at least 3 minutes to increase circulation, before performing the test. Prick the side of your finger, near the tip. It is a less sensitive area and is less likely to be calloused. It might be easier to have someone else prick your finger.

Q: How accurate is the **EarlyDETECT™** Glucose test?

A: In consumer studies, 90 out of 91 people were able to correctly classify their blood glucose as NORMAL or HIGH. If you fast properly and follow the test instructions carefully, you can expect the **EarlyDETECT™** Glucose test to be 94 to 99.95 percent accurate in determining whether your blood glucose is NORMAL or HIGH.