



INSTRUCTION BOOKLET
ATTENTION READ ALL
INSTRUCTIONS BEFORE USING
THIS KIT.

**A Complete 3 Minute Whole Blood Screening Test for
Identification of
ABNORMAL PLASMA GLUCOSE LEVELS**

IVD

CONTENTS

The following items are included:

- 2 CHEMCARD™ Glucose Test (in individual sealed foil packages)
- 2 sterile lancets for pricking your finger
- 1 Instruction Booklet

INTENDED USE

The CHEMCARD™ Glucose Test is an *in vitro*, semi-quantitative self-test used to measure your fasting blood glucose (also referred to as blood sugar) levels so you know whether it is abnormal. 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 CHEMCARD™ Glucose Test. The CHEMCARD™ Glucose Test is not intended for people who have been diagnosed as diabetic.

The CHEMCARD™ Glucose Test is a single use and cannot be reused. It is therefore very important that you read and understand all instructions before you begin the test. **Follow all instructions exactly.**

PRINCIPLE OF METHOD

A drop of whole blood from a fingerstick is deposited on the test area of the CHEMCARD™ Glucose Test. The plasma is physically separated from the rest of the blood sample. The plasma then reacts with a chemically treated pad and a color change occurs. The resulting depth and shade of the color corresponds to the amount of glucose in the blood sample.

LIMITS OF THE TEST

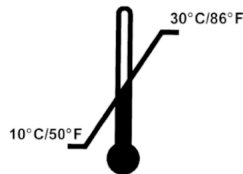
- This test will not diagnose diabetes or any other medical problem. This can only be performed by your doctor or other trained persons.
- This test is not to be used by diabetics to check their blood glucose level or adjust their medications.
- The CHEMCARD™ Glucose Test has been extensively tested to determine the effects of common medications and other substances which may be present in the blood. No interferences were noted in these studies at the concentrations which are likely to occur in the blood. For further information on the substances, test methods and results, contact the manufacturer.
- This test is intended for testing blood at normal hematocrit levels (33-58%).

PRECAUTIONS

- For in vitro diagnostic use only.
- Do not use internally
- Keep out of reach of children.
- Not to be used to test children under the age of 2 years old.
- Not to be used by women who are known to be pregnant.
- You must be able to match colors in order to use the CHEMCARD™ Glucose Test. Persons who are sight-impaired should not use this test.
- Do not use tests after the expiration date printed on the foil packaging.
- If any of the listed contents are missing, **do not** continue, instead put everything back into the box and return it to your retailer for replacement.
- If the seal of the foil package is compromised upon opening the kit, **do not** use. Contact the manufacturer for further instructions.
- Do not re-use test.

STORAGE

- Do not store at temperatures below 10°C (50°F) or above 30°C (86°F).
- Refrigeration is **not** required.
- The test should be used prior to the expiration date printed on the foil package.



WORKING RANGE

The CHEMCARD™ Glucose Test has an effective measurement range of 50 to 150 mg/dl.

CALIBRATION AND QUALITY CONTROL

Calibration of the CHEMCARD™ Glucose Test is not required. The color development for each lot of test cards is calibrated by use of precise Quality Control standards during manufacturing.

RESULTS

Results are obtained by visually comparing the developed color of the Test Area with those of the sliding color standard appearing in the windows at the side of the Test Area. After a visual match is made, the card is turned over and the total glucose concentration value appears in the window on the back side of the card.

HOW DO I KNOW THE TEST IS WORKING?

Each test card employs two design features which allow the user to verify that the test has worked properly.

- “CONTROL SPOT” changes color allowing the user to verify a sufficient blood volume (>20 µL) has been applied to the test area. Make sure CONTROL SPOT changes to red in 15 seconds after the blood is applied. If this does not happen, apply another drop of blood. CONTROL SPOT must change color to red to ensure that enough blood was added. See STEP 5.
- The presence of a green or blue color in the reagent pad indicates that the detection chemistry is working properly. A reagent pad that is white or cream colored indicates an invalid test result. If no color change is seen in the Test Area perform the test again using a new CHEMCARD™. Follow the instructions exactly. If no color change is observed in the repeated test, your glucose may be at or below 50 mg/dL, or there is a problem with the test you are using. For questions regarding test viability, contact the manufacturer. Otherwise contact your doctor for further testing. If you have questions about your test result, call your doctor or call the manufacturer: +001 574 834 2406.

TEST DIRECTIONS

BEFORE YOU BEGIN

- You must **fast** before you run the test. Do not eat or drink anything, other than water, for 9 to 12 hours before you test yourself. A good time to test yourself is in the morning before you eat breakfast.
- Read **all** the directions **before** you start the test.
- You need a **timer** and a **tissue** before you start.
- Do not trigger the finger stick device (lancet) until you are ready to draw blood for the test. **Never use a finger stick device that has been used by another person.**
- **Failure to follow instructions may cause inaccurate results.**

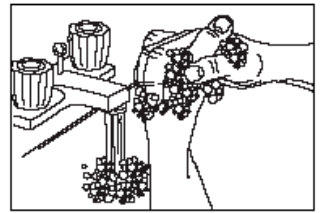
GET READY

- Choose a place indoors, which is well lit, but not in direct sunlight to perform the test. The test should be performed at normal room temperature (below 86°F/30°C). You will need a table, a timer and a tissue to perform the test.
- Familiarize yourself with the CHEMCARD™ Glucose Test.
- When you are ready to perform the test, open the test package. Place the CHEMCARD™ Glucose Test card on a table facing up.
- Throw away the desiccant (drying) packet.
- The test should be completed within 5 minutes of opening the package.

STEP 1

PREPARE TO DRAW BLOOD

- Wash your hands in warm water for at least **3 minutes**. Dry your hands completely.
- 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 finger that is not calloused near the tip.



STEP 2

PRICK YOUR FINGER



- Push the lancet cap into the body until it clicks.



- Twist the lancet cap until you feel it separate from the device. Don't pull just twist. Dispose of the cap in a suitable container.



- Position lancet body firmly against the puncture site as illustrated. Hold lancet body between fingers with one finger on the side release button. To activate, press the release button firmly. **Do not** pull the lancet away from the puncture site until after activation.
- It is important to get a “good” fingerstick in order to run the test. If you are uneasy about pricking your finger, you might consider having a friend or spouse do this for you.

STEP 3

SQUEEZE YOUR FINGER TO DRAW BLOOD

- Obtain a **large drop** of blood that hangs down from your finger.



STEP 4

PLACE BLOOD ON THE TEST AREA

- **Gently** touch the drop of blood to the Test Area
- **Do not** touch the test area with your finger. Only the blood can be allowed to touch the Test Area.
- The Test Area should be completely saturated.
- If you are unsure about the amount of blood, add another drop.



STEP 5

CHECK CONTROL SPOT

- Make sure CONTROL SPOT changes to red in 15 seconds after the blood is applied. If this does not happen, apply another drop of blood.
- CONTROL SPOT must change color to red to ensure that enough blood was added.

STEP 6

START TIMER

- Set timer for 3 minutes.

STEP 7

AFTER 3 MINUTES, PEEL OFF THE "TAB"

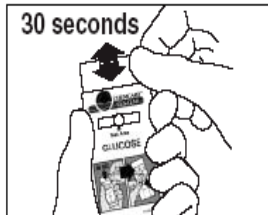
- Grasp the "TAB" near the bottom of the card and slowly peel off the entire top layer.



STEP 8

MATCH COLORS

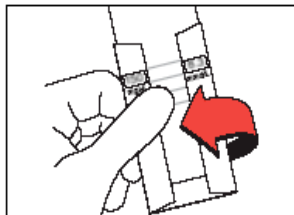
- Slide the color chart up and down to bring different colors into the windows on either side of the Test Area.
- Compare the color of the Test Area with that appearing in the windows.
- Choose the color that most closely matches the Test Area.
- Check all six colors before you make your choice.
- Complete this step in 30 seconds; after that the colors begin to fade.
- If the Test Area is unevenly colored simply match the overall color area on the test pad against the sliding color chart or perform the test again using a new CHEMCARD™. Follow the instructions **exactly**.
- If no color change is seen, perform the test again using a new CHEMCARD™. Follow the instructions **exactly**.
- If no color change is observed in the repeated test, your glucose may be at or below 50 mg/dL, or there is a problem with the test you are using. For questions regarding test viability, contact the manufacturer. Otherwise contact your doctor for further testing. If you have questions about your test result, call your doctor or call the manufacturer: +001 574 834 2406



STEP 9

READ THE NUMBERS ON THE BACK OF THE TEST

- Your glucose level is shown in the windows on the back of the card. The windows on the left show your result in mg/dL and the window on the right shows your result in mmol/L.



STEP 10

DISPOSAL

- After you get your results, place the contents of the kit back into the original box and dispose of with your normal household waste products.

WHAT DO MY RESULTS MEAN?

The normal blood glucose (blood sugar) level for a fasting adult is 60 to 100 mg/dL (3.3 to 5.6 mmol/L). Results outside this range are not normal and mean that you should see a doctor.

If your card reading was...

50 mg/dL (2.8 mmol/L)

or

Lighter than the 50 color block

...it Means:

Your blood glucose level is **Abnormally Low**. You should see your doctor without delay.

75 or 100 mg/dL

(4.2 or 5.6 mmol/L)

Your blood glucose level is **Normal**. Test yourself again in a year.

125 or 150 mg/dL (6.9 or 8.3 mmol/L)

or

Darker than the 150 color block

Your blood glucose level is **Abnormally High**. You should see your doctor without delay.

FREQUENTLY ASKED QUESTIONS

- Q: What can I do to make it easier to draw blood?
- 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's a less sensitive area and is less likely to be calloused.
 - Press the lancet device firmly against your finger. Push the trigger firmly. Try not to pull away when you trigger the lancet.
 - It might be easier to have someone else prick your finger.

Q: The color on the test pad faded after I performed the test. Is this normal?

A: Yes. The color of the test pad will begin to fade 1 to 5 minutes after removing the TAB. Try to make sure that you match the colors within 30 seconds after the TAB is removed.

Q: What can I do to make it easier to match colors?

- Make sure there is plenty of light. Fluorescent light is best for most people.
- Try viewing the test at arms length.
- Make sure you look at all five colors before you decide the best match.
- Try having someone else match the colors for you.

Q: What happens if I forgot to fast before I test myself?

A: If you do not fast before you perform the test, your results will not be reliable.

Q: How accurate is the Chemcard™ 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 Chemcard™ Glucose Test to be 94 to 99.95 percent accurate in determining whether your blood glucose is NORMAL or HIGH.

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 the 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 Chemcard™ Glucose Test tell me?

A: The Chemcard™ Glucose Test will tell you if your fasting blood glucose level is normal or abnormal. If you obtain an abnormal result using the card 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. A doctor must take into account many different symptoms, signs and risk factors before making a diagnosis. Abnormal blood 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.

The American Diabetes Association is an excellent source of information regarding diabetes and associated risk factors. Contact them at <http://www.diabetes.org>

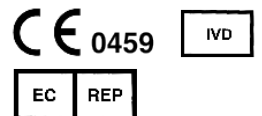
PERFORMANCE CHARACTERISTICS

The following data were calculated from the results of self-tests performed by 99 untrained volunteers.

- 97.0 % of test subjects were able to determine their glucose level within one color block as compared to laboratory based tests.
- By defining a "positive result" as a CHEMCARD™ Glucose Test result of 125 or greater then the diagnostic sensitivity and diagnostic specificity of the CHEMCARD™ Glucose Test (using the laboratory reference result as "truth") is computed. Diagnostic sensitivity is the estimate of the percent of true positives for the CHEMCARD™ Glucose Test, that is, the percent of the positive glucose reference results which are positive by the CHEMCARD™ Glucose Test. Diagnostic specificity is the percent of true negatives for the CHEMCARD™ Glucose Test, that is, the percent of negative glucose reference results which are negative by the CHEMCARD™ Glucose Test.
- The estimate of diagnostic sensitivity for the test subjects' self-interpreted CHEMCARD™ Glucose Test results when compared to the diagnosis based on a laboratory based reference glucose test is 88.9% and the estimate of diagnostic specificity is 100%.
- Among the 99 test subjects' self-interpreted results there were 0 false positives and 1 false negative.



P.O. Box 293
4519 Highway 13 South
North Webster, IN 46555, USA
Tel: +001 574 843 2406
USA (800) 348-5174



CEpartner4U
Esdoornlaan 13, 3951DB Maarn
The Netherlands
Tel: +31(0) 6-516.536.26
www.cepartner4u.eu

INFORMATION FOR THE UNISTIK-2 LANCET:



UK	NORTH AMERICA	FRANCE	GERMANY	EXPERT
Owen Mumford Ltd, Brook Hill, Woodstock, Oxford OX20 1TU, England, T: 01993 812021 F: 01993 813465 E: info@owenmumford.net	Owen Mumford Inc. 1755-A West Oak Commons Court, Marietta, Georgia 30062, USA, T: 800-421-6936 F: 770-977-2865 E: info@owenmumfordinc.com	Owen Mumford, BP 444, 27204 Vernon Cedex, France, T: 02 32 51 88 70 F: 02 32 21 96 95 E: contact@owenmumford-fr.com	Owen Mumford GmbH, Stemplatz 3, D-97896 Freudenberg/M, Germany, T: 09375/92990 F: 09375/92929 E: info@owen-mumford.de	Owen Mumford Ltd, Brook Hill, Woodstock, Oxford OX20 1TU, United Kingdom, T: +44 1993 812021 F: +44 1993 813473 E: export@owenmumford.co.uk

STERILE - SINGLE USE
Do not use if cap has been
previously removed.



REF 47611 Rev. 3