

A1CNow®

SELF CHECK

AT-HOME A1C SYSTEM

OVERVIEW AND HELPFUL HINTS

INTENDED USE

The A1CNow® SELF CHECK test provides quantitative measurement of the percent of glycated hemoglobin (%A1C) levels in capillary (fingerstick) blood samples. The test is for home use to monitor glycemic control in people with diabetes.

Before using this test, please read all instructions carefully. If you need further help, call 1-877-870-5610. We invite you to call and we will guide you through the test.

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INTRODUCTION

The percent (%) of A1C in your blood today tells you how well you have been controlling your blood sugar (glucose) levels over the past 2-3 months. About 50% of the A1C result is from the past 30 days of blood sugar levels; about 25% is from the past 30-60 days and about 25% is from the past 60-90 days.¹

The American Diabetes Association (ADA) recommends that your A1C levels should be tested at least 2 times per year if you are meeting your diabetes treatment goals and your blood sugar is stable. If your treatment changes or you are not meeting your treatment goals, the ADA recommends that you test at least every 3 months.²

The A1CNow SELF CHECK is an easy-to-use at home test to measure your A1C levels, with results in 5 minutes. In addition to blood sugar testing, you can further participate in your diabetes care using this test. You can have the results ready before you have your checkups to share with your health

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care professional. Contact your health care professional if you have any concerns about your A1C result. The A1CNow SELF CHECK test is not a substitute for regular assessment in a doctor's office or laboratory setting where a quality control program is in effect.

KIT CONTENTS

The box contains materials for two A1C tests. Make sure all of the following parts are in the box. DO NOT open the pouches until ready to use.

- A1CNow SELF CHECK Monitor (1)
- Cartridge Pouch (2)
- Shaker Pouch (2), each containing:
 - Shaker (1)
 - Blood Collector (1)
 - Lancet, disposable (1)
- Quick Reference Guide (1)
- Overview and Helpful Hints (1)

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PREPARING TO TAKE THE TEST

You may run your A1C test any time of the day. Remember to wash your hands prior to performing the test.

No special diet is necessary (you do not have to be fasting when taking this test). You may want to run this test at the same time as you do a blood sugar test.

In order to help ensure an accurate result, please complete the test from beginning to end within 15 minutes. Avoid running the test in direct sunlight, on hot or cold surfaces or near sources of hot or cold. If the test has recently been at high temperatures (greater than 77° F / 25° C) or at low temperatures (lower than 64° F / 18° C) allow the kit parts to come to room temperature (64° - 77° F / 18° - 25° C) for at least one hour before you run your test. Leave the parts in their sealed pouches while waiting.

WHAT TO DO WITH THE RESULT

The Monitor will not store your results for more than 60 minutes, so write down the

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result and the test date on the Result Log in the Quick Reference Guide as soon as possible to prevent loss of information.

WHAT THE TEST RESULT MEANS

For most people with diabetes, the American Diabetes Association (ADA) recommends that your A1C should be under 7%.² Your health care professional will tell you what target level is right for you.

HOW DOES THIS TEST COMPARE WITH THE A1C TEST FROM THE DOCTOR'S OFFICE OR THE LABORATORY?

Test results will rarely match exactly. This is true even for repeated tests done in the same lab.

A1C results may be different due to: slight differences between labs, normal variation within each test method and the time between two tests.

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STORAGE

Store and use at room temperature (64° - 77° F / 18° - 25° C) and out of direct sunlight.

If you cannot confidently store the kit under these recommended conditions, you have the option of refrigerating the kit (DO NOT freeze). However, you must bring the kit to room temperature for at least one hour prior to use.

DO NOT use the test after the expiration date shown on the box.

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WARNINGS AND PRECAUTIONS

- **DO NOT adjust your medication unless instructed to do so by your doctor or health care professional.**
- This test is NOT a substitute for regular visits to your health care professional or for monitoring your blood sugar levels.
- This test is NOT for the screening or diagnosis of diabetes.
- DO NOT substitute this test for blood sugar monitoring.
- The following conditions may affect the accuracy of your A1C result: hemoglobin variants (HbS, HbC), elevated HbF, anemia, recent significant blood loss, a recent blood transfusion, or high amounts of rheumatoid factor.
- People with hemophilia (bleeding disorder) or on anti-coagulant therapy (blood thinning medicine) should consult their doctor or health care professional before using this kit.

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- To ensure proper test performance, carefully read and follow the Quick Reference Guide.
- DO NOT use the test kit if any parts are cracked or broken.
- DO NOT eat or drink any parts of this kit.
- For use outside of the body only (in-vitro diagnostic use).
- Keep out of reach of children under the age of 7 years. When children are performing the test, be sure that testing is done under adult supervision.
- DO NOT use any other body fluids or food to perform this test. Use ONLY your fingerstick blood sample.
- DO NOT reuse the Shaker, Lancet or the Cartridge. Throw these parts away after using them once. Refer to "Disposal of Material" on the reverse side.
- If the solution from inside the Shaker touches your skin or your eyes, flush with water.

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- Leave the Cartridge Pouch sealed until ready for use.
- DO NOT add your blood directly to the cartridge. Your blood must first be added to the Shaker.
- DO NOT touch the white circle area of the Cartridge.
- This test is to be used at room temperature between 64° and 77° F (18° and 25° C). Using the test outside this temperature range will give you an error code.

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TROUBLESHOOTING

See the table below for a description of A1CNow SELF CHECK operating and error codes (“OR”= Out of Range, “QC”= Quality Control, “E”= Monitor Error).

MESSAGE	DESCRIPTION AND RESOLUTION
OR 1	The blood sample may have too little hemoglobin for the test to work properly, or you added too little blood. Call customer service.
OR 2	The blood sample may have too much hemoglobin for the test to work properly, or you added too much blood. Call customer service.
OR 3	The blood sample may have too little hemoglobin A1C for the test to work properly, or you added too little blood. Call customer service.
OR 4	The blood sample may have too much hemoglobin A1C for the test to work properly, or you added too much blood. Call customer service.
OR 5	The monitor temperature is below 64° F / 18° C. The test must be repeated with a new cartridge at room temperature (18-25° C).

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MESSAGE	DESCRIPTION AND RESOLUTION
OR 6	The monitor temperature is above 77° F / 25° C. The test must be repeated with a new cartridge at room temperature (18-25° C).
<4.0	The %A1C is less than 4%. Call customer service.
>13.0	The %A1C is greater than 13%. Call your health care professional.
QC 2	Occurs when you insert a Cartridge that already has sample added to it. Do not remove and reinsert a Cartridge after adding sample.
QC 6	Sample was added to Cartridge before “SMPL” display. This counts down one test on the Monitor. Remove and discard Cartridge. To avoid this error, do not add sample until the “WAIT” prompt clears and “SMPL” appears.
QC 7	The Cartridge remained in the Monitor without sample addition for 2 minutes after “SMPL” prompt. This counts down one test on the Monitor. Discard the Test Cartridge and insert a fresh one when you are ready to dispense the Shaker.

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MESSAGE	DESCRIPTION AND RESOLUTION
All other QC Codes	The quality control checks inside the Monitor did not pass. The test will need to be repeated with another kit. Call customer service.
E Codes	The Monitor is not working. Call customer service.

Customer Service: 1-877-870-5610

DISPOSAL OF MATERIALS

Keep the Monitor to run the second test and dispose of it after the second test has been performed. Throw away all of the other used components (except the Lancet) in your household waste. The Lancet, Shaker, Blood Collector and Cartridge can be used only once.

Since the Lancet has a sharp point, it should be disposed of in an appropriate sharps container in the same way you dispose of your blood sugar testing lancets.

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FREQUENTLY ASKED QUESTIONS

When should I do the A1CNow SELF CHECK test?

The A1CNow SELF CHECK test can be performed at any time of day. No fasting is required. You may wish to run the test at the same time you do your blood sugar test.

Sometimes I have trouble getting a blood drop that is large enough. What can I do?

Try washing your hands in warm water. Warm water will help increase blood flow for a better fingerstick. You may also massage the finger before the fingerstick.

What is the best way to fill the Blood Collector?

Hold the Blood Collector horizontally or at a 45° angle relative to the blood drop. Touch the tip gently to the drop of blood and allow the tube to fill. It will stop automatically when it is filled completely.

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My Blood Collector is not filled completely. What should I do?

Apply pressure to your finger to get more blood. Again, touch the tip gently to the drop of blood and allow the tube to fill. You may have to re-stick your finger to get the necessary blood. If the Blood Collector does not fill, call customer service.

There is extra blood on the tip of the Blood Collector. What should I do?

Carefully wipe the tip of the Blood Collector with a piece of gauze or tissue. If some of the blood comes out while doing this, touch the tip gently to the blood drop to re-fill the Blood Collector.

The Shaker seemed to leak when I pushed the Blood Collector into it. What should I do?

Call customer service.

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The Cartridge will not insert into the Monitor. What should I do?

Make sure you are inserting the Cartridge facing correctly. The Code should be on top as you insert the Cartridge into the Monitor.

I accidentally opened the Cartridge pouch too early. What should I do?

Throw away the Cartridge that has been opened for more than 2 minutes. Inaccurate results can be obtained. Use the second Cartridge in the kit instead.

The Codes on the Cartridge and the Monitor are not the same.

Do not use the Cartridge. Save the packaging materials and call customer service.

The Monitor did not turn on after I inserted the Cartridge. What should I do?

Take the Cartridge out. Re-insert in until it ‘clicks’. If the Monitor still does not turn on, this means that it may have a problem and can’t be used. Call customer service.

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I did not see ‘RUN’ and a countdown after I added the sample using the Shaker. What should I do?

Call customer service.

My result says ‘QCOK’ and a number. What should I do?

‘QCOK’ means the Monitor is working correctly. The number you see is your A1C result. Write your result down in the Result Log in the Quick Reference Guide. Monitor will show result for 60 minutes and will turn off automatically.

Review your result with your health care professional.

My result is not ‘QCOK’ and a number. What should I do?

Refer to the troubleshooting section. You can also call customer service.

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What should I do with the test after I am done with it?

After you write down your result, you can throw away the used Blood Collector, Shaker and Cartridge in your household trash. These items can be used only once. Note that the Lancet is also a single-use item.

Save the Monitor for your second test. Monitor will display “01TL” showing that there is one test left. When Monitor is displaying “00TL” it indicates that you have used both tests. Once you have used the second test, you can throw away the Monitor in your household trash.

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QUESTIONS OR COMMENTS

Call customer service at 1-877-870-5610.

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AT-HOME A1C SYSTEM

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1. Burtis, C.A., Ashwood, E.R., Tietz Textbook of Clinical Chemistry, 3rd Edition, W.B. Saunders Co., 1999.
2. American Diabetes Association. Standards of medical care in diabetes-2011. Diabetes Care, 34 (S1) 2011, pp. S11-S61.

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