91113 Rev. C 07/21

EN

ReliOn™

A1C Self Test System

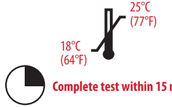
Overview & Quick Reference Guide

READ ME FIRST	
1	DO NOT use the analyzer or pouches after expiration date specified on labeling.
2	DO NOT use different lot codes.
3	DO NOT leave a gap between the blood collector and the shaker (refer to Step 4 on front of this insert).
4	DO NOT open cartridge pouch until instructed to do so (refer to Step 6 on front of this insert).
5	DO NOT use cartridge AFTER 2 MINUTES of opening the cartridge pouch.
6	DO NOT disturb the analyzer while the test is running.
7	DO see the reverse side of this insert to reference the list of analyzer codes.

1-855-776-0662
We invite you to call us and we will guide you through the test.

⚠ IMPORTANT!

- **FIRST,** we strongly recommend you read all instructions carefully and watch the brief instructional video on the manufacturer's website at: https://ptsdiagnostics.com/relion-a1c-self-test-training/. **THEN**, follow all steps as you perform the test.
- **Do not** open pouches until instructed.
- Make sure lot number on analyzer matches lot numbers on pouches.
- Use indoors between 18°C - 25°C /64°F - 77°F and out of direct sunlight.
- Do not use if the product is past the expiration date.
- If the kit has recently been kept at temperatures outside the recommended conditions, keep the kit at room temperature for at least one hour before use.



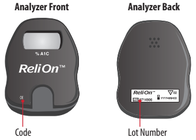
Complete test within 15 minutes.

- **DO NOT adjust your medication unless instructed to do so by your doctor or healthcare provider.**
- If you have any questions about your A1C result, please contact your doctor or healthcare provider.

Caution: This device contains material of animal origin and should be handled as a potential carrier and transmitter of disease.

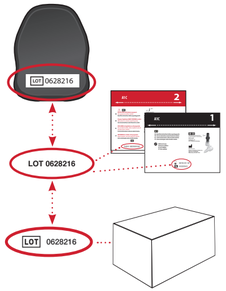
For additional information, see the reverse side of this insert.

We encourage you to call customer service at 1-855-776-0662 to walk you through the test.



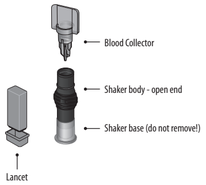
Match Lot Numbers

Use analyzer only with the materials included in the original kit. The analyzer will expire after the programmed number of tests have been run. If another test cartridge is inserted, the analyzer will display "00TL."



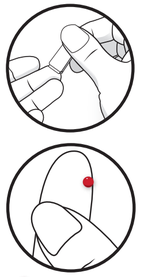
1 Open Plastic Shaker Pouch*

⚠ Do NOT open foil cartridge pouch until Step 6.



2 Stick Finger

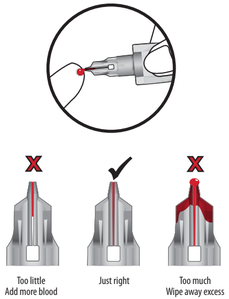
- Wash hands or clean with alcohol and dry before testing.
- Remove cap and press lancet into finger.
- Gently squeeze finger to get adequate blood.



Actual size required

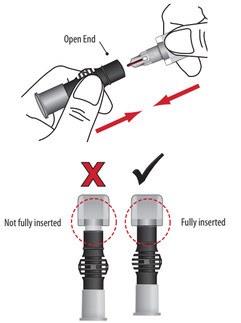
3 Collect Blood

- Gently touch blood collector to top of blood drop to fill.
- Make sure collector is adequately filled.



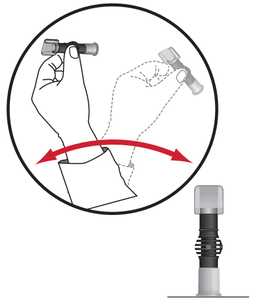
4 Insert Blood Collector

- Fully insert blood collector into shaker body.
- Push hard while twisting to fully insert.



5 Mix

- Shake vigorously 6-8 times (about 5 seconds).
  This will mix the blood with the solution.
- Stand shaker on table while preparing cartridge.

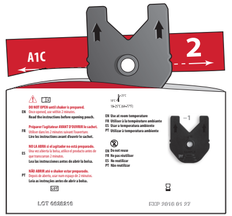


6 Open Foil Cartridge Pouch* AFTER Blood Collection

Insert cartridge into analyzer immediately and use within 2 minutes.

Tear foil pouch open at the notches on the sides.

⚠ **Caution: Do NOT open foil pouch until this step. Use within 2 minutes of opening.** If foil pouch is damaged, do not use.



7 Insert Cartridge

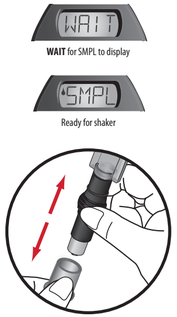
- "Click" test cartridge into place.
- Analyzer and test cartridge codes must match.
- **If codes do not match, call Customer Service at 1-855-776-0662.**

Match codes

If analyzer and cartridge codes do not match, call Customer Service at 1-855-776-0662.

8 Prepare Shaker

Remove shaker base.

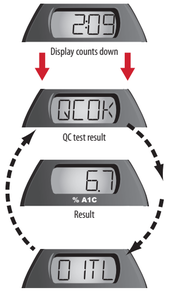


9 Dispense Sample into Cartridge

- Ensure analyzer is on level surface.
- Push down completely to dispense diluted sample and remove in a continuous motion.
- Remove shaker from cartridge quickly.
- "RUN" will appear.

Do not handle analyzer again until test is complete!

10 5 Minutes to Results



- This result cycle remains displayed for 15 minutes or until the next test cartridge is inserted.
- **If "QCOK" is not displayed, please refer to the troubleshooting section or contact Customer Service.**

11 Dispose of Cartridge / Save Analyzer

- Dispose of cartridge in your household waste.
- Save analyzer for additional tests. Analyzer will display, for example, "01TL" if there is one test left and "00TL" if you just used your last test.
- Record your A1C result in the result log in Step 12.
- Analyzer will show result for 15 minutes and will turn off automatically.

NOTE: To run another test, use a new shaker, blood collector, test cartridge, and lancet from the same kit and return to Step 1.

12 Log Result

Chart your progress here.

Record your A1C results here, and bring this with you when you see your doctor. Mark down your A1C goal in the space provided.

Date:
A1C Result:
A1C Goal:

Date:
A1C Result:
A1C Goal:

Result Interpretation

- **Do not take any decision of medical relevance without first consulting your healthcare practitioner.**
- When this device is used for monitoring of an existing disease, adapt the treatment **only** if you have received the appropriate training to do so.

Note: All instances of the box or pouches in this insert are representative ONLY. Please refer to the packaging included with your specific kit.

* Pouch illustrations may vary.

ReliOn™
A1C Self Test System

INTENDED USE
The ReliOn A1C Self Test System provides a quantitative measurement of the percent of glycated hemoglobin 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 1-855-776-0662.
We invite you to call and we will guide you through the test.

Do not take any decision of medical relevance without first consulting your medical practitioner.

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

PRINCIPLES OF THE TEST
The A1C analyzer utilizes both immunoassay and chemistry technology to measure A1C and total hemoglobin, respectively. Upon the addition of a diluted blood sample, blue microparticles conjugated to anti-A1C antibodies migrate along the reagent strips. The amount of blue microparticles captured on the strips reflects the amount of A1C in the sample.

MATERIALS PROVIDED
The box contains materials for multiple A1C tests. See outside box for quantity as it may vary. Make sure all of the following parts are in the box. DO NOT open the pouches until ready to use.

- A1C analyzer (see box label for quantity)
- Cartridge pouch (see box label for quantity). Each test cartridge contains 2 dry-reagent strips containing:
  - Anti-HbA1c antibody: latex conjugate, minimum 3 µg HbA1c minimum hapten, covalently attached to carrier protein, minimum 0.02 µg.
- Shaker pouch (see box label for quantity), each containing:
  - Shaker (1) containing: 0.2% w/v potassium ferricyanide, 2% w/v surfactant, 0.7% w/v non-reactive ingredients, 5 mM buffer in water.
  - Blood collector (1)
  - Lancet, disposable (1)
- Product insert(s)

MATERIALS NEEDED BUT NOT PROVIDED
- Gauze pad or cotton ball
- Bandage

Contact Customer Service for a list of liquid controls.

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 heat 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.

Do not move the analyzer while test is in progress.

WHAT TO DO WITH THE RESULT
The analyzer will not store your results for more than 15 minutes, so write down the result and the test date on the result log on the front of this insert to prevent loss of information.

WHAT THE TEST RESULT MEANS
For most people with diabetes, the ADA recommends that your A1C should be under 7%.[2] Your healthcare 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 tests.

STORAGE AND HANDLING
- Store and use at room temperature at 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 at 36-46°F (2-8°C). DO NOT freeze. However, you must bring the kit to room temperature for at least one hour prior to use.
- If the kit is exposed to a temperature in excess of 122°F (50°C), the the product should not be used.
- DO NOT use the test after the expiration date shown on the box.
- If disinfection of the analyzer is desired, Super Sani-Cloth® wipes are recommended (EPA Reg. No. 9480-4, Professional Disposables International (PDI), Orangeburg, New York), concentration of active ingredients (0.25%) and with a contact time of 2 minutes. The active ingredients in this disinfectant are n-Alkyl dimethyl ethylbenzyl ammonium chlorides.
- Store analyzer in protective package when not in use.

WARNINGS AND PRECAUTIONS
- **When this analyzer is used for the monitoring of an existing disease, you should only adapt the treatment if you have received the appropriate training to do so.**
- For self-testing use outside of the body only (*in vitro* diagnostic use).
- To ensure proper test performance, carefully read and follow the steps located on the front side of this product insert.
- **DO NOT adjust your medication unless instructed to do so by your doctor or healthcare professional.**
- 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 healthcare professional before using this kit.
- DO NOT use the test kit if any parts are cracked or broken.
- DO NOT eat or drink any parts of this kit.
- 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 or the cartridge. Throw these parts away after using them once. Refer to Step 11 on the front side of this insert.
- If the solution from inside the shaker touches your skin or your eyes, flush with water.
- 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.
- The test cartridges should not be used if the foil pouch or any other protective packaging is damaged.
- **Caution: The analyzer contains material of animal origin and should be handled as a potential carrier and transmitter of disease.**

LIMITATIONS
- This test is NOT for the screening or diagnosis of diabetes.
- If the user has high levels of Hemoglobin F, Hemoglobin S, Hemoglobin C, or other hemoglobin variants, the A1C test system may report incorrect results.
- Any cause of shortened red cell survival (e.g., hemolytic anemia or other hemolytic diseases, pregnancy, recent significant blood loss, etc.) will reduce exposure of red cells to glucose. This results in a decrease in % A1C values. Percent A1C results are not reliable in users with chronic blood loss and consequent variable erythrocyte life span.
- Rheumatoid Factor in high amounts will cause low results, or an error code. It is recommended that A1C be re-checked by alternate methodology, such as boronate affinity, by a healthcare professional.
- This test is NOT a substitute for regular healthcare provider visits and blood glucose monitoring.
- As with any laboratory procedure, a large discrepancy between clinical impression and test results usually warrants investigation.

QUALITY CONTROL
Each A1C analyzer performs over 50 internal chemical and electronic quality control checks, including potential hardware and software errors (e.g. cartridge alignment, programming), and potential test strip errors (e.g. insufficient sample volume, invalid calculations). The analyzer has been programmed to report an error code if these quality checks are not passed. Contact Customer Service at 1-855-776-0662, if you receive any errors.

TROUBLESHOOTING
See the table below for a description of the ReliOn A1C Self Test System operating and error codes ("OR"= Out of Range, "QC"= Quality Control, "E"= Analyzer 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 to 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 analyzer temperature is below 64°F (18°C). The test must be repeated with a new cartridge at room temperature 64-77°F (18-25°C).
OR 6	The analyzer temperature is above 77°F (25°C). The test must be repeated with a new cartridge at room temperature 64-77°F (18-25°C).
<4.0	The % A1C is less than 4%. Call Customer Service.
>13.0	The % A1C is greater than 13%. Call your healthcare 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 analyzer. 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 analyzer without sample addition for 2 minutes after "SMPL" prompt. This counts down one test on the analyzer. Discard the test cartridge and insert a fresh one when you are ready to dispense the shaker.
QC 30 to 33	The analyzer was unable to obtain a valid initial reading. Be sure to remove the shaker within one second after dispensing it into the sample port, and do not disturb the analyzer while the test is running.
QC 50 to 51 QC 55 to 56	Insufficient sample was delivered to the test cartridge. To avoid this error be sure to fully insert the blood collector into the shaker and shake immediately.
All other QC Codes	The quality control checks inside the analyzer did not pass. The test will need to be repeated with another kit. Call Customer Service.
E Codes	The analyzer is not working. Call Customer Service.

Customer Service (Toll-free): 1-855-776-0662

DISPOSAL OF MATERIALS
Keep the analyzer to run the other test(s) and dispose of it after the last test has been performed. Dispose of the other used components (except the lancet) in household waste. Each 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.

The analyzer could have residual biological material and in this case it should be regarded as contaminated waste and be disposed of in an appropriate biohazardous waste container.

PERFORMANCE CHARACTERISTICS
Expected Values (non-diabetic population)
The expected normal range for % A1C using this test system was determined by testing blood samples from 118 presumptively non-diabetic individuals (fasting glucose levels <127 mg/dL) across three US sites. The population included 33 males and 85 females, and an age range from 19 to 76 with a mean age of 43. The mean % A1C result was 5.2% ±0.71% (1 SD). The 95% confidence limits were 3.9% to 6.5%. These normal range values are similar to those reported in the literature.

Linearity
Studies were performed to evaluate the linearity of this test system across its dynamic range. Clinical samples representing low and high % A1C levels were identified, and were mixed in various proportions into nine preparations. These samples were tested in replicates of at least five (n = 5). The observed results were compared to the expected results and analyzed in terms of percent recovery. The test is linear for % A1C levels between 4% and 13%, and produces reliable results with hematocrits between 20% and 60% packed cell volume (PCV).

Precision
The precision analysis was performed with 110 diabetic (n=93) and non-diabetic (n=17) subjects across two US sites. Each subject performed 2 self-tests using this test system, with blood samples taken from two separate fingersticks. The analysis was performed on all subjects who received a numeric result for both self-tests. The data are provided below.

N	AVERAGE WITHIN SUBJECT SD	AVERAGE WITHIN SUBJECT CV
74	0.41	4.57%

Accuracy
Accuracy studies were conducted with 110 diabetic (n=93) and non-diabetic (n=17) subjects across two US sites. Each subject performed 2 self-tests using this test system, with blood samples taken from two separate fingersticks. Venous blood was also collected from each subject for comparative testing using an NGSP-certified laboratory method. All subject self-tests which resulted in evaluable numeric readings were included in the analysis. Accuracy was based on the regression of the two subject self-tests compared to the laboratory method result, and bias calculations were conducted. The data are provided below.

Fingerstick Comparative Testing Using This System

(NGSP-certified method is the TOSOH A1C 2.2 Plus)

N	R^2 ADJ.	SLOPE	Y-INTERCEPT
178	0.924	1.010	0.135

(Analytical Bias at 6, 8 and 10%)

A1C VALUE	BIAS	STANDARD ERROR
6%	0.20	0.05
8%	0.22	0.04
10%	0.24	0.07

Interference Testing/Specificity
Studies were performed to assess the effect of common test interferents, various common over-the-counter therapeutic agents, and oral antihyperglycemic agents commonly used to treat Type II diabetes. Two levels of % A1C (low and high, approximately 5% and 9%, respectively) were tested. See table below.

INTERFERENT	TEST CONCENTRATION
Bilirubin (unconjugated)	20 mg/dL
Triglyceride	3000 mg/dL
Hemoglobin	500 mg/dL
Acetaminophen/Paracetamol	8 mg/dL
Ascorbic acid	5 mg/dL
Ibuprofen	12 mg/dL
Asprin/Acetylsalicylic acid	0.1 g/dL
Glyburide (glibenclamide)	24 µg/dL
Metformin (1,1-dimenthylbiguanide HCl)	2.5 mg/dL

The studies showed no effect from any of these potential interferents at concentrations up to approximately 5-times their normal levels or therapeutic doses. Studies showed no interference from modified hemoglobins, including labile glycated hemoglobin when tested at two levels of % A1C (low and high, approximately 5% and 9% respectively). The modified hemoglobins, and the levels evaluated, were: labile hemoglobin with 1400 mg/dL glucose, carbamylated hemoglobin at a final concentration of 5 mmol/L potassium cyanate, and acetylated hemoglobin at a final concentration of 14 mmol/L acetylsalicylic acid.

There were mixed results from the testing of high levels of Hemoglobin F, Hemoglobin S, and Hemoglobin C. Unreliable results may be obtained from patients with elevated levels of variant hemoglobins.

FREQUENTLY ASKED QUESTIONS
When should I do the ReliOn A1C Self Test System test?
The ReliOn A1C Self Test System 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.

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-prick your finger to get the necessary blood. If the blood collector does not fill, call Customer Service: 1-855-776-0662.

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.

The cartridge will not insert into the analyzer. 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 analyzer.

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 another cartridge in the kit instead.

The codes on the cartridge and the analyzer are not the same.
Do not use the cartridge. Save the packaging materials and call Customer Service.

The analyzer 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 analyzer still does not turn on, this means that it may have a problem and can't be used. Call Customer Service.

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 analyzer is working correctly. The number you see is your A1C result. Write your result down in the result log on the front of this insert. The analyzer will show the result for 15 minutes and will turn off automatically.

Review your result with your healthcare professional.

My result is not 'QCOK' and a number. What should I do?
If "QCOK" is not displayed, refer to troubleshooting section or contact Customer Service.

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 appropriately. These items can be used only once. Note that the lancet is also a single-use item.

Save the analyzer for additional tests (see outside box for quantity as it may vary). The analyzer will display, for example, "01TL" showing that there is one test left. When analyzer is displaying "00TL", it indicates that you have used all tests. Once you have used all tests, you can discard the analyzer appropriately.

QUESTIONS OR COMMENTS
Call Customer Service: 1-855-776-0662.

REFERENCES

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.

CUSTOMER SERVICE
For assistance, please contact Walmart Customer Service.

Toll-free: 1-855-776-0662

EXPLANATION OF SYMBOLS
Use by

LOT Lot number

IVD *In vitro* diagnostic medical device

REF Catalog number

Consult instructions for use

Caution

Manufacturer

Temperature limit

Keep away from sunlight

Keep dry

STERILE R Sterilized using irradiation

ReliOn™
A1C Self Test System

Manufactured by:
Polymer Technology Systems, Inc.
4600 Anson Boulevard
Whitestown, IN 46075 USA
1-877-870-5610 (Toll-free)