

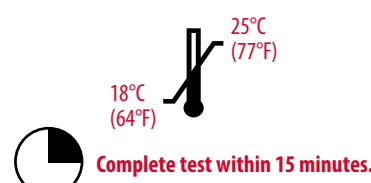
Overview & Quick Reference Guide



A1CNow[®] Self Check Test System

IMPORTANT!

- **FIRST**, we strongly recommend you read all instructions carefully and watch the brief instructional video on our website at ptsdiagnostics.com. **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 dot on the temperature label of box is red or 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.

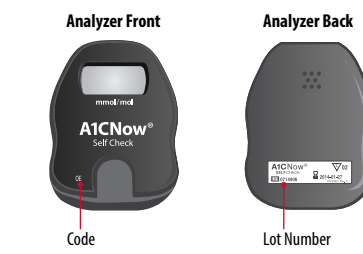


- **DO NOT** adjust your medication unless instructed to do so by your doctor or healthcare provider.
- If you have any questions about your A1C result, please contact your doctor or healthcare provider.

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

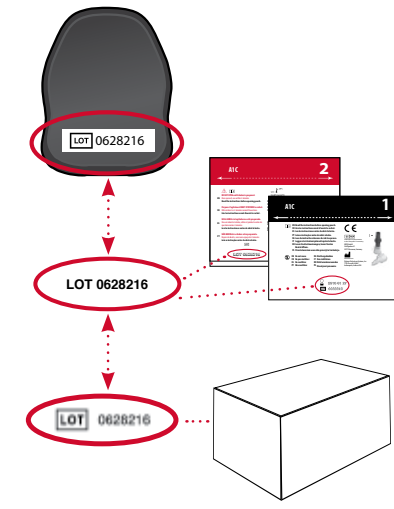
For additional information, see the reverse side of this insert.

If you are not able to access the instructional video on our website, we encourage you to call customer service at +1-317-870-5610 to walk you through the test.



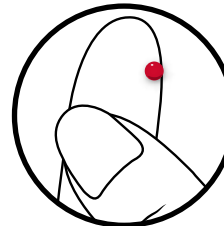
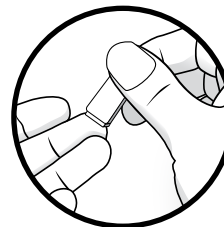
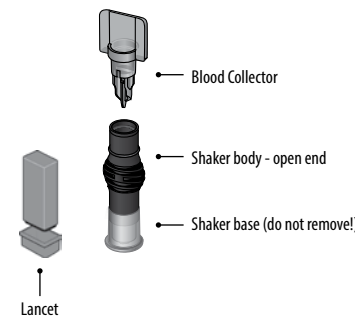
Match Lot Numbers

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*

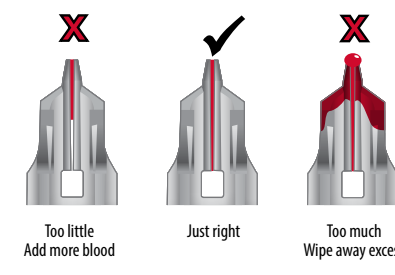
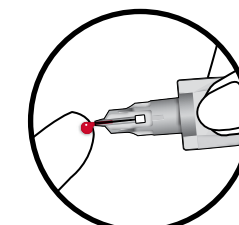
Do NOT open foil cartridge pouch until Step 6.



Actual size required

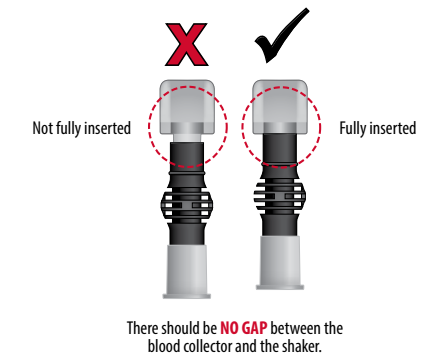
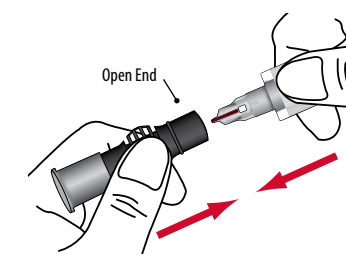
3 Collect Blood

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



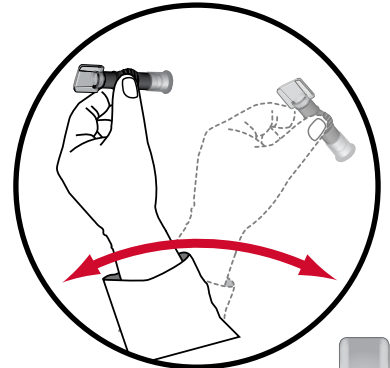
4 Insert Blood Collector

- 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.



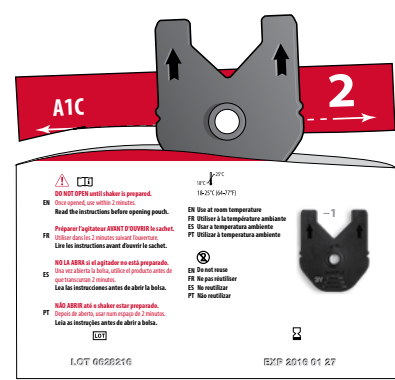
Note: All instances of the box or pouches in this insert are representative ONLY. Please refer to the packaging included with your specific kit.

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.



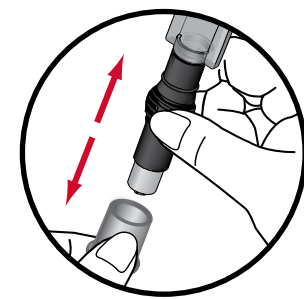
7 Insert Cartridge

- "Click" test cartridge into place.
- Analyzer and test cartridge codes must match.
- If codes do not match, call Customer Service at +1-317-870-5610.



8 Prepare Shaker

Remove shaker base.



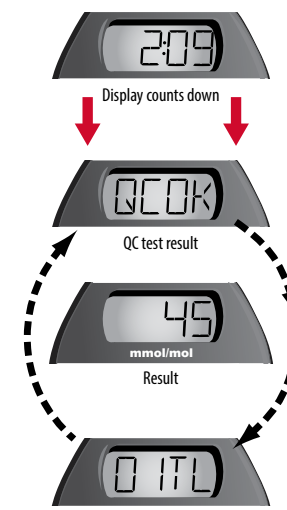
9 Dispense Sample into Cartridge

- Ensure analyzer is on level surface.
- Push down completely to dispense diluted sample and remove in a continuous motion.
- Remove sampler 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:	

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.

* Pouch illustrations may vary.

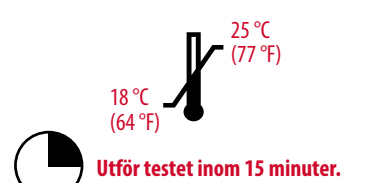
Översikt och snabbreferensguide



A1CNow[®] Self Check Testsystem

VIKTIGT!

- **FÖRST** rekommenderar vi att du läser alla anvisningar noga och tittar på den korta instruktionsvideon på vår webbplats ptsdiagnostics.com. **SEDAN** följer du alla steg när du utför testet.
- **Öppna inte** påsen innan du instrueras att göra det.
- Kontrollera att lotnumret på analysatorn matchar lotnumren på påsarna.
- Använd inomhus mellan 18 °C och 25 °C (64 °F till 77 °F) och skyddat från direkt solljus.
- Använd inte om pricken på lādans temperaturmätning är röd eller om produkten har passerat utgångsdatumet.
- Om kitet nyligen har förvarats vid temperaturer utanför rekommenderade förhållanden, ställ kitet i rumstemperatur minst en timme innan du använder det.

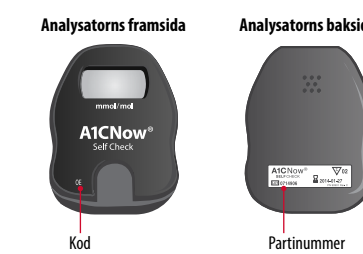


- Justera **INTE** din medicering såvida du inte instrueras att göra så av din läkare eller vårdgivare.
- Om du har några frågor rörande dina A1C-resultat kontakta din läkare eller vårdgivare.

Var försiktig! Enheten innehåller material av animaliskt ursprung och ska hanteras som potentiell bärare och spridare av smitta.

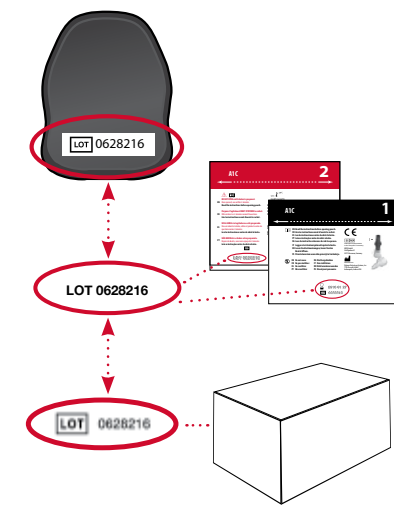
Mer information finns på baksidan av den här bipacksedeln.

Om du inte kan se videon på vår webbplats rekommenderar vi att du ringer kundtjänst på +1-317-870-5610 så att de kan guida dig genom testet.



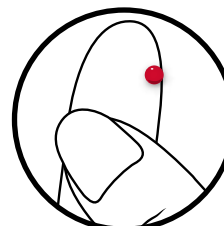
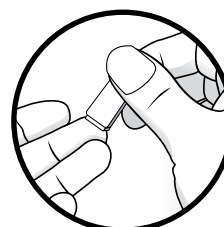
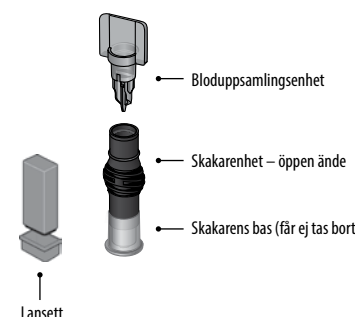
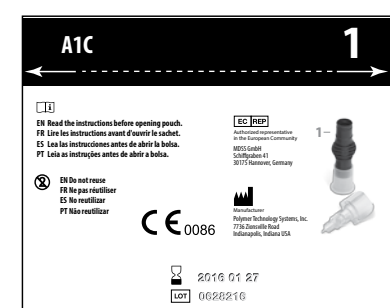
Matcha lotnummer

Använd endast analysatorn med de material som medföljer det ursprungliga kitet. Analysatorn utgår när det programmerade antalet tester har utförts. Om en annan testkassett sätts in visar analysatorn "00TL."



1 Öppna skakarens plastpåse*

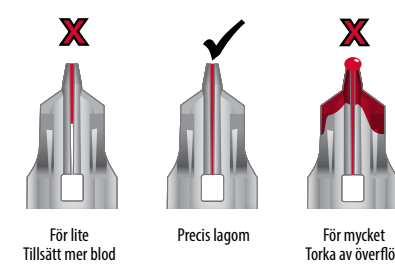
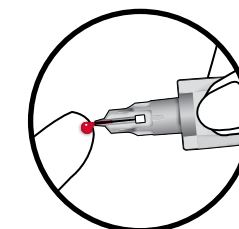
Öppna INTE kassetten följepåse före steg 6.



Mängd blod som behövs

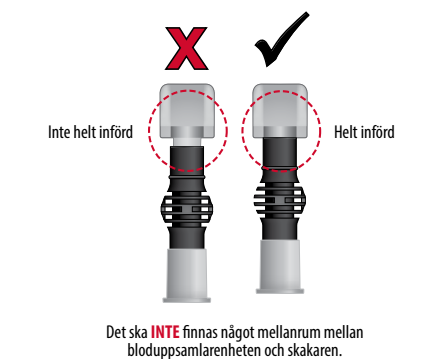
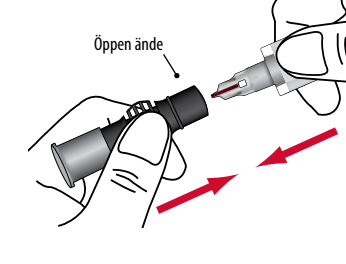
3 Samla upp blod

- För försiktigt blodsamlaren mot bloddroppens topp för att fylla den.
- Kontrollera att uppsamlaren är tillräckligt fylld.



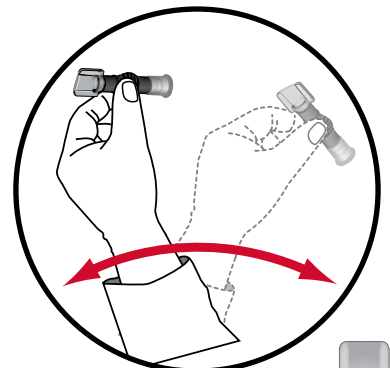
4 För in bloduppsamlingsenheten

- Skjut in blodsamlaren helt i skakaren.
- Tryck hårt samtidigt som du vridit så att delarna kopplar fast i varandra ordentligt.



5 Blanda

- Skaka kraftigt 6-8 gånger (ungefär 5 sekunder).
- Detta blandar blodet med lösningen.
- Ställ skakaren på bordet samtidigt som du förbereder kassetten.



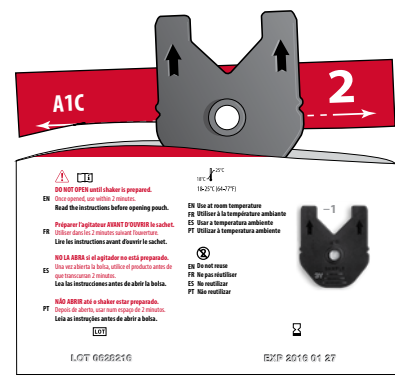
Observera! Bilderna av lādans eller påsarna i den här bipacksedeln är ENDAST avsedda som exempel. Se förpackningen som medföljde ditt kit.

6 Öppna kassetten följepåse* EFTER blodinsamlingen

- Sätt in kassetten omedelbart i analysatorn och använd den inom 2 minuter.

Öppna följepåsen vid skärorna på sidorna.

Var försiktig! Öppna INTE följepåsen före det här steget. Använd inom 2 minuter efter öppnande. Använd inte följepåsen om den är skadad.



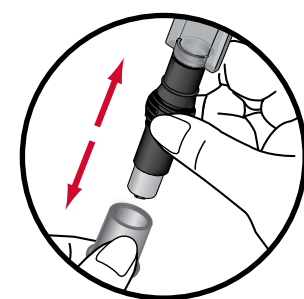
7 För in kassetten

- "Klicka" fast testkassetten.
- Analysators och testkassetters koder måste matcha.
- Om koderna inte överensstämmer, ring kundtjänst på +1-317-870-5610.



8 Förbered skakaren

Ta bort skakarens bas.



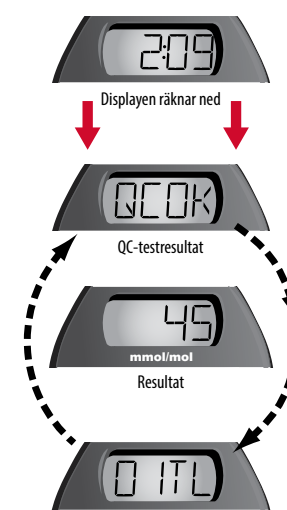
9 Dispensera provet i kassetten

- Kontrollera att analysatorn står på en plan yta.
- Tryck ned helt för att dispensera det spädda provet och ta sedan bort den med en kontinuerlig rörelse.
- Ta snabbt bort provtagaren från kassetten.
- "RUN" (kör) syns.



Rör inte analysatorn igen förrän testet är slutfört!

10 5 minuter tills resultat visas



- Denna resultatcykel fortsätter att visas i 15 sekunder eller tills nästa testkassett förs in.
- Om "QCOK" inte visas, läs igenom felsökningsavsnittet eller kontakta kundtjänst.

11 Kassera kassett/spara analysator

- Kasta kassetten i hushållsavfallet.
- Spara analysatorn för ytterligare tester. Analysatorn visar till exempel "01TL" om det bara finns ett test kvar och "00TL" om du precis har använt det sista testet.
- Registrera A1C-resultatet i resultatloggen i steg 12.
- Analysatorn visar resultat i 15 minuter och stängs sedan av automatiskt.



12 Logga resultat

Kartlägg processen här.

Registrera dina A1C-resultat här och ta med dig denna vid läkarbesök. Skriv ned dina A1C-mål i det avsedda utrymmet.

Datum:	
A1C-resultat:	
A1C-mål:	

Datum:	
A1C-resultat:	
A1C-mål:	

Datum:	
A1C-resultat:	
A1C-mål:	

Tolkning av resultat

- Ta inga beslut med medicinsk relevans utan att först rådgöra med medicinsk personal.
- Om den här anordningen används för övervakning av en befintlig sjukdom anpassar du behandlingen **endast** om du har fått lämplig utbildning för att göra det.

* Illustrationerna av påsen kan variera.

INTENDED USE

The A1CNow[®] Self Check test system provides quantitative measurement of glycated haemoglobin levels in capillary (fingerprick) 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 +1-317-870-5610. 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 concentration (mmol/mol HbA1c) 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 test system is a 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 A1CNow Self Check test system is not a substitute for regular assessment in a doctor's office or laboratory setting where a quality control program is in effect.

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.

- A1CNow Self Check analyzer (see box label for quantity)
- Cartridge pouch (see box label for quantity)
- Shaker pouch (see box label for quantity), each containing:
 - Shaker (1)
 - 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.

PREPARATION 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 25°C/77°F) or at low temperatures (lower than 18°C/64°F), allow the kit parts to come to room temperature (18-25°C/64-77°F) 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 the 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 American Diabetes Association (ADA) recommends that your A1C should be under 53 mmol/mol (7%).³ 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 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 handle analyzer at 18-25°C (64-77°F) 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 2-8°C (36-46°F). DO NOT freeze. However, you must bring the kit to room temperature for at least one hour prior to use.
- If the temperature label placed on the outside of every kit, is exposed to a temperature in excess of 50°C (122°F), the dot on the label will turn red and 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 Disinfectants 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: haemoglobin variants (HbS, HbC), elevated HbA_{1c}, 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 fingerprint blood sample.
- DO NOT reuse the shaker or 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 18 and 25°C (64 and 77°F). 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 Haemoglobin F, Haemoglobin S, Haemoglobin C, or other haemoglobin variants, the A1CNow system may report incorrect results.
- Any cause of shortened red cell survival (e.g., haemolytic anemia or other haemolytic diseases, pregnancy, recent significant blood loss, etc.) will reduce exposure of red cells to glucose. This results in a decrease in A1C concentrations (mmol/mol). Glycated haemoglobin 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 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 P1S Diagnostics A1CNow Self Check 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 +1-317-870-5610, if you receive any errors.

TROUBLESHOOTING

See the table below for a description of A1CNow Self Check test system operating and error codes ("OR" = Out of Range, "QC" = Quality Control, "E" = Analyzer Error).

OR 1	The blood sample may have too little haemoglobin for the test to work properly, or you added too little blood. Call Customer Service.
OR 2	The blood sample may have too much haemoglobin for the test to work properly, or you added too much blood. Call Customer Service.
OR 3	The blood sample may have too little haemoglobin 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 haemoglobin A1C for the test to work properly, or you added too much blood. Call Customer Service.
OR 5	The analyzer temperature is below 18°C (64°F). The test must be repeated with a new cartridge at room temperature (18-25°C).
OR 6	The analyzer temperature is above 25°C (77°F). The test must be repeated with a new cartridge at room temperature (18-25°C).
<20	The A1C is less than 20 mmol/mol. Call Customer Service.
>120	The A1C is greater than 120 mmol/mol. 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	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.
QC 55	
QC 56	
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: +1-317-870-5610

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 lance) in household waste. Each lance, 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 lances.

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 mmol HbA1c/mol Hb (or % A1C) using the A1CNow[®] system was determined by testing blood samples from 118 presumptively non-diabetic individuals (fasting glucose levels <127 mg/dL or <7 mmol/L 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 HbA1c result was 33± 7.8 mmol/mol (or 5.2± 0.71% (1 SD). The 95% confidence limits were 19-48 mmol/mol (or 3.9% to 6.5%). These values are similar to those reported in the literature.

Linearity

Studies were performed to evaluate the linearity of the A1CNow⁺ system across its dynamic range. Clinical samples representing low and high HbA1c levels were identified, and were mixed in various proportions into nine preparations. These samples were tested in replicates of at least five = 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 20 and 120 mmol/mol (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 the A1CNow Self Check 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	4.5 (0.41)	6.0% (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 the A1CNow Self Check 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.

A1CNow Self Check Fingerstick Comparative Testing

(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 42, 64 and 86 (6, 8 and 10%))

A1C VALUE	BIAS	STANDARD ERROR
42 (6%)	2 (0.20)	0.5 (0.05)
64 (8%)	2 (0.22)	0.4 (0.04)
86 (10%)	3 (0.24)	0.7 (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 31 and 75 mmol/mol, respectively) were tested. See table below.

Bilirubin (unconjugated)	20 mg/dL	0.34 mmol/L
Triglycerides	3000 mg/dL	49 mmol/L
Haemoglobin	500 mg/dL	78.8 mmol/L
Acetaminophen/Paracetamol	8 mg/dL	0.53 mmol/L
Ascorbic acid	5 mg/dL	0.28 mmol/L
Ibuprofen	12 mg/dL	0.58 mmol/L
Acetylsalicylic acid	0.1 g/dL	5.6 mmol/L
Glyburide (glibendamide)	24E-3 mg/dt	490E-6 mmol/L
Metformin (1,1-dimethylbiguanide HCl)	2.5 mg/dL	0.15 mmol/L

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 31 and 75 mmol/mol respectively). The modified hemoglobins, and the levels evaluated, were: labile hemoglobin with 78 mmol/L glucose, carbamylated hemoglobin at a final concentration of 5 mmol/L potassium cyanate, and acylated 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 A1CNow Self Check system test?

The A1CNow Self Check 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 fingerprick. You may also massage the finger before the fingerprick.

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: +1-317-870-5610.

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.

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 run on until I inserted the cartridge. What should I do?

Take the cartridge out. Re-insert it 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 'RUIW' 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, "011L" showing that there is one test left. When analyzer is displaying "001L" 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: +1-317-870-5610.

REFERENCES

1. Burts, 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(5) 2011, pp. S11-S61.

CUSTOMER SERVICE

For assistance with P1S Diagnostics products, please contact P1S Diagnostics Customer Service (M-F, 6 a.m. – 9 p.m. US EST) or your local authorized dealer.

Toll-free inside the USA and Canada: 1-877-870-5610

Direct: +1-317-870-5610

E-mail: customerservice@ptsdiagnostics.com

The A1CNow system is manufactured in the United States by Polymer Technology Systems, Inc., Indianapolis, IN 46268 USA.

© 2018 Polymer Technology Systems, Inc. A1CNow is a trademark of Polymer Technology Systems, Inc. All other trademarks and product names are the property of their respective owners.

EXPLANATION OF SYMBOLS

- Use by
- Lot number
- In vitro diagnostic medical device
- Catalog number
- Consult instructions for use
- This product fulfills the requirements of European Directive 98/79/EC on in vitro diagnostic medical devices
- Caution
- Manufacturer
- Temperature limitation
- Contains sufficient for <n> tests
- Authorized representative in the European Community
- Keep away from sunlight
- Keep dry
- Product requires separate collection for electrical and electronic equipment per the WEEE Directive

IEC REP MSS GmbH Schöffgraben 41 30175 Hannover, Germany

CE 0086

Polymer Technology Systems, Inc. 7736 Zionville Road, Indianapolis, IN 46268 USA +1-317-870-5610

AVSEDD ANVÄNDNING

A1CNow[®] Self Check testsystem ger kvantitativ mätning av glykerade hemoglobinnivåer i kapillärblodprov (fingerstick). Testet är avsett för användning i hemmet för att övervaka glykemisk kontroll hos patienter med diabetes.

Läs alla instruktioner noga innan detta test används.

Ring +1-317-870-5610 om du behöver mer hjälp. Du är välkommen att ringa, så vägleder vi dig genom testet.

Ta inga beslut av medicinsk relevans utan att först rådgöra med läkare.

INLEDNING

Koncentrationen (mmol/mol HbA1c) av A1C i ditt blod idag talar om hur väl du har kontrollerat dina blodsockernivåer (glukos) under de senaste 2–3 månaderna. Cirka 50 % av A1C-resultatet är från de senaste 30 dagarna med blodsockerivåer, cirka 25 % är från de senaste 30–60 dagarna och cirka 25 % är från de senaste 60–90 dagarna.¹

ADA (American Diabetes Association) rekommenderar att dina A1C-nivåer testas minst 2 gånger om året om du uppfyller behandlingsmålet för din diabetes och ditt blodsocker är stabilt. Om din behandling ändras, eller om du inte uppfyller dina behandlingsmål, rekommenderar ADA att du gör testet minst var tredje månad.²

A1CNow Self Check testsystem är ett lättanvänt test som du kan använda hemma för att mäta dina A1C-nivåer, med resultat inom 5 minuter. Utöver testning av blodsocker kan du delta ytterligare i din diabeteshantering med detta test. Du kan ha resultaten klara innan du går på dina uppföljningsbesök, så att du kan visa resultaten för din läkare. Kontakta din läkare om du är osäker på ditt A1C-resultat. A1CNow Self Check testsystem är ingen ersättning för regelbundna utvärderingar vid en läkarremiss eller ett laboratorium där kvalitetskontrollprogram används.

MEDFÖLJANDE MATERIAL

Lådan innehåller material för flera A1C-tester. Se lådans utsida eftersom antalet användningar kan variera. Kontrollera att lådan innehåller samtliga följande delar. Öppna INTE påsarna förän de ska användas.

- A1CNow Self Check-analysator (se etiketten på kartongen för kvantitet)
- Kassettpåse (se etiketten på kartongen för kvantitet)
- Skakarpåse (se kartongens etikett för kvantitet). Var och en innehåller:
 - Skakare (1)
 - Blodsmalare (1)
 - Lansett, för engångsbruk (1)
- Bipacksedel

NÖDVÄRDEGÅ MATERIAL SOM EJ MEDFÖLJER

- Kompress eller bomullstuss
- Förband
- Kontakta kundtjänst för en lista över vätskekontroller.

FÖRBEDDA TESTET

Du kan göra ditt A1C-test när som helst på dagen. Tänk på att tvätta händerna innan du utför testet.

Det behövs ingen speciell kost (du behöver inte vara fastande när du gör detta test). Du kanske vill köra detta test samtidigt som du gör ett blodsockertest.

För att vara säker på att få ett noggrant resultat ska testet utföras från början till slut inom 15 minuter. Undvik att utföra testet i direkt solljus, på varma eller kalla ytor eller i närheten av värme- eller kylkällor. Om testet nyligen har förvarats i höga temperaturer (över 25°C/77°F) eller låga temperaturer (under 18°C/64°F), låt kitets delar uppnå rumstemperatur (18–25°C/64–77°F) i minst en timme innan du kör testet. Låt delarna vara kvar i de förslutna påsarna medan du väntar. Flytta inte analysatorn medan testet pågår.

VAD DU SKA GÖRA MED RESULTATET

Analysatorn sparar inte dina resultat i mer än 15 minuter, så skriv ned resultatet och testdatum i resultatloggen på framsidan av det