P/N 91134 Rev. B 09/17

EN

Professional Procedure Guide

A1CNow+ Professional

Multi-Test HbA1c System

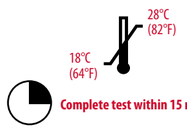
Note: All instances of the box or pouches in this insert are representative ONLY. Please refer to the packaging included with your specific kit.

pts Diagnostics

* Pouch illustrations may vary.

Introduction

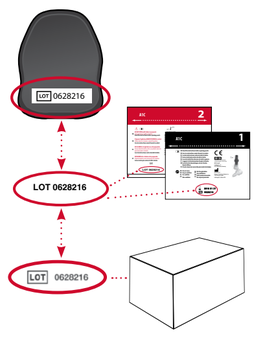
- If the temperature label, placed on the outside of every kit, is exposed to a temperature in excess of 50ºC (122ºF), the dot on the label will turn red and the product should not be used.
- Run the test with all parts of the test kit at the same temperature within the specified range.
- If the kit has recently been at high temperatures (above 28ºC/82ºF) or in the refrigerator, keep the kit at room temperature for at least one hour before use.
- Avoid running the test in direct sunlight, on hot or cold surfaces, or near sources of heat or cold.
- Quality control materials should be used to confirm the test kit is working properly. Refer to the product insert for information on when to run controls.



Complete test within 15 minutes.

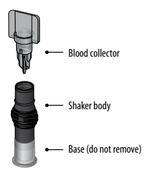
Match Lot Numbers

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 "00 TL."



1 Open Plastic Shaker Pouch*

Tear plastic pouch open at the perforation line.



2 Collect Blood

Fingerprick method

- Use your own lancet device to draw blood.
- Gently touch blood drop to fill.

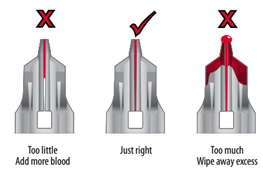
OR

OR

Venous draw method

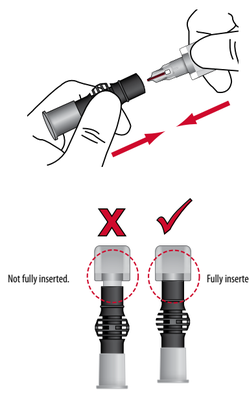
- Mix blood well before testing.
- Collect blood from a slide.

3 Verify Blood Amount



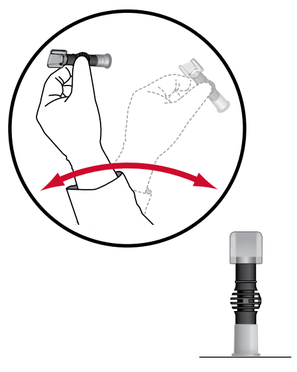
4 Insert Blood Collector

Fully insert blood collector into shaker body. Twisting motion helps.



5 Mix

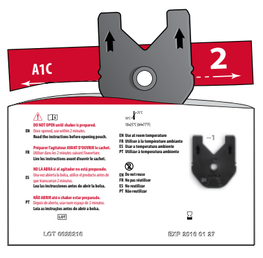
- Shake vigorously 6-8 times. This will mix the blood with the solution.
- Stand shaker on table while preparing cartridge.



6 Open Foil Cartridge Pouch*

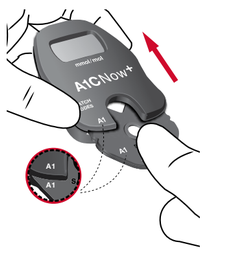
Tear foil pouch open at the notches on the sides.

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



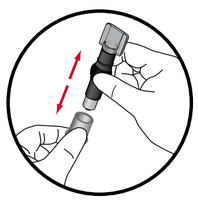
7 Insert Cartridge

- "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 or your local authorized distributor.**



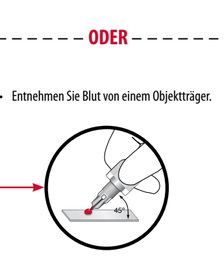
8 Prepare Shaker

Remove shaker base.



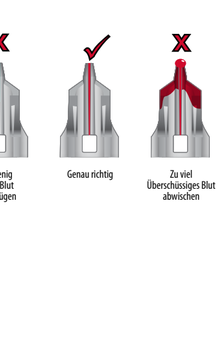
9 Dispense Sample into Cartridge

- Ensure analyzer is on level surface.
- Push down completely to dispense diluted sample. Remove quickly.



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 contact Customer Service or consult the troubleshooting section.**

11 Dispose of Cartridge / Save Analyzer

- Dispose of in accordance with your biohazard procedures.
- 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.
- Analyzer will show result for 15 minutes and will turn off automatically.

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

DE

Verfahrensleitfaden für Fachkräfte

A1CNow+ Professionell

Multitest HbA1c System

Hinweis: Jegliche Abbildungen in diesem Beiblatt, die den Karton oder die Beutel zeigen, dienen AUSSCHLIESSLICH zu Darstellungszwecken. Richten Sie sich daher nach den jeweiligen Verpackungen Ihres entsprechenden Sets.

pts Diagnostics

* Das Erscheinungsbild des abgebildeten Beutels kann vom tatsächlichen Erscheinungsbild abweichen.

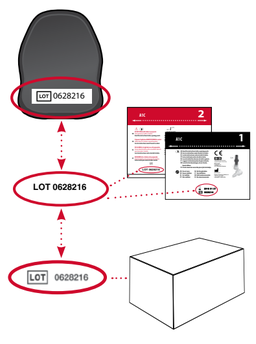
Einführung

- Wenn das Temperaturetikett, das an der Außenseite jedes Sets angebracht ist, einer Temperatur über 50 °C (122 °F) ausgesetzt ist, wechselt die Farbe des Punktes auf dem Etikett zu Rot. Das Produkt sollte in diesem Fall nicht mehr verwendet werden.
- Führen Sie den Test mit allen Testkomponenten und bei gleichbleibender Temperatur innerhalb des festgelegten Temperaturbereichs durch.
- Wenn das Set hohen Temperaturen (über 28 °C/82 °F) ausgesetzt war oder im Kühlschrank aufbewahrt wurde, muss es vor der Verwendung mindestens eine Stunde bei Raumtemperatur liegen gelassen werden.
- Führen Sie den Test nicht unter direkter Sonneneinstrahlung, auf kalten oder heißen Oberflächen oder in der Nähe von Kälte- oder Wärmequellen durch.
- Qualitätskontrollmaterialien sollten durchgeführt werden, um zu bestätigen, dass das Testset ordnungsgemäß funktioniert. Lesen Sie das Produktbeiblatt für weitere Informationen darüber, wann Kontrollen durchgeführt werden sollten.

Führen Sie den Test innerhalb von 15 Minuten durch.

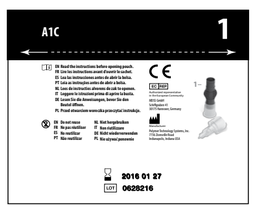
Übereinstimmung der Chargennummern

Verwenden Sie das Analysegerät ausschließlich mit den im Originalset enthaltenen Materialien. Das Analysegerät kann nicht mehr verwendet werden, wenn die programmierte Anzahl von Tests durchgeführt wurde. Wenn eine andere Testpatrone eingesetzt wird, erscheint „00 TL" auf dem Analysegerät.



1 Shaker-Kunststoffbeutel öffnen*

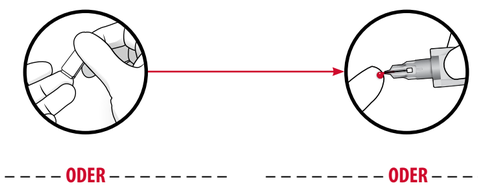
Reißen Sie den Kunststoffbeutel an der perforierten Linie auf.



2 Blut entnehmen

Blutentnahme per Fingerstich

- Verwenden Sie Ihr Lanzettengerät, um Blut zu entnehmen.
- Berühren Sie vorsichtig den Bluttropfen zum Füllen.



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ODER

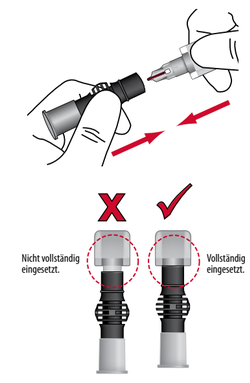
Venöse Blutprobennahme

- Mischen Sie die Probe vor der Messung gut.
- Entnehmen Sie Blut von einem Objektträger.

3 Blutmenge überprüfen

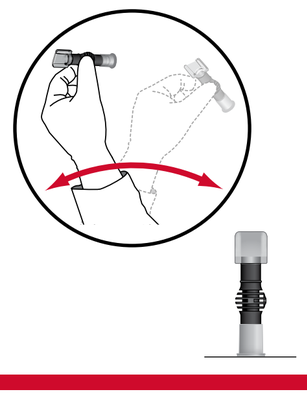
4 Blutentnahmevorrichtung einführen

Setzen Sie die Blutentnahmevorrichtung vollständig in den Shaker ein. Führen Sie dabei Drehbewegungen aus, um das Einführen zu erleichtern.



5 Mischen

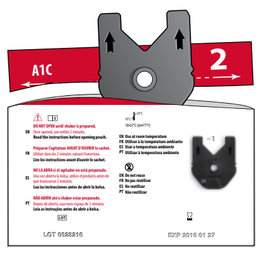
- Schütteln Sie den Shaker 6- bis 8-mal kräftig. Dadurch wird das Blut mit der Lösung vermischt.
- Stellen Sie den Shaker auf dem Tisch ab und bereiten Sie die Patrone vor.



6 Patronen-Folienbeutel öffnen*

Reißen Sie den Folienbeutel an den seitlichen Einschnitten auf.

Vorsicht: **Den Folienbeutel NICHT vor Ausführung dieses Verfahrensschritts öffnen. Die Patrone nach dem Öffnen des Beutels innerhalb von 2 Minuten verwenden.** Die Patrone nicht verwenden, wenn der Folienbeutel beschädigt ist.

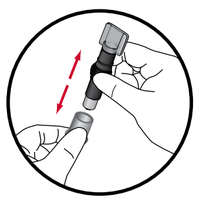


7 Patrone einsetzen

- Führen Sie die Testpatrone ein, bis ein „Klicken" zu hören ist.
- Die Codes auf dem Analysegerät und auf der Testpatrone müssen übereinstimmen.
- **Falls die Codes nicht übereinstimmen, wenden Sie sich bitte an Ihren autorisierten Händler vor Ort oder unter der folgenden Telefonnummer an den Kundendienst: +1-317-870-5610.**

8 Shaker vorbereiten

Nehmen Sie die Basis vom Shaker ab.

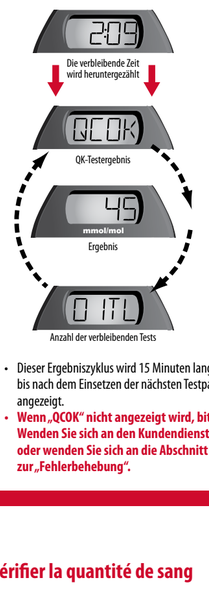


9 Probe in die Patrone abgeben

- Stellen Sie sicher, dass sich das Analysegerät auf einer ebenen Fläche befindet.
- Drücken Sie den Shaker vollständig nach unten, um die verdünnte Probe in die Patrone abzugeben. Entfernen Sie ihn schnell.

Das Analysegerät nicht mehr berühren, bis der Test abgeschlossen ist!

10 Ergebnisse in 5 Minuten



- Dieser Ergebniszyklus wird 15 Minuten lang oder bis nach dem Einsetzen der nächsten Testpatrone angezeigt.
- **Wenn „QCOK" nicht angezeigt wird, bitte Wenden Sie sich an den Kundendienst oder wenden Sie sich an die Abschnitt zur „Fehlerbehebung".**

11 Entsorgung der Patrone/ Aufbewahrung des Analysegeräts

- Entsorgen Sie die Patrone gemäß den Verfahren Ihrer Einrichtung zur Entsorgung von biogefährlichem Material.
- Bewahren Sie das Analysegerät für weitere Tests auf. Das Analysegerät zeigt beispielsweise „01TL" an, wenn ein Test übrig ist, und „00TL", wenn Sie soeben Ihren letzten Test verbraucht haben.
- Auf dem Analysegerät wird das Ergebnis 15 Minuten lang angezeigt. Danach schaltet es sich automatisch ab.

HINWEIS: Zur Durchführung eines weiteren Tests eine neue Blutentnahmevorrichtung, einen neuen Shaker und eine neue Testpatrone aus demselben Set verwenden und mit Schritt 1 beginnen.

FR

Guide des Procédures professionnelles

A1CNow+ Professionnel

Système Multi-Test HbA1c

Remarque : tous les exemples de boîte ou de sachets illustrés dans ces instructions ne sont PAS contractuels. Veuillez vous référer à l'emballage inclus avec votre kit spécifique.

pts Diagnostics

* Les illustrations des sachets peuvent varier.

Introduction

- Si l'étiquette de température située à l'extérieur de chaque kit est exposée à une température supérieure à 50 °C (122 °F), le point sur l'étiquette devient rouge et le produit ne doit pas être utilisé.
- Effectuez le test en conservant toutes les pièces du kit de test à la même température dans la plage spécifiée.
- Si le kit a récemment été exposé à des températures élevées (supérieures à 28 °C/82 °F) ou s'il a été stocké dans un réfrigérateur, laissez le kit à température ambiante pendant au moins une heure avant utilisation.
- Évitez d'effectuer ce test à la lumière directe du soleil, sur des surfaces chaudes ou froides, ou à proximité de sources de chaleur ou de froid.
- Le matériel de Contrôle-Qualité doit être utilisé pour confirmer que le test fonctionne bien. Pour en savoir plus ou connaître les modalités d'utilisation des contrôles, consultez la Notice du produit.

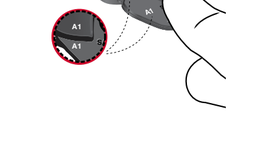
Test terminé en 15 minutes.

Faire correspondre les numéros de lot

Utiliser uniquement l'analyseur avec le matériel inclus dans le kit d'origine. L'analyseur expire une fois le nombre programmé de tests effectué. Si une autre cartouche de test est insérée, l'analyseur affiche « 00 TL ».

1 Ouvrir le sachet à agitateur en plastique*

Déchirer le sachet en plastique au niveau de la ligne de perforation pour l'ouvrir.



2 Collecter le sang

Méthode de prélèvement au doigt

- Utiliser votre propre dispositif à lancette pour prélever le sang.
- Pour remplir, touchez délicatement la goutte de sang.

OU

OU

Méthode par prélèvement veineux

- Mélangez bien le sang avant l'analyse.
- Recueillez le sang sur une lame.

3 Vérifier la quantité de sang

4 Insérer le collecteur de sang

Insérer entièrement le collecteur de sang dans le corps de l'agitateur. Un mouvement de rotation facilite l'insertion.

5 Mélanger

- Agiter vigoureusement 6 à 8 fois. Le sang se mélange alors avec la solution.
- Poser l'agitateur droit sur la table pendant la préparation de la cartouche.

6 Ouvrir le sachet de la cartouche*

Déchirer le sachet au niveau des encoches latérales pour l'ouvrir.

Mise en garde : **ne PAS ouvrir le sachet avant cette étape. Utiliser dans les deux minutes après l'ouverture.** Ne pas utiliser un sachet endommagé.

7 Insérer la cartouche

- Mettre en place la cartouche de test jusqu'à entendre un déclic.
- Les codes de l'analyseur et de la cartouche de test doivent être identiques.
- **Si les codes ne sont pas identiques, contactez le service client au +1-317-870-5610 (États-Unis) ou votre distributeur agréé local.**

8 Préparer l'agitateur

Retirer la base de l'agitateur.

9 Verser l'échantillon dans la cartouche

- S'assurer que l'analyseur se trouve sur une surface plane.
- Appuyer complètement pour verser l'échantillon dilué. Retirer rapidement.

Ne pas manipuler à nouveau l'agitateur jusqu'à ce que le test soit terminé!

10 Résultats en 5 minutes

- Ce cycle de résultats est affiché pendant 15 minutes ou jusqu'à insertion de la cartouche de test suivante.
- **Si « QCOK » ne s'affiche pas, veuillez contacter le service client ou consulter la section Dépannage.**

11 Jeter la cartouche / Conserver l'analyseur

- Éliminez les déchets conformément à vos procédures d'élimination des déchets biologiques.
- Conserver l'analyseur pour des tests ultérieurs. L'analyseur affiche, par exemple, « 01TL » s'il ne reste plus qu'un test, et « 00 TL » si vous venez d'utiliser le dernier test.
- L'analyseur affiche le résultat pendant 15 minutes, puis s'éteint automatiquement.

REMARQUE : pour effectuer un nouveau test, utiliser un nouveau collecteur de sang, un nouvel agitateur et une nouvelle cartouche de test du même kit et retourner à l'étape 1.

IT

Guida alla procedura Professionale

A1CNow+ Professionale

Sistema multi-test HbA1c

Nota: tutte le istanze relative alla confezione o alle buste presenti in questo foglietto illustrativo sono ESCLUSIVAMENTE a scopo rappresentativo. Fare riferimento alla confezione fornita con il kit specifico.

pts Diagnostics

* Le illustrazioni relative alle buste potrebbero variare.

Introduzione

- Se l'etichetta della temperatura, posizionata sulla parte esterna di ciascun kit, è esposta a una temperatura superiore a 50 °C (122 °F), l'indicatore sull'etichetta diventerà rosso e il prodotto non potrà essere utilizzato.
- Eseguire il test su tutti i componenti del kit del test alla stessa temperatura, purché questa rientri nell'intervallo specificato.
- Se il kit è stato recentemente sottoposto a temperature elevate (al di sopra di 28 °C/82 °F) o riposto nel frigorifero, mantenerlo a temperatura ambiente per almeno un'ora prima di utilizzarlo.
- Evitare di eseguire il test alla luce diretta del sole, su superfici calde o fredde, oppure vicino a fonti di calore o di aria fredda.
- Utilizzare materiali per il controllo qualità per confermare che il kit del test funzioni correttamente. Consultare il foglietto illustrativo per sapere quando eseguire i controlli.

Completare il test entro 15 minuti.

Corrispondenza dei numeri di lotto

Utilizzare l'analizzatore soltanto con i materiali inclusi nel kit originale. In seguito al raggiungimento del numero programmato di test eseguiti, l'analizzatore scade e non è più utilizzabile. Nel caso in cui venga inserita un'altra cartuccia per test, l'analizzatore indicherà "00 TL."

1 Apertura della busta in plastica dell'agitatore*

Aprire la busta in plastica dalla linea di perforazione.

2 Prelievo di sangue

Metodo di prelievo con pungidito

- Servirsi della propria lancetta pungidito per effettuare il prelievo di sangue.
- Toccare delicatamente la goccia di sangue per riempire il raccoglitore.

O

O

Metodo di prelievo di sangue venoso

- Miscelare bene il sangue prima di eseguire il test.
- Raccogliere il sangue su un vetrino.

3 Verifica della quantità di sangue

4 Inserimento del raccoglitore di sangue

Inserire completamente il raccoglitore di sangue nel corpo dell'agitatore. Aiutarsi con un movimento rotatorio.

5 Miscela

- Agitare energicamente 6-8 volte. In tal modo, il sangue verrà mescolato alla soluzione.
- Durante la preparazione della cartuccia, posizionare l'agitatore sul tavolo.

6 Aprire la busta in alluminio della cartuccia*

Aprire la busta di alluminio facendo leva sulle tacche laterali.

Attenzione: **NON aprire la busta in alluminio prima di questo passaggio. Utilizzare entro 2 minuti dall'apertura.** Se la busta in alluminio è danneggiata, non utilizzarla.

7 Inserire la cartuccia

- Inserire la cartuccia per test finché non si sente uno scatto.
- I codici dell'analizzatore e della cartuccia per test devono coincidere.
- **Se i codici non corrispondono, contattare l'assistenza clienti al numero +1-317-870-5610 o il distributore locale autorizzato.**

8 Preparazione dell'agitatore

Rimuovere la base dell'agitatore.

9 Erogazione del campione nella cartuccia

- Assicurarsi che l'analizzatore sia posto su una superficie piana.
- Spingere completamente verso il basso per erogare il campione diluito. Rimuovere rapidamente.

Non riutilizzare l'analizzatore fino al completamento del test.

10 Attendere 5 minuti per i risultati

- Questo ciclo di risultati rimane visualizzato per 15 minuti o fino all'inserimento della cartuccia per test successiva.
- **Se non si visualizza "QCOK" contattare l'assistenza clienti o consultare la sezione relativa alla risoluzione dei problemi.**

11 Smaltimento della cartuccia/conservazione dell'analizzatore

- Smaltire la cartuccia nel rispetto delle procedure relative ai rifiuti a rischio biologico.
- Conservare l'analizzatore per ulteriori test. Ad esempio, sull'analizzatore viene visualizzato il messaggio "01TL" in caso di un test rimanente e "00TL" se è stato utilizzato l'ultimo test.
- L'analizzatore visualizzerà il risultato per 15 minuti, poi si spegnerà automaticamente.

NOTA: per eseguire un altro test, utilizzare un nuovo raccoglitore di sangue, un nuovo agitatore e una nuova cartuccia per test dello stesso kit e tornare al passaggio 1.

EN

A1CNow®+ Professional

Instructions for Use

INTENDED USE

The A1CNow®+ test provides quantitative measurement of glycated haemoglobin levels in capillary (fingerprick) or venous whole blood samples. This test can be used to monitor glycemic control in people with diabetes and as an aid to diagnose diabetes and identify patients at risk of developing diabetes.

SUMMARY

High levels of blood glucose result in over-glycation of proteins throughout the body including haemoglobin.[1] Glycation of haemoglobin can occur at the amino termini of the alpha and beta chains, as well as other sites with free amino groups.[1] Haemoglobin A undergoes a slow glycation with glucose that is dependent on the time-average concentration of glucose over the 120-day life span of red blood cells.

The most prevalent and well-characterized species of glycated haemoglobin A is A1C, making up approximately 3% to 6% of total haemoglobin in healthy individuals.[1] The correlation of A1C (HbA1c) and blood glucose levels make it a useful method of monitoring long-term blood glucose levels in people with diabetes.[2] Previous studies, such as the Diabetes Control and Complications Trial (DCCT) and the United Kingdom Prospective Diabetes Study (UKPDS), used glycated haemoglobin as a way to measure overall glycemic control during the studies. These studies, and others, have shown that tight glycemic control is associated with fewer diabetes-related complications (e.g., vision problems, cardiovascular problems, and kidney problems).[3] The National Glycohaemoglobin Standardization Program (NGSP) was established to ensure traceability of haemoglobin A1C (A1C) results to the DCCT. Studies show a direct relationship from a mmol/mol (or %) A1C to estimated average blood glucose (eAG) levels. For every 11 mmol/mol (or 1%) change in A1C there is a change of about 1.6 mmol/mol (30 mg/dL) in eAG.[4] The formula used to calculate the estimated average blood glucose (eAG) levels from the A1C levels is **eAG (mg/dL) = (28.7 * A1C) - 46.7.** To calculate eAG in mmol/L: eAG (mmol/L)=(1.59 * % A1C)-2.59 or eAG (mmol/L)=((0.145 * A1C mmol/mol)+0.8).[4]

The relationship between the National Glycohaemoglobin Standardization Program (NGSP) A1C calibration (expressed as % A1C) and the International Federation of Clinical Chemistry (IFCC) network calibration (expressed as mmol/mol) has been shown to be stable and is given by the master equations: (IFCC = [10.93 * NGSP]-23.50) and (NGSP = [0.09148 * IFCC] + 2.152). For further details and additional references see the NGSP website at http://www.ngsp.org/ifcc.asp.

A1C can be measured by a variety of techniques, and over the past decade they have expanded to include point-of-care assays. Point-of-care assays are well suited to environments such as healthcare professionals' offices and clinics, because they are generally easy to perform, require no laboratory equipment, and provide rapid turn-around-time from sampling to result.[5] This immediate feedback of results enhances provider/patient interaction and, therefore better enables disease management.[6]

PRINCIPLES OF THE TEST

This PTS Diagnostics test utilizes enabling technology that incorporates microelectronics, optics, and dry-reagent chemistry strips within a reusable, self-contained, integrated handheld analyzer and a single-use test cartridge. An unmeasured whole blood mixture (diluted) is directly applied to the sample port, and results are displayed in numeric form on the analyzer's liquid crystal display after 5 minutes. Having no switches or buttons, the analyzer self-activates upon insertion of the test cartridge. The A1CNow+ analyzer utilizes both immunoassay and chemistry technology to measure A1C and total haemoglobin, 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.

For the total haemoglobin (Hb) portion of the test, the sample diluent converts Hb to met-Hb. The intensity of met-Hb color measured on the reagent strips is proportional to the concentration of haemoglobin in the sample. Test results are expressed as mmol HbA1c/mol Hb.

Calibration of the PTS Diagnostics A1CNow+ analyzer is performed with a set of blood samples that have been value-assigned by a National Glycohaemoglobin Standardization Program (NGSP) certified laboratory using an NGSP reference method. Total Hb calibration values for those samples are obtained with a Total Hb analyzer (HemoCue® Haemoglobin Test System, HemoCue, Inc., Brea, CA). The calibration of the A1CNow+ test is thus traceable to the NGSP and to an NGSP Certified Network reference method.

MATERIALS PROVIDED

- A1CNow+ analyzer (1)
- A1CNow+ test cartridges (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 kit (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)
- Instructions for Use
- Patient result labels (matches quantity of tests in box)

MATERIALS NEEDED BUT NOT PROVIDED

- Fingerprick sample: lancet, or other blood fingerprick collection device or,
- Venous sample: Heparin (sodium or lithium ["green top"]) preferred, venous collection supplies.
- Gauze pad or cotton ball
- Bandage
- Liquid control solution. Contact Customer Service (+1-317-870-5610) for a list of liquid controls that may be used.

STORAGE AND HANDLING

- Pouched test cartridges, A1CNow+ analyzers, and shaker kits may be stored at room temperature at 64-82°F (18-28°C) for up to **four months** prior to use. Analyzers, test cartridges, and dilution kits stored at room temperature must be thrown away if not used within those **four months**.
- If the temperature label, placed on the outside of every kit, is exposed to a temperature in excess of 122°F (50°C), the dot on the label will turn red and the product should not be used.
- The analyzers, test cartridges, and shaker kits may be used until the expiration date printed on the box and pouches when stored refrigerated at 36-46°F (2-8°C). Analyzers, test cartridges, and shaker kits stored in the refrigerator must be thrown away if not used by the expiration date.
- Leave all components in their sealed pouches until use. If refrigerated, ensure pouches are at room temperature before use.
- Do not mix pouches and analyzers from different lots.
- If disinfection of the analyzer is desired, Super Sani-Cloth® wipes are recommended. If the analyzer is used for multiple patients, it is recommended to clean and disinfect the analyzer between patients, to change gloves between patients, and to only use auto-disabling, single-use lancing devices. Store analyzer in protective package when not in use.

WARNINGS AND PRECAUTIONS

- For *in vitro* diagnostic use only.
- Carefully read and follow the Professional Procedure Guide to ensure proper test performance.
- If refrigerated, bring sealed pouches and analyzer to room temperature for one hour prior to use.
- The A1CNow+ analyzer and test cartridges should not be used if either are cracked or broken.
- The test cartridges should not be used if the foil pouch or any other protective packaging is damaged.
- Add sample to A1CNow+ test cartridge within 2 minutes after pouch is opened.
- All components of the A1CNow+ system are potentially biohazardous. Dispose of as biohazardous waste.
- The dilution buffer in the shaker contains ferricyanide in a buffered detergent solution. Do not ingest. In case of contact with skin or eyes, flush the area with large amounts of water.
- Do not reuse test cartridges or shaker kits.
- Do not mix analyzers with cartridges and shaker kits from different lots.
- Do not move analyzer while test is in progress.
- After the analyzer has been used with the enclosed test cartridges and shaker kits, the analyzer batteries should be removed for recycling. To remove batteries, separate the analyzer's two case halves. Removal of batteries must be performed by authorized personnel only.
- The cartridge, the shaker, and blood collector, once used, represent a biological risk. Dispose as contaminated biological waste according to the relevant laws. The analyzer could have residual biological material and in this case it should be regarded as a contaminated waste.
- **Caution:** The device contains material of animal origin and may transmit infectious agents and should be handled with caution.

SPECIMEN COLLECTION AND PREPARATION

Note: No fasting or special diet is necessary.

1. **Fingerprick**
   The PTS Diagnostics A1CNow+ test requires 5 microliters (µL) of whole blood (1 large drop). Fingerprick blood is obtained by standard techniques and single-use, auto-disabling lancets. If alcohol is used for cleansing, be sure the finger is completely dry before lancing.
2. **Venipuncture/Sample Collection for Venous Draw**
   Venous blood should be collected into heparin tubes (sodium or lithium, "green tops"). Blood samples should be well-mixed and tested at room temperature. Venous blood samples are stable for up to 8 hours at room temperature and up to 14 days in the refrigerator.

TEST RESULTS

A1C results reflect blood glucose control over the last three months. About 50% of the A1C result is from the past 30 days; about 25% is from the past 30-60 days and about 25% is from the past 60-120 days.[1] Depending on the test methodology used, laboratory methods show that the reference range of the A1C test is approximately 4.0-6.5% (20-48 mmol/mol) A1C, and 6% to 9% (42 to 75 mmol/mol) in people with well to moderately controlled diabetes.[1] Levels can be as high as 20% (195 mmol/mol) in people with poorly controlled diabetes.[7] The American Diabetes Association's (ADA's) most recent Clinical Practice Recommendation for diabetes specifies a treatment goal for patients in general of less than 7% A1C (53 mmol/mol) with a treatment goal for patients even lower than 7% A1C (53 mmol/mol), if possible, without significant hypoglycaemia or other adverse effects.[8]

QUALITY CONTROLS

Each PTS Diagnostics A1CNow+ analyzer performs over 50 internal chemical and electronic quality control checks, including potential hardware and software errors (e.g. cartridge alignment, programming), and potential reagent 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.

Quality control testing with A1C liquid quality control samples should be performed at the following times:

- With each new shipment.
- With each new lot.
- Whenever problems (storage, operator, instrument, or other) are identified.
- To ensure that storage conditions have not affected the product, run a control sample before running a patient sample if the test kit has been stored for more than a month and it has been at least a month since the last control testing.
- In accordance with your facility's or accrediting agency's guidelines.

The measured value should be within the acceptable limits stated for the control material. If the results obtained are outside the acceptable limit, please review the procedure and re-test the control material. If the measured value continues to fall outside the acceptable limit, please do not test additional patient samples and contact your local representative.

Good laboratory practices include a complete quality control program. This entails proper sample collection and handling practices, ongoing training of testing personnel, ongoing evaluation of control results, proper storage of test kits, etc. A permanent record of control results should be retained.

TROUBLESHOOTING

See the table below for a description of A1CNow+ 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 haemoglobin (less than 20% hematocrit), not enough blood was collected, or the blood was not well mixed inside the shaker.** You may wish to check hematocrit by another method.
OR 2	The blood sample may have too much haemoglobin (greater than 60% hematocrit), or excess blood was collected.** You may wish to check hematocrit by another method.
OR 3	The blood sample may have too little A1C, or insufficient blood was collected.**
OR 4	The blood sample may have too much A1C, or excess blood was collected.**
OR 5	The analyzer temperature is below 18°C (64°F). Repeat the test at room temperature (18-28°C).
OR 6	The analyzer temperature is above 28°C (82°F). Repeat the test at room temperature (18-28°C).
<20	The A1C is less than 20 mmol/mol.
>120	The A1C is greater than 120 mmol/mol.
QC 2	Occurs when you insert a test cartridge that already has sample added to it. Do not remove and reinsert a test cartridge after adding sample.**
QC 6	Sample was added to test cartridge before "SMPL" display. This counts down one test on the analyzer. Remove and discard test cartridge. To avoid this error, do not add sample until the "WAIT" prompt clears and "SMPL" appears.
QC 7	The test 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 did not pass. The test will have to be repeated with another test cartridge and shaker kit.
E1 to E99	The analyzer has a Fatal Error. Call your local PTS Diagnostics representative.

**Carefully repeat the test using a new test cartridge and a new shaker kit.

LIMITATIONS OF THE PROCEDURE

- This test should not be used to replace glucose testing in persons with or suspected of having type 1 diabetes, who are pregnant, or a paediatric patient.
- **This test should not be used to diagnose diabetes in the following:**
  - Children, young people, or patients with symptoms of diabetes less than 2 months.
  - Acutely ill (hospitalized) patients.
  - Patients taking medication (steroids, antipsychotics) that may cause rapid rise in glucose.
  - Patients with acute pancreatic damage, including pancreatic surgery.
  - Patients with genetic, haematologic and illness-related factors that influence HbA1c or its measurement.
- If the patient has high levels of Haemoglobin F, Haemoglobin S, Haemoglobin C, or other haemoglobin variants, the A1CNow+ system may report incorrect results.
- Use of serology tubes containing EDTA anti-coagulant may cause a negative accuracy bias.
- 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 values. Percent A1C results are not reliable in patients 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.
- 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.

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. Each laboratory should determine its own reference range to conform to the population being tested.

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 (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 20 and 120 mmol/mol (4% and 13%), and produces reliable results with hematocrits between 20% and 60% packed cell volume (PCV).

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 20 and 86 mmol/mol (4% and 10%), respectively) were tested. See table.

INTERFERENT	TEST CONCENTRATION	
Bilirubin (unconjugated)	20 mg/dL	0.34 mmol/L
Triglycerides	3000 mg/dL	49 mmol/L
Haemoglobin	500 mg/dL	78E-3 mmol/L
Acetaminophen/Paracetamol	8 mg/dL	0.53 mmol/L
Ascorbic acid	5 mg/dL	0.28 mmol/L
Ibuprofen	12 mg/dL	0.53 mmol/L
Acetylsalicylic acid	1 mg/dL	56E-3 mmol/L
Glyburide (glibenclamide)	24E-3 mg/dL	490E-6 mmol/L
Metformin (1.1-dimenthylbiguanide 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 haemoglobins, including labile glycated haemoglobin when tested at two levels of A1C (low and high, approximately 31 and 97 mmol/mol (5% and 11%) respectively). The modified haemoglobins, and the levels evaluated, were: labile haemoglobin with 1400 mg/dL (78 mmol/L) glucose, carbamylated haemoglobin at a final concentration of 5 mmol/L potassium cyanate, and acetylated haemoglobin at a final concentration of 14 mmol/L acetylsalicylic acid.

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

Precision

Precision testing was done under a specialized protocol (% A1C, NGSP). Following this protocol, two whole blood samples, one of approximately 42 mmol/mol (6%) A1C (low), and one of approximately 75 mmol/mol (9%) A1C (high), were tested over 20 days and four runs per day, for a total of 80 assays per level. The overall imprecision (including within-day and between-day) was 3.00% CV (NGSP) at the low level and 4.02% CV (NGSP) at the high level.

Accuracy

Accuracy studies were conducted with 189 diabetic and non-diabetic subjects across three US sites. Fingerprick sampling was performed on each subject for testing with the A1CNow+ system, and venous blood was collected from each subject for comparative testing using an NGSP-certified method. A1CNow+ results were compared to the NGSP reference results. The A1C results ranged from 31 mmol/mol (5.0%) A1C to 116 mmol/mol (12.8%) A1C, with a mean of 56 mmol/mol (7.3%) A1C (reference results). Data analysis consisted of least squares linear regression (x = reference results), bias calculation, and Bland-Altman limits. The data are provided below.

A1CNow+ Fingerprick Comparative Testing

(NGSP-certified method is the Tosoh A1c 2.2 Plus)

n	189	Bias at 6% A1C (42 mmol/mol) (% difference-NGSP)	5.89 A1C (40.87 mmol/mol) (-1.83%)
Slope	1.02	Bias at 7% A1C (53 mmol/mol) (% difference-NGSP)	6.91 A1C (52.03 mmol/mol) (-1.29%)
y-intercept	-0.23	Bias at 9% A1C (75 mmol/mol) (% difference-NGSP)	8.95 A1C (74.32 mmol/mol) (-0.56%)
"r"	0.95	Avg. % diff.	-1.23%

The above results showed that the accuracy of the A1CNow+ system, with fingerprick samples was, on average, 99%. This means that, on average, a true 53 mmol/mol (7%) A1C would have read approximately 52 mmol/mol (6.9%) A1C. An individual A1CNow+ result may differ by as much as -11 to +9 mmol/mol (-1.0% to +0.8%) A1C from the true result. This represents the 95% confidence limits of a Bland-Altman plot.

A1CNow+ Venous Comparative Testing

(NGSP-certified method is the Tosoh A1c 2.2 Plus)

Venous blood was collected from 110 diabetic subjects, and each sample was tested on one of three different lots. Aliquots of the venous samples were also tested by the NGSP-certified method, providing comparative results. Data analysis again consisted of least squares linear regression (x = reference results), bias calculation and Bland-Altman limits. The data are provided below, see table.

n	110	Bias at 6% A1C (42 mmol/mol) (% difference-NGSP)	5.95 A1C (41.5 mmol/mol) (-0.8%)
Slope	1.03	Bias at 7% A1C (53 mmol/mol) (% difference-NGSP)	6.98 A1C (52.8 mmol/mol) (-0.3%)
y-intercept	-0.237	Bias at 8% A1C (64 mmol/mol) (% difference)	8.01 A1C (64.1 mmol/mol) (+0.1%)
"r"	0.97	Avg. % diff.	-0.3%

The results showed that the accuracy with venous sampling was, on average, 99.7%. An individual result may differ by -9 mmol/mol to +8 mmol/mol (-0.8% to +0.7%) A1C from the true result. This represents the 95% confidence limits of the Bland-Altman plot. The A1CNow+ system reports out accurately with either fingerprick (capillary) or venous (heparin-anticoagulated) whole blood samples.

Expected Performance When Used by Untrained Users

Clinical studies were performed at three US sites with over 180 untrained people (most with diabetes). These study subjects read the instructions and then performed one A1CNow+ test on themselves. A venous blood sample was collected from each subject, and this sample was tested by an NGSP-certified laboratory method for % A1C. The two results were then compared.

Untrained User on the A1CNow+ System and an NGSP-Certified Method

(Tosoh A1c 2.2 Plus)

n	188	Bias at 6% A1C (42 mmol/mol) (% difference-NGSP)	6.02 A1C (42.4 mmol/mol) (+0.33%)
Slope	0.99	Bias at 7% A1C (53 mmol/mol) (% difference-NGSP)	7.01 A1C (53.1 mmol/mol) (+0.14%)
y-intercept	0.08	Bias at 9% A1C (75 mmol/mol) (% difference-NGSP)	8.99 A1C (74.7 mmol/mol) (-0.11%)
"r"	0.93	Avg. % diff.	+0.12%

The above results showed that untrained users could perform A1CNow+ testing on themselves with the same accuracy as trained individuals.

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AVAILABILITY

REF/CAT NO.	DESCRIPTION
3037	A1CNow+ test system – 10 count
3038	A1CNow+ test system – 20 count

Product availability may vary per country. Please contact Customer Service or your local distributor for more infomation about availability in your region.

CUSTOMER SERVICE

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

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

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EXPLANATION OF SYMBOLS

- Use by
- LOT – Lot number
- IVD – *In vitro* diagnostic medical device
- REF – Catalog number
- Consult instructions for use
- CE – 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
- EC REP – 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

pts Diagnostics