

pts panels®

Glucose Test Strips

For professional use with CardioChek® brand analyzers

INTENDED USE

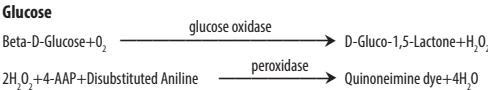
Glucose measurements are used in the diagnosis and treatment of carbohydrate metabolism disorders including diabetes mellitus, neonatal hypoglycemia, and idiopathic hypoglycemia, and of pancreatic islet cell carcinoma.

SUMMARY

Glucose is a sugar that is the major energy source in the body. Maintaining appropriate glucose levels is very important. This system may be used to measure glucose levels, and provide a quantitative result. A MEMo Chip® is provided with each package of test strips and must be properly inserted into the analyzer before any test can be run. The MEMo Chip contains the test name, calibration curve, lot number, and test strip expiration date. After the test strip is inserted into the analyzer and blood applied to the test strip, test results are displayed in about a minute. PTS Panels® test strips are designed for use with fresh capillary (fingerstick) whole blood or fresh venous whole blood collected in EDTA or heparin tubes.

PRINCIPLES OF THE TEST

Glucose test results are based on the analyzer reading light reflected off a test strip that has changed color after blood has been placed on it. The darker the color, the higher the glucose level. The analyzer converts this reading into a glucose result and displays the results.



MATERIALS PROVIDED

- PTS Panels® glucose test strips
- MEMo Chip (contains lot-specific test strip information)
- Instructions for use

MATERIALS NEEDED BUT NOT PROVIDED

- CardioChek PA or CardioChek Plus professional analyzer
- Quality control materials
- Lancets for fingerstick (or venous blood collection supplies)
- Alcohol wipes and gauze
- Capillary blood collector or other precision pipet for blood collection and application

CHEMICAL COMPOSITION

Each glucose test strip contains the following active ingredients:

Glucose oxidase (<i>Aspergillus niger</i>)	≥ 0.2 I.U.
Peroxidase (<i>Horseradish</i>)	≥ 0.2 I.U.
4-aminoantipyrine	≥ 10 µg
N,N-disubstituted aniline	≥ 20 µg

Test strips are contained in a desiccated vial to control moisture. Molecular sieve is integrated into the vial.

STORAGE AND HANDLING

- Store test strip package in a cool, dry place at room temperature 68-86°F (20-30°C) or refrigerated at 35-46°F (2-8°C). Test strips must be brought to room temperature 68-86°F (20-30°C) before using. Do not freeze.
- Keep away from heat and direct sunlight.
- Always replace vial cap immediately after removing a test strip.
- Use test strip as soon as you have removed it from the vial.
- Keep the MEMo Chip in the original box that held the test strips.
- Store the test strips in the original vial. Do not combine with other test strips and do not store the MEMo Chip in the test strip vial.
- After opening, the test strips are stable until expiration date if vial is properly stored and always capped.

WARNINGS AND PRECAUTIONS

- For *in vitro* diagnostic use.
- PTS Panels glucose test strips can only be used in the CardioChek professional analyzers.
- Make sure the MEMo Chip and test strip lot numbers match. Never use a MEMo Chip from a different lot than the test strip.
- Out-of-date or expired test strips cannot be used in your test system. Check vial for expiration date before use.
- Add all of the blood to the test strip at one time. If you do not get all of the blood on the test strip, do not add blood to the same test strip. Test again with a new, unused test strip and a fresh blood sample.
- Discard test strip after using. Test strips are to be read once. Never insert or read a used test strip.
- If you get an unexpected result, test again.
- Do not ingest.
- Users should adhere to Standard Precautions when handling or using this analyzer. All parts of the system should be considered potentially infectious and are capable of transmitting blood-borne pathogens between patients and healthcare professionals. For more information, refer to "Guideline for Isolation Precautions: Preventing Transmission of Infectious Agents in Healthcare Settings 2007", <http://www.cdc.gov/hicpac/2007ip/2007isolationprecautions.html>.
- The analyzer should be cleaned and disinfected after use on each patient. This test system may only be used for testing multiple patients when Standard Precautions and the manufacturer's disinfection procedures are followed.
- Please refer to the analyzer user guide for cleaning and disinfection instructions. This procedure is important to prevent the potential transmission of infectious diseases.
- Only auto-disabling, single-use lancing devices may be used with this analyzer.

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

SPECIMEN COLLECTION AND PREPARATION

PTS Panels test strips are designed for use with fresh capillary (fingerstick) whole blood or fresh venous whole blood collected in EDTA or heparin tubes. To obtain a drop of blood from a fingerstick, follow the steps below:

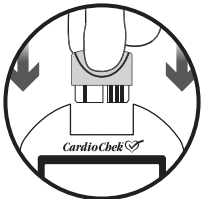
- **Use of lotions and handcreams should be avoided before testing.**
- Hands should be washed in warm water with antibacterial soap, rinsed and dried thoroughly.
- If you wipe the fingertip with alcohol, be sure that the alcohol dries completely before sticking the finger.
- Use a sterile, disposable lancet to puncture the side of the fingertip.
- Wipe away the first drop of blood with a clean piece of gauze.
- Gently, without force, apply pressure to the fingertip to accumulate a drop of blood.
- Excessive squeezing of the finger may alter test results.
- See the "TESTING" section for information on how to apply the blood to the test strip.
- Discard used materials properly.

Caution: Handle and dispose of all materials coming in contact with blood according to universal precautions and guidelines.

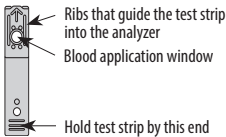
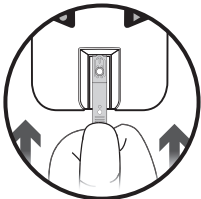
DIRECTIONS FOR USE - TESTING

IMPORTANT: Read all instructions carefully before testing.

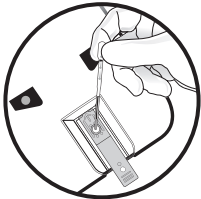
1. Insert the MEMo Chip that matches the lot number on the test strip vial and press one of the buttons to turn the analyzer ON.



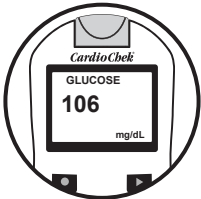
2. Hold the test strip by the end with the horizontal raised lines. Insert the opposite end of the test strip into analyzer. Push the test strip in as far as it will go.*



3. When APPLY SAMPLE appears on the display, use a capillary blood collector or pipet to apply 15 µL of whole blood to the test strip blood application window.

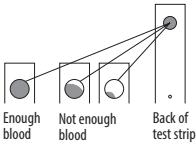


4. In about a minute, the result will appear on the display. Remove and discard test strip. Do not add more blood to a test strip that has been used.



* As an alternative, the test strip may be inserted into the analyzer within 10 seconds AFTER blood is applied to the test strip, when blood is applied to the test strip directly from a finger. Touch a drop of blood hanging from the finger to the blood application window of the test strip. The blood drop must fill the entire window. Insert the test strip into the analyzer. In about a minute, read result.

To verify that enough blood has been applied to the test strip, after testing is completed, remove test strip and check back of test strip. If areas are not completely and evenly colored, discard test strip and test again. See diagram.



TEST RESULTS

Results are displayed in either milligrams per deciliter (mg/dL) or in millimoles per liter (mmol/L). The analyzer is preset to mg/dL, which is the appropriate unit in the United States and many other countries. Other countries use mmol/L. Select the units that are correct for your country. For instructions on how to change the units, please see the analyzer user guide. No calculation of results is necessary.

QUALITY CONTROL

Quality control tests are used to ensure that the total system (analyzer, test strips, MEMo Chip) is working properly and that the test results are accurate and reliable within the limits of the system. Users should run controls when results are questionable or to comply with their own facility's quality control requirements. See instructions for use provided with the quality control materials for information on how to run controls. The CardioChek PA and CardioChek Plus professional analyzers are factory calibrated before they are packaged. Use the gray Check Strip supplied with the analyzer to verify that the analyzer's electronics and optics are working properly. The Check Strip is NOT a quality control test.

CAUTION: If your quality control test result falls outside the control range shown on the control range card, DO NOT use the system to test blood. The system may not be working properly. If you cannot correct the problem, contact Customer Service for help.

EXPECTED VALUES

Blood glucose levels will vary from time to time depending on food consumed, activity levels, health status, medication dosages, stress or exercise. Your physician or healthcare professional will discuss "target values" (that is, highs and lows) specifically appropriate for you. A glucose level below 50 mg/dL (2.78 mmol/L) or above 240 mg/dL (13.32 mmol/L) may indicate a serious medical condition. If your test result should fall below 50 mg/dL (2.78 mmol/L) or exceed 240 mg/dL (13.32 mmol/L), you should contact your physician or healthcare professional as soon as possible. The expected fasting blood glucose value in a person without diabetes is ≤99 mg/dL (5.5 mmol/L) and the expected 2-hour postprandial blood glucose is ≤139 mg/dL (7.7 mmol/L).⁶

MEASURING RANGE

This test system will detect glucose levels from 20-600 mg/dL (1.11-33.3 mmol/L) and will display a number value for results in this range. Results below this range will read, "LOW" or "<20 mg/dL (1.11 mmol/L)." Results above this range will read, "HIGH" or ">600 mg/dL (33.3 mmol/L)." The analyzer will display "CHECK KETONE LEVEL" for glucose test results greater than 240 mg/dL (13.32 mmol/L).

IMPORTANT: If you get one of these results, or an unexpected result for any test, test again with a new unused test strip.

LIMITATIONS OF THE PROCEDURE

- 1. The analyzer should not be used to test critically ill patients.
- 2. Blood samples from patients in shock, patients with severe dehydration, or patients in a hyperosmolar state (with or without ketosis) have not been tested. It is not recommended to test those samples with this system.
- 3. Not for use on patients who are severely hypotensive.
- 4. **PRESERVATIVES:** Blood samples preserved with Fluoride or Oxalate should not be used for testing with this system.
- 5. **NEONATAL USE AND ARTERIAL BLOOD:** This product has not been tested using neonatal or arterial blood. This test system should not be used with these blood samples.
- 6. **METABOLITES:** This test system is specific for glucose. Other sugars or reducing substances such as ascorbic acid at normal blood concentrations have no significant effect on test results. Acetaminophen (Tylenol) and dopamine may interfere causing the test result to be higher than the actual glucose. Not every drug was tested.
- 7. **HEMATOCRIT:** Hematocrit values above 55% or lower than 30% may incorrectly lower the glucose result.
- 8. **ALTITUDE:** Testing at altitudes up to 5280 feet has no effect on results.
- 9. **DEHYDRATION:** Severe dehydration and excessive water loss may produce falsely low results.

PERFORMANCE CHARACTERISTICS

- 1. **ACCURACY:** PTS Panels glucose test strip results are calibrated to provide plasma glucose values. The glucose test strips were calibrated to an automated glucose hexokinase laboratory method run on plasma samples. In a method comparison to a leading commercially available glucose system (a biosensor glucose dehydrogenase method) that is calibrated to provide "plasma-like" values⁵, the results below show that the PTS Panels glucose test strips compare well. This means that the PTS Panels glucose test strips should compare well to a laboratory plasma method:

PTS Panels Glucose Test Strips vs. Commercially Available Glucose System
Number of patients = 120
slope = 0.951
y-intercept = 5.36 r = 0.99

Previously, glucose test strips were calibrated to provide whole blood glucose values. In a patient-use clinical study performed in a diabetes clinic, glucose test strip patient-run test results from fresh capillary blood specimens were compared to the results from the same specimens run by a professional on a Yellow Springs Instruments (YSI) Glucose Analyzer:

PTS Panels Glucose Test Strips vs. YSI Glucose
Number of patients = 86
slope = 0.99
y-intercept = 4.63 r = 0.978

A professional patient study of 161 patients performed by healthcare professionals at three different sites gave the following results:

PTS Panels Glucose Test Strips vs. YSI Glucose
Number of patients = 161
slope = 0.983
y-intercept = .67 r = 0.97

- 2. **PRECISION:** Twenty replicates of various levels of whole blood were tested for glucose. The following results were obtained:

No. of Samples	20	20	20	20	20
Mean Glucose Conc. (mg/dL)	41	87	104	197	368
Std. Deviation (mg/dL)	2.75	4.66	5.90	5.24	13.69
Coefficient of Variation (%)	6.67	5.35	5.68	2.67	3.72

This means that the variation between test strips is not greater than 6.7%

- 3. **INTERFERENCES:** See LIMITATIONS section.

USA: RX ONLY

Caution: Federal law restricts this device to sale by or on the order of a licensed healthcare practitioner.

AVAILABILITY

REF/CAT NO.	DESCRIPTION
1708	CardioChek PA professional analyzer
2700	CardioChek Plus professional analyzer
1713	PTS Panels glucose test strips – 25 count
2863	PTS Collect™ capillary tubes, 15µL – 25 count
0721	PTS Panels multi-chemistry controls – level 1 & level 2

REFERENCES

- 1. Data on file, Polymer Technology Systems, Inc., Indianapolis, IN 46268.
- 2. Clinical Diagnosis and Management by Laboratory Methods, Eighteenth Edition, John Bernard Henry, Editor, W.B. Saunders Company, Philadelphia, 1991.
- 3. CLSI. Evaluation of the Linearity of Quantitative Measurement Procedures: A Statistical Approach: Approved Guideline. CLSI Document EP06-A, Wayne, PA: Clinical and Laboratory Standards Institute, 2003.
- 4. CLSI. Interference Testing in Clinical Chemistry: Approved Guideline-Second Edition. CLSI Document EP7-A2. Clinical and Laboratory Standards Institute, Wayne, PA, 2005.
- 5. Accu-Chek Comfort Curve instructions, Roche Diagnostics, 2000.
- 6. American Diabetes Association Standards of Medical Care in Diabetes – 2015. Diabetes Care 2015; 38 (Suppl. 1): S10
- 7. Clinical Chemistry, Third Edition, Norbert W. Tietz, Ph.D., Editor, W.B. Saunders Company, Philadelphia, 1987.
- 8. FDA Public Health Notification: Use of Fingerstick Devices on More than One Person Poses Risk for Transmitting Bloodborne Pathogens: Initial Communication" (2010) <http://www.fda.gov/MedicalDevices/Safety/AlertsandNotices/ucm224025.htm>.
- 9. CDC Clinical Reminder: Use of Fingerstick Devices on More than One Person Poses Risk for Transmitting Bloodborne Pathogens (2010) <http://www.cdc.gov/injectionsafety/Fingerstick-DevicesBGM.html>.

CUSTOMER SERVICE

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

1-877-870-5610 (Toll-free inside the USA)
+1-317- 870-5610 (Direct)
+1-317-870-5608 (Fax)
E-mail: customerservice@ptsdiagnostics.com

The PTS Panels test strips are manufactured in the United States by Polymer Technology Systems, Inc., Indianapolis, IN 46268 USA.

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EXPLANATION OF SYMBOLS

	Use by		Manufacturer
	Batch code		Temperature limitation
	<i>In vitro</i> diagnostic medical device		Keep away from sunlight
	Catalog number		Keep dry
	Consult instructions for use		Caution
	This product fulfills the requirements of European Directive 98/79/EC on <i>in vitro</i> diagnostic medical devices.		Contains sufficient for <n> tests
			Authorized representative in the European Community.