pts panels®

eGLU

Glucose Test Strips

For professional use with CardioChek® Plus analyzers

INTENDED USE

The CardioChek Plus glucose test system is intended for the quantitative determination of glucose in human whole blood for use by healthcare professionals. 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. 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 10 seconds if testing eGLU only, or as little as 90 seconds if, for example, run in conjunction with a Lipid Panel test strip. 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

PTS Panels eGLU glucose test strips use electrochemical (amperometric) technology to produce a glucose result. When the blood is applied to the test strip, the blood starts a chemical reaction that produces an electrical current. The current is converted into a glucose result and is displayed on the analyzer screen.

MATERIALS PROVIDED

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

MATERIALS NEEDED BUT NOT PROVIDED

- 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 PTS Panels eGLU glucose test strip contains the following active ingredients:
Glucose oxidase (Aspergillus niger) ..... > 0.2 I.U.
Potassium ferricyanide..... > 0.05 mg
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 eGLU glucose test strips can only be used in the CardioChek Plus 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.
- Do not use if vial/cap is open or damaged.
- Out-of-date or expired test strips cannot be used in your test system. Check vial for expiration date before use.
- 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 bloodborne 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.

SPECIMEN COLLECTION AND PREPARATION

PTS Panels eGLU glucose test strips are designed for use with fresh capillary (fingerstick) whole blood. Venous whole blood collected in EDTA or heparin tubes and tested within 20 minutes of the draw is also an acceptable sample. 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 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.
- 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 "DIRECTIONS FOR USE - TESTING" section for information on how to apply the blood to the test strip.
- Discard used materials properly.

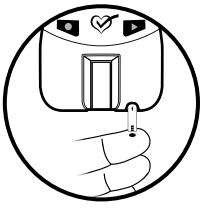
Caution: Handle and dispose of all materials coming in contact with blood according to universal precautions and guidelines.

DIRECTIONS FOR USE - TESTING

IMPORTANT: Read all instructions carefully before testing.

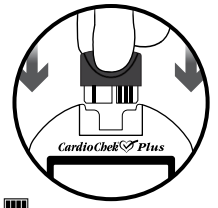
Testing with eGLU test strips only

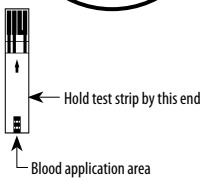
1. Insert the MEMo Chip that matches the lot number on the test strip vial and press one of the buttons to turn the analyzer ON.
2. Remove a single eGLU test strip from test strip vial and immediately replace cap.
3. Insert the eGLU test strip into the designated eGLU test port.
4. APPLY SAMPLE icon appears on the display.
5. Obtain a drop of blood using a lancet per the "SPECIMEN COLLECTION AND PREPARATION" section.
6. Gently touch finger to the tip of the glucose test strip to apply a 1.1 µL drop of blood. Do not press the glucose test strip into the finger.
7. TESTING will appear. The glucose result will be displayed within 10 seconds of the blood sample being applied to the test strip.



Testing with both eGLU and lipid panel test strips

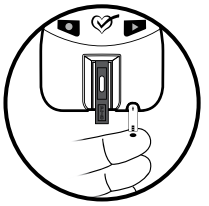
1. Insert the MEMo Chip that matches the lot number on both the eGLU and the lipid panel test strip vials and press one of the buttons to turn the analyzer ON.
2. Remove one eGLU test strip from test strip vial and immediately replace cap.
3. Insert the eGLU test strip into the designated eGLU test port.
4. Remove one lipid panel test strip from test strip vial and immediately replace cap.
5. Insert the lipid panel test strip into the designated reflectance test strip port.
6. Lipid panel icon and eGLU icon will display together.





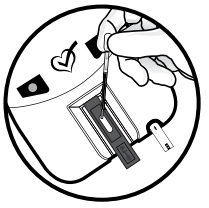
eGLU testing

7. Obtain a drop of blood using a lancet per the "SPECIMEN COLLECTION AND PREPARATION" section.
8. Gently touch finger to the tip of the glucose test strip to apply a 1.1 µL drop of blood. Do not place blood on top of the test strip. Do not press the glucose test strip into the finger.
9. Blood will be drawn into the test strip automatically by capillary action.
10. Test result will display upon completion of lipid panel test results.



Lipid panel testing

11. After applying blood to the eGLU test strip, wipe the finger to remove any blood with a clean piece of gauze.
12. Gently, without force, apply pressure to the fingertip to accumulate a drop of blood. Excessive squeezing of the finger may alter test results.
13. Use a capillary blood collector or pipet to apply 40 µL of whole blood to the test strip blood application window.
14. In as little as 90 seconds, the results will appear on the display. Remove and discard test strips. Do not add more blood to any test strip that has been used.



Note: eGLU can be tested alone or with another reflectance-type test strip such as the lipid panel that has the same lot number.

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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).[5]

MEASURING RANGE

The test system will detect glucose levels from 40-600 mg/dL (2.22-33.3 mmol/L) and will display a number value for results in this range.

Results below this range will read, "LOW" or "<40 mg/dL (2.22 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. **PRESERVATIVES:** Blood samples preserved with Fluoride or Oxalate should not be used for testing with this system.
4. **VENOUS SAMPLES:** To minimize glycolysis, venous whole blood samples must be tested within 20 minutes of the draw. Grossly lipemic samples may interfere with some methodologies. Critically ill patients should not be tested by this method, or should be tested with extreme caution.
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 whole blood samples.
6. **METABOLITES:** This test system is specific for glucose. Other sugars and other 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:** No hematocrit effect was observed for samples between 30 and 55% HCT.
8. **ALTITUDE:** Testing at altitudes up to 10,000 feet has no effect on results.
9. **DEHYDRATION:** Severe dehydration and excessive water loss may produce falsely low results.

PERFORMANCE CHARACTERISTICS

1. **ACCURACY:** A patient-use clinical study was performed at five sites. Glucose levels were measured on fresh capillary blood specimens by 237 persons and by healthcare professionals. A professional ran a glucose on the same 237 persons with a CardioChek Plus professional analyzer to compare results.
   The results follow:

   CardioChek Plus Professional Analyzer
   vs. BioScanner Beyond Glucose Analyzer
   Obtained by 237 persons who tested themselves:
   number of persons = 237 slope = 1.048
   y-intercept = 1.5 r = 0.9722

   The same 237 persons were tested by a healthcare professional with the following results.

   CardioChek Plus Professional Analyzer
   vs. BioScanner Beyond Glucose Analyzer
   Obtained by Healthcare Professionals
   number of persons = 237 slope = 0.997
   y-intercept = -0.03 r = 0.9858

   This shows that the CardioChek Plus Glucose results run by both professionals and consumers compare well to the BioScanner Beyond Glucose results.
2. **PRECISION:** A laboratory professional tested twenty replicates of various levels of whole blood for glucose on the CardioChek Plus analyzer using eGLU glucose test strips. The following results were obtained:

No. samples	20	20	20	20	20
Mean Glucose Conc. (mg/dL)	37	81	149	190	334
Std. Deviation (mg/dL)	3.40	6.59	9.36	12.89	14.24
Coefficient of Variation (%)	9.10	8.15	6.28	6.77	4.26

   This means that the variation between test strips is not greater than 9%
3. **INTERFERENCE:** 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
2700	CardioChek Plus professional analyzer
2713	PTS Panels eGLU glucose test strips – 50 count
2729	PTS Panels Lipid+eGLU smart bundle test strips – 2 pack
2866	PTS Collect™ capillary tubes, 40µL – 16 count
0721	PTS Panels multi-chemistry controls – Level 1 & Level 2
0722	PTS Panels HDL cholesterol controls – Level 1 & Level 2

REFERENCES

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5. American Diabetes Association Standards of Medical Care in Diabetes - 2015. Diabetes Care 2015; 38 (Suppl. 1): S10
6. Clinical Chemistry, Third Edition, Norbert W. Tietz, Ph.D., Editor, W.B. Saunders Company Philadelphia, 1987.
7. 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.
8. 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 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.

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

PTS Panels test strips are manufactured in the United States by Polymer Technology Systems, Inc., Whitestown, IN 46075 USA.

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CE

EXPLANATION OF SYMBOLS

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