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PTS Panels® eGLU™ Test Strips

for use with CardioChek® Plus Analyzers

INTENDED USE

The PTS Panels eGLU test strips are intended to be used to quantitatively measure glucose in whole blood. Glucose measurements are used in the diagnosis and treatment of carbohydrate metabolism disorders. The PTS Panels eGLU test strips are for *in vitro* diagnostic use. The PTS Panels eGLU test strips are currently marketed for professional use.

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 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 about 2 minutes if, for example, run in conjunction with a PTS Panels Lipid Panel test strip.

PRINCIPLES OF THE TEST

The eGLU 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 test strips
- MEMo Chip (contains lot-specific test strip information)
- Instructions

MATERIALS NEEDED BUT NOT PROVIDED

- CardioChek Plus analyzer
- Quality Control Materials
- Lancets for fingerstick (or venous blood collection supplies)
- Alcohol wipes and/or gauze

CHEMICAL COMPOSITION

Each Glucose test strip contains the following active ingredients:
Glucose oxidase (Aspergillus niger) . . . . . > 0.2 I.U.
Potassium ferricyanide . . . . . > 0.05 mg
Each vial contains not more than 5g silica gel desiccant.

STORAGE AND HANDLING

- Store test strip package in a cool, dry place at room temperature of 68-86°F (20-30°C). Test strips may be stored in a refrigerator at 35-46°F (2-8°C), but must be brought to room temperature before using. Do not freeze.
- Keep away from heat and direct sunlight.
- Do not remove or discard the desiccant packet in the vial.
- 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 either in the analyzer or stored with the original lot of 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.

PRECAUTIONS

- For *in vitro* diagnostic use.
- 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.
- Add all of the blood to the test strip at once. 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 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.**

SPECIMEN COLLECTION AND PREPARATION

PTS Panels 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 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. (Reflectance-type testing only, such as Lipid Panel.)
- 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.

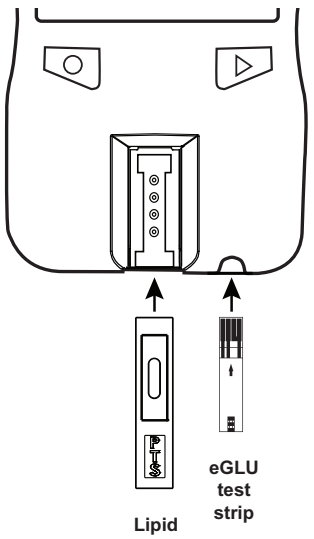
Caution: Handle and dispose of all materials coming in contact with blood according to universal precautions and guidelines.

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 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 about 2 minutes, 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 Lipid Panel.

ADDITIONAL CONSIDERATIONS

1. If no result is displayed, make sure:
   – Analyzer is ON. (If it won't turn ON, refer to analyzer User Guide section on changing batteries.)
   – MEMo Chip is properly installed in port.
   – Enough blood was added to the test strip to completely fill the blood application window.
2. If you get a reading of "<___", or ">___" or any unexpected result, test again.
3. See analyzer User Guide Troubleshooting section for additional help.
4. To verify enough blood has been applied to the test strip, remove test strip after testing and check back side of reaction area. Reaction area should be completely and evenly colored. If the area is not completely and evenly colored, discard the used test strip and test again. (Reflectance-type testing only, such as Lipid Panel.)

TEST RESULTS

Results are displayed in either milligrams per deciliter (mg/dL), millimoles per liter (mmol/L), or grams per liter (g/L). To change analyzer units, please see the analyzer User Guide.

PTS®

Manufactured by
Polymer Technology Systems, Inc.
7736 Zionsville Road
Indianapolis, IN 46268 USA
+1-877-870-5610 (Toll-free inside USA)
+1-317-870-5610 (Direct)
+1-317-870-5608 (Fax)
www.cardiochek.com

QUALITY CONTROL
Please refer to the analyzer User Guide for the proper procedure and materials to be used to perform Quality Control tests. Quality Control tests are used to ensure that the system (analyzer, test strips and MEMo Chip) is working properly. Users should run controls when results are questionable or to comply with their own facility's quality control requirements.

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. Expected values for a fasting person, who does not have diabetes, are: 70-105 mg/dL (3.9-5.8 mmol/L).[5]

MEASURING RANGE
The glucose 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. If the display reads "<___" (less than measuring range), the glucose level is below 40 mg/dL (2.22 mmol/L). Results above 600 mg/dL (33.3 mmol/L) will read ">___" (greater than measuring range). The analyzer will display "CHECK KETONE" for glucose test results greater than 240 mg/dL (13.32 mmol/L).
IMPORTANT: If a "<" or ">" or any unexpected result is displayed, always test again with a new, unused test strip.

LIMITATIONS OF THE PROCEDURE
1. PRESERVATIVES: Blood samples preserved with Fluoride or Oxalate should not be used for testing with this system.
2. 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 tested with extreme caution.
3. NEONATAL USE and ARTERIAL BLOOD: This product has not been tested using neonatal or arterial blood. Until testing is done, this test system should not be used with these whole blood samples.
   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.
4. METABOLITES: This test system is specific for glucose. Other sugars and other reducing substances such as absorbic acid at normal blood concentrations have no significant effect on test results.
5. HEMATOCRIT: Hematocrit values above 55% or lower than 30% may incorrectly lower the glucose result.
6. ALTITUDE: Testing at altitudes up to 5280 feet has no effect on results.
7. 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 Bioscanner Beyond analyzer to compare results. The results follow:

   CardioChek Plus 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 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 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
Coeff. 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. INTERFERENCES: See LIMITATIONS section.

AVAILABILITY

REF/CAT NO.	DESCRIPTION
2713	PTS Panels eGLU test strips – 50 tests
0721	PTS Panels Multi-Chemistry controls – Level 1 & Level 2
2700	CardioChek Plus analyzer
1710	PTS Panels Lipid Panel test strips – 15 tests

CLIA INFORMATION (US only)
Complexity Categorization: Waived

REFERENCES

1. Data on file, Polymer Technology Systems, Inc., Indianapolis, IN 46268.
2. Clinical Diagnosis and Management by Laboratory Methods, Eighteenth Edition, John Berna Henry, Editor,. W.B. Saunders Company, Philadelphia, 1991.
3. CLSI Guideline EP6, Evaluation of the Linearity of Quantitative Analytical Methods. Villano National Committee for Clinical Laboratory Standards, 1986.
4. CLSI Guideline EP7. Interference Testing in Clinical Chemistry. Villanova, PA: National Co for Clinical Laboratory Standards, 1986.
5. Clinical Chemistry, Third Edition, Norbert W. Tietz, Ph.D., Editor, W.B. Saunders Company Philadelphia, 1987.

CUSTOMER SERVICE
PTS, Inc. Customer Service is available to answer questions regarding the CardioChek brand analyzers and PTS Panels test strips. Outside Customer Service hours, please contact your healthcare professional.

+1 (877) 870-5610 (8 a.m. – 7 p.m. EST, M-F toll-free inside the USA)
+1 (317) 870-5610 (Direct)
+1 (317) 870-5608 (Fax)
E-mail: inforequest@cardiochek.com

The CardioChek brand analyzers and PTS Panels test strips are manufactured in the U.S. by Polymer Technology Systems, Inc., Indianapolis, IN 46268 USA.

CE

EC REP Authorized European Representative
MDSS GmbH
Schiffgraben 41
30175 Hannover, Germany

Explanation of Symbols

	Use By	REF	Catalog number
			Consult instructions for use
LOT	Batch Code		Manufacturer
IVD	In vitro diagnostic medical device		Temperature limitation
CE	This product fulfills the requirements of the European Directive 98/79 EC for in vitro diagnostic medical devices.	EC REP	Authorized representative in the European Community