

PTS PANELS™ Ketone Test Strips

for use with CardioChek™ Brand Analyzers

INTENDED USE

PTS PANELS Ketone Test Strips provide a quantitative measurement of ketones (β -hydroxybutyrate) in whole blood. This testing system is intended for in-home (self-testing) or professional use.

SUMMARY

Ketones are the end products of fatty acid metabolism. Ketones in the blood indicate ketosis or diabetic keto-acidosis (DKA). Acidosis is a condition characterized by abnormally high acidity of bodily fluids. Diabetics and those on ketogenic diets are most susceptible to ketosis. Consult a healthcare professional if you have elevated ketone levels and for advice on when to use this test. 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 strip, test results are displayed in about a minute.

PRINCIPLES OF THE TEST

Ketone test results are based on a reading of light reflected off a test strip that has changed color after blood is applied. The deeper the color is, the higher the ketone level. The analyzer converts this reading into a ketone result and displays it. Ketone is measured as β -hydroxybutyrate.

MATERIALS PROVIDED

- PTS PANELS Ketone Test Strips
- MEMo Chip (contains lot-specific test strip information)
- Instructions.

MATERIALS NEEDED BUT NOT PROVIDED

- CardioChek brand analyzer
- Quality Control Materials
- Lancets for fingerstick (or venous blood collection supplies)
- Alcohol wipes and/or gauze
- Capillary Blood Collector or other precision pipet for blood collection and application

CHEMICAL COMPOSITION

Each Ketone Test Strip contains the following active ingredients:

NAD (yeast)	≥ 0.03 mg
Tetrazolium salt	≥ 0.015 mg
Diaphorase (Bacillus stearothermophilus)	≥ 1 I.U.
β -hydroxybutyrate dehydrogenase (pseudomonas sp.)	≥ 0.5 I.U.

Each vial contains not more than 5 g 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). 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 strips.
- Store the test strips in the original vial. Do not combine with other 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. Intended for self-testing.
- PTS PANELS Test Strips can only be used in the CardioChek brand analyzer.
- 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 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 strip, do not add blood to the same strip. Test again with a new unused test strip and fresh blood sample.
- Discard test strip after using. Strips are to be read once. Never insert or read a used test strip.
- **Do not ingest.**

SPECIMEN COLLECTION AND PREPARATION

PTS PANELS Test Strips are designed for use with fresh capillary (fingerstick) whole blood. Fresh venous whole blood, plasma from a heparin or an EDTA tube, or serum may be used as a sample for ketone testing. If test is not run immediately after blood is drawn, refrigerate sample until ready to test. Test within four hours. Gently invert whole blood tube to mix and pipet 15 μ L of whole blood (or 10 μ L of serum or plasma) onto test strip.

To obtain a drop of blood from a fingerstick, follow the steps listed below:

- Use of lotions and handcreams should be avoided before testing.
- Hands should be washed in warm water with antibacterial soap and 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.

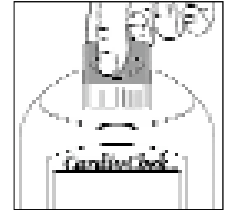
- Wipe away the first drop of blood with a clean piece of gauze.
- Gently, without force, apply pressure to the fingertip to accumulate a drop of blood.
- Excessive squeezing of the finger may alter test results.
- See the "TESTING" section for information on how to apply the blood to the test strip.
- Discard used materials properly.

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

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.

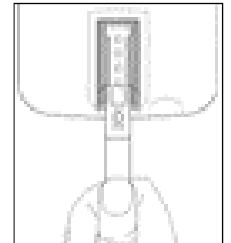


- 2.* Hold the test strip by the end with the horizontal raised lines. Insert the opposite end of the strip into analyzer. Push the strip in as far as it will go.

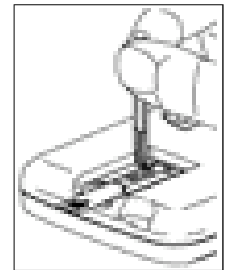
Ribs that guide the strip into the analyzer

Blood application window

Hold strip by this end.



3. When APPLY SAMPLE appears on the display, use a capillary blood collector or pipet to apply 15 μ L of whole blood (or 10 μ L serum or plasma) to the test strip blood application window.



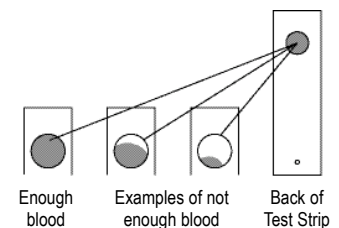
4. In about a minute, the result will appear on the display. Remove and discard strip. DO NOT add more blood to a test strip that has been used.



* As an alternative, the test strip may be inserted into the analyzer within 10 seconds AFTER blood is applied to the strip, when blood is applied to the 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 strip into the analyzer. In about a minute, read result.

ADDITIONAL CONSIDERATIONS

1. If no result is displayed, make sure:
 - Enough blood was added to the test strip to completely fill the blood application window.
 - 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.
2. If you get a reading of "LOW", "< ___", "HIGH", "> ___" 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 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.



TEST RESULTS

Results are displayed in either milligrams per deciliter (mg/dL) or in millimoles per liter (mmol/L). The mg/dL measurement is a US version, while mmol/L is used in many countries around the world. The analyzer is preset to US units by the manufacturer. No calculation of results is necessary. To change to INTL (mmol/L) units, please see the analyzer User Guide.

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, 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 ketone levels will vary from time to time depending on food consumed, activity levels, health status, medication dosages, stress or exercise. Serum reference ranges for Ketone bodies are 0.5-3.0 mg/dL (0.05-0.29 mmol/L).⁵ Whole Blood ketone levels (β -hydroxybutyrate) in fasting healthy individuals are reported from 0.21-2.81 mg/dL (0.02-0.27 mmol/L).^{6,7} ALWAYS CONSULT A HEALTHCARE PROFESSIONAL BEFORE MAKING ANY CHANGES IN TREATMENT PLANS OR MEDICATION.

MEASURING RANGE

The Ketone test system will detect ketones from 2-70 mg/dL (0.19-6.72 mmol/L) and will display a numeric value for results in this range. If the display reads "LOW" or "<____" (less than measuring range), the Ketone level is below 2 mg/dL (0.19 mmol/L). Results above 70 mg/dL (6.72 mmol/L) will read "HIGH" or ">____" (greater than measuring range). If a "LOW", "HIGH", "<" or ">" result is displayed, always test again.

LIMITATIONS OF THE PROCEDURE

1. PRESERVATIVES: EDTA and Heparin do not interfere with the test. Fingertick whole blood is the specimen of choice.
2. NEONATAL USE: This product has not been tested using neonatal blood. Until testing is done this test system should not be used on neonatal blood samples.
3. METABOLITES: Ascorbic acid (Vitamin C) may interfere with this test to produce increased results.
4. HEMATOCRIT: Hematocrit values between 32% and 52% have no effect on ketone results.

PERFORMANCE CHARACTERISTICS

1. ACCURACY: A clinical study was performed using serum, plasma and whole blood samples from 74 patients. Ketone Test Strips results were compared to a commercially available β -hydroxybutyrate reference method:

PTS PANELS Ketone vs. Reference Method

Combined whole blood, plasma, and serum samples vs. Reference method:

Number of samples = 102

Sample Range: <2 mg/dL to 70 mg/dL

Slope = 1.06

y-intercept = 0.8

r = 0.99

Serum and plasma samples vs. Reference method:

Number of samples = 63

Sample range: <2 mg/dL to 70 mg/dL

Slope = 1.05

y-intercept = 1.5

r = 0.99

Whole blood samples vs. Reference method:

Number of samples = 73

Sample range: 2.4 mg/dL to 37 mg/dL

Slope = 1.02

y-intercept = -0.5

r = 0.99

2. PRECISION: Twenty whole blood samples were tested for ketones.

The following are the results:

Within-run Precision:

No. of Samples	20	20	20	20
Mean Ketone Conc. (mg/dL)	3.3	11.9	21.7	37.7
Std. Deviation (mg/dL)	0.14	0.32	0.78	0.44
Coefficient of Variation (%)	4.24	2.69	3.59	1.17

Controls were tested over ten days with the following results:

Day-to-day Precision:

No. of Samples	10	10	10	10
Mean Ketone Conc. (mg/dL)	8.1	16.3	25.6	55.3
Std. Deviation (mg/dL)	0.51	0.50	1.01	2.37
Coefficient of Variation (%)	6.30	3.07	3.95	4.29

3. INTERFERENCES: See LIMITATIONS section.

AVAILABILITY

REF/CAT NO.	DESCRIPTION
1718	PTS PANELS Ketone Test Strips – 25 Tests
1719	PTS PANELS Ketone Test Strips – 6 Tests
1709	CardioChek Analyzer
1708	CardioChek P•A Analyzer
0721	PTS PANELS Multi-Chemistry Controls – Level 1 & Level 2

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 Bernard Henry, Editor, W.B. Saunders Company, Philadelphia, 1991.
3. NCCLS Proposed Guideline EP6-P, Evaluation of the Linearity of Quantitative Analytical Methods. Villanova, PA: National Committee for Clinical Laboratory Standards, 1986.
4. NCCLS Tentative Guideline EP7-T, Interference Testing in Clinical Chemistry. Villanova, PA: National Committee for Clinical Laboratory Standards, 1986.
5. Textbook of Clinical Chemistry, Norbert W. Tietz, W. B. Saunders Co., Philadelphia, PA, 1986.
6. Koch, D.D. and Feldbruegge, D.H., Clin. Chem 33:1761 (1987).
7. Li, P.K, et al., Clin. Chem., 26:1713 (1980).

CUSTOMER SERVICE

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.











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CE 0197



Explanation of Symbols

	Use By/Expiration date		Catalog number
	Batch Code/Lot number		Consult instructions for use
	For in vitro diagnostic use		Manufacturer
	This product fulfills the requirements of Directive 98/79/EC on in vitro diagnostic medical devices.		Store at/Temperature limitation