

SPOTCHEM™II CPK [CPK]

Intended Use

SPOTCHEM II CPK Reagent Strip is an *in vitro* diagnostic reagent intended for the quantitative determination of CPK (Creatine phosphokinase) activity in serum or plasma. This product is intended for professional use with the SPOTCHEM Analyzer.

Composition

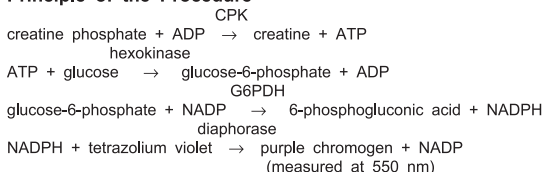
Reactive Ingredients per 100 Reagent Strips	
Creatine phosphate	36.0 mg
Adenosine-5'-diphosphate, potassium (ADP)	9.0 mg
Hexokinase	231 unit
Glucose-6-phosphate-dehydrogenase(G6PDH)	171 unit
Glucose	2.7 mg
Nicotinamide adenine dinucleotide phosphate(NADP)	14.0 mg
Tetrazolium violet	5.0 mg
Diaphorase	155 unit

Summary

SPOTCHEM II CPK Reagent Strip provides a simple, specific and reliable method for the determination of CPK activity in blood. These features make it useful for a wide range of clinical applications from routine diagnosis to bedside or emergency testing.

The reagent strip is composed of a multi-layered test field containing reagents necessary to generate a color that is quantitated by reflectance spectrophotometry. These measurements are made by the SPOTCHEM Analyzer.

Principle of the Procedure



Warnings and Precautions

- For *in vitro* diagnostic use only.
- Exercise the normal precautions required for handling blood samples, containers, used reagent strips and pipette tips. Follow local regulations for disposal of biohazardous waste.

Storage and Stability

- Store the reagent strip in a refrigerator at temperatures between 2°-8°C (35.6°-46.4°F).
- Use the reagent strip prior to its expiration.
- Once the aluminum foil package containing the reagent strip has been opened, the reagent strip must be used immediately.

Interfering Substances

- Substance which brings the bias higher
 - Hemolysis
- Substance which brings the bias lower
 - Ascorbic acid
- Others
 - The activity of CPK tends to gradually decrease.

Materials Provided

50 Aluminum Foil Packages 50 reagent strips
 One Reagent Card (For use with the SP-4420 and SP-4430 only)


General Instructions

See the Operating Manual of the respective SPOTCHEM Analyzer for the use of the analyzer, reagent strips, calibration procedures and calibration frequency.

Procedural Limitations

The measurement range for SPOTCHEM II CPK Reagent Strip is 50-2000 IU/L (0.83-33.34 μ kat/L).

Calibration

 Handle calibrators as biohazardous material.

1. For use with the SP-4410:

Use the SPOTCHEM Calibrator Kit (Low, High) for calibration. For detailed instructions, see the Operating Manual of the SP-4410.

2. For use with the SP-4420 and SP-4430:

There are two methods of calibration:

- Calibration by Reagent Card
 By inserting Reagent Card provided in the reagent strip box to the SP-4420 or SP-4430, calibration is completed.
 This is to calibrate reagent's lot-to-lot difference.
- Calibration by SPOTCHEM Calibrator Kit
 Calibration can also be made using a SPOTCHEM Calibrator Kit. Calibration is recommended for occasions such as every 6 months after periodic maintenance or when service staff considers necessary.
 This will keep the SPOTCHEM Analyzer at a constant state.

Performance Characteristics

1. Accuracy

Fifteen consecutive replicate measurements were made on the SPOTCHEM Analyzer using SPOTCHEM II CPK Reagent Strip from pools of serum with known concentrations. The following results were obtained:

	Level I		Level II	
	IU/L	μ kat/L	IU/L	μ kat/L
Known Concentration	98	1.63	1171	19.52
Mean Value	94.7	1.579	1255.6	20.932

2. Precision

Fifteen consecutive replicate measurements were made on the SPOTCHEM Analyzer using SPOTCHEM II CPK Reagent Strip from pools of serum. The following results were obtained:

	Level I		Level II	
	IU/L	μ kat/L	IU/L	μ kat/L
S.D.(Standard Deviation)	3.59	0.0599	29.17	0.4862
C.V.(Coefficient of Variation, %)	3.8	3.8	2.3	2.3

3. Correlation to Another Method

Fifty samples with varying concentrations of CPK were measured using the SPOTCHEM Analyzer and SPOTCHEM II CPK Reagent Strip(Y), and simultaneously measured using the JSCC transferable method(X) (JSCC : the Japan Society of Clinical Chemistry). The following correlation equation was calculated from the results along with a correlation coefficient:

$$Y = 0.960X + 13.9 \text{ and } r = 0.991$$

4. Reference Values (human being)

	IU/L	μ kat/L
Reference Values (37°C)	56 - 244	0.93 - 4.07

Note : Each laboratory should establish reference ranges for its own patient population.

General Precautions

- Samples containing sodium fluoride, mono-iodoacetic acid or EDTA may cause false negative results on the test items of measuring enzymes.
- Samples containing sodium fluoride or ammonium fluoride as a preservative should not be used on the SPOTCHEM Analyzer for measurement of Blood Urea Nitrogen [BUN], Total Bilirubin [T-Bil], Albumin [Alb] or Inorganic Phosphorus [IP] as these strips contain an acidic buffer. The resulting generation of hydrogen fluoride or iodide can cause severe damage to the SPOTCHEM Analyzer.

Precautions for Use

1. Blood Samples

 Handle samples as biohazardous material.

- Use only serum or plasma (when using whole blood, centrifuge the samples before measurement).
- Allow samples that have been refrigerated to return to room temperature before measurement.
- Samples should be stored in sealed containers to prevent evaporation.
- Heparin is the preferred anticoagulant if plasma is to be collected.
- When serum is to be used in the measurement, it is important to be sure that the blood has sufficiently clotted so that fibrin strands are not present during the measurement. Fibrin strands in the serum may obstruct the sampling port and affect the results. If fibrin strands are observed, recentrifuge the serum sample and carefully decant the serum into a clean sample tube.
- Occasionally, air bubbles may adhere to the walls of the sample tube. Aspiration of an air bubble may affect measurement results. If air bubbles are observed, tap the sample tube to dislodge the bubble from the sample.








2. SPOTCHEM II CPK Reagent Strip

- Whenever you open a new box of reagent strips, insert Reagent Card into the SP-4420 and SP-4430. However, when you use reagent strips of the same lot number, you may not need to do this preparation.
Note: Reagent Card is for use with the SP-4420 and SP-4430 only.
- Do not reuse a reagent strip. These strips are designed to be used on a single sample and then discarded.
- Store in a refrigerator at 2°-8°C (35.6°-46.4°F). Improper storage may affect the performance of the strip. Allow sufficient time for the refrigerated strips to reach ambient temperature before opening the aluminum foil package. Opening strips that have not equilibrated to ambient temperature may cause moisture to condense on the strips and possibly affect the performance characteristics of the reagent strip.
- Do not touch the reagent field of the reagent strip with your fingers.
- Exercise care in not exerting a strong tearing force on the reagent field such as when opening the aluminum foil package. Do not fold or bend when removing the reagent strip from its package.
- Volatile chemicals should not be allowed to contaminate the laboratory in which the test is being performed.
- While the reagent strip may be used until it reaches its expiration date, do not use a strip if the reagent field shows signs of discoloration, deformation or other signs of deterioration.
- In order to avoid interference from carbon dioxide, make sure there is adequate ventilation in those areas where carbon dioxide may be produced.

Expiration

The expiration date is listed on each aluminum foil package and reagent strip box.

Glossary of Symbols

	Storage temperature limitation
	In Vitro Diagnostic Medical Device
	Biohazard
	Batch code
	Use by
	This product conforms to the Directive 98/79/EC.
	Consult Instructions for Use

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