

SPOTCHEM™II Hemoglobin [Hb]

Intended Use

SPOTCHEM II Hemoglobin Reagent Strip is an *in vitro* diagnostic reagent intended for the quantitative determination of hemoglobin in whole blood. This product is intended for professional use with the SPOTCHEM Analyzer.

Composition

Reactive Ingredients per 100 Reagent Strips

Sodium lauryl sulfate 15.8 mg

Summary

SPOTCHEM II Hemoglobin Reagent Strip provides a simple, specific and reliable method for the determination of hemoglobin 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

hemoglobin + sodium lauryl sulfate → brown chromogen (measured at 550 nm)

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.

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 Hemoglobin Reagent Strip is 3-25 g/dL (30-250 g/L).

Calibration

 Handle calibrators as biohazardous material.

1. For use with the SP-4410:

Use the SPOTCHEM Calibrator Hb Kit 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 Hb Kit

Calibration can also be made using a SPOTCHEM Calibrator Hb 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 Hemoglobin Reagent Strip from whole blood with known concentrations. The following results were obtained:

	Level I		Level II	
	g/dL	g/L	g/dL	g/L
Known Concentration	16.3	163	18.7	187
Mean Value	15.95	159.5	19.16	191.6

2. Precision

Fifteen consecutive replicate measurements were made on the SPOTCHEM Analyzer using SPOTCHEM II Hemoglobin Reagent Strip from whole blood. The following results were obtained:

	Level I		Level II	
	g/dL	g/L	g/dL	g/L
S.D.(Standard Deviation)	0.383	3.83	0.450	4.50
C.V.(Coefficient of Variation, %)	2.4	2.4	2.3	2.3

3. Correlation to Another Method

Fifty samples with varying concentrations of hemoglobin were measured using SPOTCHEM SP-4410 and SPOTCHEM II Hemoglobin Reagent(Y), and simultaneously measured using the cyanomethemoglobin method(X). The following correlation equation was calculated from the results along with a correlation coefficient:

$$Y = 0.948X + 0.66 \text{ and } r = 0.987$$

4. Reference Values (human being)

	g/dL	g/L
Reference Values (Male)	14 - 18	140 - 180
Reference Values (Female)	12 - 16	120 - 160

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 whole blood that is well inverted and diluted six times by distilled water.
- 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. Add the anticoagulant to the sample immediately after collection of blood and stir well.
- 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.
- 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 Hemoglobin 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

MANUFACTURER

ARKRAY Factory, Inc.

1480 KOJI, KONAN-CHO, KOKA-SHI,
SHIGA, JAPAN

EUROPEAN REPRESENTATIVE

ARKRAY Europe, B.V.

PROF. J.H. BAVINCKLAAN 5 1183 AT
AMSTELVEEN, THE NETHERLANDS

