



For the quantitative determination of hemoglobin in capillary, venous or arterial whole blood.

### CLIA Complexity: Waived

### Intended Use

The Alere **HemoPoint® H2** Microcuvettes are intended to be used in the Alere **HemoPoint® H2** Meter. The reagents/microcuvettes and the Alere **HemoPoint® H2** Meter form an analytical system.

### Summary and Principle

The Alere **HemoPoint® H2** System is intended to be used for the quantitative determination of hemoglobin (Hgb) concentration in human blood. It consists of a meter instrument and individual single-use microcuvettes filled with reagents. Using the Alere **HemoPoint® H2** Microcuvette, a small amount of capillary, venous or arterial blood is taken up by capillary action. The Alere **HemoPoint® H2** Microcuvettes are intended to be used once only and must be disposed of after use as potentially infectious waste, in accordance with the current regulations applicable to your establishment. The Alere **HemoPoint® H2** System is designed for use in medical practices and in clinical laboratories to assist in medical diagnostics. In addition it can be used in emergency and intensive care units and in medical facilities such as blood donor sessions and blood banks. Blood sampling and operating the Alere **HemoPoint® H2** System should be carried out by trained personnel with sound knowledge of the system.

The recognized reference method for total hemoglobin is the cyanmethemoglobin method, which is also known as the cyanhemoglobin method.<sup>1</sup> The blood sample is diluted 1:251 with a reagent buffering solution. Here the erythrocytes are hemolyzed and the bivalent iron in oxyhemoglobin and desoxyhemoglobin are oxidized by the reagent potassium hexacyanoferrate (III) to trivalent iron and so converted to methemoglobin. Together with cyanide ions, which are also contained in the reagents, the methemoglobin forms a stable, colored complex, namely cyanmethemoglobin. This has a wide absorption maximum at 540 nm. This absorption is proportional to the Hgb concentration. In 1966, Vanzetti suggested to replace KCN by NaN<sub>3</sub> and thus he was able to reduce the toxicity of the reagent mixture considerably.<sup>2</sup> Vanzetti's method is also known as the azide methemoglobin method. A modified azide methemoglobin method is used in the Alere **HemoPoint® H2** System.

### Principles of the Procedure

In the Alere **HemoPoint® H2** System, the use of Alere **HemoPoint® H2** Microcuvettes with short light pathways makes it possible to analyze undiluted blood. The filled Alere **HemoPoint® H2** Microcuvette is inserted into the Alere **HemoPoint® H2** Meter, the color produced by the chemical reaction in the Alere **HemoPoint® H2** Microcuvette is measured, and the hemoglobin level is calculated and displayed.

For this purpose, light is directed through the blood sample and the absorption is measured. From the amount of light absorbed by the sample, the concentration of the hemoglobin in the Alere **HemoPoint® H2** Microcuvette can be calculated using the Beers-Lambert Law. Light emitting diodes (LED's) are used as light sources and a photodiode is used to detect the light. The light emitting diodes utilize the central wavelengths 570 nm (for measurement) and 880 nm (for turbidity compensation).

### The Alere HemoPoint® H2 Microcuvette

The plastic Alere **HemoPoint® H2** Microcuvette consists of a clear body with a cavity which takes up approximately 8 µL of blood which combines with the dry reagent chemistry. The optical distance between the Alere **HemoPoint® H2** Microcuvette walls is fixed and permits photometric determination of the hemoglobin in undiluted blood samples.

### The Chemistry Principle

In order to use the azide methemoglobin method in undiluted blood, three reagents are necessary: sodium deoxycholate dissolves and disperses the cell walls of the red blood corpuscles. Hence the hemoglobin formerly contained in the erythrocytes is now available free in the solution. The bivalent iron of the oxyhemoglobin and the deoxyhemoglobin become oxidized by sodium nitrite NaNO<sub>2</sub> to trivalent iron, in methemoglobin. Existing and formed methemoglobin and azide ions from sodium azide NaN<sub>3</sub> form a colored complex which exhibits maximal absorption at 540 and 575 nm and hence it can be quantitatively determined photometrically.

### Reagents

#### Alere HemoPoint® H2 Microcuvettes

40% w/w sodium deoxycholate, 20% sodium azide, 20% w/w sodium nitrite and 20% w/w non-reactive ingredients.

### Warnings and Precautions

Alere **HemoPoint® H2** Microcuvettes are designed for in-vitro diagnostic use only. The reagents which coat the inner walls of the Alere **HemoPoint® H2** Microcuvettes are harmful and must not be swallowed. Wear suitable protection (gloves) at all times when handling blood samples. Please note that all human blood samples or products must be handled as potentially infectious waste per your local regulations.

### Storage

Alere **HemoPoint® H2** Microcuvettes are to be stored solely in the original container and at room temperature 59 – 86°F (15–30°C). DO NOT refrigerate! Use Alere **HemoPoint® H2** Microcuvettes within 3 months after opening container. Document the initial opening date on the container label in the space provided. Only remove one Alere **HemoPoint® H2** Microcuvette at a time from the container and then immediately close the lid. The Alere **HemoPoint® H2** Microcuvettes are analyzed optically in the Alere **HemoPoint® H2** Meter.

Measurement light must pass through the sample Alere **HemoPoint® H2** Microcuvette to the photo detector with the least possible interference. It is therefore crucial not to touch the optical eye of the Alere **HemoPoint® H2** Microcuvette with fingers, dirty or sharp objects.

### Sample Collection and Preparation

The Alere **HemoPoint® H2** Meter can be used with capillary, venous, or arterial blood. Use EDTA, heparin or heparin/fluoride as anticoagulants, preferably in solid form, to avoid dilutional effects. Venous and arterial blood samples may be used if the blood collected is not more than 24 hours old and the samples have been stored refrigerated 35 – 46°F (2–8°C).

Prepare stored samples for measurement as follows:

1. Remove sample tube from the refrigerator and bring it to room temperature.
2. Mix the sample tube well. (i.e. by a mechanical rotator or hand inversion at least 10 times).

### Procedure

Refer to the Alere **HemoPoint® H2** User's Guide for proper use of the meter.

### Materials Provided

Alere **HemoPoint® H2** Microcuvettes, Ref.No. 80549

### Materials Required But Not Provided

Alere **HemoPoint® H2** Meter<sup>3</sup>

Alere **HemoPoint® H2** Control Cuvette (optional)

Alere™ Hemoglobin Controls (Ref. No. 88772) (optional)

Disposable pipettes (venous or arterial blood only)

Plastic film (venous or arterial blood only)

Lint-free material

### Instructions For Use (Capillary)

1. Make sure that the meter is ready for use.
2. Make sure that your patient is sitting comfortably.
3. There should be a good blood circulation in the hand from which you wish to take blood, i.e., it should be warm and relaxed.
4. Lightly massage the fingers, in order to stimulate circulation.
5. Disinfect the puncture site and allow to dry.
6. Take out a Alere **HemoPoint® H2** Microcuvette from the container and close the lid immediately.
7. Press lightly on the fingertip and puncture with a suitable sampling device on the side of the fingertip.
8. Blot away the first drop of blood then, if necessary, press gently once again to get a 2nd drop of blood which is large enough to fill the Alere **HemoPoint® H2** Microcuvette completely. Avoid "milking" the finger.
9. Hold the center of the Alere **HemoPoint® H2** Microcuvette in the middle of the drop of blood and let the cavity fill in one step. In case of air bubbles in the optical eye, discard the Alere **HemoPoint® H2** Microcuvette and take another sample using a new Alere **HemoPoint® H2** Microcuvette.
10. In order to avoid contamination of the Alere **HemoPoint® H2** Microcuvette holder, remove surplus blood from the outside of the Alere **HemoPoint® H2** Microcuvette.
11. The Alere **HemoPoint® H2** Microcuvette sample prepared in this way can now be measured immediately or within 10 minutes at the latest.

## Instructions For Use (Venous or Arterial)

1. Make sure that the meter is ready for use. See the Alere **HemoPoint® H2** User Manual for additional information.
2. Remove sample tube from the refrigerator and bring it to room temperature.
3. Mix the sample tube well (i.e. by a mechanical rotator or mixing by hand at least 10 times).
4. Take out a Alere **HemoPoint® H2** Microcuvette from the container and close the lid immediately.
5. Pipette a sufficient drop of blood on a non-absorbent material (e.g. plastic film).
6. Hold the center of the Alere **HemoPoint® H2** Microcuvette in the middle of the drop of blood and let the cavity fill in one step. In case of air bubbles in the optical eye, discard the Alere **HemoPoint® H2** Microcuvette and take another sample using a new Alere **HemoPoint® H2** Microcuvette.
7. In order to avoid contamination of the Alere **HemoPoint® H2** Microcuvette holder, remove surplus blood from the outside of the Alere **HemoPoint® H2** Microcuvette.
8. The Alere **HemoPoint® H2** Microcuvette sample prepared in this way can now be measured immediately or within 10 minutes at the latest.

## Limitations of the Procedure

1. The Alere **HemoPoint® H2** Microcuvette sample can be measured immediately or within 10 minutes at the latest, otherwise false results may be obtained.
2. Air bubbles in the optical eye, caused by inadequate filling of the Alere **HemoPoint® H2** Microcuvette cavity, may cause false results. Discard the Alere **HemoPoint® H2** Microcuvette and take another sample using a new Alere **HemoPoint® H2** Microcuvette.
3. Ensure that you do not hold the Alere **HemoPoint® H2** Microcuvette at its filling end because this may contaminate the optical eye.
4. In order to avoid contamination of the Alere **HemoPoint® H2** Microcuvette holder, remove surplus blood from the outside of the Alere **HemoPoint® H2** Microcuvette.
5. All results above 23.5 g/dL or equivalent must be confirmed by laboratory method.
6. Sulfhemoglobin is not measured by this method.
7. Carboxyhemoglobin and turbidity due to leukocytosis or hyperlipemia do not interfere.
8. Always place Alere **HemoPoint® H2** Microcuvette right side up in holder. Placing the Alere **HemoPoint® H2** Microcuvette upside down can lead to erroneous results.

## Expected Values<sup>4,5,6,7,8</sup>

The following hemoglobin values are considered normal:

Adult males:	13.0 – 18.0 g/dL
Adult females:	11.0 – 16.0 g/dL
Children:	11.0 – 16.0 g/dL
Infants (postnatal):	10.0 – 14.0 g/dL

Due to a wide range of conditions which affect normal values, it is recommended that each laboratory establish its own "normal" range.

## Quality Control

The Alere **HemoPoint® H2** AutoCheck performs an internal check of the meter's optic system every time the Alere **HemoPoint® H2** Microcuvette holder is opened. If additional regulatory quality control is required in your facility, the following checks may be performed: (1) If a Alere **HemoPoint® H2** Control Cuvette was supplied with the Alere **HemoPoint® H2** Meter it can be used for a simple check of the Alere **HemoPoint® H2** Meter's calibration. (2) Use of external controls to assure that the Alere **HemoPoint® H2** Microcuvettes and the Alere **HemoPoint® H2** Meter are performing correctly. For this purpose, we recommend the use of the Alere™ Hemoglobin Controls, Ref. No. 88772.

Do not use cyanmethemoglobin standards with this test.

## Results

The test result is displayed directly on the screen of the Alere **HemoPoint® H2** Meter. No calculations are necessary. The test is linear up to 23.5 g/dL.

## Performance Characteristics

### Precision

Within-run precision using the Alere **HemoPoint® H2** Meter with the Alere **HemoPoint® H2** Microcuvettes is 2%. The precision evaluation was carried out in accordance with NCCLS EP5-A<sup>9</sup>. On each of 20 testing days, two separate runs with duplicate measurements within each run were carried out. Three commercially available control materials were used. The test was carried out using: (6) Alere **HemoPoint® H2** devices; (16) lots of Alere **HemoPoint® H2** Microcuvettes; and (3) operators.

### Correlation

Correlation coefficient of the Alere **HemoPoint® H2** System compared to the NCCLS H15-A3 reference method.

Venous blood:  $r = 0.998$

NCCLS EP5-A Protocol	Alere <b>HemoPoint® H2</b> Microcuvette measured in Alere <b>HemoPoint® H2</b> device
Hgb/Low (8.0 g/dL): Within-run Precision Total Precision	S <sub>wr</sub> 0.058 g/dL, CV 0.7% S <sub>T</sub> 0.122 g/dL, CV 1.5%
Hgb/Normal (11.8 g/dL): Within-run Precision Total Precision	S <sub>wr</sub> 0.070 g/dL, CV 0.6% S <sub>T</sub> 0.162 g/dL, CV 1.4%
Hgb/High (15.7 g/dL): Within-run Precision Total Precision	S <sub>wr</sub> 0.087 g/dL, CV 0.6% S <sub>T</sub> 0.174 g/dL, CV 1.2%
Day-to-Day Precision	8.0 g/dL: SD 0.111 g/dL, CV 1.4% 11.8 g/dL: SD 0.176 g/dL, CV 1.5% 15.7 g/dL: SD 0.179 g/dL, CV 1.1%

Alere **HemoPoint® H2** System (Alere **HemoPoint® H2** microcuvettes measured in Alere **HemoPoint® H2** device):

Regression line and correlation coefficients compared to NCCLS H15A3 reference method (g/dL), venous blood	<ol style="list-style-type: none"> <li>1. <math>Y = 0.2929 + 1.0086x</math></li> <li>2. <math>R = 0.998</math></li> <li>3. <math>N = 100</math>, duplicate measurements</li> <li>4. Summary of results</li> </ol>
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## References

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## Alere™ Technical Support

Contact one of the following Alere™ Technical Support Care Centers or your local distributor if you have any questions regarding the use of your Alere™ product. You may also contact us at [www.alere.com](http://www.alere.com).

Region	Phone	E Mail Address
US	+(1)866.216.0073	HemoPoint.H2.Support@alere.com

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+(1) 877.441.7440	clientservices@alere.com

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PN: 26274 Rev. B 2012/09