Mission® HemoPro Hemoglobin Microcuvette Package Insert

REF C133-3011-201	# CCS-171	English

For measuring the hemoglobin concentration in capillary or venous whole blood.
For professional in vitro diagnostic use only.

INTENDED USE

The *Mission® HemoPro* Hemoglobin Microcuvette is specifically designed to work with the *Mission® HemoPro* Hemoglobin Meter to measure the hemoglobin concentration in capillary or venous whole blood. Microcuvettes are designed for professional *in vitro* diagnostic use only.

SUMMARY

The major role of hemoglobin is to carry oxygen from the lungs to the tissues and return carbon dioxide from the tissue to the lungs. So, the changes of Hb concentration in the blood can cause several diseases such as anemia and even death. One has to be noted that hemoglobin is a key hematological metric in medical diagnostics, therefore, the accurate determination of this hemo-protein is essential in a number of human pathologies[1]. Hemoglobin assessments are used widely to screen individuals for anemia, to draw inferences about the iron status of populations, and to evaluate responses to nutritional interventions[2].

The *Mission® HemoPro* Hemoglobin Testing System can quickly and accurately test the hemoglobin concentration and calculate hematocrit level. The measurement range of the *Mission® HemoPro* Hemoglobin Testing System is 0.0-26.0 g/dL.

PRINCIPLE AND REFERENCE VALUES

Principle

The system consists of a meter together with microcuvettes. The microcuvette serves as both a pipette and a measuring cuvette which is designed for single use only. A blood specimen or control solution of approximately 10 µL is drawn into the cavity by capillary action. The meter measures whole blood absorbance at the Hb/HbO_2 isobestic point. It measures at two wavelengths (505 and 880 nm) to compensate for turbidity. The *Mission® HemoPro* testing system is calibrated against the international reference method (HiCN), recommended by the ICSH for hemoglobin determination[3]. It requires no further calibration.

Reference values

The reference hemoglobin values are listed in the following table:

Unit	Hemoglobin		
	g/dL	g/L	mmol/L
Men	13.0-17.0	130-170	8.1-10.5
Women	12.0-15.0	120-150	7.4-9.3
Children	11.0-14.0	110-140	6.8-8.7

The data in the above table are from Dacie and Lewis Practical Hematology[4]. Reference ranges may vary between laboratories. Every laboratory should establish its own reference range as needed.

REAGENTS

This product is composed of polystyrene plastic and does not contain any active ingredients.
The performance characteristics of these hemoglobin microcuvettes have been determined in both laboratory and clinical tests. This test has been developed to be specific for the measurement of hemoglobin with the exception of the interferences listed. Refer to the **Limitations** section for detailed information.

PRECAUTIONS

- Do not use after expiration date.
- Always handle blood specimens with care as they may be infectious. Consult local environmental authorities for proper disposal.
- Any serious incident that has occurred in relation to the meter shall be reported to the manufacturer and the competent authority of the Member State in which the user and/or the patient is established.

STORAGE AND STABILITY

- The microcuvettes should be stored at 2-40 °C (35.6-104 °F).
- The microcuvettes in the canister can be used until the expiration date printed on the package, regardless of whether the package has been opened or not.
- Always keep the canister closed. All unused microcuvette must be kept in the original package.

SPECIMEN COLLECTION AND PREPARATION

See User's Manual before using for complete instructions on blood specimen collection.

For Venous whole blood specimen:

- EDTA or heparin anticoagulants can be used when collecting the venous whole blood specimen.
- Venous whole blood specimen with EDTA or heparin anticoagulants can be stored in a cool, dry area at 2-30°C (35.6-86°F) for 24 hours. Store them away from heat and direct sunlight.
- Do not freeze. Frozen blood specimen is severely lysed and may lead to incorrect results.
- Some venous whole blood specimens are easily lysed. A red color present in the plasma is a clear indication of blood lysis. If the red color is present, do not use the specimen for testing. Collect a new specimen and conduct the test immediately or within a very short period of time.
- Gently mix the venous whole blood for at least 15 minutes before testing. To avoid blood lysis, do not stir the specimen excessively or mix the specimen for too long.

For Capillary blood specimen:

- Prior to testing, wipe the test site with an alcohol swab or wash with soapy water. Then dry hands and test site thoroughly. Any cream or lotion residue on the testing site may affect the test results.
- Do not use iodine tincture disinfectants. The residual iodine tincture on the skin may lead to inaccurate results.
- Capillary blood specimens should be used immediately to avoid blood clotting.

MATERIALS

Materials Provided

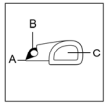
- Microcuvettes
- Package Insert

Materials Required But Not Provided

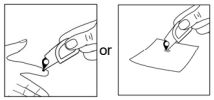
- Meter
- Sterile Lancets
- Lancing Device
- Control Solution

DIRECTIONS FOR USE

Please make sure the meter, microcuvette, venous whole blood specimen, and/or control solution are placed at 10-40°C (50-104 °F) for at least one hour before testing. Refer to User's Manual for detailed instructions.



A. Filling end
B. Optical eye
C. Handheld end



1. Remove the microcuvette from the canister then close the canister tightly. Hold the handheld end and bring the microcuvette into contact with the specimen, filling the cavity in one continuous process.

Note: *Always avoid touching the optical eye. Do not refill the cavity of the microcuvette. When collection tubes or control solution are used, place a drop of well-mixed specimen or control solution onto a hydrophobic surface or glass slide.*

2. Wipe off the excess specimen outside of the microcuvette with a clean lint-free cloth, being careful not to touch the open edge of the filling end. Check if air bubbles are present in optical eye of the microcuvette. If bubbles are present, discard the microcuvette and fill a new microcuvette with a new drop of specimen. Small bubbles around the edge can be ignored.

3. Place the microcuvette into the microcuvette holder and start the test as soon as possible after filling the microcuvette, gently pushing the microcuvette holder to its measuring position within 40 seconds or less. The measuring time is less than 2 seconds after closing the microcuvette holder. After the test has completed, pull the microcuvette holder out to its loading position and discard the used microcuvette. You may run another test or press the ⏻ button to turn off the meter. Otherwise, the meter will automatically turn off after 5 to 60 minutes of inactivity, depending on the meter setting.

INTERPRETATION OF RESULTS

The Hemoglobin Meter automatically measures hemoglobin concentration. In the event of unexpected or questionable results, the following steps are recommended:

- Confirm the microcuvettes have been used within the expiration date printed on the canister label.
- Compare results to control solutions with known levels and repeat the test by using a new microcuvette.
- If the problem persists, discontinue using the microcuvettes immediately and contact your local distributor.

QUALITY CONTROL

The meter has an optical path self-check each time the meter is turned on, refer to User's Manual for detailed instructions. It is recommended that the meter's optical path be initialized every six months.

Follow local guidelines regarding quality control procedures. The quality control test should be performed if it is required by local or other regulations. Only use *Mission® HemoPro* Hemoglobin Control Solution. Refer to the Quality Control section of the User's Manual for further information.

The quality control test should be used to check that the meter and microcuvettes are working together properly. Follow the test procedure in the Quality Control section of the User's Manual for information on running a quality control test.

The hemoglobin meter must be handled carefully. See the User's Manual for detailed instructions on meter care.

CAUTION: If the quality control test results are not in the control range shown on the control solution canisters, DO NOT continue using the system. If the problem cannot be corrected, please contact your local distributor for technical support.

PERFORMANCE CHARACTERISTICS

The *Mission® HemoPro* Hemoglobin Meter is calibrated with an automated hematology analyzer, which is traceable to the ICSH recommend international reference method.

Linearity

Ten replicate assays were drawn from three microcuvette lots and tested on the Hemoglobin Meter (y), using 12 concentration levels of EDTA-K2 preserved venous whole blood specimens. The same specimens were also tested by using a market leader automated hematology analyzer (x). Linearity results are presented below:

Microcuvette Lot	Equation	R^2
Lot 1	y = 0.9969x - 0.9798	0.9993
Lot 2	y = 0.9932x - 0.5521	0.9990
Lot 3	y = 0.9968x - 0.7914	0.9993

Precision

Fifty replicate assays were tested by using Hemoglobin meters. EDTA preserved venous whole blood specimens at three concentration levels were used with three microcuvette lots, producing the following within-run precision and total precision. Within-run precision and total precision were determined using whole blood specimens and statistical analysis, which provided the average and coefficients of variation (CV) listed below:

Microcuvette Lot	/	83 g/L (n=50)	131 g/L (n=50)	192 g/L (n=50)
Lot 1	Average	83	133	194
	CV	1.7%	1.6%	1.2%
Lot 2	Average	83	134	194
	CV	1.5%	1.2%	1.2%
Lot 3	Average	83	133	194
	CV	1.4%	1.3%	1.3%
Total precision	Average	83	133	194
	CV	1.6%	1.4%	1.2%

Accuracy

Venous whole blood specimens with EDTA-K2 anticoagulant and fingertip capillary blood specimens were collected from separate subjects. All specimens were tested with automated hematology analyzer and *Mission® HemoPro* Hemoglobin Microcuvette on *Mission® HemoPro* Hemoglobin Meters. The summary of the test results is presented below:

Linear regression of meter reading (y) versus reference value (x) with venous whole blood specimens				
Test item	Slope	Intercept	R^2	N
Hemoglobin	1.0083	-0.477	0.9975	98
Linear regression of meter reading (y) versus reference value (x) with fingertip capillary blood specimens				
Test item	Slope	Intercept	R^2	N
Hemoglobin	0.9848	1.5476	0.9812	55

LIMITATIONS

- For professional *in vitro* diagnostic use only.
- Do not remeasure the microcuvette.
- Do not use with any components from other brands.
- Use only with capillary or venous whole blood specimens. Do not use with serum or plasma specimens.
- Begin the test no later than 40 seconds after filling the microcuvette.
- Mixing specimen for an extended period can increase oxygen pressure and viscosity which may give false results.
- If "HI" is displayed, the result has exceed the measuring range of the system.
- Values above 23.5 g/dL (235 g/L, 14.6 mmol/L) must be confirmed by using a suitable laboratory method.

Interferences:

The following substances at or below the following concentrations do not interfere with test results:

Substance	Amount	Substance	Amount
Uric acid	7 mg/dL	Dopamine	5.87 µmol/L
Creatinine	2 mg/dL	Tetracycline	34 µmol/L
Urea	30 mg/dL	Acetaminophen	30 µg/mL
Bilirubin	2 mg/dL	Ammonium ferric citrate	300 mg/L
Protein	7 g/dL	Iron Dextran	2838 mg/L
Ascorbic acid	342 µmol/L	$FeSO_4 \cdot 7H_2O$	222 mg/L
Ibuprofen	2425 µmol/L	Lithium Carbonate	225 mg/L
Methyldopa	71 µmol/L	Vitamin B12	700 ng/L
Sodium Salicylate	4.34 mmol/L	Folic Acid	15 µg/L

- Severely ill persons should not run a hemoglobin test with the *Mission® HemoPro* Hemoglobin Testing System.
- Dispose of blood specimens and other tested materials according to local regulations for medical waste.
- In order to obtain more precise results, run the test at consistent temperature conditions. Do not run the test under conditions of rapid temperature changes; for example, near the air outlet of an air conditioner.

BIBLIOGRAPHY

1. Edyta Matysiak, Mikolaj Donten, Agata Kowalczyk, Michal Bystrzejewski, Ireneusz P. Grudzinski, Anna M. Nowicka. A novel type of electrochemical sensor based on ferromagnetic carbon-encapsulated iron nanoparticles for direct determination of hemoglobin in blood samples. Biosensors and Bioelectronics 64 (2015) 554-559.
2. Saul S Morris, Marie T Ruel, Roberta J Cohen, Kathyyn G Dewey, Bénédicte de la Brière, and Mohammed N Hassan. Precision, accuracy, and reliability of hemoglobin assessment with use of capillary blood. Am J Clin Nutr 1999; 69:1243-8.
3. Reference and Selected Procedures for the Quantitative Determination of Hemoglobin in Blood; Approved Standard CLSI Document H15-A3.
4. Dacie and Lewis Practical Hematology, 10th ed., 2006.

INDEX OF SYMBOLS

	Consult instructions for use		Use-by date	REF	Catalogue number
IVD	*In vitro* diagnostic medical device	LOT	Batch code	CTRL	Control Range
	Temperature limit		Manufacturer	#	Model number
EC REP	Authorized representative in the European Community		Do not reuse	Σ	Contains sufficient for <n> tests

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