Mission® Plus

Hb Hemoglobin Test Strips (Whole Blood)
Package Insert

REF C132-3011	REF C132-3031	English

For testing hemoglobin (Hb) in human whole blood.
For in vitro diagnostic use only.

INTENDED USE

The Hb Hemoglobin Test Strips (Whole Blood) are firm plastic strips onto which a multilayer dry reagent is affixed and are intended to be read on the *Mission® Plus* Hb Hemoglobin Meter. The test strips function by lysing erythrocytes and converting the released hemoglobin into methemoglobin. This test is for the quantitative determination of hemoglobin (Hb) and calculated hematocrit (Hct) in capillary and venous whole blood. The test strips are for professional use only.

SUMMARY

Hemoglobin is the main component of red blood cells whose main function is to transport oxygen. The determination of hemoglobin concentration in whole blood is useful in the clinical diagnosis of diseases such as anemia and polycythemia. The measurement range of the *Mission® Plus* Hb Hemoglobin Testing System is 4.5 – 25.6 g/dL.

PRINCIPLE AND REFERENCE VALUES

Erythrocytes in the specimen are lysed to release hemoglobin. The hemoglobin is converted to methemoglobin. The intensity of the color produced from this reaction is proportional to the hemoglobin concentration. Reference values are listed in the chart below:

Men	13.0 – 17.0 g/dL (130 – 170 g/L, 8.1 – 10.5 mmol/L)
Women	12.0 – 15.0 g/dL (120 – 150 g/L, 7.4 – 9.3 mmol/L)
Children	11.0 – 14.0 g/dL (110 – 140 g/L, 6.8 – 8.7 mmol/L)

Reference ranges may vary between laboratories. Every laboratory should establish its own reference range as needed. [1]

REAGENTS AND PERFORMANCE CHARACTERISTICS

Based on the dry weight at the time of impregnation, the concentrations given may vary within manufacturing tolerances.

Reagent	Composition
Sodium dexycholate	3% w/w
Sodium nitrite	1.5% w/w
Non-reactive Ingredients	95.5% w/w

The performance characteristics of these Hb Hemoglobin Test Strips have been determined in both laboratory and clinical tests. This test has been developed to be specific for the parameters to be measured with the exception of the interferences listed. Refer to the **Limitations** section for detailed information.

PRECAUTIONS

- For *in vitro* diagnostic use only.
- The strip should remain in the closed canister until use.
- Do not use after the expiration date.
- Do not touch the reagent area of the strip.
- Discard any discolored or damaged strips.
- All specimens should be considered potentially hazardous and handled in the same manner as an infectious agent.
- The used strip should be discarded according to local regulations after testing.
- Check the code chip before performing a test. Make sure to use the code chip that is included with the canister of strips. Insert the code chip into the code chip slot. The code chip slot is located on the right side of the meter.

STORAGE AND STABILITY

Store as packaged in the closed canister, either at room temperature or refrigerated (2-30°C). Keep out of direct sunlight. Strips are stable through the expiration date printed on the canister label. Remove only enough strips for immediate use. Replace cap immediately and tightly. DO NOT FREEZE. Do not use beyond the expiration date.
Note: Once the canister has been opened, the remaining strips are stable for up to 3 months. Stability may be reduced in high humidity conditions.

SPECIMEN COLLECTION AND PREPARATION

- Acceptable specimens include fresh capillary or venous blood, following NCCLS Guideline H4A4 for capillary blood specimen's collection.
- Fresh capillary or venous blood specimens must be collected and tested immediately.
- Specimens with EDTA or heparin anticoagulants may be used. Preserved specimens must be kept in a closed container and must be used within 8 hours of collection. Mix stored specimens adequately before testing.
- A Capillary Transfer Tube or pipette should be used to collect capillary specimens for accurate results.

MATERIALS

Materials Provided

- Test strips
- Code chip
- Package insert

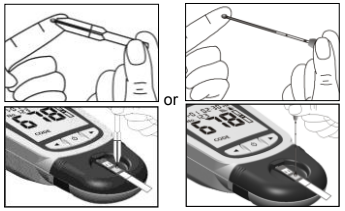
Materials Required But Not Provided

- Lancing device
- Sterile lancet
- Hb meter
- Gauze for puncture site
- Latex gloves
- Alcohol swab
- Capillary Transfer Tubes

DIRECTIONS FOR USE

Allow the strip, specimen, and/or controls to reach room temperature (15-30ºC) prior to testing. Refer to the Hb Hemoglobin Testing System User's Manual for detailed instructions.

1. Insert the code chip into the meter and code the meter correctly. Refer to Coding the Meter in the User's Manual for details. Compare the code number on the code chip with the code number printed on the test strip canister label, and ensure the two numbers are identical to avoid inaccurate results.
2. Remove the strip from the closed canister and use it as soon as possible. Immediately close the canister tightly after removing the required number of strip(s).
3. Wait for the meter to flash the strip symbol. Insert the strip completely into the Strip Channel in the same direction as the arrows printed on the test strip until the white edge above the black line on the test strip is no longer visible.
4. Wipe away the first drop of blood. Collect 10 µL of the second drop of capillary blood specimen using a Capillary Transfer Tube, or pipette. Refer to the User's Manual for details. Hold the tube slightly downward and touch the tip of the Capillary Transfer Tube to the blood drop. Capillary action will automatically draw the sample to the fill line and stop.



Note: Make sure the blood covers the air vent of the tube or it will be hard to squeeze blood out. Do not squeeze the Capillary Transfer Tube while collecting specimen.

5. While the meter is flashing the blood drop symbol, align the tip of the Capillary Transfer Tube with the Specimen Application Area of the strip to apply the blood (10 µL). 3 dashed lines will appear on the meter to show the test is in progress.
6. Read the results on the screen after 15 seconds. Refer to Testing in the User's Manual for detailed test procedures.

INTERPRETATION OF RESULTS

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

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

PERFORMANCE CHARACTERISTICS

Linearity

Ten replicate assays were drawn from three strip lots and tested on the Hemoglobin Meter (y), using ten concentration levels of heparin preserved venous blood specimens. Several Hb Hemoglobin Meters were used to perform tests at each concentration (n=5). The same specimens were also tested using a market leader analyzer (x). Linearity results are presented below:

Strip Lot	Linearity equation	r
Strip Lot 1	y = 0.9814x + 0.2168	0.9990
Strip Lot 2	y = 1.0094x + 0.0071	0.9990
Strip Lot 3	y = 0.9937x + 0.3093	0.9991

Reproducibility and Precision

100 replicate assays were tested using the Hb Hemoglobin Meter. Fresh heparin preserved venous blood specimens at three concentration levels were used with three strip lots, producing the following within-run precision and total precision estimates. Within-run precision using whole blood specimens statistical analysis gives the mean, standard deviations (SD), and coefficients of variation (CV%) listed below:

	Level I (n=100)			Level II (n=100)			Level III (n=100)		
Precision	Lot 1	Lot 2	Lot 3	Lot 1	Lot 2	Lot 3	Lot 1	Lot 2	Lot 3
Mean (g/dL)	9.6	9.9	9.7	13.6	14.0	13.8	17.5	17.9	17.8
SD (g/dL) or %CV	0.21	0.20	0.24	1.40%	1.80%	1.30%	1.30%	1.50%	1.40%

Total precision is listed below:

Test level	Level I (n=300)	Level II (n=300)	Level III (n=300)
Mean (g/dL)	9.7	13.8	17.7
SD (g/dL) or %CV	0.26	2.0%	1.7%

Accuracy

The Hb Hemoglobin meter (y) and strips were used by a trained technician to test heparin preserved venous blood specimens from 159 participants. The same specimens were analyzed using a market leader hemoglobin analyzer (x). The same testing was performed using capillary blood specimens from 51 participants. The results are compared below:

Specimen	Slope	Intercept	R	N
Venous blood	0.9582	0.5673	0.992	159
Capillary blood	1.0006	0.026	0.993	51

QUALITY CONTROL

For best results, performance of test strips should be confirmed by testing known specimens/controls whenever a new test is performed or whenever a new canister is first opened. Each laboratory should establish its own goals for adequate standards of performance. Contact your local distributor for information on specific controls for this product.

LIMITATIONS

The following substances do not interfere with test results:

Substance	Amount	Substance	Amount
Acetaminophen	200 mg/dl	Cholesterol	5 g/l
Ascorbic Acid	60 mg/dl	Tetracycline	15 mg/dl
Creatinine	5 mg/dl	Urea	2.574 g/l
Ibuprofen	500 mg/dl	Uric Acid	235 mg/l
Dopamine	0.9 mg/l	Methyldopa	15 mg/l

High concentrations of triglycerides and salicylic acid can lead to low Hb measurements. High concentration of bilirubin can lead to high hb measurement. Anticoagulants, such as heparin and EDTA, are recommended for use with venous whole blood. Do not use anticoagulants such as iodoacetate, sodium citrate or those containing fluoride. Do not use plasma or serum with the Hb Hemoglobin Testing System.

BIBLIOGRAPHY

1. Henry, J. B. Clinical Diagnosis and Management by Laboratory Methods. 15-290, 2001.

Index of Symbols

	Consult instructions for use		Use by	CODE	Code Number
IVD	For *in vitro* diagnostic use only	LOT	Lot Number	CTRL	Control Range
2°C 30°C	Store between 2-30°C		Manufacturer	REF	Catalog #
Σ	Contents sufficient for <n> tests	EC REP	Authorized Representative		Do not reuse

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