

REF C131-3011	REF C131-3021	English
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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® 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® Hb Hemoglobin Testing System is 4.0 – 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.<sup>1</sup>

### 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 dexcholate	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
- Capillary Transfer Tubes (Only provided in C131-3021)

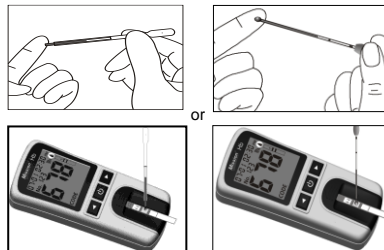
#### Materials Required But Not Provided

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

### DIRECTIONS FOR USE

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

- 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.
- 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).
- 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.
- Wipe away the first drop of blood. Collect 10 µL of the second drop of capillary blood 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:** Never squeeze the bulb and/or cover the air vent while sampling.
- 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. **Note:** The air vent should be covered while expelling the blood sample.

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:

Precision	Level I (n=100)			Level II (n=100)			Level III (n=100)		
	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

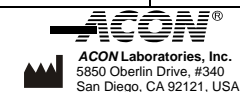
High concentrations of triglycerides and salicylic acid can lead to low Hb measurements. High concentration of bilirubin can lead to high Hb measurement. Anticoagulants, such as heparin and EDTA, are recommended for use with venous whole blood. Do not use anticoagulants such as iodoacetate, sodium citrate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

### BIBLIOGRAPHY

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

### Index of Symbols

	Consult instructions for use		Use by		Code Number
	<i>In vitro</i> diagnostic medical device		Lot Number		Control Range
	Temperature limit		Manufacturer		Catalogue number
	Contains sufficient for <n> tests		Authorized representative in the European Community		Do not reuse





# Hb Hemoglobin Control Solution Package Insert

REF C121-3091	English
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For validating hemoglobin (Hb) testing.  
For *in vitro* diagnostic use only.

## PRINCIPLE AND INTENDED USE

The *Mission*® and *Mission*® Plus Hb Hemoglobin Control Solution is intended for use in validating hemoglobin testing using the *Mission*® and *Mission*® Plus Hb Hemoglobin Testing System. The control solution contains a stabilized bovine hemoglobin with added chemicals, stabilizers and preservatives. The control solution is dispensed onto the *Mission*® and *Mission*® Plus Hb Hemoglobin Test Strip inserted in the meter to confirm that the test strips and meter are working together properly and that the test is being performed correctly. The control solution is available in three levels and is ready to use.

## PRECAUTIONS

- For *in vitro* diagnostic use only. Do not use after the expiration date.
- Shake well and let the controls reach room temperature (15-30°C) prior to test.
- All materials should be considered potentially hazardous and handled in the same manner as an infectious agent.
- The used materials should be discarded according to local regulations after testing.
- This product is not intended for use as a standard.
- The use of quality control materials is an important part of good laboratory practices. Quality control materials are an objective method of assessing techniques or practices in use.
- Control solution tests are specified to be accurate only when tested between 15-30°C.
- Use only a *Mission*® and *Mission*® Plus control solution with a *Mission*® and *Mission*® Plus meter and test strips.
- 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.

## REAGENTS

The product is a liquid stable control prepared from bovine hemoglobin with added chemicals, constituents of animal origin, preservatives and stabilizers. The control does not include human resource materials.

## STORAGE AND STABILITY

- Store the control solution at temperature of 2-8°C.
- Do not freeze.
- If the control solution is cold, do not use until it has warmed to room temperature.
- Use before the expiration date that is shown on the bottle.
- Each bottle of control solution can be used for 30 days after you first open it. The control solution will expire 30 days after the bottle is opened for the first time. Record this opened expiration date on the bottle label.

## MATERIALS REQUIRED

- Control Solution 0
- Control Solution 1
- Control Solution 2
- Package Insert

## MATERIALS REQUIRED BUT NOT PROVIDED

- Hb Meter
- Test Strips
- Latex gloves
- Capillary Tubes or Pipette

## RE-CALIBRATION PROCEDURE

To get an accurate control results, you should re-calibrate the Hb/Plus Hb meter before using Hb control solution to do QC test. Do the re-calibration as per following procedures.

- Make sure the optical system works properly. Set the unit at 'g/dL' or 'g/L'.

- With the meter turn off, press '◀' and '⏻' at the same time, and hold for at least 5 seconds until the meter displays screen 1. Release the button to display calibration Screen 2. Make sure the original value shows on meter is 10.0g/dL. If not, press '◀' or '▶' until it displays 10.0g/dL.

- Press '⏻' to save. Screen 3 will display. Make sure the original value shows on meter is 20.0g/dL. If not, press '◀' or '▶' until it displays 20.0g/dL.

- Press '⏻' to save. Press '◀' to display Screen 4, and '⏻' to exit the setup system. The re-calibration is finished.



## INSTRUCTIONS FOR USE

Allow all test materials to reach room temperature (15-30°C) prior to testing. Refer to the Hb Hemoglobin Testing System User's Manual for detailed instructions.

- Invert the control solution bottle back and forth for at least 15 minutes.
- Turn on the meter.
- 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.
- Remove a test 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).
- 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.
- While the meter is flashing the blood drop symbol, use a pipette to apply 10 µl of the control solution to the center of the Specimen Application Area. 3 dashed lines will appear on the meter to show the test is in progress.
- Read the results on the screen after 15 seconds. Refer to Testing in the User's Manual for detailed test procedures.

## EXPECTED RESULTS

The results should fall within the range(s) listed on bottle label and are specific for each lot of control solution. If the results fall within the specified control range, it indicates the Hb Hemoglobin Test System is working properly and the procedures are being performed properly.

If the results do not fall within the respective range(s):

- Check the expiration date of the test strip and control solution. Make sure the test strip canister was first opened no more than 3 months prior to testing. Also make sure the control solution bottle was first opened no more than 30 days prior to use. Discard any expired test strips or control solution.
- Confirm all test materials are between 15 and 30°C.
- Make sure that the test strip canister and the control solution bottle have been tightly capped.
- Confirm that only the brand of control solution is the same brand as the Hb Hemoglobin Testing System.
- Make sure that all test procedures are followed correctly.
- Make sure the meter is not contaminated.
- Make sure the code chip number matches the code number printed on the strip canister and the code that appears on the meter screen.
- Mix the control solution well prior to testing.

After checking all of the conditions listed above, repeat the control solution test with a new test strip. If results still fall outside the control range(s), the meter may not be working properly. Contact your local distributor for further assistance.

## INDEX OF SYMBOLS

	Consult instructions for use		Use-by date	<b>CODE</b>	Code Number
<b>IVD</b>	<i>In vitro</i> diagnostic medical device	<b>LOT</b>	Batch code	<b>CTRL</b>	Control Range
	Temperature limit		Manufacturer	<b>REF</b>	Catalogue number
<b>CONTROL 0</b>	Low level Control Solution	<b>CONTROL 1</b>	Normal level Control Solution	<b>CONTROL 2</b>	High level Control Solution
<b>EC REF</b>	Authorized representative in the European Community				

**ACON**®  
ACON Laboratories, Inc.  
5850 Oberlin Drive, #340  
San Diego, CA 92121, USA

**EC REF**  
MDSS GmbH  
Schiffgraben 41  
30175 Hannover, Germany



Number: 1151126902  
Effective date: 2023-01-11

For checking the performance of the Mission® Hb Hemoglobin Meter optical system.  
For *in vitro* diagnostic use only.

### INTENDED USE

The Mission® Hb Hemoglobin Control Strip is a firm plastic strip onto which a brown reference pad is affixed on the back of the strip for checking the performance of the optical system of the Mission® Hb Hemoglobin Meter. The Mission® Hb Hemoglobin Control Strip reference pad provides a standardized reflectance value as a reference for the optical system. After the control strip is inserted into the meter, the meter will compare the reflectance value to the pre-calibrated value stored in the meter software. The meter will display **YES** if the optical system is working properly, or **no** if the optical system is not working properly. Contact your local distributor for more details.

### PRECAUTIONS

- For *in vitro* diagnostic use only.
- The strip should remain in the closed canister until use.
- Do not use after the expiration date.
- Keep the control strip clean. Do not touch the brown reference pad on the back of the strip.
- Do not bend the control strip.
- Do not use a contaminated, discolored, bent or damaged control strip.

### STORAGE AND STABILITY

Store as packaged in the closed canister at room temperature (2-30°C). Keep out of direct sunlight, extreme temperature and humidity. Remove the strip for immediate use and put it back into the canister with which it was packaged after each use. Close the canister immediately.

**Note:** Once the canister has been opened, the remaining strips are stable for up to 1 year. Stability may be reduced in high humidity conditions.

### MATERIALS

#### Materials Provided

- Control strip(s)
- Package insert

#### Materials Required But Not Provided

- Hb Hemoglobin Meter
- User's manual

### DIAGNOSTIC USE










Allow the Mission® Hb Hemoglobin Control Strips and Meter to reach room temperature (15-30°C) prior to testing. Refer to the Hb Hemoglobin Testing System User's Manual for detailed instructions.

1. Remove a Mission® Hb Hemoglobin Control Strip from the closed canister. Immediately close the canister tightly after removing the strip.
2. Enter the Optical Check submenu from the **Setup Screen**.  
**Note:** Refer to the Instruction Manual for detailed test procedures.
3. Wait for the meter to flash the strip symbol. Insert the Control Strip completely into the Strip Channel in the same direction as the arrows printed on the strip.  
**Note:** Ensure the strip is inserted completely for accurate results.
4. Press the middle button to start the Optical Check.
5. If the meter displays **YES**, the optical system is working properly. Refer to the User's Manual for performing specimen testing as usual. If the meter displays **no**, the optical system is not working properly. Repeat the test using a new Control Strip that has not been contaminated, bent, damaged or discolored.
6. If the meter displays **no** after performing the test again, contact your local distributor for further assistance.

### LIMITATIONS

1. This Optical Check should be performed under normal lab lighting conditions.
2. Do not perform this test under extreme overhead lighting conditions.

### Index of Symbols

	Consult instructions for use		Use by		Catalogue number
	<i>In vitro</i> diagnostic medical device		Lot Number		Contains sufficient for <n> tests
	Temperature limit		Manufacturer		Authorized representative in the European Community