

For checking the performance of the *Insight[®]* Hb Hemoglobin Meter optical system.

For *in vitro* diagnostic use only.

INTENDED USE

The *Insight[®]* 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 *Insight[®]* Hb Hemoglobin Meter. The *Insight[®]* 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.

MATERIALS

Materials Provided

- Control strip(s)
- Package insert

Materials Required But Not Provided

- Hb Hemoglobin Meter
- User's manual

DIRECTIONS FOR USE

Allow the *Insight[®]* 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 *Insight[®]* 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	REF	Catalog #		Store between 2-30°C
	For <i>in vitro</i> diagnostic use only		Lot Number		Contains sufficient for <n> tests		Manufacturer