

# CONTROL SOLUTION

**McKESSON**  
**CONSULT® Hb**

## Intended Use

The McKesson Consult® Control Solution may be used by professionals in the verification of the precision and accuracy of McKesson Consult® Hemoglobin Testing Systems and McKesson Consult® Hemoglobin Cuvettes. For *in vitro* diagnostic use only.

## IVD Medical Device

The McKesson Consult® Control Solution complies with the applicable US FDA regulations.

## Summary and Principle

The McKesson Consult® Control Solution is a non-biological quality control material with pre-determined optical density corresponding with assayed levels of human hemoglobin. Please refer to local guidelines for recommended frequency of use.

## Reagents

The McKesson Consult® Control Solution is produced in three concentrations that correspond to three levels of human hemoglobin. Each vial contains 1.9 mL of a solution of a red dye (Rhodamine) in purified water. The reagent does not contain any material of human or animal origin.

## Warnings and Precautions

For *in vitro* diagnostic use only. Do not use beyond the expiration date. This product contains chemical synthetic dye (concentration <0.2 %). Although the McKesson Consult® Control Solution does not contain biological material, it must be handled according to good laboratory practices with the same precautions used with patient blood samples. Avoid contact with skin and eyes, do not swallow. Dispose of all used material in a suitable way. Consult local environmental authorities for proper disposal.

## Storage and Stability

Unopened, stored at +2°C to +25°C (+35°F to +77°F), the product is stable until the expiry date shown on the label. Temperatures of -30°C to +70°C (-22°F to +158°F) are temporarily permitted during transport (24 hours max.) as long as the product is stored in the original package. Do not expose the bottles to direct sunlight. After opening, when properly recapped, the product is stable for 60 days stored at +2°C to +35°C (+35°F to +95°F).

## Procedure and Instructions for Use






Perform measurements according to instructions for patient samples described in the McKesson Consult® Hemoglobin Testing System user manual and the McKesson Consult® Hemoglobin Cuvettes package insert.

1. Allow the control solution to reach operating temperature of the McKesson Consult® Hemoglobin Testing System.
2. Mix the control material by gentle inversion 5 times immediately before sampling.
3. Open the vial and discard the first drop.
4. Dispense a drop of the control to be measured onto a hydrophobic surface (e.g. parafilm) and immediately fill the cuvette.
5. Place the cuvette in the cuvette holder of the McKesson Consult® Hemoglobin Analyzer and measure.
6. Wipe any excess material from the vial and cap with a clean tissue and recap the vial tightly, immediately.
7. If the measured values fall outside the expected range, verify that the test was performed correctly. Check operator technique, expiration date and storage conditions for controls and cuvettes. Repeat the test. If the control still does not perform as expected, contact Technical Support at 1-800-531-5535.

## Expected Results

The expected ranges provided are derived from replicate measurements on factory calibrated McKesson Consult® Hemoglobin Testing System. Results obtained should fall within the expected range specified for the control and are only valid on the McKesson Consult® Hemoglobin Testing System. Refer to the label on the individual control vials for acceptable ranges.

## Symbols used

	Rx Only		LOT code
	Used-by date		<i>In vitro</i> Diagnostic Medical Device
	Consult instructions for use		

General Questions? Call 1-800-777-4908  
Technical Support? Call 1-800-531-5535

**Satisfaction Guaranteed**  
If you are not completely satisfied with any McKesson Brands product, you may return it for a full refund or credit.

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