HEMOGLOBIN CUVETTES

McKESSON

CONSULT® diagnostics

Intended Use
The McKesson Consult® Hemoglobin Testing System is intended for the *in vitro* quantitative measurement of total hemoglobin in non-anticoagulated capillary whole blood and venous whole blood drawn in K2EDTA or lithium heparin tubes. The McKesson Consult® Hemoglobin Testing System consists of the McKesson Consult® Hemoglobin Analyzer and specifically designed disposable cuvettes, the McKesson Consult® Hemoglobin Cuvettes. The device is intended for use in point-of-care settings. The McKesson Consult® Hemoglobin Analyzer is only to be used with McKesson Consult® Hemoglobin Cuvettes.

Caution: Federal law restricts this device for sale by or on the order of a physician or other licensed practitioner (Rx only).

CLIA Complexity for whole blood: Waived

Laboratories with a Certificate of Waiver must follow the manufacturer's instructions for performing the test or the test will no longer be considered CLIA waived.

Summary and Explanation of the Test
The McKesson Consult® Hemoglobin Testing System provides rapid and reliable measurements of total hemoglobin in one drop of blood. Cuvettes are ready for use upon removal from the package. The disposable cuvette requires a 10 µL sample and serves as a sample collector and measuring cuvette at the same time. The blood sample is drawn into the cavity by capillary force. The measurement takes place in the McKesson Consult® Hemoglobin analyzer.

Principles of Method/Procedure
Based on a photometric principle, the McKesson Consult® Hemoglobin Analyzer utilizes a broad-spectrum, multi-chromatic sensor with compensation for turbidity and scattering, which measures the absorbance of whole blood over a wide spectral range. The light path length through the cuvette cavity, in combination with the McKesson Consult® Hemoglobin analyzer, determines the exactness of the hemoglobin measurement. The hemoglobin concentration is calculated from the measured absorbance at multiple wavelengths.

The cuvettes do not contain any reagent.

The system is factory calibrated (and requires no further calibration) against the hemoglobincyanide (HiCN) method, the international reference method for the determination of hemoglobin concentration in blood as described in NCCLS H15-A3 and ICSH standard 1995.[1,2]

Warnings and Precautions
The McKesson Consult® Hemoglobin Cuvettes are for *in vitro* diagnostic use only. The McKesson Consult® Hemoglobin Cuvettes are for single use only.

Always handle blood specimens as potentially infectious and dispose of it in an appropriate biohazard container. Consult local environmental authorities for proper disposal.

Storage and Handling of the McKesson Consult® Hemoglobin Cuvettes
The McKesson Consult® Hemoglobin Cuvettes are packed in reclosable bags of 100 pieces.

Operating ambient temperature: 10 to 35°C (50 to 90°F)
Storage temperature: 0 to 50°C (32 to 122°F)
Transport temperature: -30 to 70°C (-22 to 158°F). These temperatures are temporarily permitted during transport for a maximum of 24 hours if the cuvettes are stored in the original bag.

Use the McKesson Consult® Hemoglobin Cuvettes prior to expiration date (same expiration date for unopened or opened bag). Unused cuvettes should be stored in the original bag.

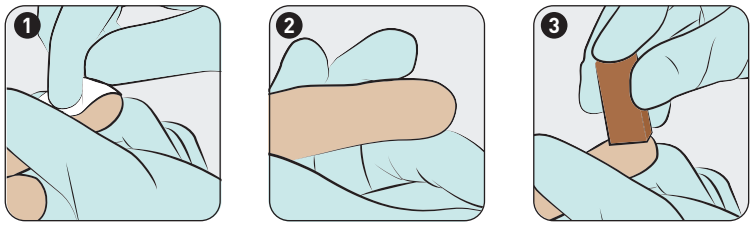
Specimen Collection and Handling
Capillary whole blood or venous blood drawn in K2EDTA or lithium heparin tubes may be used. If venous blood will not be tested immediately, ensure the tubes are properly mixed and then refrigerated. Samples must be analyzed within 72 hours.

Procedure and Instructions for Use
For full instructions, please see the McKesson Consult® Hemoglobin Testing System User Manual.

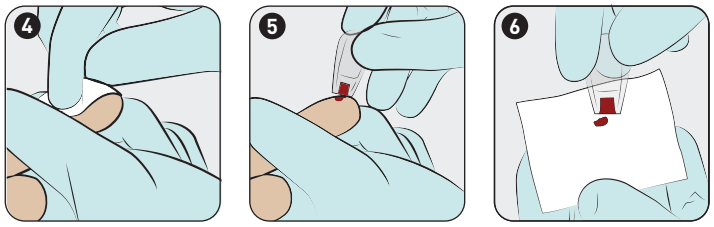
Capillary Sampling

With gloved hands, take a McKesson Consult® Hemoglobin Cuvette out of the foil bag and close the bag.
Make sure the hand is warm and relaxed. Use the middle or ring finger for sampling. Avoid fingers with rings on.

1. Disinfect and dry the puncture site.
2. Gently massage the finger towards the tip to increase blood flow. Avoid going past the first knuckle.
3. Make the incision on the upward-facing side of the fingertip, so that the blood drop sits on top of the finger, to facilitate filling of the cuvette.



4. Apply light pressure towards the fingertip (but not past the first knuckle) until a blood drop appears.
   Wipe away the first 3 drops and make sure there is a free blood flow before filling the cuvette with the fourth drop.
5. Be sure to have a sufficient sized blood drop to fill the cuvette.
   Fill the cuvette completely by touching the corner of the cuvette to the blood drop. Do not refill the cuvette.
   If a cuvette cannot be filled in one continuous process, or if the cuvette contains air bubbles, discard the cuvette and use a new one, repeating steps 4 and 5.
6. Gently wipe off the excess blood on the outside of the cuvette with a gauze pad. Be sure to gently wipe both sides. Do not wipe too close to the open end as this can draw blood out of the cuvette.



Venous Sampling

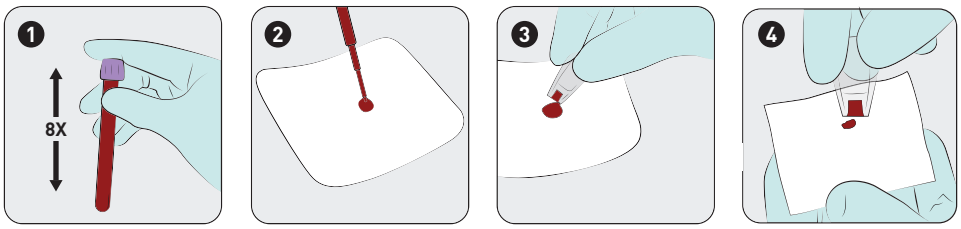
If a venous sample cannot be run immediately, it may be refrigerated up to 72 hours. If the blood is refrigerated, then the blood should be allowed to reach room temperature before testing. K2EDTA or lithium heparin tubes may be used.
With gloved hands, take a McKesson Consult® Hemoglobin Cuvette out of the foil bag and close the bag.

1. Make sure the sample is at room temperature before testing. Mix the tube by gentle inversion at least 8 times.
2. Place a drop of blood on to a hydrophobic surface (e.g. Parafilm) using a commercially available transfer pipette or DIFF-SAFE® Blood Dispenser.
3. Fill the cuvette completely by touching the corner of the cuvette to the blood drop. Do not refill the cuvette.

If a cuvette cannot be filled in one continuous process, or if the cuvette contains air bubbles, discard the cuvette and use a new one, repeating steps 2 and 3.

4. Gently wipe off the excess blood on the outside of the cuvette with a gauze pad.

Be sure to gently wipe both sides. Do not wipe too close to the open end as this can draw blood out of the cuvette.



Warnings and Precautions

Use only completely filled cuvettes for measuring.

Keep filled cuvette horizontal and take the reading within 1 minute of filling.

Specificity & Disease States

The following substances and disease states do not affect the test results.

Potential Interferent	Test Concentration	Potential Interferent	Test Concentration
Bilirubin	20.0 mg/dL	Ferrous Fumarate	30 mg/dL
Cholesterol	500 mg/dL	Iron Dextran	284 mg/dL
Creatinine	5 mg/dL	Folic Acid	1000 ng/dL
Protein	12 mg/dL	Vitamin B12	2500 ng/dL
Triglyceride	1000 mg/dL	Lithium Carbonate	23 mg/dL
Urea	258 mg/dL	Immunoglobin	500 mg/dL
Uric Acid	24 mg/dL	Methyldopa	1.7 mg/dL
Acetaminophen	2 mg/dL	Salicylic Acid	100 mg/dL
Ascorbic Acid	6 mg/dL	5x EDTA	Tube filled to 1/5 volume
Dopamine	0.1 mg/dL	Hypochromia	Disease state
Ibuprofen	55 mg/dL	High WBC Count	Disease state
Tetracycline	1.5 mg/dL	Polycythemia	Disease state
Ferrous Sulfate	22 mg/dL	Sickle Cell	Disease state
Ammonium Ferric Citrate	30 mg/dL		

Expected Values

Population	Age Range	Potential Interferent
Adult Male	≥ 22 years	13.0 – 17.0 g/dL
Adult Female	≥ 22 years	12.0 – 15.0 g/dL
Child/Adolescent	> 2 years to 21 years	11.0 – 15.5 g/dL
Infant	1 month to 2 years	9.4 – 16.5 g/dL

*Reference ranges are based on medically accepted published reference ranges (Dacie and Lewis, Practical Haematology, Twelfth Edition, Elsevier Limited 2017). These ranges are for general guidance only. Each laboratory should establish its own normal range.

Performance Characteristics

a) Within Run and Total Precision: Repeatability and overall reproducibility of three samples was tested over 20 days.

Sample	Mean Hb Concentration	Within-Run (SD, %CV)	Total (SD, %CV)
Level 1	7.99 g/dL	(0.085, 1.06%)	(0.11, 1.38%)
Level 2	12.58 g/dL	(0.11, 0.88%)	(0.14, 1.09%)
Level 3	15.82 g/dL	(0.15, 0.92%)	(0.22, 1.41%)

b) Accuracy: The results of the comparison studies between the McKesson Consult® Hemoglobin Testing System and the predicate device are summarized in the following table. The study was performed across four external sites.

Sample Type	N	Min	Max	Slope	Correlation Coefficient (r)
EDTA	344	4.1g/dL	24.5g/dL	0.9858	0.986
Capillary	363	8.5g/dL	20.1g/dL	0.9903	0.963

McKesson Consult® Hemoglobin Testing System has not been evaluated for capillary samples with hemoglobin values below 8.5 g/dL as such samples are very rarely seen in the primary care setting. It is recommended that patients showing a capillary hemoglobin of less than 8.5 g/dL are referred to a confirmatory laboratory test.

Bibliography
1. Reference and Selected Procedures for the Quantitative Determination of Hemoglobin in Blood; Approved Standard NCCLS Document H15-A.
2. Recommendations for reference method for haemoglobinometry in human blood (ICSH standard 1995) and specifications for international haemiglobincyanide standard (4th edition).

Symbols used

Do not re-use


Use-by date

In vitro diagnostic medical device

Rx Only

Lot number


Caution


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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