The STAT-Site® MHgb Test consists of a plastic card with reagent pads* for determining the concentration of hemoglobin in whole blood between 6 and 21 g/dL. Values below or above this range will be reported as <Lo> or <Hi> respectively.

The STAT-Site® MHgb Test Kit is intended for the quantitative determination of hemoglobin in whole blood using the STAT-Site® MHgb Meter. The STAT-Site® MHgb Test may be used with adults, infants, and children in a physician’s office or other professional point-of-care setting.

**Summary and Principle**

Hemoglobin is the oxygen-carrier pigment and major component of red blood cells. Low hemoglobin levels may indicate anemia, recent hemorrhage or fluid retention. Elevated hemoglobin levels may indicate hemolysis from auto-antibodies or dehydration.

The STAT-Site® MHgb Test is a direct reading of hemoglobin concentration in whole blood between 6 and 21 g/dL. Values below or above this range will be reported as <Lo> or <Hi> respectively.

The STAT-Site® MHgb Test consists of a plastic card with reagent pads* for determining the concentration of hemoglobin. When a drop of whole blood is applied to the top of the STAT-Site® MHgb Test Card, hemolysis occurs, with release of hemoglobin. Sodium nitrite converts the hemoglobin to methemoglobin. Sodium azide then reacts with methemoglobin to form azide-methemoglobin, which is brown in color and is detected at 565 nm with a small portable reflectance analyzer. The amount of the color produced due to azide-methemoglobin is proportional to the concentration of hemoglobin in the sample.

To order call (858) 481-5031

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**Labeling Instructions**

- **For in vitro diagnostic use only:**
- **Do not use with serum or plasma.**
- **Fetal, newborn, or variant hemoglobin samples have not been evaluated with the STAT-Site® MHgb Test.** Children as young as 3 weeks old were evaluated and included in the study.
- **As with all chemical reagents, contact with the skin should be avoided with the reactive areas of the Card.**
- **Handle blood specimens as potentially infectious samples and follow the guidelines established by the Centers for Disease Control (CDC) Atlanta, GA, for blood collection and handling (Document 20 CFR 1910.130).**
- **If the patient is experiencing symptoms which are not consistent with the hemoglobin results obtained AND you have eliminated common procedural errors (described in the STAT-Site® MHgb Meter User’s Guide) as the cause, follow your facility’s policies for treating the symptoms and confirm the blood hemoglobin results with another laboratory method.**
- **Never make significant changes to the patient’s medication program or ignore physical symptoms without consulting a physician.**

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**Intended Use**

The STAT-Site® MHgb Test Kit is intended for the quantitative determination of hemoglobin in whole blood using the STAT-Site® MHgb Meter. The STAT-Site® MHgb Test may be used with adults, infants, and children in a physician’s office or other professional point-of-care setting.

**Availability**

- **Reference No.** 901025
  - **Product Description:** STAT-Site® MHgb Test Cards (100 Test Cards, (4 x 25/Container), and CODE Key)
  - **Availability:**
    - **501000**
      - **STAT-Site® Hemoglobin Controls**
        - 6 x 1.5 mL (3 Low and 3 High level)
    - **909005**
      - **STAT-Site® MHgb Battery Pack**
        - 5 Batteries (approximately 5,000 tests)
    - **909090**
      - **STAT-Site® MHgb Meter** (Battery Included)
    - **202012**
      - 12 µL Transfer Tubes (100 tubes/box)

**Reference**

Test Procedure

The STAT-Site® M™ Hemoglobin System is a rapid, manual, one-step test for the determination of hemoglobin concentration in whole blood. The system is designed for use by healthcare professionals in healthcare settings to monitor patients and assess their need for blood transfusions. The test is intended for use with the STAT-Site® MHgb Meter (Catalog #900900). Additional materials needed include the STAT-Site® MHgb Meter, STAT-Site® M™ Hemoglobin Controls, and STAT-Site® Hemoglobin Test Cards.

Materials Provided
- STAT-Site® M™ Test Cards
- CODE Key

Additional Materials Needed
- Latex Gloves
- Lancets for capillary blood collection
- Biohazardous waste container
- Alcohol swabs and gauze for cleaning puncture site
- STAT-Site® Hemoglobin Controls, Cat. No. 503000
- STAT-Site® M™ Meter (Catalog #900900)

Before You Test: Read the STAT-Site® M™ Meter User’s Guide for complete information on meter setup, maintenance and display messages.

STEP 1. CODE the Meter

If the CODE number on the display matches the CODE number of the Test Card that you are using, GO TO STEP 2 (see Figure 2).

If no CODE number or a CODE number different from the CODE of the Test Card that you are using is displayed on the screen, remove the Test Card Platform by gently pushing up on the tab at the bottom of the Test Card Platform (see Figure 1). Insert the appropriate CODE Key in the opening marked with an arrow (see Figure 4). When the CODE Key has been correctly inserted, the meter will display “CODE,” the coded TEST NAME (i.e., Hgb), and the CODE number. You may then leave the CODE Key in place and replace the Test Card Platform by lining up the top edge (see Figure 3), sliding up, and pressing into place.

STEP 2. Insert the Test Card

The flashing Test Card symbol indicates that you should insert the Test Card. Insert a STAT-Site® M™ Test Card with a CODE number that matches the CODE displayed on the screen at power on.

Slide the edges of the Test Card under the Guide tabs on the Test Card Holder. It is important that you insert the card fully (see Figure 5) to the back. You will feel and hear the Test Card “lock” into place.

When the display shows the Test Type (i.e. Hgb), an unblinking Test Card symbol, and a Flashing Drop symbol, it is time to apply the sample (see Figure 6).

About Obtaining The Fingertip Sample
- Washing hands under warm water greatly increases blood flow and should help to relax the patient.
- The fingertip should provide a free-flowing drop of blood without squeezing the fingertip.
- See Page 1 of this insert for additional information on specimen collection and preparation.

STEP 3. Apply the Sample

Position the drop of blood directly over the center of the Test Card. Carefully lay the drop of blood on the center of the Test Card (see Figure 7). If desired, a Transfer Tube (Catalog #202012) or a device capable of delivering approximately 12µL of blood can be used to collect and apply the sample (see Figure 8) (needed if sample is not a large hanging drop applied directly from a fingertip). After applying the sample to the center of the Test Card, the countdown to test result will begin. The Test may finish before reaching zero.

DISPLAY MESSAGES
(For more information see the meter User’s Guide.)

Lo Result is less than (<) 6 mg/dL
Hi Result is greater than (>21 mg/dL
E-1 Room Temperature is outside of operating range
E-2 Too much sample. Repeat test with new Card.
E-3 Not enough sample. Repeat test with new Card.
E-4 Meter Error Clean meter and retest.
E-5 Card Error Use new card and try again.
E-6 Calibration Error Call Technical Service.
E-8 CODE Key Error Call Technical Service.

TEST PROCEDURE

1) Remove the used Test Card.
2) Press the On/Off button to turn the meter off.
3) Press and hold the Up button to display the last result.
4) Press the On/Off button to turn the meter off.

Analyze the test result through the procedure are displayed.

When the test is completed, the final result is displayed along with the test type and appropriate units (g/dL or mmol/L). The STAT-Site® M™ Test provides a direct reading of hemoglobin concentration in whole blood between 6 and 21 g/dL. Values below or above this range will be reported as <Lo> or <Hi> respectively.

Record your result and remove the Test Card. Remove test card and inspect the bottom of card to confirm even color development. To remove the Test Card, lift very slightly as you slide the Test Card out of the meter. Dispose of the Test Card properly. Note: see meter User’s Guide for instructions on setting up units to display.

Expected Results

Different blood hemoglobin values have been reported in the literature (1,2,3). These ranges are intended to provide a general guideline for interpreting test results.

Adult Males 13-18 g/dL
Adult Females 11-14 g/dL
Infants (<2 yrs.) 10-14 g/dL
Children (2 yrs-teenage) Gradual increase from infant to adult levels.

Due to the wide range of conditions (dietary, geographical, smoking, exercise, recumbency, etc.) which affect reference values (1), it is recommended that each laboratory establish its own expected ranges.

Quality Control

To assure consistent performance of your STAT-Site® M™ System, it is recommended that control material be assayed according to the established quality assurance guidelines for your facility. For this purpose, we recommend STAT-Site® Hemoglobin Controls, Ref. No. 503000. External controls should be tested with each new lot or shipment of test cards, once for each test kit, and as otherwise required by your laboratory’s standard GLP quality control procedures.

Process the controls as you would a patient specimen.

Always test control material when you first use your meter or if you drop your analyzer, or if there is any indication the Test System is not functioning properly.

Replicate testing is recommended to ensure that good technique has been achieved. If results with the quality control material do not fall within the expected range, and the reason cannot be identified, consult the Technical Assistance section of the STAT-Site® M™ User’s Guide before calling Technical Service.

Limitations

- For in vitro diagnostic use.
- Do not use with serum or plasma.
- Fetal, newborn, or variant hemoglobin samples have not been evaluated with STAT-Site® M™. Children as young as 3 weeks old were tested and included in the study.
- The performance characteristics of arterial blood have not been determined.