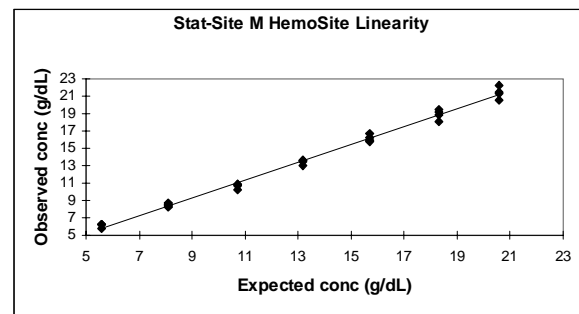


PERFORMANCE CHARACTERISTICS

1. **Linearity** - Linearity was established over the range 5.6 to 20.6 g/dL with venous blood using NCCLS EP6-P guidelines. The linearity regression line is:
 $y = 1.03 + 0.08x$, $R = 0.9968$.



2. **Within Run Precision** - Precision studies with the STAT-Site® M^{Hgb} method using whole blood samples yielded the following mean values, standard deviations (SD), and coefficients of variation (CV%). Values are for testing of 20 replicates on each of four meters (n=80).

Whole Blood Sample	Mean	SD	CV%	n
8.8 g/dL	9.1	0.3	3.5	80
14.3 g/dL	14.1	0.7	4.7	80
17.1 g/dL	16.9	0.8	4.9	80

3. Total Precision –

Total precision studies were conducted with four instruments over 20 days using 2 levels of a whole blood control solution per NCCLS EP5-T2 guidelines. A total of 80 tests were run on each instrument. The resulting total precision estimate ranges over four meters are presented in the following table.

Sample	Mean	SD	Range	CV%	Range	n
Low Control	9.9	0.28	0.41	2.9	4.2	80
Normal Control	13.0	0.37	0.55	2.9	4.2	80

4. Accuracy -

The STAT-Site M^{Hgb} system was evaluated at three clinical sites with a patient population consisting of adults, children, and infants.

The correlation obtained between STAT-Site M^{Hgb} system results and the reference method for venous samples was:
 $N = 103$; $y = 1.00x - 0.84$; $R = 0.96$.

The correlation obtained between STAT-Site M^{Hgb} system results for capillary samples (transfer tube and directly applied samples used) and the reference method (venous for adults, capillary samples for children and infants) was: $N = 236$; $y = 0.98X + 0.16$; $R = 0.93$.

5. Interferences -

Triglycerides (1,005 mg/dL) and bilirubin (20 mg/dL) do not interfere with the STAT-Site® M^{Hgb} Test.

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TECHNICAL SERVICE

For technical assistance with this product, in the U.S., please call our Technical Service Department at (800) 531-5535. Outside of the U.S., please call (830) 249-0772 or FAX +(830) 249-0851.

AVAILABILITY

Reference No.	Product Description
901025	STAT-Site® M ^{Hgb} Test Cards (100 Test Cards, (4 x 25/Container), and CODE Key)
503000	STAT-Site® Hemoglobin Controls 6 x 1.5 mL (3 Low and 3 High level)
900905	STAT-Site® M ^{Hgb} Battery Pack 5 Batteries (approximately 5,000 tests)
900900	STAT-Site® M ^{Hgb} Meter (Battery Included)
202012	12 µL Transfer Tubes (100 tubes/bag)

To order call (858) 481-5031

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Whole Blood Hemoglobin Test Cards



CODE KEY
 CODE meter with
 this key before
 using this pack
 of Test Cards.

REF/Cat.# 901025

Use only with STAT-Site® M^{Hgb} Meter.

For *in vitro* diagnostic use only.

CLIA Category - Waived

INTENDED USE

The STAT-Site® M^{Hgb} Test Kit is intended for the quantitative determination of hemoglobin in whole blood using the STAT-Site® M^{Hgb} Meter. The STAT-Site® M^{Hgb} 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-carrying pigment and main component of red blood cells. Low hemoglobin levels may indicate anemia, recent hemorrhage or fluid retention. Elevated hemoglobin levels may indicate hemoconcentration from polycythemia or dehydration.

The STAT-Site® M^{Hgb} 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.

The STAT-Site® M^{Hgb} 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® M^{Hgb} 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.¹

REAGENTS

Reagents used in STAT-Site® M^{Hgb} Test Cards contain the following ingredients:

Sodium azide	0.6% w/w
Sodium nitrite	0.8% w/w
Inactive ingredients:	98.6% w/w

PRECAUTIONS

- 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^{Hgb}. Children as young as 3 weeks old were tested 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 1910.1030).

* U.S. Patent 5,104,619

- 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® M^{Hgb} 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.

STORAGE AND STABILITY

The **container of Test Cards** can be stored at or below room temperature (28°C/82°F) until the expiration date. This product can be stored in the refrigerator. If stored refrigerated, it is important to bring the package to room temperature before opening and removing Test Cards for testing.

The **desiccant** included with the Test Cards is not part of the test. It is included only to keep the Test Cards dry. To ensure the remaining Test Cards in the container are kept dry, keep the desiccant inside the container and **reseal immediately after removing the needed Test Card**.

Write the date opened on the container label where indicated. Once you open the container, Test Cards must be used within 90 days.

Reseal the container immediately after removing a Test Card. Test Cards should remain in the resealed container, with the desiccant, until being removed for use.

Avoid contact with the reagent pads on either side of the **Test Card** at all times.

Each box of STAT-Site® M^{Hgb} Test Cards comes with one **CODE Key** that must be inserted into the STAT-Site® M^{Hgb} Meter before the test can be run. The **CODE Key** and Test Cards are matched for product type and **CODE** number and are intended to be used with the Test Cards from the same box. The **CODE Key** contains electronic information. Handle with care and keep clean.

Dispose of the CODE Key after using the last Test Card from the kit.

SPECIMEN COLLECTION AND PREPARATION

To perform a blood hemoglobin test with STAT-Site® M^{Hgb} Test Cards on the STAT-Site® M^{Hgb} Meter you will need a drop (approximately 12 µL) of whole blood. Follow NCCLS Guideline H4A4 for obtaining a capillary blood sample.

Capillary blood can be obtained from a skin puncture. The puncture site should be cleaned and dried before pricking the site. Wipe away the first drop with a gauze pad. Allow a large drop to form at the puncture site. Avoid "milking" the finger to improve blood flow.

If using venous whole blood, collection tubes containing EDTA or Heparin as anticoagulants are recommended. Do not use blood collection tubes containing Sodium Fluoride or Oxalate/Fluoride. **Refrigerated blood should be allowed to reach room temperature before testing.**

TEST PROCEDURE

The STAT-Site® M^{Hgb} Test procedure is detailed in this insert and in the STAT-Site® M^{Hgb} Meter User's Guide.

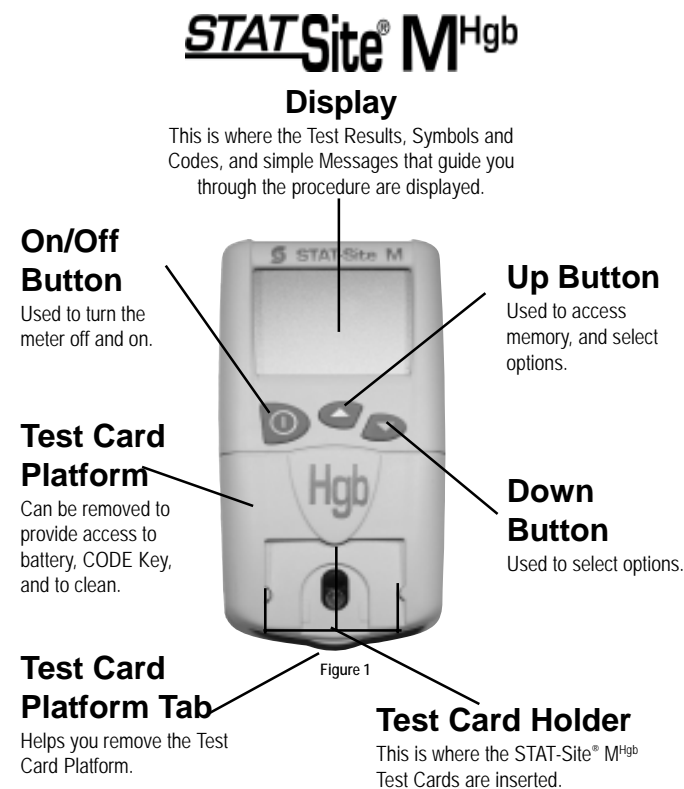
Before You Test: Read the STAT-Site® M^{Hgb} Meter User's Guide for complete information on meter setup, maintenance and display messages.


Materials Provided

- STAT-Site® M^{Hgb} 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^{Hgb} Meter (Catalog #900900).



Press  **to turn on power.** To conserve battery power, the meter will automatically shut off if left idle for more than 2 minutes.

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).

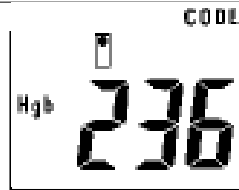


Figure 2


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 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^{Hgb} 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 Fingertick Sample

- Washing hands under warm water greatly increases blood flow and should help to relax the patient.
- The fingertick 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 fingertick). **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.**

CODE THE METER.



Figure 3



Figure 4

INSERT THE TEST CARD.



Figure 5



Figure 6

APPLY THE SAMPLE.



Figure 7

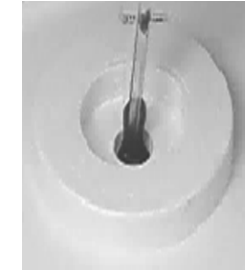


Figure 8
(Optional-
see Step 3)


TEST RESULT

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^{Hgb} 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.*

USING MEMORY

The meter will shut off automatically after two minutes of inactivity. To retrieve the last result from meter memory:

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

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. |

QUALITY CONTROL

To assure consistent performance of your STAT-Site® M^{Hgb} 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^{Hgb} 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^{Hgb}. Children as young as 3 weeks old were tested and included in the study.
- The performance characteristics of arterial blood have not been determined.

EXPECTED RESULTS

Different blood hemoglobin values have been reported in the literature ^(2,3,4,5).

Adult Males	13-18 g/dL
Adult Females	11-14 g/dL
Infants (postnatal)	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 ⁽⁶⁾, it is recommended that each laboratory establish its own expected ranges.