STAT-Site® M Hgb

METHOD: Azide Methemoglobin

SPECIMEN: Whole Blood (Fingerstick or Venous)

ASSAY TEMPERATURE: Room Temperature

CONTROLS: STAT-Site® M Hgb

LIMITATIONS: The STAT-Site ®M Hgb Test is for in vitro diagnostic use only. The test is intended for the quantitative determination of hemoglobin in whole blood. 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.

Do not use with serum or plasma.

Fetal, newborn, or variant hemoglobin samples have not been evaluated with STAT-Site® M Hgb.

The performance characteristics of arterial blood have not been determined.

As with all diagnostic test, all results must be interpreted together with other clinical information available to the physician.

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.

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.

STORAGE:

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 60 days.

Reseal the container immediately after removing a Test Card. Test Cards should remain in the resealed container, with the dessicant, 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.

PROCEDURE: The STAT-Site® M^{Hgb} Test procedure is detailed in this procedure 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 On/Off button 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 Test Card that you are using, GO TO STEP 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.

Insert the appropriate CODE Key in the opening marked with an arrow.

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, 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 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.

About Obtaining The Fingerstick Sample

- Washing hands under warm water greatly increases blood flow and should help to relax the patient.
- The fingerstick should provide a free-flowing drop of blood without squeezing the fingertip.

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. If desired, a GDS® Transfer Tube (Catalog #202012) or a device capable of delivering approximately 12µL of blood can be used to collect and apply the sample (needed if sample is not a large hanging drop applied directly from a fingerstick). 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.

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. 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.

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, it is

recommend that STAT-Site® Hemoglobin Controls, Cat. No. 503000, be used. 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 Trouble Shooting section of the STAT-Site® M^{Hgb} User's Guide before calling Technical Service.

REFERENCE: STAT-Site® M Hgb Instruction For Use, RBR.901025

ASC American Screening Corporation

To Order Please Contact:
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Date of Review/Revision

Reviewed by_____
Lab Director/Supervisor

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