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BLOOD/GLUCOSE REAGENT STRIPSBGRS- 50

TEST PRINCIPLE: Both zones of reagents areas contain the enzymes glucose oxidase, peroxidase and color indicators. When a drop of whole blood sample is applied to the reagent areas, glucose oxidase catalyzes the oxidation of glucose in the blood by oxygen in the atmosphere and oxygen in the blood. D-glucose is oxidized to gluconic acid and hydrogen peroxidase. Hydrogen peroxide oxidizes the indicators in the presence of preoxidase. The intensities of the color formed are proportional to the glucose concentration in the specimen.

The semi-quantitative estimation of glucose is determined by visual comparison of both zones with colors for 20, 40, 80, 120, 180, 240, 400, and 800 mg/dl on the vial label.

SUMMARY: BGRS is used for semi-quantitative visual estimation of whole blood glucose. The reagent test area is attached to an inert plastic strip. The reagent pads consist of two distinct zones, each containing different reagent concentrations, specifically designed to provide optimal sensitivity to glucose levels ranging from 20 mg/dl to 800 mg/dl. BGRS are packaged in a plastic bottle with a screw cap. A drying agent is contained inside the bottle. Each Gluco Check V is stable and ready for use when removed from the vial.

WARNINGS AND PRECAUTIONS:

- Do not use BGRS beyond the expiration date printed on the vial label.
- BGRS are for *in vitro* diagnostic use.
- BGRS must not be cut or altered in any way.

STORAGE AND HANDLING: A new vial of BGRS can be used for 6

months after first opened.

- Store opened and unopened bottles at temperature between 15°- 30°C(59°-86° F) and out of direct sunlight.
- Do not use after expiration date. Deterioration rate will be affected by mishandling of device.
- All unused strips must remain in the original bottle. Transfer to any other container may cause reagent strips to deteriorate and become unreactive.
- Do not remove desiccant(s) from bottle. Replace cap immediately and tightly after removing reagent strip. Do not touch test areas of the reagent strip. Work areas and specimen containers should be free of detergents and other contamination substances.
- Replace the vial cap immediately after removing a test strip.

IMPORTANT: Protection against ambient moisture, light and heat is essential to guard against altered reagent reactivity. Discoloration or darkening of reagent areas may indicate deterioration. If this is evident, or if test results are questionable or inconsistent with expected finding, the following steps are recommended: (1) confirm that the product is within the expiration date shown on the label. (2) check performance against known positive control materials. (3) retest with fresh product.

SPECIMEN COLLECTION AND PREPARATION:

The BGRS is designed specifically for use with fresh capillary whole box taken from the fingertip or earlobe. Venous blood samples may also be used. However venous and capillary blood may differ in glucose concentration by 10% to 15% depending on the time of blood collection after food intake. Always use the bloods sample as close as possible to the time the sample was collected. The blood glucose determination should be performed within 10 minutes of specimen collection to minimize glycolysis. Blood glucose decreases at a rate of 7mg/dl each hour at room temperature (1). Blood specimens obtained in containers with common anticoagulants and preservatives (citrate, heparin, EDTA) may be used. Do not use preservatives that contain fluoride.

MATERIALS PROVIDED:

1. 1 bottle contains 50 strips of BGRS.
2. A visual comparison Color Chart for reading test results is printed on the bottle.

MATERIALS REQUIRED BUT NOT PROVIDED:

1. Cotton ball or rayon balls only. Lancet to prick finger.
2. Alcohol swab
3. Timer or watch capable of measuring accurately in seconds.

PROCEDURE: MUST BE FOLLOWED EXACTLY TO ACHIEVE RELIABLE TEST RESULTS.

1. Carefully place a large drop of whole blood onto the reagent area of BGRS. Do not smear. Simultaneously start a timer.
2. After exactly 30 seconds, using gentle to moderate pressure, wipe off blood with a dry cotton ball once.
3. After waiting an additional 60 seconds (total time elapsed: 1 ½ minutes) match the colors on the test strip to the color scale on the vial label. If the colors developed are darker than 240 mg/dl, wait an additional 60 seconds (total time elapsed: 2 ½ minutes), before comparing the final reaction colors with color scale.

Note: Intermediate values can be estimated when the colors of the strip zones fall between those on the vial label. For

example: If the lower zone on the strip matches the lower zone 80 on the vial, and the upper zone of the strip matches the upper zone 120 on the vial, the estimated value is $(80+120)/2=100$

4. If strip is to be saved for the future reference, the following procedure is recommended.
 - a. Label and date the strip for future reference.
 - b. Store the reacted strip in a BGRS vial, make sure to cap the vial tightly.

1.

QUALITY CONTROL: For best results, performance of reagent strips should be confirmed by testing known negative and positive specimens or controls whenever a new bottle is first opened. Negative and positive specimens or controls may also be randomly hidden in each batch of specimens tested. Each laboratory should establish its own goals for adequate standards of performance, and should question handling and testing procedures if these standards are not met.

RESULTS: Results with BGRS are obtained in clinically meaningful units directly from the **Color Chart** comparison. The color blocks represent nominal values; actual values will vary around the nominal values. NO calculations are required.

CAUTION: If you get unusually high or unusually low-test results repeat the test. Diagnosis and/or treatment decisions should not be based on only one result. Consult your health care professional for changes made in your diabetes control plan.

LIMITATIONS OF PROCEDURE:

BGRS is designed for use with fresh whole blood only. Do not use preservatives that contain fluoride. Do not use serum or plasma. Extremes in hematocrit can affect the test results. High hematocrit (above 60%) cause low results. Very low hematocrit (below 30%) can cause high results. Reducing substances such as uric acid, ascorbic acid, etc. (when occurring in physiological blood concentrations) do not interfere with the results. However, abnormally high concentration in blood will cause low results.

Clinical investigations with neonates have not been completed. Therefore, BGRS is not recommended for use with neonatal blood specimens.

The result of specimens with elevated cholesterol and/or triglycerides should be interpreted with caution.

EXPECTED VALUES:

Target blood glucose levels associated with well-controlled diabetes are as follows: (2)

Fasting: 60-130 mg/dl (3.3 to 7.2 mmole/L)

After meals (1 hour): Less than 180 mg/dl (10.0 mmole/L)

The target blood glucose values appropriate for you should be established by your health care professional.

PERFORMANCE CHARACTERISTICS:

The performance characteristics of BGRS have been determined both in the laboratory and the clinical tests.

Parameters of importance to the users are sensitivity, accuracy, precision and stability.

Generally the tests are specific to the D-glucose with the exception of interference's listed previously. The stability data

has been developed by testing a various temperature for two years.

Due to differences in individual color perception, precision is difficult to establish in a visual test. Therefore, it is recommended that each user develop his or her own standards for performance.

Accuracy: BGRS provide semi-quantitative results. Several comparison studies have been performed using BGRS with Yellow Springs Instrument Model 23a Gluco Analyzer as the reference procedure. The results of BGRS readings were found to be at least 95% of the time to be within one color block at 80, 120, 180,240, and 400 mg/dl color blocks. The total numbers of samples tested were 235. Because of difficulties in obtaining natural samples at the extremes of glucose range, a lesser number of contrived samples were tested covering the range of 20, 40, and 800mg/dl color blocks. Similar results to those mentioned above.

Note: Performance of the BGRS interpreted by the individual operator may differ from the above example. The above results represent the performance of properly trained, experienced operators.

COMPARATIVE METHOD:

Comparative methods measuring serum or plasma glucose will generally give results, which are 10% to 15% higher than the whole blood glucose result (3)

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