CHEMCARD™ SYSTEMS

A Complete 3 Minute Whole Blood Screening Test for Identification of ABNORMAL PLASMA GLUCOSE LEVELS

INTENDED USE

The Chemcard™ Glucose Test is intended for use as a rapid, *in vitro* method for early identification of abnormal fasting plasma glucose concentration which can be a sign of diabetes or other medical problems. The Chemcard™ provides a preliminary, semi-quantitative result using fingerstick blood as the test specimen. Any abnormal result obtained using the Chemcard™ should be verified using a quantitative method.

The Chemcard™ Glucose Test is not intended for use with individuals who are known to be diabetic or pregnant.

SUMMARY

It is estimated that 3.2 percent of the adult population in the U.S., between the ages of 20 and 74, suffers from undiagnosed Diabetes Mellitus.[1] Diagnosis often occurs after the onset of severe and often irreversible complications. The Chemcard™ Glucose Test is a highly effective test for use in glycemic screening and early identification of generally asymptomatic individuals, for abnormal blood glucose levels often associated with diabetes or other carbohydrate metabolic disorders. These individuals can then be referred for more definitive diagnostic testing, often before the onset of complications.

Chemcard™ Glucose Test is a rapid, convenient, cost effective test system which is effective in screening for abnormal blood glucose concentrations. Each test card is a self contained assay that combines proven detection methods with a patented whole blood separator for unsurpassed convenience and simplicity.

PRINCIPLE

The Chemcard™ Glucose Test is a disposable device which uses a unique blood cell separator coupled with a dry phase enzymatic chemistry to provide a semi-quantitative measurement of fasting blood glucose concentration, from a single, unmeasured drop of fingerstick blood. The separator removes cellular constituents from the specimen and delivers a volumetric sample of plasma to the detection chemistry. Results are visually interpreted by comparing the color change in the reagent pad with an integral color standard. The glucose detection method is based on that described by Keston;[2] Comer[3] and Free[4] but uses tetramethylbenzidine (TMB) in the chromogenic complex as follows:

$$\text{d-glucose} + O_2 + H_2O \xrightarrow{\text{GLUCOSE OXIDASE}} \text{d-glucono-1,5 lactone} + H_2O_2$$

$$H_2O_2 + \text{chromogen} \xrightarrow{\text{PEROXIDASE}} \text{dye} + H_2O$$

COMPOSITION

Glucose Oxidase (1.1.3.4)	8.40% w/w
Peroxidase (1.11.1.7)	6.70% w/w
pH Buffers	34.30% w/w
Tetramethylbenzidine	47.50% w/w
Non-reactive ingredients	3.10% w/w

STORAGE AND STABILITY

Chemcard™ Glucose Tests should be stored at room temperature, not to exceed 86°F (30°C). Refrigeration is not required. Test cards may be used until the expiration date appearing on each package. Any packages that appear to have a broken seal should not be used for testing. Once the foil package is opened, the test should be used immediately.

MATERIALS PROVIDED

Each individual test package contains a single test card along with a sterile lancet.

MATERIALS NEEDED BUT NOT PROVIDED

Clean Dry Tissue
Timing Device (3 minute)

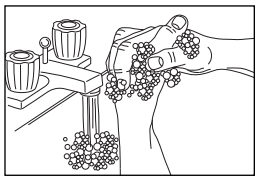
PRECAUTIONS

- For *in vitro* diagnostic use only.
- Never use a test beyond the expiration date specified on the test package.
- The individual to be tested should fast for 6 to 12 hours before specimen collection.
- The Chemcard™ Glucose Test is intended for use with fresh, capillary blood only.
- The Chemcard™ Glucose Test is not intended for use to monitor diabetic patients.
- Not recommended for use in children under the age of 2 years old.
- Not recommended for use with patients known to be pregnant.

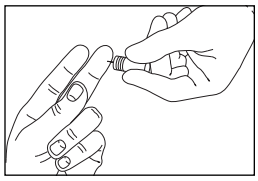
PROCEDURE

1 The individual to be tested must FAST for 6 to 12 hours before testing. No food or drink (other than water) should be consumed during the fasting period.

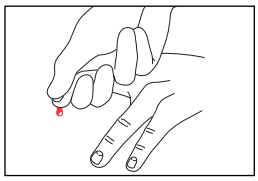
2 CLEAN FINGERTIP area thoroughly using soap and warm water. Dry thoroughly.



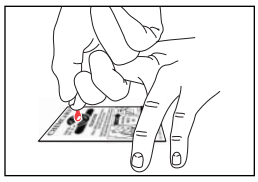
3 PRICK FINGER with lancet. Discard the first drop of blood by wiping on clean dry tissue.



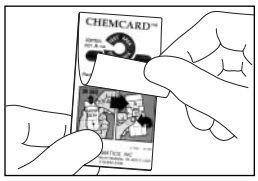
4 Squeeze finger to obtain a LARGE DROP of blood, enough to hang down from the fingertip.



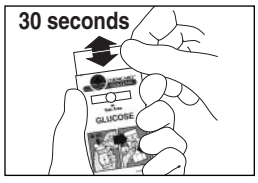
5 PLACE BLOOD ON TEST AREA: Gently bring the lower part of the blood drop into contact with the test area. Verify that “Control Dot A” changes color (if not, add another drop of blood). START TIMER.



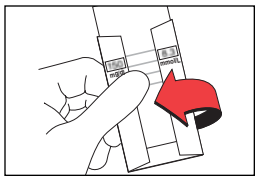
6 After 3 MINUTES, PEEL OFF THE “TAB” to remove the top layer of the test card and discard.



7 COMPARE COLOR of the “Test Area” with the color in the adjacent windows by sliding inner card up and down. Find the closest matching color within 30 seconds. Note: The “Test Area” will begin to fade within 3–5 minutes.



8 TURN THE TEST CARD OVER. The plasma glucose concentration appears in the windows on the back side in both mg/dl and mmol/l.



RESULTS

Semi-quantitative plasma glucose concentration values are obtained by visual comparison of the reagent pad with the sliding color chart, then turning the test card over and reading the glucose level from the windows on the back. A reagent pad which appears lighter than the 50 mg/dl color block should be interpreted as being less than 50 mg/dl (2.8 mmol/l). A reagent pad which appears darker than the 150+ color block should be interpreted as being higher than 150 mg/dl (8.3 mmol/l).

Chemcard results of 50 mg/dl (2.8 mmol/l) or less are considered abnormally low. Chemcard results of 125 mg/dl (6.9 mmol/l) or higher are considered abnormally high for a fasting individual. Any abnormal result obtained using the Chemcard™ should be verified using a quantitative method.

LIMITATIONS OF PROCEDURE

- Failure to fast prior to testing may affect results.
- Not for use to test patients under the age of two years.
- Not for use with patients who are known to be pregnant.
- Since the effective range of the Chemcard™ is 50 to 150 mg/dl, this test should not be used for monitoring of known diabetics or for instituting or modifying drug therapy.
- All abnormal results obtained using this test should be verified using quantitative diagnostic methods.
- The Chemcard™ is designed for use with free flowing, capillary blood, usually obtained from a fingerstick. Other specimens should not be used with this test.

EXPECTED RESULTS

Normal values for fasting blood glucose concentration are widely reported to be in the 60 to 100 mg/dl range.[1, 5] The American Diabetes Association[7] defines normoglycemia as fasting plasma glucose levels <110 mg/dl (6.1 mmol/l) and states that fasting plasma glucose levels ≥126 mg/dl (7.0 mmol/l) are indications for retesting.

The Chemcard™ Glucose Test is designed to implement the American Diabetes Association's decision level strategy[7] for screening. Semi-quantitative interpretation is visually accomplished by matching colors with any of five color blocks, each representing a range of values with medians at 50, 75, 100, 125 and 150+ mg/dl. Chemcard™ results of 125 or 150+ are considered abnormally high and are recommended for follow-up diagnostic testing. Readings of 50 mg/dl or lower are considered abnormally low and should also be followed with additional testing.

CALIBRATION AND QUALITY CONTROL

The Chemcard™ Glucose Test is calibrated at the time of manufacture and requires no calibration by the user. The Chemcard™ Glucose Test has been categorized, by level of complexity, as a WAIVED TEST in accordance with regulations codified in 42 CFR 493.17, implementing the Clinical Laboratory Improvement Amendments of 1988 (CLIA 88). Each site should establish standards of performance in accordance with good laboratory practice.

Each test card employs two design features which allow the user to verify that the test has worked properly. "Control Dot A" changes color allowing the user to verify a sufficient blood volume (>20 µL) has been applied to the test area. The presence of a green or blue color in the reagent pad indicates that the detection chemistry is working properly. A reagent pad that is white or cream colored indicates an invalid test result.

PERFORMANCE CHARACTERISTICS

Measuring Range

The Chemcard™ Glucose Test has an effective measurement range of 50 to 150 mg/dl.

Correlation

The accuracy of the Chemcard™ Glucose Test has been demonstrated by determining correlation with a Kodak Ektachem 700® clinical analyzer. Chemcard™ results, obtained by a nurse, were paired with results obtained for each of 197* patients, whose glucose levels were within the measuring range of the Chemcard,™ using the Ektachem® 700. The following least-squares regression equation was obtained:

$y = 1.02x - 2.11$ (Chemcard on y axis)

correlation coefficient $r = 0.94$

*An additional 33 patients had plasma glucose levels outside the measuring range of the Chemcard™ (30 above, 3 below). All 33 were correctly read on the Chemcard™ as being below 50 mg/dl or above 150 mg/dl.

Classification Accuracy

Studies were conducted at five separate sites to evaluate the ability of an untrained individual to perform the test and interpret their result as being either normal or abnormal. In this study, 90 of 91 subjects correctly classified blood glucose level as normal or abnormally high. By computing the 95 percent confidence interval for the binomial distribution,[6] we find that the Chemcard™ exhibited a classification accuracy of greater than 94 percent in this study.

Precision

Within-lot precision of two different lots of Chemcard™ tests was determined by running 20 tests with whole blood at each of three different glucose levels across the measuring range of the Chemcard.™ Color development on the Chemcard™ was quantitated using colorimetric densitometry and optical densities converted to glucose concentration using a standard curve. Average, standard deviation, percent coefficient of variation and 95 percent confidence intervals were computed as follows:

Lot 1

57 mg/dl	76 mg/dl	125 mg/dl
Avg.: 54.9 mg/dl	Avg.: 78.9 mg/dl	Avg.: 124.0 mg/dl
s.d.: 1.9 mg/dl	s.d.: 2.4 mg/dl	s.d.: 4.8 mg/dl
CV: 3.5%	CV: 3.0%	CV: 3.9%
95% CI: 50.5–59.3 mg/dl	95% CI: 73.5–84.4 mg/dl	95% CI: 113.1–135.3 mg/dl

Lot 2

58 mg/dl	79 mg/dl	120 mg/dl
Avg.: 56.5 mg/dl	Avg.: 81.3 mg/dl	Avg.: 119.2 mg/dl
s.d.: 2.4 mg/dl	s.d.: 1.8 mg/dl	s.d.: 2.1 mg/dl
CV: 4.2%	CV: 2.2%	CV: 1.8%
95% CI: 51.1–61.9 mg/dl	95% CI: 77.1–85.5 mg/dl	95% CI: 114.1–124.0 mg/dl

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