

**510(k) SUBSTANTIAL EQUIVALENCE DETERMINATION
DECISION SUMMARY
ASSAY ONLY TEMPLATE**

A. 510(k) Number: K080003

B. Purpose for Submission: New submission

C. Measurand: G6PD

D. Type of Test: Qualitative

E. Applicant: Binax, Inc., d/b/a Inverness Medical

F. Proprietary and Established Names: BinaxNOW[®] G6PD

G. Regulatory Information:

1. Regulation section: 864.7360
2. Classification: II
3. Product code: JBF
4. Panel: Hematology (81)

H. Intended Use:

1. Intended use(s):

The BinaxNOW[®] G6PD (Glucose-6-Phosphate Dehydrogenase) Test is an *in vitro* enzyme chromatographic test for the qualitative detection of G6PD enzyme activity in human venous whole blood, collected in heparin or ethylenediaminetetraacetic acid (EDTA). The BinaxNOW[®] G6PD Test is a visual screening test used for differentiating normal from deficient G6PD activity levels in whole blood and is intended to aid in the identification of people with G6PD deficiency. Samples which generate deficient results should be assayed using a quantitative G6PD test method to verify the deficiency.

2. Indication(s) for use: Same as Intended Use
3. Special conditions for use statement(s): N/A
4. Special instrument requirements: N/A

I. Device Description:

The BinaxNOW® G6PD test kit consists of:

- Test devices: a cardboard, book-shaped, hinged test device containing the test strip
- Reagent A: Tris buffer containing detergent and red dye
- Sample preparation vials: used to mix reagent A with whole blood samples prior to transfer to the test devices

J. Substantial Equivalence Information:

1. Predicate device name(s): Trinity Biotech Glucose-6-Phosphate Dehydrogenase Deficiency reagent set
2. Predicate K number(s): K933934
3. Comparison with predicate:

Similarities		
Item	Device	Predicate
Intended Use	The BinaxNOW® G6PD Test is an <i>in vitro</i> enzyme chromatographic test for the qualitative detection of G6PD enzyme activity in human venous whole blood, collected in heparin or EDTA. The BinaxNOW® G6PD Test is a visual screening test used for differentiating normal from deficient G6PD activity levels in whole blood and is intended to aid in the identification of people with G6PD deficiency. Samples which generate deficient results should be assayed using a quantitative G6PD test method to verify the deficiency.	Trinity Biotech G6PD reagents are for qualitative, visual fluorescence screening of G-6-PDH in whole blood. Samples which have been determined deficient or intermediate should be assayed by a quantitative G-6-DPH method such as Trinity Biotech Procedure No. 345-UV

Differences		
Item	Device	Predicate
Sample type	Heparin or EDTA whole blood	Heparin, EDTA, or ACD whole blood
Quality Control	Pool of heparin or EDTA whole blood G6PD normal and G6PD deficient samples	Three separate levels of commercial control
Technology	Lateral flow, enzyme chromatographic assay	Liquid system, fluorescing assay

Differences		
Item	Device	Predicate
Interference	Not affected by the presence of lactic acid, lactate dehydrogenase, glucose, conjugated and unconjugated bilirubin, triglyceride, cholesterol, and copper sulfate at concentrations above normal levels. Abnormally low and high Hematocrit levels affect the test performance.	Leukocytosis, thrombocytosis, and reticulocytosis may cause some interference.

K. Standard/Guidance Document Referenced (if applicable): N/A

L. Test Principle:

The BinaxNOW® G6PD Test uses lateral flow, enzymatic chromatographic technology. It is a qualitative test based on for the visual determination of G6PD in whole blood. The test consists of a test strip comprised of 2 pads: a white sample pad and a reaction pad. The reaction pad contains reagents necessary for the G6PD reaction and the subsequent reduction of a nitro blue tetrazolium dye into its concomitant formazan product. The change of color on the strip indicates the sample is normal in G6PD enzyme activity. The sample is presumed to be deficient if there is no change in color.

M. Performance Characteristics (if/when applicable):

1. Analytical performance:

a. *Precision/Reproducibility:*

- Inter-assay precision study: One lot of reagent was used in the study to evaluate two different whole blood samples (normal and deficient) collected in heparin and EDTA tubes. Each sample was run in duplicate over 10 days by a single operator. Results generated from both heparin and EDTA samples were correct 100% of the time.
- Reproducibility: The study was conducted at 3 sites, two operators at each site over 3 days using a different lot of reagent to evaluate blood samples with varying levels of G6PD activity. 125 test results generated 98.4% agreement with expected results.

b. *Linearity/assay reportable range:* N/A

c. *Traceability, Stability, Expected values (controls, calibrators, or methods):* N/A

d. *Detection limit:* N/A

e. *Analytical specificity:*

- Interference study was conducted using whole blood samples with varying levels of G6PD. The effects on the BinaxNOW® G6PD Test on lactic acid, lactate dehydrogenase, glucose, conjugated and unconjugated bilirubin, triglyceride, cholesterol, and copper sulfate at concentrations above normal levels were evaluated. The BinaxNOW® G6PD Test generated expected results.
- The BinaxNOW® G6PD Test performance was also evaluated on low (17-18%), normal (35-46%), and high (54-65%) hematocrit blood samples with deficient and normal G6PD. Test results demonstrate that abnormally low and high hematocrit levels affect test performance.

f. *Assay cut-off:* N/A

2. Comparison studies:

a. *Method comparison with predicate device:*

World Health Organization defines severe G6PD deficiency activity is < 10% of a normal activity level and moderate G6PD deficiency is 10-60% of a normal enzyme activity of the conventional reference range. Binax developed its test such that samples with < 2.0 U/gHb enzyme activity will generate deficient test results, and majority of samples with activity levels between 2 and 4.0 U/gHb will generate deficient test results.

The method comparison study includes 246 subjects. Both heparin and EDTA whole blood samples were evaluated on the BinaxNOW® test and compared to a quantitative G6PD test, which spanned the range from 0.0 – 15.1 U/gHb. All of the samples that generated a result ≤ 2.0 U/gHb on the comparative method generated deficient results on the BinaxNOW® G6PD test. The comparative method cutoff value of 4.2 U/gHb was used in the percent agreement analysis for both heparin and EDTA samples, the results are as follows:

% Agreement with heparin samples:

		Comparative Deficient	Method → Normal
BinaxNOW Test →	Deficient	48	4
	Normal	1	190

- Deficient result: percent agreement = $48 / 49 = 98.0\%$ (CI = 89.3 – 99.6%)
- Normal result: percent agreement = $190 / 194 = 97.9\%$ (CI = 94.8 – 99.2%)

- Overall: percent agreement = $238 / 243^* = 97.9\%$ (CI = 95.3 – 99.1%)
 (* 3 invalid tests: sample front fails to completely cover the top of the reaction pad)

% Agreement with EDTA samples:

		Comparative Deficient	Method → Normal
BinaxNOW	Deficient	49	5
Test →	Normal	1	191

- Deficient result: percent agreement = $49 / 50 = 98.0\%$ (CI = 89.5 – 99.6%)
- Normal result: percent agreement = $191 / 196 = 97.4\%$ (CI = 94.2 – 98.9%)
- Overall: percent agreement = $240 / 246 = 97.6\%$ (CI = 94.8 – 98.9%)

b. *Matrix comparison:* BinaxNOW[®] G6PD test results on the heparin samples were compared to the test results on the EDTA samples. The percent agreement was 99% (240/243).

3. Clinical studies:

a. *Clinical Sensitivity:* N/A

b. *Clinical specificity:* N/A

c. Other clinical supportive data (when a. and b. are not applicable): N/A

4. Clinical cut-off: N/A

5. Expected values/Reference range: The package insert provides color graphics depicting deficient and normal results.

N. Proposed Labeling: The labeling is sufficient and it satisfies the requirements of 21 CFR Part 809.10.

O. Conclusion: The submitted information in this premarket notification is complete and supports a substantial equivalence decision.

