

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

A. 510(k) Number: k041427

B. Purpose for Submission: Notification of intent to market 3 assays: SpotChem EZ Glucose, fructosamine, and Aspartate Amino Transferase (AST)

C. Measurand: Glucose, Fructosamine, Aspartate Amino Transferase (AST)

D. Type of Test: quantitative, colorimetric

E. Applicant: Polymedco, Inc.

F. Proprietary and Established Names:

Spotchem EZ Glucose
Spotchem EZ Fructosamine
Spotchem EZ AST

G. Regulatory Information:

1. Regulation section:

Glucose 21 CFR 862.1175 – Glucose Test System
Fructosamine 21 CFR 864.7470 – Glycosylated Hemoglobin Assay
AST 21 CFR 862.1100 – Aspartate Amino Transferase (AST/SGOT) Test System

2. Classification:

Glucose – Class II
Fructosamine – Class II
AST – Class II

3. Product code:

Glucose – CGA, Glucose Oxidase, Glucose
Fructosamine – LCP, Assay, Glycosylated Hemoglobin
AST – CIS, Hydrazone Colorimetry, AST/SGOT

4. Panel:

Glucose, AST - Chemistry 75
Fructosamine – Immunology 82

H. Intended Use:

1. Intended use(s): The SpotChem EZ Glucose, Fructosamine and AST test systems

are in vitro diagnostic procedures intended to measure Glucose, Fructosamine, and AST quantitatively in human serum and plasma on the SpotChem EZ Analyzer

2. Indication(s) for use: Glucose measurements are used in the diagnosis and treatment of carbohydrate metabolism disorders, including diabetes mellitus, neonatal hypoglycemia and idiopathic glycemia, and of pancreatic isle cell carcinoma.

Fructosamine measurements are used to assess the level of control of a patient's diabetes and to determine the proper insulin dosage for a patient. Elevated levels of fructosamine indicate uncontrolled diabetes in a patient.

AST measurements are used in the diagnosis and treatment of certain liver and heart diseases.

3. Special conditions for use statement(s): for prescription use only

4. Special instrument requirements: these assays are intended for use on the previously cleared SpotChem EZ analyzer (k040332).

I. Device Description: The Polymedco, Inc SPOTCHEM EZ Glucose, Fructosamine and AST assays are in vitro diagnostic procedures intended to measure Glucose, Fructosamine, and AST quantitatively in human serum and plasma on the SpotChem EZ Analyzer.

The device is composed of plastic strips to which a multilayered test field is affixed. The layers consist of a sample retention layer, a layer containing the reagents and a support layer.

A fixed amount of serum or plasma is placed on the test field of the reagent strip. The plasma or serum spreads in a uniform fashion across the entire surface of the sample retention layer. The serum or plasma then permeates into the reagent layer where the reaction is initiated.

J. Substantial Equivalence Information:

1. Predicate device name(s):
Bayer Glucose Hexokinase II Assay for Advia 1650
Roche COBAS MIRA Fructosamine Assay
Bayer Aspartate Aminotransferase Assay for Advia 1650
2. Predicate 510(k) number(s):
k011963
k003120
k990346

3. Comparison with predicate:

| | Glucose | Fructosamine | AST |
|-----------------------------------|--|--|--|
| Predicate Methodology | hexokinase | colorimetric enzyme-based | Colorimetric enzyme-based |
| Test Methodology | Glucose oxidase | colorimetric enzyme-based | Colorimetric enzyme-based |
| Predicate Reagent Storage | 2-8 °C | 2-8 °C | 2-8 °C |
| Test Reagent Storage | 2-8 °C | 2-8 °C | 2-8 °C |
| Predicate Sample types | Serum/Plasma, Whole blood | Serum/Plasma, Whole blood | Serum/Plasma, Whole blood |
| Test Sample Types | Serum/Plasma, Whole blood | Serum/Plasma, Whole blood | Serum/Plasma, Whole blood |
| Predicate Controls | Recommended | Recommended | Recommended |
| Test Controls | Recommended | Recommended | Recommended |
| Correlation with Predicate device | N = 116. Range spanned from 49 – 372 mg/dL. The regression equation was $y = 0.9905x - 0.5654$ and $r = 0.985$ | N = 76. Range spanned from 198 – 722 umol/L. The regression equation was $y = 0.840x - 21.182$ and $r = 0.972$ | N = 100. Range spanned from 10 - 145 IU/L. The regression equation was $y = 0.93x - 0.658$ and $r = 0.978$. |

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

L. Test Principle:

Glucose in the sample is oxidized in a concentration dependent manner by glucose oxidase found in the reagent layer. The glucose oxidase oxidizes the glucose with the quantitative production of hydrogen peroxide. The hydrogen peroxide oxidizes and condenses 4-aminoantipyrine and 1-naphthol-3,6-disulfonic acid disodium by the catalytic action of peroxidase to form a reddish-purple color. During the reaction, the reagent layer is completely dissolved and is absorbed by the sample-retention layer. These two layers thus form a single detection layer. The intensity of the reddish-purple color, as determined by reflectance spectrophotometry, is proportional to the concentration of glucose in the sample.

Fructosamine in the sample reacts with 2-(4-iodophenyl)-3-(4-nitrophenyl)-5-phenyl-2H tetrazolium chloride to generate a red color. During the reaction, the reagent layer is completely dissolved and is absorbed by the sample-retention layer. These two layers thus form a single detection layer. During the reaction, the reagent layer is completely dissolved and is absorbed by the sample-retention layer. These two layers thus form a single detection layer. The rate at which the red color is generated in the detection layer is proportional to the concentration of fructosamine in the sample.

AST in the sample catalyzes the transfer of the amino group of L-aspartic to alpha-ketoglutaric acid to produce L-glutamic acid and oxalacetic acid. Oxalacetic acid is decarboxylated by oxalic acid decarboxylase to produce pyruvic acid. The pyruvic acid, in the presence of magnesium ion and thiamine pyrophosphoric acid, is oxidized by the catalytic action of pyruvate oxidase to produce hydrogen peroxide. The hydrogen peroxide oxidizes and condenses 4-aminoantipyrine and N-ethyl-N-(2-hydroxy-3-sulfopropyl)-3,5-dimethoxyaniline by the catalytic action of peroxidase to form a blue color. During the reaction, the reagent layer is completely dissolved and is absorbed by the sample-retention layer. These two layers thus form a single detection layer. The rate at which the blue color is generated in the detection layer is proportional to the AST activity in the sample.

M. Performance Characteristics (if/when applicable):

1. Analytical performance:

a. *Precision/Reproducibility:* Intra-assay precision was assessed by assaying three samples twenty times in one run. Inter-assay precision was assessed by assaying three samples in duplicate in ten runs over ten days. The results are presented in the tables below:

Intra Assay Precision on Spot Chem Analyzer.

| Analyzer Poly Chem | | Level 1 | Level 2 | Level 3 |
|--------------------|---------------|---------|---------|---------|
| Glucose | n | 20 | 20 | 20 |
| | Mean (mg/dL) | 64 | 107 | 267 |
| | SD | 0.73 | 2.49 | 8.71 |
| | %CV | 1.14 | 2.32 | 3.26 |
| Fructosamine | Mean (umol/L) | 202 | 485 | 563 |
| | SD | 9.96 | 22.19 | 21.74 |
| | %CV | 4.93 | 4.58 | 3.86 |
| AST | Mean (IU/L) | 24.27 | 105.95 | 188.5 |
| | SD | 0.967 | 3.694 | 6.525 |
| | %CV | 3.99 | 3.44 | 3.46 |

Inter Assay Precision on Poly-Chem Analyzer.

| Analyzer Poly Chem | | Level 1 | Level 2 | Level 3 |
|--------------------|---------------|---------|---------|---------|
| Glucose | Days | 10 | 10 | 10 |
| | n | 20 | 20 | 20 |
| | Mean (mg/dL) | 63 | 106 | 9.46 |
| | SD | 1.52 | 3.91 | 7.46 |
| | %CV | 2.42 | 3.69 | 3.61 |
| Fructosamine | Mean (umol/L) | 206 | 483 | 578 |
| | SD | 9.21 | 27.66 | 16.86 |
| | %CV | 4.46 | 5.72 | 2.92 |
| AST | Mean (IU/L) | 24.75 | 106.95 | 180.35 |
| | SD | 2.173 | 5.790 | 6.226 |
| | %CV | 8.78 | 5.41 | 3.45 |

- b. *Linearity/assay reportable range:* The linearity was assessed by assaying serial dilutions. The linearity claim is based on a percent deviation of $\leq 5\%$ at the two highest concentrations. The results obtained were as follows: Glucose up to 416 mg/dL, Fructosamine up to 617 umol/L, AST up to 859 IU/L
- c. *Traceability, Stability, Expected values (controls, calibrators, or methods):* None provided.
- d. *Detection limit:* Functional sensitivity was assessed by diluting a pool of 10 different concentrations below the lower limit of the analyte range. Three runs were performed over three different days on the SpotChem EZ analyzer. The mean, standard deviation and percent coefficient of variation was calculated for the ten replicates of each dilution. The functional sensitivity of the test was defined as the value of the dilution where the CV is approximately 20% (taking into consideration that the actual mean was within $\pm 10\%$ of the expected target) It was determined that functional sensitivity was 27 mg/dL with a CV reported at 1.3% for Glucose, 102.06 umol/L with a CV of 1.99% for Fructosamine, and 10 IU/L with a CV reported at 0.6% for AST.
- e. *Analytical specificity:* Studies were performed to assess common or known substances that could interfere with the method. A summary of the data or of known interferences appears for the common interferences:

| | Glucose | Fructosamine | AST |
|---------------|---|---|---|
| Sample | Highest Level Tested with No Interference | Highest Level Tested with No Interference | Highest Level Tested with No Interference |
| Hemoglobin | 150 mg/dL | 350 mg/dL | 100 mg/dL |
| Bilirubin | 9 mg/dL | 3.0 mg/dL | 1.5 mg/dL |
| Triglycerides | 200 mg/dL | 350 mg/dL | 200 mg/dL |

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

2. Comparison studies:

a. *Method comparison with predicate device:*

Clinical correlation studies were performed comparing the Glucose and AST results generated on the Spotchem analyzer against results from the Bayer Advia 1650 using serum and plasma samples, and on Fructosamine results generated on the Spotchem analyzer against results from the Roche COBAS MIRA using serum and plasma samples. The correlations were as follows:
 Glucose $y = 0.9905x - 0.5654$, $r = 0.985$, $n = 116$, range = 49-372 mg/dL
 Fructosamine $y = 0.84x - 21.18$, $r = 0.97$, $n = 76$, range = 198-722 umol/L
 AST $y = 0.927x - 0.6577$, $r = 0.978$, $n = 100$, range = 10-145 IU/L

b. Matrix comparison:

Clinical correlation studies were performed comparing the Glucose and AST results generated against whole blood samples when performed on the Spotchem analyzer. The correlations were as follows:

Glucose $y = 0.9909x + 0.3761$, $r = 0.999$, $n = 31$, range = 65-311 mg/dL

Fructosamine $y = 1.020x - 0.615$, $r = 0.9915$, $n = 42$, range = 35-414 umol/L

AST $y = 0.999x + 0.864$, $r = 0.999$, $n = 33$, range = 10 – 545 IU/L

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 following literature reference values were provided;

Glucose¹ - normal = fasting 70-105 mg/dL

Fructosamine² - adult = 205-285 umol/L, child = 5% below adult levels

AST³ - males = 15-40 U/L, females = 13-35 U/L

1. American Diabetes Association; Diabetes Care, Volume 24 Supplement 1, Clinical practice Recommendations (2001).

2. Burtis, C.A. and Ashwood, E.R. Tietz Textbook of Clinical Chemistry, Second Edition, W.B. Saunders Company, 2189.

3. Siest, G.; et. al. Clin Chem **1975**, *21*, 1077-1087.

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.