

**510(k) SUBSTANTIAL EQUIVALENCE DETERMINATION
DECISION SUMMARY
DEVICE AND INSTRUMENT TEMPLATE**

A. 510(k) Number:

k040332

B. Purpose for Submission:

To obtain 510(k) clearance in a Physician's Office Laboratory (POL) setting.

C. Analyte:

Alanine amino transferase (ALT/SGPT) test system.

D. Type of Test:

Quantitative

E. Applicant:

POLYMEDCO, INC.

F. Proprietary and Established Names:

POLYMEDCO SPOTCHEM EZ CHEMISTRY ANALYZER

G. Regulatory Information:

1. Regulation section:

21CFR §862.1030 -Alanine amino transferase (ALT/SGPT) test system.

21CFR §862.2170 -Micro chemistry analyzer for clinical use.

2. Classification:

Class 1 meets the limitations of exemptions 862.9 (c) (9)

3. Product Code:

CKA, JJF

4. Panel:

Chemistry (75)

H. Intended Use:

1. Indication(s) for use:

The Polymedco SpotChem EX and ALT test system is an in vitro diagnostic instrument and procedure intended to measure the enzyme alanine amino transferase or ALT (also known as a serum glutamic pyruvic transaminase of SGPT) in serum plasma and whole blood. ALT measurements are used in the diagnosis and treatment of certain liver diseases (e.g., viral hepatitis and cirrhosis) and heart diseases.

2. Special condition for use statement(s):

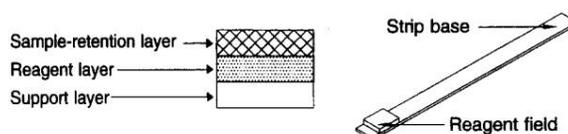
Prescription Use

3. Special instrument Requirements:
Polymedco SpotChem EX

I. Device Description:

The Polymedco SPOTCHEM EZ ALT test system is an in vitro diagnostic procedure intended to measure alanine amino transferase (ALT) quantitatively in human serum, plasma, and whole blood on the SPOTCHEM EZ (SP-4430) analyzer.

The SPOTCHEM EZ ALT Reagent Strip is composed of a plastic strip to which a multi-layered test field is affixed. The layers consist of a sample-retention layer, a layer containing the reagents and a support layer.



The patient sample (serum, plasma, or whole blood) is placed in a disposable sample cup and installed in the centrifuge of the SPOTCHEM EZ analyzer. When the analyzer is activated the sample is automatically centrifuged to remove the solid fraction. After centrifugation the analyzer removes a portion of the cell-free supernatant and automatically delivers it to the reagent test strip. A fixed amount of supernatant is placed on the test field of the reagent strip. The supernatant spreads in a uniform fashion across the entire surface of the sample retention layer. The supernatant then permeates into the reagent layer where the reaction is initiated.

J. Substantial Equivalence Information:

1. Predicate device name(s):
Polymedco Poly-Chem System, Alanine Aminotransferase (ALT)
2. Predicate K number(s):
k020852/A010
3. Comparison with predicate:

Similar colorimetric enzyme-based methods for determining ALT levels are well established. The modified NADH oxidation/NAD reduction method for ALT detection used in the SPOTCHEM EZ analyzer is based on several predicate devices. Examples are, but are not limited to: Trace Reagent Line for the COBAS Mira (k973869); HiChem ALT Reagent Kit (k 951818); **Polymedco's Poly-Chem ALT Kit (k020852/A010)**; Roche Reagent for ALT (k 924245); and COBAS Ready Stat Profile Reagent Strip (k 896234).

The similarities of these in vitro diagnostic test methods are summarized as follows:

- a) All tests are based on a modified NADH oxidation/NAD reduction method for colorimetric detection of the ALT present.
- b) All of these tests may use serum and/or plasma patient sample; the SPOTCHEM EZ ALT Test may also use whole blood specimens (as well as serum or plasma), but the SPOTCHEM EZ instrument automatically

centrifuges the sample prior to addition onto the reagent test strip; only the cell-free supernatant is added to the reagent test strip.

- c) All tests make use of a calibrator to verify the stability of the reagents.
- d) All products recommend the use of controls.
- e) In a correlation utilizing 40 samples with the **Polymedco Poly-Chem System, Alanine Aminotransferase (ALT) kit** the regression equation was $y = 0.991x - 7.602$ and the $r = 0.999$

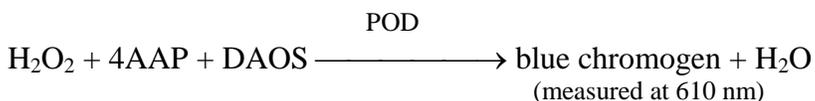
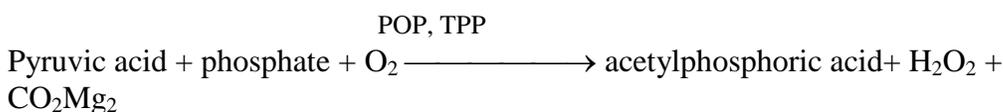
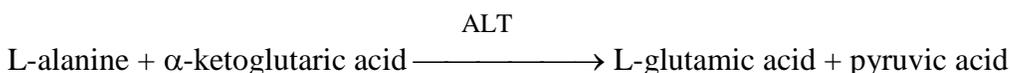
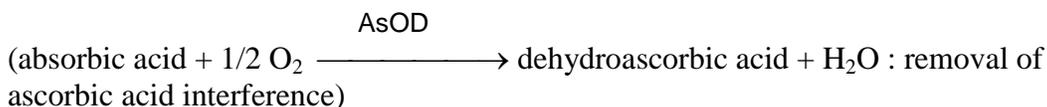
K. Standard/Guidance Document Referenced (if applicable):

None referenced

L. Test Principle:

ALT in the sample transfers amino group of L-alanine to α -ketoglutaric acid and produces L-glutamic acid and pyruvic acid. The pyruvic acid, in the presence of magnesium ion and thiamine pyrroline, is oxidized by the catalytic action of pyruvic acid oxidase, to produce hydrogen peroxide.) The hydrogen peroxide oxidizes and condenses 4-aminoantipyrine (4AAP) and DAOS 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 this detection layer is proportional to the ALT activity in the patient sample.



The intensity of the blue chromogen as measured at 610 nm by reflectance spectrophotometry is directly proportional to the ALT concentration in the patient sample. After the completion of the measurement, the SPOTCHEM EZ analyzer calculates the concentration of ALT [D] as follows:

$$D = a \cdot (K/S)^3 + b \cdot (K/S)^2 + c \cdot (K/S) + d$$

Where (K/S) is the Kubelka-Munk value for reflectance and a, b, c and d are coefficients derived from the calibration curve.

M. Performance Characteristics (if/when applicable):1. Analytical performance:a. *Precision/Reproducibility:*

Intra assay Precision

Intra assay precision (within run) was assessed at three levels: below the normal range, within the normal range and above the normal range on the SPOTCHEM EZ analyzer. Twenty replicates of the same sample within one analytical run were evaluated at three levels. The mean, standard deviation (SD) and coefficient of variation (CV) in percent were calculated. An intra assay CV of < 5% was determined to be acceptable.

Intra Assay Precision ALT on SPOTCHEM EZ Analyzer. Results reported in IU/L.

ANALYZER SPOTCHEM EZ	LEVEL 1	LEVEL 2	LEVEL 3
N=	20	20	20
Mean=	19.85	99.6	180
SD=	0.988	2.722	3.464
%CV=	4.98	2.73	1.92

Inter Assay Precision

Inter assay (between run) precision was determined by analyzing three different samples in each of four different runs repeated over five different occasions. An inter assay CV of <10% was determined to be acceptable.

Inter Assay Precision ALT on SPOTCHEM EZ Analyzer. Results reported in IU/L.

ANALYZER SPOTCHEM EZ	LEVEL 1	LEVEL 2	LEVEL 3
Days	5	5	5
n=	20	20	20
Mean=	20.6	103.2	173.15
SD=	0.883	6.221	3.897
%CV=	4.28	6.03	2.25

b. *Linearity/assay reportable range:*

Linearity/calibration curve fit data was generated for a pool that spanned the linear range of the test. Serial dilution sets were prepared using 0.9% saline solution and made up fresh and assayed with each of three calibrated runs. The results at each level of analyte were averaged and the linear fit was assessed. The linearity claim is based on a percent deviation of not more than 10% at the two highest analyte concentrations. The measured ALT was found to be linear up to 1200 IU/L.

