

**510(k) SUBSTANTIAL EQUIVALENCE DETERMINATION
DECISION SUMMARY**

A. 510(k) Number:

k090236

B. Purpose for Submission:

Adding new sample type

C. Measurand:

Alpha-Fetoprotein (AFP)

D. Type of Test:

Quantitative, Chemiluminescence

E. Applicant:

Siemens Healthcare Diagnostics, Inc.

F. Proprietary and Established Names:

Dimension Vista® AFP Flex® reagent cartridge

G. Regulatory Information:

1. Regulation section:

21 CFR 866.6010 Tumor-associated antigen immunological test system

2. Classification:

Class II

3. Product code:

LOJ Kit, Test, Alpha-fetoprotein for testicular cancer

4. Panel:

Immunology (82)

H. Intended Use:

1. Intended use(s):

Dimension Vista® AFP Method: The AFP method is an in vitro diagnostic test for the quantitative measurement of alpha-fetoprotein in human serum and lithium heparinized plasma on the Dimension Vista® system. Measurements of alpha-fetoprotein are used as an aid in managing non-seminomatous testicular cancer when used in conjunction with physical examination, histology/pathology and other clinical evaluation procedures.

2. Indication(s) for use:

Same as above

3. Special conditions for use statement(s):

Prescription use only

4. Special instrument requirements:

Dimension Vista® System

I. Device Description:

The Dimension Vista® AFP method consists of two synthetic bead reagents and a biotinylated murine-anti-AFP antibody. The first bead reagent (Chemibeads) is coated with an anti-AFP monoclonal antibody and contains a chemiluminescent dye. The second bead reagent (Sensibeads) is coated with streptavidin and contains a photosensitizer dye. All are supplied in liquid format in a reagent cartridge.

J. Substantial Equivalence Information:

1. Predicate device name(s):
Dimension Vista® AFP Flex® reagent cartridge
2. Predicate 510(k) number(s):
k071597
3. Comparison with predicate:

Similarities		
Item	Device	Predicate
Intended Use/Indications for Use	As an aid in managing non-seminomatous testicular cancer when used in conjunction with physical examination, histology/pathology and other clinical evaluation procedures	Same
Technology	Homogeneous, sandwich chemiluminescent immunoassay based on LOCI® technology	Same
Reagent cartridge components	Chemibeads, Sensibeads and a biotinylated murine-anti-AFP antibody in a reagent cartridge.	Same
Instrument platform	Dimension Vista® System	Same

Differences		
Item	Device	Predicate
Sample matrix	Human serum and lithium heparinized plasma	Human serum

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

CLSI/NCCLS Approved Guideline for Evaluation of Precision Performance of Quantitative Measurement Methods (EP5-A2).

L. Test Principle:

The Dimension Vista® AFP method is a homogeneous, sandwich chemiluminescent immunoassay based on LOCI® technology. The LOCI® reagents include two synthetic bead reagents and a biotinylated anti-AFP monoclonal antibody fragment. The first bead reagent (Chemibeads) is coated with an anti-AFP monoclonal antibody and contains chemiluminescent dye. The second bead reagent (Sensibeads) is coated with streptavidin and contains a photosensitizer dye. Sample is incubated with biotinylated antibody and Chemibeads to form bead-AFP-biotinylated antibody sandwiches. Sensibeads are added and bind to the biotin to form bead-pair immunocomplexes. Illumination of the complex at 680 nm generates singlet oxygen from Sensibeads which diffuses into the Chemibeads, triggering a chemiluminescent reaction. The resulting signal is measured at 612 nm and is a direct function of the

AFP concentration in the sample.

M. Performance Characteristics (if/when applicable):

1. Analytical performance:

a. *Precision/Reproducibility:*

In addition to the original precision results using serum samples, a precision study using a lithium heparinized plasma pool sample was conducted in accordance with the CLSI EP5-A2 Approved Guideline for Evaluation of Precision Performance of Quantitative Measurement Methods.

Material	Mean ng/mL	SD (%CV) Repeatability	SD (%CV) Within-Lab
Plasma Pool	249.0	2.9 (1.2)	5.1 (2.0)

To determine the precision at the lower end of the assay range, the sponsor provided data from a 5-day precision study using a lithium heparinized plasma pool sample with 8 ng/mL AFP. The results are summarized below.

Material	Mean ng/mL	SD (%CV) Repeatability	SD (%CV) Within-Lab
Plasma Pool	7.5	0.08 (1.0)	0.13 (1.7)

b. *Linearity/assay reportable range:*

Same as k071597

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

Same as k071597

d. *Detection limit:*

Same as k071597

e. *Analytical specificity:*

Same as k071597

f. *Assay cut-off:*

Same as k071597

2. Comparison studies:

a. *Method comparison with predicate device:*

Not applicable.

b. *Matrix comparison:*

Matched serum and lithium (Li) heparinized plasma samples (N=70), were collected from patients and immediately frozen at -20°C. All samples were tested within 60 days from the date of collection. On the date of testing, serum and Li heparinized plasma samples were thawed at 20 - 25°C for 30 minutes and the AFP values were determined with the Dimension Vista® AFP assay. Samples above the assay range (0.5-1000 ng/mL) were manually diluted with matched normal human serum and Li heparinized plasma. Samples were run in triplicate. AFP recovery in serum versus Li heparinized plasma was compared by Passing & Bablok regression analysis.

The range of AFP values in the correlation study was 0.9 to 999.5 ng/mL [0.7 to 825.6 IU/mL].

Sample comparison	Slope(95% CI)	Intercept ng/mL [IU/mL] (95% CI)	Correlation Coefficient	N
Lithium heparin vs. serum	0.99(0.96 - 1.00)	-0.05 [-0.04] (-0.10 - 0.06)	0.997	70

3. Clinical studies:

a. *Clinical Sensitivity:*

Not applicable.

b. *Clinical specificity:*

Not applicable.

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

Not applicable.

4. Clinical cut-off:

Not applicable.

5. Expected values/Reference range:

Not applicable.

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.