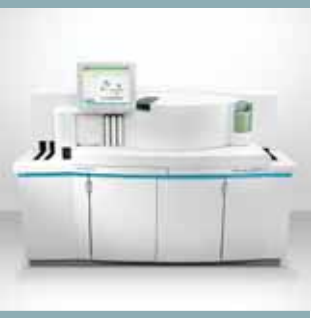
Dimension Vista AFP Assay Specifications



The Siemens Healthcare Diagnostics Dimension Vista® AFP Assay is a homogeneous, sandwich chemiluminescent immunoassay based on LOCI® technology.

Outstanding Assay Performance

- Excellent precision to ensure accurate monitoring (1.6% - 2.3% CV)
- Broad dynamic assay range (0.5-1000 ng/mL)
- Rapid assay kinetics (10 minutes)

Clinical Utility

- Quantitative measurement of alpha-fetoprotein is used as an aid in managing non-seminomatous testicular cancer
- 97.4% of the 231 samples from apparently healthy males (age 18-61 years) had AFP levels less than 8.0 ng/mL[1]

Dimension Vista System – Intelligence at Work

- Ultra-integration – Four best-in-class technologies in one smart workstation: Photometry, Nephelometry, LOCI advanced chemiluminescense and V-LYTE® integrated multi-sensor technology
- LOCI Advanced Chemiluminescence – The only homogeneous chemiluminescent technology
- Onboard automation – Increased efficiency, simplicity, and convenience for your laboratory

Changes in AFP concentrations and in disease status were analyzed on a per visit basis. Patients were categorized as Active/Progressive, Responding, Stable, or No Evidence of Disease (NED) by attending physicians based on the clinical information (medical imaging, physical examination, and other clinical investigations). All 70 patient sets were analyzed to determine the change in disease status per sequential pair (n=244). The reference change value (RCV) was used to determine if a significant change in AFP occurred. The RCV for the Dimension Vista AFP was calculated to be 33.7%. Table 1 shows the distribution of results when compared to disease status.

Table 1. Dimension Vista AFP Value vs. Disease Progression

	Change in Disease State				
Change in AFP	**Responding n (%)**	**Stable n (%)**	**No Evidence of Disease n (%)**	**Progression n (%)**	**Total**
33.7% increase	5 (2.1%)	10 (4.1%)	9 (3.78%)	16 (6.6%)	40 (16.5%)
No Significant Change	4 (1.6%)	13 (5.3%)	94 (38.5%)	22 (9.0%)	133 (54.4%)
33.7% decrease	16 (6.6%)	24 (9.8%)	10 (4.1%)	21 (8.6%)	71 (29.1%)
Total	25 (10.3%)	47 (19.2%)	113 (46.3%)	59 (24.2%)	244 (100.0%)

Answers for life.

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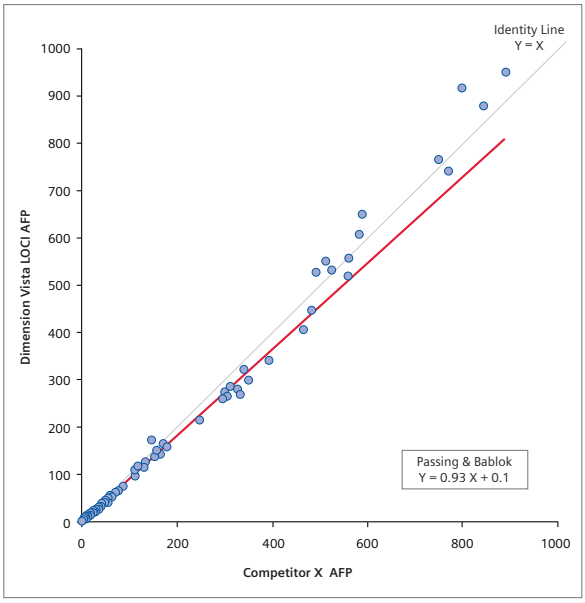
Per visit clinical performance results for the Dimension Vista AFP test are given in Table 2. In this evaluation, disease status was classified as "Progression" and "No Progression" with "No Progression" consisting of responding, stable, and no evidence of disease.

Table 2. Dimension Vista AFP Value vs. Disease Progression

	Progression	No-Progression	Total
>33.7% increase	16	24	40
≤33.7% increase	43	161	204
Total	59	185	244
		Estimate	**Exact 95% Confidence Interval**
% Accuracy		72.5%	(66.5% - 78.0%)
% Sensitivity		27.1%	(16.4% - 40.3%)
% Specificity		87.0%	(81.3% - 91.5%)

Dimension Vista AFP vs. Competitor X



AFP Performance Summary

	Sample Type	Sample Volume	Assay Range	Analytical Sensitivity	Calibration Inerval	Onboard Stability
Dimension Vista	Serum/ Plasma	2 µL	0.5-1000 ng/ml	0.5 ng/mL	30 days	30 days

Ordering Information		
Catalog No.	**Description**	**Contents**
K6454	• AFP Flex® Reagent Cartridge	• 120 tests
KC600	• LOCI 5 Calibrator	• 2 x 5 levels

[1]Siemens Healthcare Diagnostics Dimension Vista AFP Instructions for Use

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