# Dimension Vista CEA Assay Specifications

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

## Outstanding Assay Performance

- Excellent precision to ensure accurate monitoring (2.1% - 3.6% CV)
- Broad dynamic assay range (0.2 - 1000 ng/mL)
- Rapid assay kinetics (10 minutes)

## Clinical Utility

- Measurements of carcinoembryonic antigen is used as an aid in the management of cancer patients with changing CEA concentrations
- 96% of non-smokers had expected values between 0.0-3.0 ng/mL, while 96.6% of smokers had expected values between 0.0-5.0 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 CEA 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 74 patient sets were analyzed to determine how the change in disease status per sequential pair (n=217). The reference change value (RCV) was used to determine if a significant change in CEA occurred. The RCV for the Dimension Vista CEA was calculated to be 36.2%. Table 1 shows the distribution of results when compared to disease status.

**Table 1. Dimension Vista CEA Assay Value vs. Disease State**

| | Change in Disease State | | | | |
|---|---|---|---|---|---|
| **Change in CEA** | **Responding n (%)** | **Stable n (%)** | **No Evidence of Disease n (%)** | **Progression n (%)** | **Total** |
| **36.2% Increase** | 6 (2.8%) | 14 (6.5%) | 6 (2.8%) | 32 (14.8%) | 58 (26.7%) |
| **No Significant Change** | 12 (5.5%) | 33 (15.2%) | 62 (28.6%) | 22 (10.1%) | 129 (59.5%) |
| **36.2% Decrease** | 5 (2.3%) | 15 (6.9%) | 6 (2.8%) | 4 (1.8%) | 30 (13.8%) |
| **Total** | 23 (10.6%) | 62 (28.6%) | 74 (34.1%) | 58 (26.7%) | 217 (100.0%) |

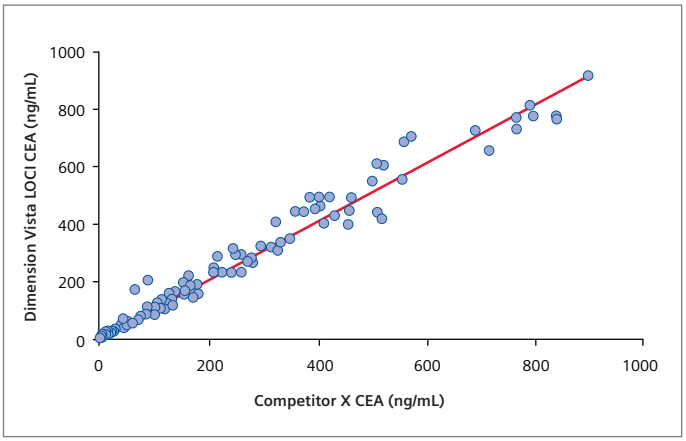
# Dimension Vista CEA Assay Specifications

Per visit clinical performance results for the Dimension Vista CEA 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. Using these classifications, sensitivity and specificity were determined.

### Table 2. Dimension Vista CEA Value vs. Disease State

| | Progression | No-Progression | Total |
|---|---|---|---|
| **>36.2% increase** | 32 | 26 | 58 |
| **≤36.2% increase** | 26 | 133 | 159 |
| **Total** | 58 | 159 | 217 |
| | | **Estimate** | **Exact 95% Confidence Interval** |
| % Overall Agreement | | 76.0% | (69.8% - 81.6%) |
| % Sensitivity | | 55.2% | (41.5% - 68.3%) |
| % Specificity | | 83.6% | (77.0% - 89.0%) |

### Dimension Vista CEA vs. Competitor X




### CEA Performance Summary

| | Sample Type | Sample Volume | Assay Range | Analytical Sensitivity | Calibration Interval | Onboard Stability |
|---|---|---|---|---|---|---|
| **Dimension Vista** | Serum/ Plasma | 2 µL | 0.2-1000 ng/ml | 0.2 ng/mL | 30 days | 30 days |

| Ordering Information | | |
|---|---|---|
| **Catalog No.** | **Description** | **Contents** |
| **K6453** | • CEA Flex® Reagent Cartridge | • 120 tests |
| **KC600** | • LOCI 5 Calibrator | • 2 x 5 levels |

[1]Siemens Healthcare Diagnostics Dimension Vista CEA Instructions for use



**Siemens Global Headquarters**

Siemens AG
Wittelsbacherplatz 2
80333 Muenchen
Germany

**Global Siemens Healthcare Headquarters**

Siemens AG
Healthcare Sector
Henkestrasse 127
91052 Erlangen, Germany
Telephone: +49 9131 84 - 0
www.siemens.com/healthcare

**Global Division**

Siemens Healthcare Diagnostics Inc.
1717 Deerfield Road
Deerfield, IL 60015-0778
USA
www.siemens.com/diagnostics



Order No. A91DX-0701470-GC1-4A00 | Printed in USA | © 2009 Siemens Healthcare Diagnostics Inc.