Siemens Healthcare Diagnostics, a global leader in clinical diagnostics, provides healthcare professionals in hospital, reference, and physician office laboratories and point-of-care settings with the vital information required to accurately diagnose, treat, and monitor patients. Our innovative portfolio of performance-driven solutions and personalized customer care combine to streamline workflow, enhance operational efficiency, and support improved patient outcomes.

Product availability may vary from country to country and is subject to varying regulatory requirements. Please contact your local representative for availability.

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Dimension Vista LOCI CA 125II, CA 15-3, and CA 19-9

Assay Specifications

Dimension Vista LOCI CA 125II, CA 15-3, and CA 19-9 Assay Specifications

The Siemens Healthcare Diagnostics Dimension Vista® LOCI® CA 125II,™ CA 15-3, and CA 19-9 assays are homogeneous, sandwich chemiluminescent immunoassays based on LOCI advanced technology.

Outstanding Assay Performance

- Excellent precision to ensure accurate monitoring
  – (LOCI CA 125II: 2.2%–3.8% CV; LOCI CA 15-3: 2.4%–3.5% CV; LOCI CA 19-9: 2.4%–8.9% CV)
- Broad dynamic assay range
  – (LOCI CA 125II: 1.5–1,000 U/mL; LOCI CA 15-3: 1.0–300 U/mL; LOCI CA 19-9: 2.0–1,000 U/mL)
- Rapid assay kinetics
  – (LOCI CA 125II: 21 minutes; LOCI CA 15-3: 16 minutes; LOCI CA 19-9: 10 minutes)

Clinical Utility

- CA 125II: as an aid in monitoring disease progress or response to therapy or for recurrent or residual disease for patients with epithelial ovarian cancer
- CA 15-3: as an aid in the management of previously treated stage II and III breast cancer patients and for monitoring response to therapy in metastatic breast cancer patients
- CA 19-9: as an aid in managing patients diagnosed with cancers of the exocrine pancreas

Dimension Vista System—Intelligence at Work

- Ultra-integration—four technologies, including best-in-class LOCI advanced chemiluminescence, photometry, nephelometry, and V-LYTE® integrated multisensor technology
- LOCI advanced chemiluminescence—the only homogeneous chemiluminescent technology
- Onboard automation—increased efficiency, simplicity, and convenience for your laboratory

LOCI CA 125II

Changes in CA 125II 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 the attending physician based on the clinical information (medical imaging, physical examination, and other clinical investigations). All 75 patient sets were analyzed to determine the change in disease status per sequential pair (n = 255). Table 1 shows the distribution of results when compared to the disease status.

Table 1. Disease State Frequency Using the Dimension Vista LOCI CA 125II Assay

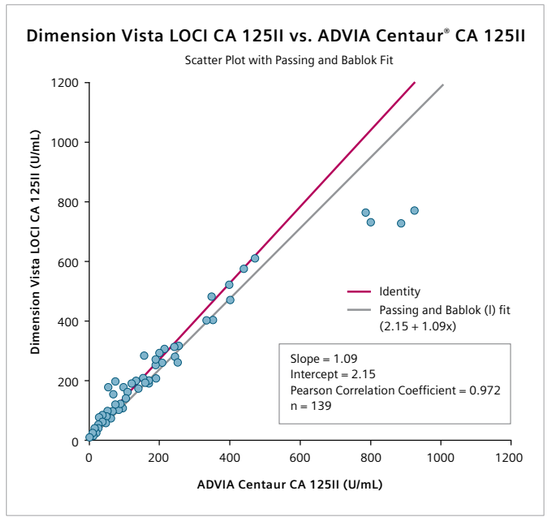
	Change in Disease State				
Change in CA 125II	**Responding n (%)**	**Stable n (%)**	**No Evidence of Disease n (%)**	**Progression n (%)**	**Total**
> 70.1% Increase	3 (1.2%)	17 (6.8%)	4 (1.6%)	42 (16.5%)	66 (25.9%)
No Significant Change	22 (8.6%)	45 (17.7%)	54 (21.2%)	29 (11.4%)	150 (58.8%)
> 70.1% Decrease	11 (4.3%)	13 (5.1%)	12 (4.7%)	3 (1.2%)	39 (15.3%)
Total	36 (14.1%)	75 (29.4%)	70 (27.5%)	74 (29.0%)	255 (100.0%)

Per patient visit clinical performance results for the Dimension Vista LOCI CA 125II assay and predicate devices 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 LOCI CA 125II Value vs. Disease Progression

	Progression	No Progression	Total
> 70.1% Increase	42	24	66
≤ 70.1% Increase	32	157	189
Total	74	181	255

	Estimate	Exact 95% Confidence Interval
Total Concordance	78.0%	(72.5%–83.0%)
Positive Concordance	56.8%	(44.7%–68.2%)
Negative Concordance	86.7%	(80.9%–91.3%)



LOCI CA 15-3

Changes in CA 15-3 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 the attending physician based on the clinical information (medical imaging, physical examination, and other clinical investigations). All 75 patient sets were analyzed to determine the change in disease status per sequential pair (n = 258). Table 3 shows the distribution of results when compared to the disease status.

Table 3. Disease State Frequency Using the Dimension Vista LOCI CA 15-3 Assay

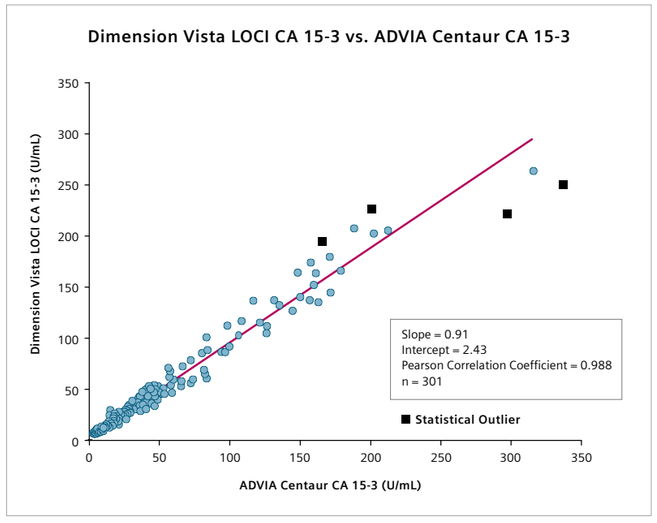
	Change in Disease State				
Change in CA 15-3	**Responding n (%)**	**Stable n (%)**	**No Evidence of Disease n (%)**	**Progression n (%)**	**Total**
> 27.9% Increase	4 (1.5%)	27 (10.5%)	3 (1.2%)	64 (26.8%)	98 (38%)
No Significant Change	10 (3.9%)	42 (16.3%)	37 (14.3%)	17 (6.6%)	106 (41%)
> 27.9% Decrease	8 (3.1%)	28 (10.9%)	3 (1.2%)	15 (5.8%)	54 (21%)
Total	22 (8.5%)	97 (37.7%)	43 (16.7%)	96 (37.2%)	258 (100.0%)

Per patient visit clinical performance results for the Dimension Vista LOCI CA 15-3 assay and predicate devices are given in Table 4. 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 4. Dimension Vista LOCI CA 15-3 Value vs. Disease Progression

	Progression	No Progression	Total
> 27.9% Increase	64	34	98
≤ 27.9% Increase	32	128	160
Total	96	162	258

	Estimate	Exact 95% Confidence Interval
Total Concordance	74.4%	(68.6%–79.6%)
Positive Concordance	66.7%	(56.3%–76.0%)
Negative Concordance	79.0%	(71.9%–85.0%)



LOCI CA 19-9

Changes in CA 19-9 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 the attending physician based on the clinical information (medical imaging, physical examination, and other clinical investigations). All 72 patient sets were analyzed to determine the change in disease status per sequential pair (n = 189). Table 5 shows the distribution of results when compared to the disease status.

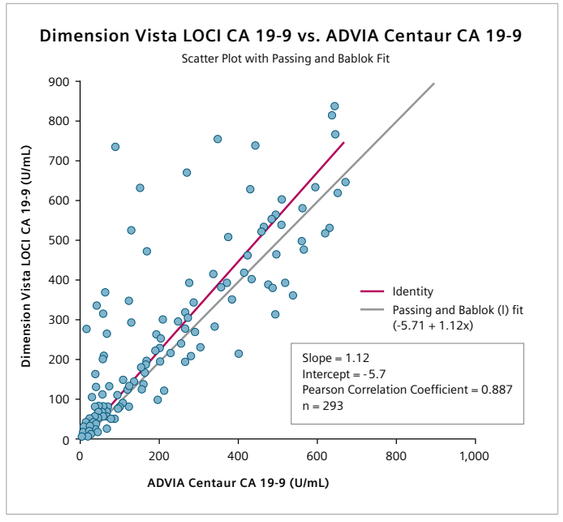
Table 5. Disease State Frequency Using the Dimension Vista LOCI CA 19-9 Assay

	Change in Disease State				
Change in CA 19-9	**Responding n (%)**	**Stable n (%)**	**No Evidence of Disease n (%)**	**Progression n (%)**	**Total**
> 84.7% Increase	3 (1.6%)	10 (5.3%)	0 (0.0%)	14 (7.4%)	27 (14.3%)
No Significant Change	44 (23.3%)	50 (26.5%)	8 (4.2%)	59 (31.2%)	161 (81.5%)
> 84.7% Decrease	0 (0.0%)	0 (0.0%)	1 (0.5%)	0 (0.0%)	1 (3.2%)
Total	47 (24.9%)	60 (31.8%)	9 (4.7%)	73 (38.6%)	189 (100.0%)

Per patient visit clinical performance results for the Dimension Vista LOCI CA 19-9 Assay and predicate devices are given in Table 6. 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 6. Dimension Vista LOCI CA 19-9 Value vs. Disease Progression

	Progression	No Progression	Total
> 84.7% Increase	14	13	27
≤ 84.7% Increase	59	103	162
Total	73	116	189
		Estimate	Exact 95% Confidence Limits
Total Concordance		61.9%	(54.6%–68.9%)
Positive Concordance		19.2%	(10.9%–30.1%)
Negative Concordance		88.8%	(81.6%–93.3%)



Performance Summary

LOCI CA Assays Performance Summary

	Sample Type	Sample Volume	Assay Range	Limit of Detection	Cutoff	Calibration Interval	Onboard Stability
LOCI CA 125II	Serum/Plasma	5 µL	1.5–1,000 U/mL	1.5 U/mL	35 U/mL	21 days	30 days
LOCI CA 15-3	Serum/Plasma	1 µL	1.0–300 U/mL	1.0 U/mL	35 U/mL	30 days	30 days
LOCI CA 19-9	Serum/Plasma	4 µL	2.0–1,000 U/mL	2.0 U/mL	37 U/mL	21 days	30 days

Ordering Information		
Catalog No.	Description	Contents
K6455	CA 125 Flex® reagent cartridge	160 tests
K6456	CA 15-3 Flex reagent cartridge	160 tests
K6457	CA 19-9 Flex reagent cartridge	160 tests
KC604	LOCI 6 CAL	2 x 5 levels
KC605	LOCI 7 CAL	2 x 5 levels

LOCI CA 125II requires LOCI 6 CAL. LOCI CA 15-3 and LOCI CA 19-9 require LOCI 7 CAL.