VIDAS® CEA (S) (CEAS)

IVD

Caution : The concentrations of CEA in a given specimen determined with assays from different manufacturers can vary due to differences in assay methods and reagent specificity. The results reported by the laboratory to the physician must include the identity of the CEA assay used. Values obtained with different assay methods cannot be used interchangeably. If, in the course of monitoring a patient, the assay method used for determining CEA levels serially is changed, additional sequential testing should be carried out. Prior to changing assays, the laboratory MUST confirm baseline values for patients being serially monitored.

VIDAS® CEA (S) (CEAS) is an automated quantitative test for use on the instruments of the VIDAS family, for the quantitative measurement of Carcinoembryonic antigen (CEA) in human serum using the ELFA technique (Enzyme Linked Fluorescent Assay). The VIDAS CEA (S) (CEAS) assay is indicated as an aid in the monitoring of cancer patients in whom changing concentrations of CEA are observed.

SUMMARY AND EXPLANATION OF THE TEST

Carcinoembryonic antigen is a glycoprotein with a molecular weight of approximately 200,000 daltons (1, 2).
CEA was first described in 1965 by Gold and Freedman (1). CEA is produced by cells during embryonic and fetal life and production ceases at birth. A very low serum concentration can be detected in healthy individuals.
Increased CEA levels can be found in certain cases of cancer (colorectal, breast, lung cancer, etc.) (2-4), but also in non-malignant diseases. Serum CEA levels decrease after treatment and increase in the event of cancer recurrence, residual disease and metastases (5).
It can be used to monitor the disease status in patients with confirmed colorectal cancer in whom measurable and changing CEA values over the course of their disease have been observed.
It enables the efficacy of treatment to be evaluated. In particular, high postoperative levels are an indication of incomplete exeresis. Recurrence can also be diagnosed, allowing the decision to re-operate to be made at an early stage.
The VIDAS CEA(S) (CEAS) is used as an aid for the monitoring of disease progression or response to therapy in patients previously diagnosed with colorectal cancer. It can also be used as an aid in the monitoring of other cancer patients in whom changing concentrations of CEA are observed on the VIDAS System analyzers.Test results must be interpreted in conjunction with all other clinical and laboratory findings.

PRINCIPLE OF THE PROCEDURE

The assay principle combines a 2-step enzyme immunoassay sandwich method with a final fluorescent detection (ELFA).
The Solid Phase Receptacle (SPR®) serves as the solid phase as well as the pipetting device. It is coated with anti-CEA monoclonal immunoglobulins (mouse). The other reagents for the assay are pre-dispensed in the strip.
All of the assay steps are performed automatically by the instrument. The reaction medium is cycled in and out of the SPR several times.
After dilution, the sample is incubated with the SPR, which will bind the CEA antigen present in the sample. A first wash step eliminates unbound components.
A second incubation step is then performed with alkaline phosphatase-labeled anti-CEA polyclonal antibodies (goat). The unbound conjugate is then eliminated during washing steps.
During the final detection step, the substrate (4-Methyl-umbelliferyl phosphate) is cycled in and out of the SPR. The conjugate enzyme catalyzes the hydrolysis of this substrate into a fluorescent product (4-Methyl-umbelliferone) the fluorescence of which is measured at 450 nm. The intensity of the fluorescence is proportional to the concentration of antigen present in the sample. At the end of the assay, results are automatically calculated by the instrument in relation to the calibration curve stored in memory, and then printed out.

KIT COMPOSITION (60 TESTS)

60 CEAS strips	STR	Ready-to-use.
60 CEAS SPRs 2 x 30	SPR	Ready-to-use. Interior of SPRs coated with anti-CEA monoclonal immunoglobulins (mouse).
CEAS control 1 x 2 mL (lyophilized)	C1	Reconstitute with 2 mL of distilled water. Wait for 5 to 10 minutes, then mix. **After reconstitution, the control is stable for 1 month at 2-8°C or until the expiration date at - 25** ± **6°C**. 3 freeze / thaw cycles are possible. Bovine albumin + human CEA + preservative. MLE data indicate the confidence interval in ng/mL ("Control C1 Dose Value Range").
CEAS calibrator 3 x 2 mL (lyophilized)	S1	Reconstitute with 2 mL of distilled water. Wait for 5 to 10 minutes, then mix. **After reconstitution, the calibrator is stable for 1 month at 2-8°C or until the expiration date at - 25** ± **6°C**. 3 freeze / thaw cycles are possible. Bovine albumin + human CEA + preservative. MLE data indicate the concentration in ng/mL ("Calibrator (S1) Dose Value") and the confidence interval in "Relative Fluorescence Value" ("Calibrator (S1) RFV Range").
CEAS diluent 3 x 6.7 mL (liquid)	R1	Ready-to-use. Bovine albumin + 1 g/L sodium azide.
Specifications for the factory master data required to calibrate the test: • MLE data (Master Lot Entry) provided in the kit, or • MLE bar codes printed on the box label		
1 Package insert provided in the kit or downloadable from www.biomerieux.com/techlib.		

The SPR®

The interior of the SPR is coated during production with anti-CEA monoclonal immunoglobulins (mouse). Each SPR is identified by the "CEAS" code. Only remove the required number of SPRs from the pouch and **carefully reseal the pouch after opening**.

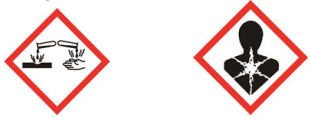
The strip

The strip consists of 10 wells covered with a labeled, foil seal. The label comprises a bar code which mainly indicates the assay code, kit lot number and expiration date. The foil of the first well is perforated to facilitate the introduction of the sample. The last well of each strip is a cuvette in which the fluorometric reading is performed. The wells in the center section of the strip contain the various reagents required for the assay.

Description of the CEAS strip

Wells	Reagents
1	Sample well.
2 - 3 - 4	Empty wells.
5	Conjugate: alkaline phosphatase labeled anti-CEA polyclonal immunoglobulins (goat) + 1 g/L sodium azide (400 µL).
6 - 7	Wash buffer: sodium phosphate (0.01 mol/L, pH 7.4) + 1 g/L sodium azide (600 µL).
8	Diluent: Tris (0.1 mol/L) + calf serum (5%) + 1 g/L sodium azide (400 µL).
9	Wash buffer: diethanolamine* (1.1 mol/L or 11.5%, pH 9.8) + 1 g/L sodium azide (600 µL).
10	Reading cuvette with substrate: 4-Methyl-umbelliferyl phosphate (0.6 mmol/L) + diethanolamine (DEA**) (0.62 mol/L or 6.6%, pH 9.2) + 1 g/L sodium azide (300 µL).

* Signal Word: **DANGER**



Hazard statement

H318 : Causes serious eye damage.
H373 : May cause damage to organs through prolonged or repeated exposure.
H315 : Causes skin irritation.
H302 : Harmful if swallowed.

Precautionary statement

P280 :Wear protective gloves/protective clothing/eye protection/face protection.
P305 + P351 + P338: IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing.
P309 + P311 : IF exposed or if you feel unwell: Call a POISON CENTER or doctor/physician.

** Signal Word: **DANGER**

Hazard statement

H318 : Causes serious eye damage.

Precautionary statement

P280 :Wear protective gloves/protective clothing/eye protection/face protection.
P305 + P351 + P338: IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing.

For further information, refer to the Material Safety Data Sheet.

MATERIAL REQUIRED BUT NOT PROVIDED

- Pipette with disposable tip to dispense 2 mL and 200 µL.
- Powderless, disposable gloves.
- For other specific materials, please refer to the Instrument Operator's Manual.
- Instrument of the VIDAS family.

WARNINGS AND PRECAUTIONS

- **For *in vitro* diagnostic use only.**
- **For professional use only.**
- **This kit contains products of human origin. No known analysis method can totally guarantee the absence of transmissible pathogenic agents. It is therefore recommended that these products be treated as potentially infectious and handled observing the usual safety precautions (see Laboratory biosafety manual - WHO - Geneva - latest edition).**
- This kit contains products of animal origin. Certified knowledge of the origin and/or sanitary state of the animals does not totally guarantee the absence of transmissible pathogenic agents. It is therefore recommended that these products be treated as potentially infectious and handled observing the usual safety precautions (do not ingest or inhale).
- Do not use the SPRs if the pouch is pierced.
- Do not use visibly deteriorated STRs (damaged foil or plastic).
- Do not use reagents after the expiration date indicated on the label.
- Do not mix reagents or disposables from different lots.
- Use **powderless** gloves, as powder has been reported to cause false results for certain enzyme immunoassay tests.
- Kit reagents contain 1 g/L sodium azide which can react with lead or copper plumbing to form explosive metal azides. If any liquid containing sodium azide is disposed of in the plumbing system, drains should be flushed with water to avoid build-up.
- The wash buffer (well 9) contains a harmful agent (11.5% diethanolamine). Refer to the hazard statements "H" and the precautionary statements "P" above.
- The substrate (well 10) contains an irritant agent (6.6% diethanolamine). Refer to the hazard statements "H" and the precautionary statements "P" above.
- Spills should be wiped up thoroughly after treatment with liquid detergent and a solution of household bleach containing at least 0.5% sodium hypochlorite. See the Operator's Manual for cleaning spills on or in the instrument. Do not autoclave solutions containing bleach.
- The instrument should be regularly cleaned and decontaminated (see the Operator's Manual).

STORAGE CONDITIONS

- Store the VIDAS® CEA (S) (CEAS) kit at 2-8°C.
- **Do not freeze reagents, with the exception of calibrator and control after reconstitution.**
- **Store all unused reagents at 2-8°C.**
- After opening the kit, check that the SPR® pouch is correctly sealed and undamaged. If not, do not use the SPRs.
- **Carefully reseal the pouch with the desiccant inside after use to maintain stability of the SPRs and return the complete kit to 2-8°C.**
- If stored according to the recommended conditions, all components are stable until the expiration date indicated on the label. Refer to the kit composition table for special storage conditions.

SPECIMENS

Specimen type

Serum.

Sample preparation

Follow the tube manufacturer's recommendations for use.

Serum collection tubes with no additive: wait for samples to coagulate and **centrifuge** to eliminate fibrin.

Note: blood sampling tube results may vary from one manufacturer to another depending on the materials and additives used.

It is the responsibility of each laboratory to validate the type of sample tube used and to follow the manufacturer's recommendations for use.

Specimen stability

Serum samples can be stored at 2-8°C in stoppered tubes for up to 2 days; if longer storage is required, freeze the sera at- 25 ± 6°C. Avoid successive freezing and thawing.

Sample-related interference

None of the following factors have been found to significantly influence this assay:
- hemolysis (after spiking samples with hemoglobin up to 4.88 mg/mL (monomer)),
- lipemia (after spiking samples with lipids up to 30 mg/mL equivalent in triglycerides),
- bilirubinemia (after spiking samples with unconjugated bilirubin up to 0.34 mg/mL).

However, it is recommended not to use samples that are clearly hemolyzed, lipemic or icteric and, if possible, to collect a new sample.

INSTRUCTIONS FOR USE

For complete instructions, see the User's Manual.

Reading VIDAS® Protocole Test Change (PTC) protocol data and MLE data

When using the assay for the first time:

With the external instrument barcode reader,
1. Scan the PTC barcode(s) at the end of the package insert. or downloadable from www.biomerieux.com/techlib. This reading allows VIDAS® PTC protocol data to be transferred to the instrument software for its update.
2. Scan the MLE data on the box label.

Note: If the MLE data have been read before the VIDAS® PTC protocol, read the MLE data again.

When opening a new lot of reagents:

Enter the specifications (or factory master data) into the instrument using the master lot entry (MLE) data.
If this operation is not performed **before initiating the tests**, the instrument will not be able to print results.
Note: the master lot data need only be entered once for each lot.

It is possible to enter MLE data **manually or automatically** depending on the instrument (refer to the User's Manual).

Calibration

Calibration, using the calibrator provided in the kit, must be performed each time a new lot of reagents is opened, after the master lot data have been entered. Calibration should then be performed every 14 days. This operation provides instrument-specific calibration curves and compensates for possible minor variations in assay signal throughout the shelf-life of the kit.
The calibrator, identified by S1, must be tested in **duplicate** (see the Operator's Manual). The calibrator value must be within the set RFV "Relative Fluorescence Value" range. If this is not the case, recalibrate.

Procedure

1. **Remove the required reagents from the refrigerator.**
2. Use one "CEAS" strip and "CEAS" SPR® for each sample, control or calibrator to be tested. **Make sure the storage pouch has been carefully resealed after the required SPRs have been removed.**
3. The test is identified by the "CEAS" code on the instrument. The calibrator must be identified by "S1", and tested in **duplicate**. If the control is to be tested, it should be identified by "C1".
4. Mix the calibrator, control and samples using a vortex-type mixer (for serum separated from the pellet).
5. **For this test, the calibrator, control, and sample test portion is 200 µL.**
6. Insert the "CEAS" SPRs and "CEAS" strips into the appropriate position on the instrument. Check to make sure the color labels with the assay code on the SPRs and the Reagent Strips match.
7. Initiate the assay as directed in the Operator's Manual. All the assay steps are performed automatically by the instrument.
8. Reclose the vials and return them to the required temperature after pipetting.
9. The assay will be completed within approximately 60 minutes. After the assay is completed, remove the SPRs and strips from the instrument.
10. Dispose of the used SPRs and strips into an appropriate recipient.

QUALITY CONTROL

A control is included in each VIDAS CEA (S) (CEAS) kit.
This control must be performed immediately after opening a new kit to ensure that reagent has not been altered. Each calibration must also be checked using this control. The instrument will only be able to check the control value if it is identified by C1.
Results cannot be validated if the control value deviates from the expected values.

Note

It is the responsibility of the user to perform Quality Control in accordance with any local applicable regulations.

RESULTS AND INTERPRETATION

Once the assay is completed, results are analyzed automatically by the computer. Fluorescence is measured twice in the Reagent Strip's reading cuvette for each sample tested. The first reading is a background reading of the substrate cuvette before the SPR® is introduced into the substrate. The second reading is taken after incubating the substrate with the enzyme remaining on the interior of the SPR. The RFV (Relative Fluorescence Value) is calculated by subtracting the background reading from the final result. This calculation appears on the result sheet.
The results are automatically calculated by the instrument using calibration curves which are stored by the instrument (4-parameter logistic model). The CEA concentrations are expressed in ng/mL.
The VIDAS® CEA (S) (CEAS) assay is calibrated against an EIA method.
1 ng/mL of VIDAS CEA (S) (CEAS) corresponds to 15.43 mIU/mL. The International Units are defined according to the 1st International Reference Preparation for CEA antigen (NIBSC code 73/601) established by the WHO in 1976 (6).
Samples with CEA concentrations > 200 ng/mL should be retested after being diluted, for example, by 1/10 (1 volume of sample + 9 volumes of diluent) in the VIDAS CEA (S) (CEAS) diluent (R1).
If the dilution factor has not been entered when the analysis has been requested (see the Operator's Manual), multiply the result by the dilution factor to obtain the sample concentration.

Interpretation of test results should be made taking into consideration the patient's history, and the results of any other tests performed. A baseline value of CEA needs to be established for serial monitoring.

LIMITATIONS OF THE METHOD

- Interference may be encountered with certain sera containing antibodies (e.g. human anti-mouse antibodies (HAMA) or heterophilic antibodies) directed against reagent components. Interference may be also observed in patients treated with Rifampicin and in patients with Rheumatoid factor. For this reason, assay results should be interpreted taking into consideration the patient's history, and the results of any other tests performed.
- It is not advisable to perform a CEA assay on patients who have received a contrast medium less than 24 hours previously (7).
- Sample CEA concentrations determined using kits from different manufacturers may vary according to the assay technique and reagent specificity. To ensure correct patient follow-up when changing techniques, previously determined concentrations must be confirmed by the laboratory (8).
- CEA concentrations should be interpreted as part of a complete clinical profile and in relation to other diagnostic methods.
- The VIDAS CEA (S) (CEAS) assay is not intended for use as a screening test for cancer (8).

RANGE OF EXPECTED VALUES

Normal Healthy Cohort

The reference values were determined from a healthy population of 432 individuals (212 women and 220 men). This population includes 283 non-smokers and 149 smokers.

Normals		Number of subjects	Percentage of the population (%) according to the range of values in ng/mL			
			0-3.00	3.01-5.00	5.01-10.00	>10.00
Women	Non smokers	133	98.50	0.00	1.50	0.00
	Smokers	79	93.67	5.06	1.27	0.00
Men	Non smokers	150	96.67	2.00	0.67	0.67
	Smokers	70	82.86	11.43	5.71	0.00
	Total	432	94.44	3.47	1.85	0.23

Calculation of 95th percentile of CEA values in the tested healthy population

		95th percentile (ng/mL)	95% CI*
Women	Non smokers	1.77	[1.34-2.44]
	Smokers	3.12	[2.42-3.53]
Men	Non smokers	2.78	[2.19-3.23]
	Smokers	5.10	[3.63-6.44]

*Confidence Interval

These figures are provided as a guide. It is recommended that each laboratory establishes its own reference values from a rigorously selected population.

Non Malignant Disease Cohort

Prospectively collected serum samples from a total of 423 subjects with diagnosed benign diseases were tested using the VIDAS® CEA (S) (CEAS) assay.

Non malignant disease	Number of subjects	Percentage of the population (%) according to the range of values in ng/ml			
		0-3.00	3.01-5.00	5.01-10.00	>10.00
Urogenital	54	92.59	7.41	0.00	0.00
Gastrointestinal tract and lung	110	95.45	2.73	0.91	0.91
Diabetes	106	83.02	12.26	3.77	0.94
Heart Disease/Hypertension/benign Liver	108	92.59	4.63	1.85	0.93
Breast	45	91.11	8.89	0.00	0.00
Total	423	90.78	6.86	1.65	0.71

Calculation of 95th percentile of CEA values in the tested population with non malignant diseases:

Non malignant disease	95th percentile (ng/ml)	95% CI
Urogenital	3.46	[2.48-3.99]
Gastrointestinal tract and lung	2.88	[2.21-4.50]
Diabetes	4.68	[3.43-6.15]
Heart Disease/Hypertension/benign Liver	3.72	[2.74-5.34]
Breast	3.24	[2.55-3.58]
Total	3.85	[3.30-4.36]

These figures are provided as a guide. It is recommended that each laboratory establishes its own reference values from a rigorously selected population.

Malignant Disease Cohort

Using banked serum samples from a total of 514 subjects with a diagnosed malignant carcinoma, the following results were observed using the VIDAS® CEA (S) (CEAS) assay:

Malignant disease	Number of subjects	Percentage of the population (%) according to the range of values in ng/ml			
		0-3.00	3.01-5.00	5.01-10.00	>10.00
Colorectal cancer	151	55.63	8.61	7.28	28.48
Lung/liver cancer	102	59.80	15.69	12.75	11.76
Prostate/Testicular/Bladder cancer	147	92.52	6.62	0.68	0.68
Gall bladder/Biliary/Gastric/Pancreatic cancer	59	59.32	6.78	11.86	22.03
Breast cancer	55	63.64	9.09	12.73	14.55
Total	514	68.29	9.14	7.59	14.98

Calculation of 95th percentile of CEA values in the tested population with malignant diseases:

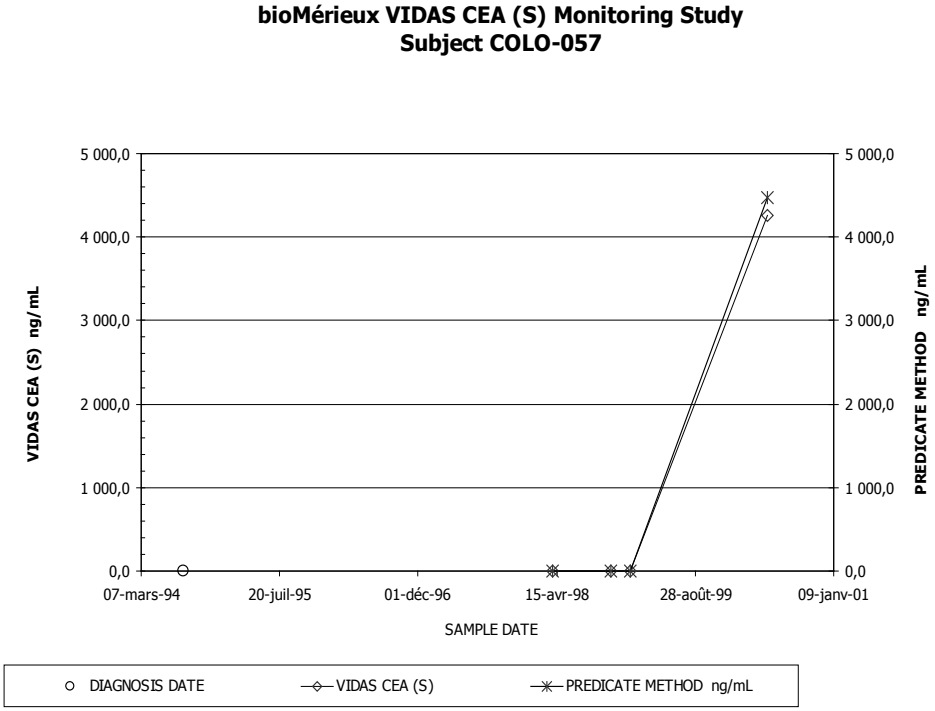
Malignant disease	95th percentile (ng/ml)	95% CI
Colorectal cancer	444.60	[121.36 - 923.00]
Lung/liver cancer	63.70	[13.51 - 156.31]
Prostate/Testicular/Bladder cancer	3.43	[2.70 - 4.28]
Gall bladder/Biliary/Gastric/Pancreatic cancer	42.21	[17.91 - 63.01]
Breast cancer	28.36	[11.08 - 49.12]
Total	73.82	[39.71 - 114.80]

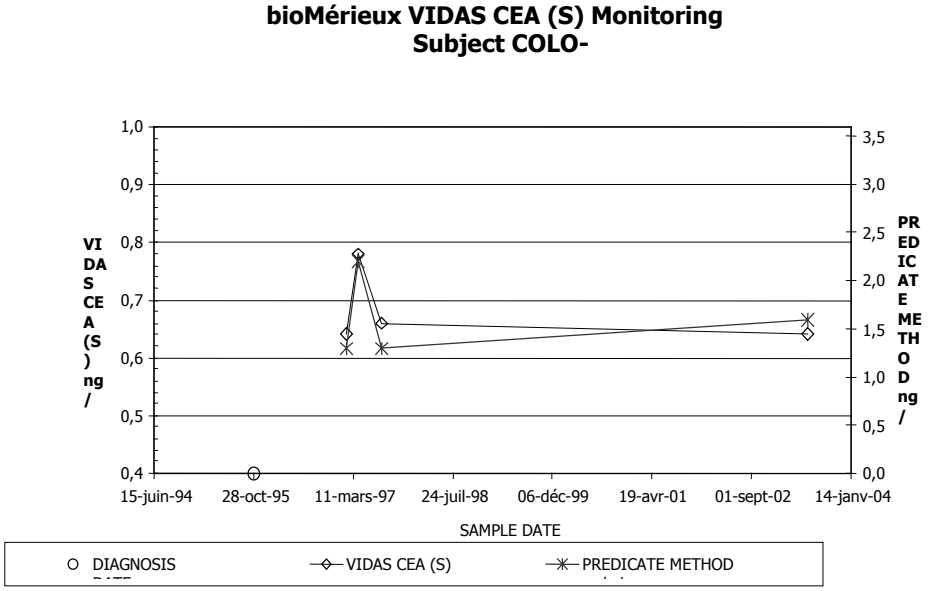
These figures are provided as a guide. It is recommended that each laboratory establishes its own reference values from a rigorously selected population.
The reported distribution table is derived from monitored carcinoma patients representing both active (clinical evidence of disease progression) and inactive (no clinical evidence of disease progression) disease states.

CEA Serial samples

Three hundred and two (302) samples were tested from 79 evaluable serial sets collected from subjects with histologically confirmed colorectal adenocarcinoma. The resulting test values were incorporated into graphs to analyze the longitudinal history per subject of CEA values as determined with VIDAS CEA (S) (CEAS) method and a predicate method.

Two examples of such graphs are presented below :





PERFORMANCE

Studies performed using the VIDAS® CEA (S) (CEAS) assay gave the following results:

Measurement range

The measurement range of the VIDAS CEA (S) (CEAS) assay is: **0.5 to 200** ng/mL.

Detection limits

Based on CLSI document EP17-A, detection limit results are estimated to be less than 0.5 ng/mL.

Hook effect

No hook effect was found up to CEA concentrations of 108,000 ng/mL.

Precision

Three serum samples were tested in duplicate in 40 different runs (2 runs per day over 20 days) with 2 reagent lots using a single instrument at each of three sites (N = 480).
The repeatability (intra-run precision), inter-run precision, inter-day precision, and total precision (intra-run, inter-run, inter-day) were calculated according to the CLSI EP5-A2 document:

Site	Source	Pool A (160 ng/mL)		Pool B (25.0 ng/mL)		Pool C (3.4 ng/mL)	
		Lot 1 (CV%)	Lot 2 (CV%)	Lot 1 (CV%)	Lot 2 (CV%)	Lot 1 (CV%)	Lot 2 (CV%)
1	Day-to-day	2.33	4.46	1.74	2.93	1.18	2.87
	Run-to-run	1.01	0	0.25	0.53	0	0.41
	Repeatability	5.02	4.91	3.52	3.80	3.84	4.40
	Total	5.63	6.63	3.93	4.83	4.02	5.27
2	Day-to-day	1.24	3.04	1.33	1.90	0.93	1.89
	Run-to-run	0	0	1.63	1.26	1.31	1.30
	Repeatability	4.79	3.71	3.82	3.68	4.27	3.50
	Total	4.95	4.8	4.36	4.33	4.56	4.18
3	Day-to-day	3.75	3.22	2.05	3.03	2.66	2.49
	Run-to-run	0	0	0	0	0.58	0
	Repeatability	5.29	3.97	4.43	3.71	4.33	2.66
	Total	6.48	5.11	4.88	4.79	5.11	3.64

Analytical Specificity

No cross-reactivity was observed with AFP, βHCG, CA 125, CA 27.29, CA 19-9, PSA, or PAP.

Interference and Cross-reactivity

The following interferent and cross-reacting materials were tested by adding the identified substances in known concentrations to a serum pool containing carcinoembryonic antigen (CEA) at a mean concentration of approximately 25 ng/mL, per CLSI EP07-A2. With the exception of Rheumatoid Factor and Rifampicin, the compounds showed no significant interference with the VIDAS® CEA(S) (CEAS) assay at the specific levels indicated.

Material Tested	Tested Concentration	Material Tested	Tested Concentration	Material Tested	Tested Concentration
5-Fluorouracil	1 mg/mL	Cefoxitin	1 mg/mL	Levodopa	1.65 mg/mL
Acetominophen	1 mg/mL	Cisplatin	1 mg/mL	Methotrexate	1 mg/mL
N-Acetyl-L-cysteine	2 mg/mL	Cyclophosphamide	1 mg/mL	Metronidazole	1 mg/mL
Acetylsalycilic acid	1 mg/mL	Cyclosporine	1 mg/mL	Naprosyn (Na)	1 mg/mL
Doxorubicin	100 µg/mL	Dactinomycin	1 µg/mL	Phenylbutazone	1 mg/mL
Ampicillin (Na)	100 µg/mL	Doxocycline	100 µg/mL	Rifampicin	1 mg/mL
Ascorbic acid	100 µg/mL	Etoposide	1 mg/mL	Paclitaxel	1 mg/mL
Bleomycin (Sulfate)	0.1 units/mL	Mitomycin C	100 µg/mL	Vinblastine (Sulfate)	100 µg/mL
Carboplatin	1 mg/mL	Ibuprofen	1 mg/mL	Vincristine (Sulfate)	10 µg/mL
HAMA	912.5 ng/mL	Rheumatoid Factor	100.7 IU/mL	Human Albumin	150 mg/mL

Linearity

VIDAS® CEA (S) (CEAS) kit linearity and dilution was evaluated according to CLSI EP06-A document.

- Linearity: One high natural serum sample with a CEA concentration > 200 ng/mL was mixed in varying proportions up to a 1/20 dilution factor. Each dilution was tested in singulate in 4 runs. The VIDAS® CEA (S) (CEAS) assay is linear over the entire measurement range.

- Dilution: 6 samples (including samples > 200 ng/mL) were diluted up to a 1/20 dilution with the kit diluent and tested in singulate in 3 runs. The ratio of the mean concentration measured over the expected concentration is expressed as a mean recovery percentage. The VIDAS® CEA (S) (CEAS) assay is linear over the entire measurement range when the kit diluent is used.

Comparison with other test methods

Serum samples tested using the VIDAS® CEA (S) (CEAS) (Y) assay were compared with another commercially available CEA assay (X). The results obtained are presented below (Deming regression). The equation represents the relationship between the two techniques.

Y = 0.9410 X -1.2905
95% Confidence interval for the intercept: – 1.6812 to – 0.8998
95% Confidence interval for the slope: 0.8238 to 1.0582

WASTE DISPOSAL

Dispose of used or unused reagents as well as any other contaminated disposable materials following procedures for infectious or potentially infectious products.
It is the responsibility of each laboratory to handle waste and effluents produced according to their nature and degree of hazardousness and to treat and dispose of them (or have them treated and disposed of) in accordance with any applicable regulations.

LITERATURE REFERENCES

1. GOLD P., FREEDMAN S.O. Demonstration of Tumor-Specific Antigens in Human Colonic Carcinomata by Immunological Tolerance and Absorption Techniques. J. Exp. Med. 1965, 121, 439-471.
2. HERNANDO J.J., VON KLEIST S., GRUNERT F. A repertoire of monoclonal antibodies reveals extensive epitope heterogeneity in CEA purified from neoplasms originating from different organs. Int. J. Cancer, 1994, 56, 655-661.
3. THERIAULT R.L., HORTOBAGYI G., FRITSCHE H., FRYE D., MARTINEZ R., BUZDAR A. The role of serum CEA as a prognostic indicator in stage II and III Breast cancer patients treated with adjuvant chemotherapy. Cancer, 1989, 63, 825-835.
4. MOERTEL C.G., FLEMING T., MACDONALD J., HALLER D, LAURIE J., TANGEN C. An evaluation of the Carcinoembryonic Antigen (CEA) Test for monitoring patients with resected colon cancer. JAMA. 1993, 270, 943-947.
5. BORMER O.P. Immunoassays for carcinoembryonic antigen: specificity and interferences. Scand. J. Clin. Lab. Invest., 1993, 53, 1-9.
6. LAURENCE D.J.R. et al. First British Standard for Carcinemembryonic Antigen (CEA). Br. J. Cancer, 1975, 32, 295.
7. WATANABE N. et al. *In vitro* effect of contrast agents during immunoradiometric assay for tumour-associated antigens. Nuclear Medicine Communications, 1998, 19, 63-70.
8. ZWIRNER M. Longitudinal quality control of tumor marker assays : results of an international proficiency study with CEA in R. KLAPDOR (ed). Tumor associated antigens, oncogenes, receptors, cytokines in tumor diagnosis and therapy at the beginning of the nineties. Cancer of the breast. State and trends in diagnosis and therapy, W. Zuckschwerdt Verlag München, Bern, Wien, New-York, 1992, 283-290.

INDEX OF SYMBOLS

Symbol	Meaning
REF	Catalog number
IVD	*In Vitro* Diagnostic Medical Device
	Manufacturer
	Temperature limit
	Use by date
LOT	Batch code
	Consult Instructions for Use
	Contains sufficient for <n> tests
	Date of manufacture

WARRANTY

bioMérieux disclaims all warranties, express or implied, including any implied warranties of MERCHANTABILITY AND FITNESS FOR A PARTICULAR USE. BioMérieux shall not be liable for any incidental or consequential damages. IN NO EVENT SHALL BIOMERIEUX'S LIABILITY TO CUSTOMER UNDER ANY CLAIM EXCEED A REFUND OF THE AMOUNT PAID TO BIOMERIEUX FOR THE PRODUCT OR SERVICE WHICH IS THE SUBJECT OF THE CLAIM.

REVISION HISTORY

Change type categories :

N/A	Not applicable (First publication)
Correction	Correction of documentation anomalies
Technical change	Addition, revision and/or removal of information related to the product
Administrative	Implementation of non-technical changes noticeable to the user

Minor typographical, grammar, and formatting changes are not included in the revision history.

Release date	Part Number	Change Type	Change Summary
2015/01	14037D	Administrative	INDEX OF SYMBOLS REVISION HISTORY
		Technical	KIT COMPOSITION (60 tests) WARNINGS AND PRECAUTIONS
2015/06	14037E	Technical	KIT COMPOSITION (60 tests) INSTRUCTIONS FOR USE

BIOMÉRIEUX

bioMérieux SA
376 Chemin de l'Orme
69280 Marcy-l'Etoile – France
673 620 399 RCS LYON
Tel. 33 (0)4 78 87 20 00
Fax 33 (0)4 78 87 20 90
www.biomerieux.com

Distributed by
bioMérieux, Inc.
100 Rodolphe Street
Durham, North Carolina 27712 - USA
www.biomerieux.com