VIDAS® CA 15-3® (153)

IVD

Caution : The concentrations of CA 15-3 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 CA 15-3 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 CA 15-3 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® CA 15-3 (153) is an automated quantitative test for use on the instruments of the VIDAS family for the quantitative measurement of CA 15-3 reactive antigenic determinants in human serum using the ELFA technique (Enzyme Linked Fluorescent Assay). The VIDAS CA 15-3 (153) is indicated for the serial measurement of CA 15-3 reactive antigenic determinants as an aid in the monitoring of patients previously diagnosed with breast cancer for disease progression or response to therapy in conjunction with other clinical methods. The VIDAS CA 15-3 (153) assay can also be used as an aid in the detection of recurrence in previously treated Stage II and III breast cancer patients.

SUMMARY AND EXPLANATION OF THE TEST

VIDAS CA 15-3 (153) is intended for use on the instrument as an automated assay for the quantitative measurement of CA 15-3 reactive antigenic determinants in human serum.

The VIDAS CA 15-3 (153) test uses two monoclonal antibodies (115D8 and DF3) which react with a circulating CA 15-3, antigen expressed in human breast cancer cell. The monoclonal 115D8 antibody directed against human milk fat globule membranes, and the monoclonal DF3 antibody directed against an enriched fraction of human metastatic breast cancer membrane, react with the epitopes expressed by a family of high molecular weight glycoproteins known as polymorphic epithelial mucins (1, 2, 3, 4).

Serial measurement of CA 15-3 reactive antigenic determinants is used in patients with previously diagnosed malignant tumors for the monitoring of therapy and of disease progression.

An increase in the concentration of CA 15-3 is frequently found in breast cancer, as in some other cancers, but also in non-cancerous pathologies. The CA 15-3 concentration decreases after therapy and increases in cases of relapse, residual disease and metastasis.

A decrease in the CA 15-3 concentration can indicate a positive response to therapy and therefore good prognosis (4-13, 14, 15-18, 19).

The VIDAS CA 15-3 (153) is indicated for the serial measurement of CA 15-3 reactive antigenic determinants as an aid in the monitoring of patients previously diagnosed with breast cancer for disease progression or response to therapy. It can be also be used as an aid in the detection of recurrence in previously treated Stage II and III breast cancer patients.

CA 15-3 assay values must be interpreted in conjunction with all other clinical and laboratory data before a medical decision is made.

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 for the assay. Reagents for the assay are ready-to-use and pre-dispensed in the sealed reagent strips.

All of the assay steps are performed automatically by the instrument. The reaction medium is cycled in and out of the SPR several times.

The sample is cycled in and out of the SPR several times. This operation enables the monoclonal 115D8 antibody fixed onto the interior wall of the SPR to capture the reactive antigenic determinants present in the sample. Unbound components are eliminated during the washing steps. Alkaline phosphatase labeled monoclonal DF3 antibody is then incubated in the SPR where it binds with the DF3 reactive antigenic determinants. Unbound conjugate is then eliminated during the 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 CA 15-3 reactive antigenic determinants 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 (30 TESTS):

30 CA 15-3 strips	STR	Ready-to-use.
30 CA 15-3 SPRs 1 x 30	SPR®	Ready-to-use. Interior of SPR coated with monoclonal 115D8 antibodies (mouse).
CA 15-3 Control 1 x 1 mL (liquid)	C1	Ready-to-use. Bovine albumin + DF3 reactive antigenic determinants (human origin) + 0.9 g/L sodium azide. The confidence interval in U/mL is indicated on the MLE card after the following mention : "Control C1 Dose Value Range".
CA 15-3 Calibrator 1 x 1.5 mL (liquid)	S1	Ready-to-use. Bovine albumin + DF3 reactive antigenic determinants (human origin) + 0.9 g/L sodium azide. The concentration in U/mL is indicated on the MLE card after the following mention: "Calibrator (S1) Dose Value". The confidence interval in “Relative Fluorescence Value” is indicated on the MLE card after the following mention : "Calibrator (S1) RFV Range".
CA 15-3 Diluent 1 x 5 mL (liquid)	R1	Ready-to-use. Calf serum + 0.9 g/L sodium azide.
1 MLE card (Master Lot Entry)		Specifications for the factory master data required to calibrate the test: to read the MLE data, please refer to the Operator’s Manual.
1 Clip seal		
1 Package insert		

The SPR®

The SPR is coated during production with monoclonal 115D8 antibodies (mouse). Each SPR is identified by the "153" code. Only remove the required number of SPRs from the pouch and **carefully reseal the pouch after opening using the clip seal provided with the kit.**

The Reagent 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 CA 15-3 Reagent Strip

Wells	Reagents
1	Sample well.
2 - 3 - 4	Empty wells.
5	Conjugate: Alkaline phosphatase labeled monoclonal DF3 antibody + 0.9 g/l sodium azide (400 µl).
6 - 7	Wash buffer: Tris (0.1 mol/L, pH 7.4) + NaCl (0.1 mol/L) + Tween (0.05 %) + 0.9 g/L sodium azide (600 µL).
8	Diluent: Tris (0.1 mol/L) + NaCl (0.1 mol/L) + calf serum (5 %) + 0.9 g/L sodium azide (400 µL).
9	Wash buffer: Tris (0.1 mol/L, pH 7.4) + NaCl (0.1 mol/L) + Tween (0.05 %) + 0.9 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).

*** IRRITANT reagent:**
- **R 36 :** Irritating to eyes.
- **S 26 :** In case of contact with eyes, rinse immediately with plenty of water and seek medical advice.

For further information, refer to the Safety Data Sheet available on request.

MATERIAL REQUIRED BUT NOT PROVIDED

- Pipette with disposable tip to dispense 100 µL.
- Powderless, disposable latex 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 SPRs (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 reading cuvette with substrate (well 10) contains an irritant agent (6.6% diethanolamine). Refer to the risk phrase "R" and the precautions "S" 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 place solutions containing bleach in the autoclave.
- The instrument should be routinely cleaned and decontaminated. See the Operator's Manual for the appropriate procedures.

STORAGE CONDITIONS

- Store the VIDAS® CA 15-3 (153) kit at 2-8°C.
- **Do not freeze reagents.**
- **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.
- **To maintain stability of the remaining SPRs, carefully reseal the pouch after use with the desiccant inside using the clip seal provided, 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.

SPECIMENS

Specimen type

Serum

Sample preparation

Follow the tube manufacturer's recommendations for use.

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

Sera can be stored at 2-8°C in stoppered tubes for up to 48 hours; if longer storage is required, freeze at - 25 ± 6°C.
Avoid successive freezing and thawing.
A study performed on frozen samples over a period of 2 months, showed that the quality of results is not affected.

Sample-related interference

It is recommended that each laboratory checks the compatibility of collection tubes used.
None of the following factors have been found to significantly influence this assay:

- hemolysis (after spiking samples with hemoglobin up to 322 µmol/L (monomer)),
- lipemia (after spiking samples with lipids up to 30 g/L equivalent in triglycerides),
- bilirubinemia (after spiking samples with bilirubin up to 523 µmol/L).
- cholesterol (after spiking samples with cholesterol) up to 20 mmol/L.

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

INSTRUCTIONS FOR USE

Master lot data entry

Before each new lot of reagents is used, specifications (or factory master data) must be entered into the instrument using the master lot entry (MLE). If this operation is not performed **before initiating the tests**, the instrument will not be able to print results. 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 (for complete instructions refer to the Operator's Manual).

Calibration

Calibration, using the calibrator provided in the kit, must be performed upon receipt of a new lot of reagents 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 Operator's Manual).
The calibrator value must be within the set RFV "Relative Fluorescence Value" range. If this is not the case, recalibrate.

Assay Procedure

1. **Only remove the required reagents from the refrigerator and allow them to come to room temperature for at least 30 minutes.**
2. Use one "153" strip and one "153" SPR® from the kit for each sample, control or calibrator to be tested. **Make sure the storage pouch has been carefully resealed with the clip seal after the required SPRs have been removed.**
3. The test is identified by the "153" 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 100 µl.**
6. Insert the "153" SPRs and 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 2–8°C 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® CA 15-3 (153) kit.
This control must be performed immediately after opening a new kit to ensure that reagent performance 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 concentrations are expressed in U/mL.

The VIDAS® CA 15-3 (153) assay is calibrated against Fujirebio Diagnostics, Inc. radioimmunoassay method.
Samples with CA 15-3 titers > 365 U/mL should be reassayed after maximum dilution by 1/10 (1 volume of sample and 9 volumes of CA 15-3 diluent).
If the dilution factor has not been entered when the analysis has been requested (see Operator's Manual), multiply the result by the dilution factor to obtain the CA 15-3 sample concentration.
Interpretation of test results should be made taking into consideration the patient history, and any other tests performed.
CA15-3 values can be high for several benign conditions including endometriosis, pregnancy, lactation, and pelvic inflammatory disease.
A baseline value of CA 15-3 needs to be established for monitoring. For patients being serially monitored, a percent change of 12% in CA 15-3 value can be agreed upon as being statistically significant and could be considered as a positive change. This figure is provided as a guide. It's recommended that each laboratory establishes its own significant positive change.

LIMITATIONS OF THE METHOD

- The VIDAS CA 15-3 (153) assay is not intended for use as a screening test for cancer.
- It is advised not to perform CA 15-3 assays in patients who have received a contrast agent in the previous 24 hours [20].
- The VIDAS CA 15-3 (153) assay is based on the use of monoclonal DF3 and 115D8 antibodies which are supplied exclusively by Fujirebio Diagnostics Inc., their distributors and licensed organizations. Methods using antibodies other than DF3 and 115D8 can give different clinical results.
- Sample CA 15-3 assay 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.
- VIDAS CA 15-3 (153) Performances have only been determined on female breast cancer specimens. VIDAS CA 15-3 (153) is not indicated for use on male breast cancer.
- CA 15-3 test values should be interpreted as part of a complete clinical profile and in relation to other diagnostic techniques.
- CA 15-3 test values may be high for several other cancers and several non-malignant conditions, and may not be high for early stage breast cancers.

RANGE OF EXPECTED VALUES

Normal Healthy Cohort

The reference values were determined from a healthy population of 202 ambulatory women from 18 – 80 years old. The group was made of approximately two-thirds pre-menopausal and one-third post menopausal women. Any woman older than 50 years of age is declared as being post-menopausal. All test values were generated on the VIDAS instrument.

Normal females	Number of subjects	Percentage (%) of the population according to the range of values in U/mL				95th percentile (U/mL)	95% CI
		< 30.00	30.01 – 60.00	60.01 – 120.00	> 120.00		
Pre-menopausal*	130	99.23	0.77	0.00	0.00	23.16	22.07 – 24.09
Post-menopausal**	72	87.50	12.50	0.00	0.00	33.79	29.62 – 36.95
Total	202	95.05	4.95	0.00	0.00	29.10	26.99 – 32.07

* Age 50 or less

** Over age 50

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 433 subjects with diagnosed benign diseases were tested using the VIDAS® CA 15-3 (153) assay. All test values were generated on the VIDAS instrument.

Non malignant disease	Number of subjects	Percentage (%) of the population according to the range of values in U/mL				95th percentile (U/mL)	95% CI
		< 30.00	30.01 – 60.00	60.01 – 120.00	> 120.00		
Gastro-intestinal/Lung	59	98.31	1.69	0.00	0.00	26.42	24.84 – 28.56
Urogenital disease	96	90.63	9.37	0.00	0.00	32.20	29.34 – 38.14
Chronic heart disease/ Hypertension/Benign liver	116	92.24	7.76	0.00	0.00	32.64	29.05 – 36.99
Benign breast	55	98.18	1.82	0.00	0.00	24.33	22.17 – 30.80
Diabetes	107	86.92	12.15	0.93	0.00	39.06	33.72 – 48.54
Total	433	92.15	7.62	0.23	0.00	34.97	30.46 – 37.13

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

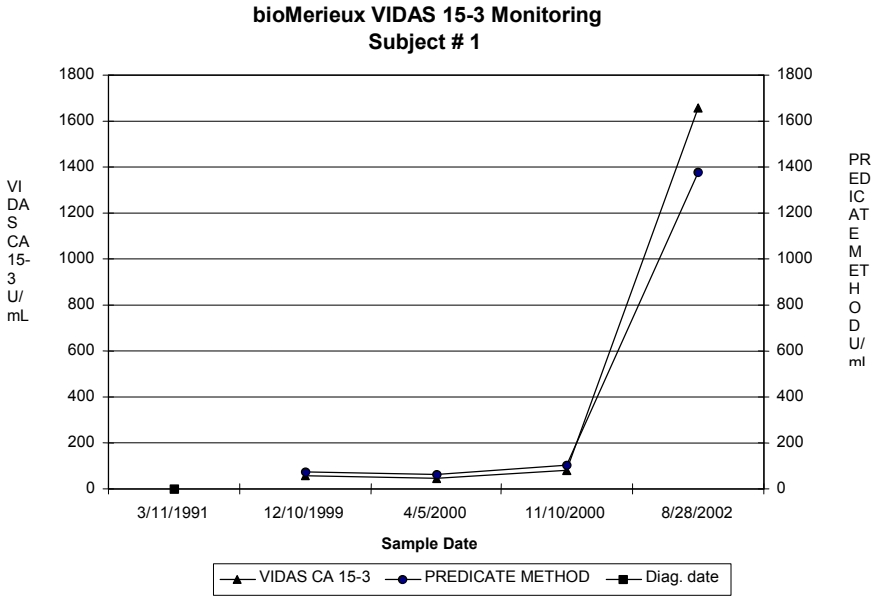
Using banked serum samples from a total of 406 subjects with a diagnosed malignant carcinoma, the following results were observed using the VIDAS® CA 15-3 (153) assay. All test values were generated on the VIDAS instrument.

Malignant disease	Number of subjects	Percentage (%) of the population according to the range of values in U/mL				95th percentile (U/mL)	95% CI
		< 30.00	30.01 – 60.00	60.01 – 120.00	> 120.00		
Lung/liver cancer	53	58.49	33.96	3.77	3.77	65.60	46.60 – 225.57
Uterine/cervical cancer	40	80.00	15.00	2.50	2.50	47.10	33.35 – 155.74
Ovarian cancer	55	65.45	21.82	9.09	3.64	71.82	45.19 – 210.25
Colorectal cancer	101	78.23	20.79	0.99	0.00	48.36	37.71 – 57.40
Breast	105	52.38	26.67	7.62	13.33	272.16	184.61 – 663.20
Other cancers (Gall bladder/ gastric/pancreatic…)	52	76.92	23.08	0.00	0.00	40.98	34.00 – 44.93
Total	406	67.24	23.89	4.19	4.68	94.29	66.53 – 209.27

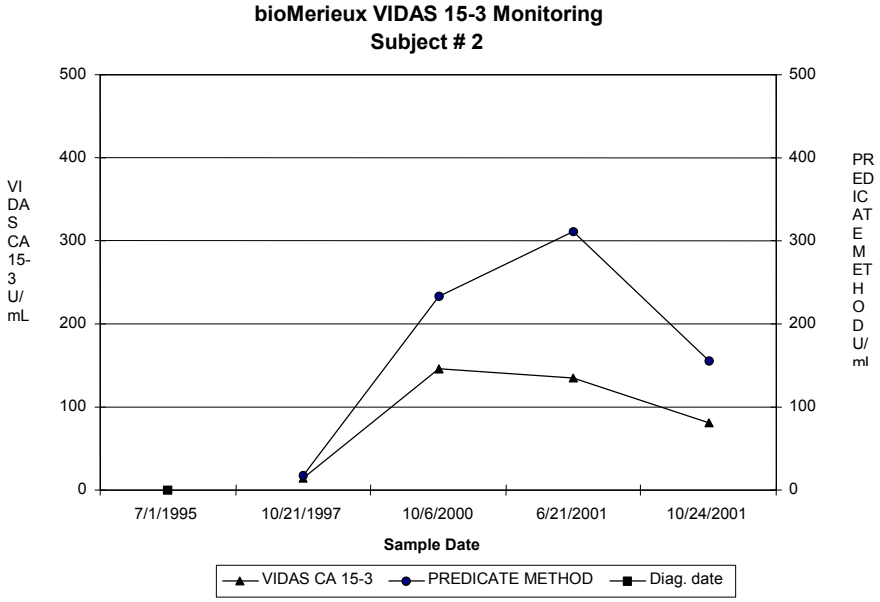
These figures are provided as a guide. It is recommended that each laboratory establishes its own reference values from a rigorously selected population.
The reported distribution table is derived from monitored carcinoma patients representing both active (clinical evidence of disease progression) and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

CA 15-3 Serial samples

Three hundred and fifty three (353) samples were tested from 80 evaluable serial sets collected from subjects with confirmed breast cancer. The resulting test values were incorporated into graphs to analyze the longitudinal history per subject of CA 15-3 values as determined with VIDAS® CA 15-3 (153) assay and a predicate method.



Caucasian female diagnosed with Stage II (tumor2/node2/metastases0 (T2N2M0)), moderately differentiated infiltrating ductal cell adenocarcinoma of right breast on 3/11/91 at 40 years old. Lymphatic invasion detected. 5-fluorouracil, adriamycin, cytoxan x 4 cycles then right Mastectomy and axillary node dissection 7/11/91. Second round of chemotherapy cyclophosphamide, vincristine, prednisone x 2 after surgery, followed by CPT-11 (Ironotecan) on 12/91. Routine followup exams until computed tomography (CT) abdomen showed suspicious area in liver. Fine needle aspiration liver 2/98 confirmed metastases. Tamoxifen from 2/13/98. Continuous chemotherapy throughout rest of disease course. Subject deceased from disease on 12/05.



Caucasian female diagnosed with Stage IIIA (tumor2/node2/metastases0 (T2N2M0)), moderately differentiated infiltrating ductal cell adenocarcinoma of left breast in 1995 at 46 years old. Healthy prior to this diagnosis with only bilateral fibrocystic disease reported. Metastases were found on chest wall. Several rounds of chemo and then left and right Mastectomy 12/04/95. Radiation between 8/96 - 10/96 followed by more courses of chemotherapy of several types. Subject deceased on 2/02 from disease.

PERFORMANCE

All test values were generated on the VIDAS instrument. Studies performed using VIDAS® CA 15-3 (153) gave the following results:

Measurement range

The measurement range of the VIDAS CA 15-3 (153) kit extends from 2 to 365 U/mL.

Detection limit

Based on CLSI document EP17-A, detection limit results are estimated to be less than 2 U/mL.

Hook effect

No hook effect was found up to CA 15-3 reactive antigenic determinants concentrations of 13,000 U/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 one instrument at each of three sites (N = 480).
The between-site precision, between-lot precision, between-recalibration precision, between-day precision, between-run precision, repeatability (within-run precision) and total precision (within-run, between-run, between-day, between-recalibration, between-lot and between-site) were calculated using an approved protocol, which was written based on the recommendations of CLSI® EP5-A2:

Source	Pool A (270 ng/mL)	Pool B (67.7 ng/mL)	Pool C (21.4 ng/mL)
	CV (%)	CV (%)	CV (%)
Between-site	0.00	0.00	1.92
Between-lot	3.17	2.10	2.01
Between-recalibration	2.81	2.03	2.36
Between-day	0.76	0.00	1.08
Between-run	1.71	1.93	2.23
Within-run	3.09	3.36	3.32
Total	5.57	4.85	5.52

Analytical specificity

No cross-reactivity was observed with ß HCG, CA 125, AFP, CEA, PSA, PAP, CA 19-9 and PRL.

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 CA 15-3 at a mean concentration of approximately 67.7 ± 10.38 U/mL, per CLSI® EP07-A2. The compounds showed no significant interference with the VIDAS CA 15-3 (153) 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	100 µg/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 U/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	100.5 IU/mL	Human Albumin	150 mg/mL

Linearity

The VIDAS® CA 15-3 (153) kit linearity and the diluent validation were studied according to a protocol based on the recommendations of the document CLSI® EP06-A.

- Linearity range: two samples, one with a low concentration and one with a high concentration, were mixed in varying proportions distributed over the measurement range. Each dilution was tested in duplicate. VIDAS CA 15-3 (153) is linear over the entire measurement range.
- **Dilution: four samples were diluted up to 1/20 using the kit diluent. Each dilution was tested in duplicate. VIDAS CA 15-3 (153) 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® CA 15-3 (153) (Y) assay were compared with another commercially available CA 15-3 assay (X). The results obtained are presented below (Deming regression). The equation represents the relationship between the two techniques.

n = 1035
Y = 0.96 X – 1.94
95% Confidence interval for the intercept: - 4.90 to 1.01
95% Confidence interval for the slope: 0.83 to 1.09

Serum samples from women with breast cancer using the VIDAS® CA 15-3 (153) (Y) were compared with another commercially available CA 15-3 assay (X). The results obtained are presented below (Deming regression). The equation represents the relationship between the two techniques.

n = 105
Y = 1.01 X – 8.39
95% Confidence interval for the intercept: - 41.34 to 24.56
95% Confidence interval for the slope: 0.36 to 1.67

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

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INDEX OF SYMBOLS

Symbol	Meaning
REF	GB : Catalogue number US : Catalog number
IVD	In Vitro Diagnostic Medical Device
	Manufacturer
	Temperature limitation
	Use by
LOT	Batch code
	Consult Instructions for Use
Σ	Contains sufficient for <n> tests
	Caution,consult accompanying documents

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