SIEMENS Healthineers

Carcinoembryonic Antigen (CEA)

Current Revision and Date[a]	Rev. 05, 2022-10	
Product Name	Atellica IM Carcinoembryonic Antigen (CEA)	REF 10995523 (100 tests) REF 10995524 (500 tests)
Abbreviated Product Name	Atellica IM CEA	
Test Name/ID	CEA	
Systems	Atellica IM Analyzer	
Materials Required but Not Provided	Atellica IM CAL D	REF 10995509 (2-pack) REF 10995510 (6-pack)
Optional Materials	Atellica IM CEA DIL Atellica IM CEA MCM	REF 10995525 REF 10995526
Specimen Types	Serum, EDTA plasma, lithium heparin plasma	
Sample Volume	50 µL	
Measuring Interval	2.00–100.00 ng/mL (µg/L)	

[a] A vertical bar in the page margin indicates technical content that differs from the previous version.

WARNING

The concentration of CEA in a given specimen, as determined by 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 serial CEA levels is changed, the laboratory must perform additional serial testing to confirm baseline values.

Intended Use

The Atellica® IM Carcinoembryonic Antigen (CEA) assay is for *in vitro* diagnostic use in the quantitative measurement of carcinoembryonic antigen in human serum and plasma (EDTA and lithium heparin) to aid in the management of cancer patients in whom changing concentrations of CEA are observed using the Atellica® IM Analyzer.

Summary and Explanation

Carcinoembryonic antigen is a glycoprotein normally found in embryonic entodermal epithelium. In the mid-1960s, Gold and Freedman isolated CEA from extracts of malignant tissue.[1,2] CEA belongs to a group of tumor markers referred to as oncofetal proteins. Increased serum CEA levels have been detected in persons with primary colorectal cancer[1,2] and in patients with other malignancies including gastrointestinal tract, breast, lung, ovarian, prostatic, liver, and pancreatic cancers.[1-5] Elevated serum CEA levels have also been detected in patients with nonmalignant disease, especially patients who are older or who are smokers.[5,6] CEA levels are not useful in screening the general population for undetected cancers. However, CEA levels provide important information about patient prognosis, recurrence of tumors after surgical removal, and effectiveness of therapy.[1-6]

Serial CEA levels are useful in monitoring the course of disease. CEA levels generally fall to normal or near normal levels within 1–4 months after surgical removal of cancerous tissue. A rise in CEA levels may be the first indication of recurrence, and may precede physical signs and symptoms.[2,6,7] Serial CEA levels are also useful in assessing the effectiveness of chemotherapy or radiation treatment. A sustained rise in CEA levels can indicate ineffective therapy or possible metastasis.[1-5,7]

CEA is a useful tool for monitoring and managing cancer therapy, and provides the clinician with additional information about patient prognosis.

Principles of the Procedure

The Atellica IM CEA assay is a 2-site sandwich immunoassay using direct chemiluminometric technology which uses constant amounts of 2 antibodies. The first antibody, in the Lite Reagent, is a purified rabbit polyclonal anti-CEA antibody labeled with acridinium ester. The second antibody, in the Solid Phase, is a mouse monoclonal anti-CEA antibody covalently coupled to paramagnetic particles.

A direct relationship exists between the amount of CEA present in the patient sample and the amount of relative light units (RLUs) detected by the system.

Reagents

Material Description	Storage	Stability[a]
Atellica IM CEA ReadyPack® primary reagent pack **Lite Reagent** 5.0 mL/reagent pack Rabbit polyclonal anti-CEA antibody (~400 ng/mL) labeled with acridinium ester in phosphate buffered saline; protein stabilizers; sodium azide (0.12%); preservatives **Solid Phase** 25.0 mL/reagent pack Mouse monoclonal anti-CEA antibody (~120 µg/mL) covalently coupled to paramagnetic particles in phosphate buffered saline; protein stabilizers; sodium azide (0.11%); preservatives	Unopened at 2–8°C Onboard	Until expiration date on product 84 days
Atellica IM CEA DIL ReadyPack ancillary reagent pack[b] 5.0 mL/reagent pack Bicine buffer; gelatin; bovine serum albumin; preservatives; sodium azide (0.1%)	Unopened at 2–8°C Onboard	Until expiration date on product 28 days

[a] Refer to *Storage and Stability*.

[b] Refer to *Optional Materials*.

Warnings and Precautions

For *in vitro* diagnostic use.

For Professional Use.

CAUTION

Federal (USA) law restricts this device to sale by or on the order of a licensed healthcare professional.

Safety data sheets (SDS) available on siemens-healthineers.com.

CAUTION

This device contains material of animal origin and should be handled as a potential carrier and transmitter of disease.

Contains sodium azide as a preservative. Sodium azide can react with copper or lead plumbing to form explosive metal azides. On disposal, flush reagents with a large volume of water to prevent buildup of azides. Disposal into drain systems must be in compliance with prevailing regulatory requirements.

Dispose of hazardous or biologically contaminated materials according to the practices of your institution. Discard all materials in a safe and acceptable manner and in compliance with prevailing regulatory requirements.

Note For information about reagent preparation, refer to *Preparing the Reagents* in the *Procedure* section.

Storage and Stability

Store reagents in an upright position. Protect the product from heat and light sources. Unopened reagents are stable until the expiration date on the product when stored at 2–8°C.

Store Atellica IM CEA DIL in an upright position. Unopened Atellica IM CEA DIL is stable until the expiration date on the product when stored at 2–8°C.

Do not use products beyond the expiration date printed on the product labeling.

Onboard Stability

Reagents are stable onboard the system for 84 days. Discard reagents at the end of the onboard stability interval.

Atellica IM CEA DIL is stable onboard the system for 28 days.

Do not use products beyond the expiration date printed on the product labeling.

Specimen Collection and Handling

Serum and plasma (EDTA and lithium heparin) are the recommended sample types for this assay.

Collecting the Specimen

- Observe universal precautions when collecting specimens. Handle all specimens as if they are capable of transmitting disease.[8]
- Follow recommended procedures for collection of diagnostic blood specimens by venipuncture.[9]
- Follow the instructions provided with your specimen collection device for use and processing.[10]

- Allow blood specimens to clot completely before centrifugation.[11]
- Keep tubes capped at all times.[11]

Storing the Specimen

- Do not use samples that have been stored at room temperature for longer than 8 hours.
- Tightly cap and refrigerate specimens at 2–8°C if the assay is not completed within 8 hours.
- Freeze samples at ≤ -20°C if the sample is not assayed within 48 hours.
- Freeze samples only 1 time and mix thoroughly after thawing.

The handling and storage information provided here is based on data or references maintained by the manufacturer. It is the responsibility of the individual laboratory to use all available references and/or its own studies when establishing alternate stability criteria to meet specific needs.

Transporting the Specimen

Package and label specimens for shipment in compliance with applicable federal and international regulations covering the transport of clinical specimens and etiological agents.

Preparing the Samples

This assay requires 50 µL of sample for a single determination. This volume does not include the unusable volume in the sample container or the additional volume required when performing duplicates or other tests on the same sample. For information about determining the minimum required volume, refer to the online help.

The sample volume required to perform onboard dilution differs from the sample volume required to perform a single determination. Refer to *Dilutions*.

Note Do not use specimens with apparent contamination.

Before placing samples on the system, ensure that samples are free of:

- Bubbles or foam.
- Fibrin or other particulate matter.

Note Remove particulates by centrifugation according to CLSI guidance and the collection device manufacturer's recommendations.[11]

Note For a complete list of appropriate sample containers, refer to the online help.

Procedure

Materials Provided

The following materials are provided:

REF	Contents	Number of Tests
10995523	1 ReadyPack primary reagent pack containing Atellica IM CEA Lite Reagent and Solid Phase Atellica IM CEA master curve and test definition MC TDEF	100
10995524	5 ReadyPack primary reagent packs containing Atellica IM CEA Lite Reagent and Solid Phase Atellica IM CEA master curve and test definition MC TDEF	500

Materials Required but Not Provided

The following materials are required to perform this assay, but are not provided:

REF	Description	
	Atellica IM Analyzer[a]	
10995509	Atellica IM CAL D (calibrator)	2 x 2.0 mL low calibrator CAL L 2 x 2.0 mL high calibrator CAL H Calibrator lot-specific value sheet CAL LOT VAL
10995510	Atellica IM CAL D (calibrator)	6 x 2.0 mL low calibrator CAL L 6 x 2.0 mL high calibrator CAL H Calibrator lot-specific value sheet CAL LOT VAL

[a] Additional system fluids are required to operate the system: Atellica IM Wash, Atellica IM Acid, Atellica IM Base, and Atellica IM Cleaner. For system fluid instructions for use, refer to the Document Library.

Optional Materials

The following materials may be used to perform this assay, but are not provided:

REF	Description	
10995525	Atellica IM CEA DIL (diluent)	2 ReadyPack ancillary reagent packs containing 5.0 mL/pack DIL
10995526	Atellica IM CEA MCM (master curve material)	6 x 1.0 mL levels of master curve material MCM

Assay Procedure

The system automatically performs the following steps:

1. Dispenses 50 µL of sample into a cuvette.
2. Dispenses 50 µL of Lite Reagent and 250 µL of Solid Phase, then incubates for 12 minutes at 37°C.
3. Separates, aspirates, then washes the cuvette with special reagent water.

   Note For information about special reagent water requirements, refer to the online help.
4. Dispenses 300 µL each of Atellica IM Acid and Atellica IM Base to initiate the chemiluminescent reaction.
5. Reports results.

Preparing the Reagents

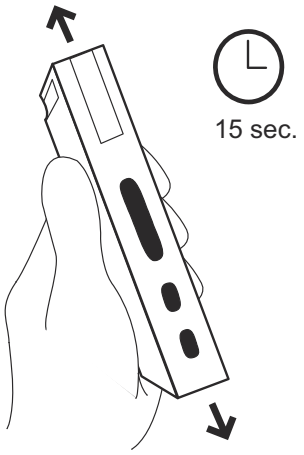
All reagents are liquid and ready to use. Before loading primary reagent packs onto the system, mix them by hand (as shown below) and visually inspect the bottom of the reagent pack to ensure that all particles are resuspended. For information about preparing the reagents for use, refer to the online help.

Use this procedure to mix Atellica IM CEA primary reagent packs that are unpierced.

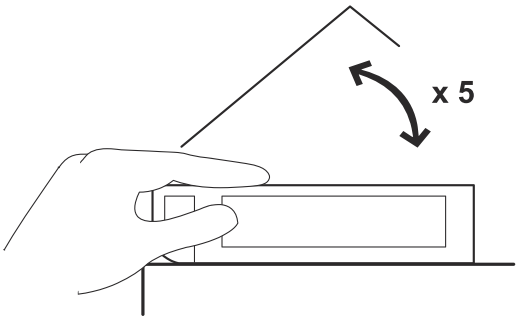
CAUTION

Do not use this procedure for pierced Atellica IM CEA reagent packs. Discard pierced Atellica IM CEA reagent packs that have been removed from the system.

1. Hold the reagent pack firmly with thumb on 1 side and fingers on the other side. Shake vigorously for 15 seconds, using a back and forth motion.



2. Hold the reagent pack firmly at one end, with film side up, and tap sharply on a bench top 5 times to reduce foaming caused by shaking.



Preparing the System

Ensure that the system has sufficient reagent packs loaded in the reagent compartment. The system automatically mixes reagent packs to maintain homogeneous suspension of the reagents. For information about loading reagent packs, refer to the online help.

For automated dilutions, ensure that Atellica IM CEA DIL is loaded on the system.

Master Curve Definition

Before initiating calibration on each new lot of reagent, load the assay master curve and test definition values by scanning the MC TDEF 2D barcodes. For loading instructions, refer to the online help.

Performing Calibration

For calibration of the Atellica IM CEA assay, use the Atellica IM CAL D. Use the calibrators in accordance with the calibrator instructions for use.

Calibration Frequency

Perform a calibration if one or more of the following conditions exist:

- When changing lot numbers of primary reagent packs.
- At the end of the lot calibration interval, for a specified lot of calibrated reagent on the system.
- At the end of the pack calibration interval, for calibrated reagent packs on the system.

- When indicated by quality control results.
- After major maintenance or service, if indicated by quality control results.

At the end of the onboard stability interval, replace the reagent pack on the system with a new reagent pack. Recalibration is not required, unless the lot calibration interval is exceeded.

Stability Interval	Days
Lot Calibration	28
Pack Calibration	28
Reagent Onboard Stability	84

For information about lot calibration and pack calibration intervals, refer to the online help.

Follow government regulations or accreditation requirements for calibration frequency. Individual laboratory quality control programs and procedures may require more frequent calibration.

Performing Quality Control

For quality control of the Atellica IM CEA assay, use an appropriate quality control material of known analyte concentration with at least 2 levels (low and high) at least once during each day that samples are analyzed.

Additional quality control material can be used at the discretion of the laboratory. Use the quality control material in accordance with the quality control instructions for use.

In addition, perform quality control:

- Following a valid calibration
- With use of a new lot of reagent
- When troubleshooting test results that do not match clinical conditions or symptoms

Follow government regulations or accreditation requirements for quality control frequency. Individual laboratory quality control programs and procedures may require more frequent quality control testing.

Acceptable performance is achieved when the analyte values obtained are within the expected control interval for the system, as indicated by the manufacturer of the control material or within the interval determined by an internal laboratory quality control procedure.

Follow your laboratory's quality control procedures if the results obtained do not fall within the acceptable limits. For information about entering quality control definitions, refer to the system online help.

Taking Corrective Action

If the quality control results do not fall within the assigned values, do not report results. Perform corrective actions in accordance with established laboratory protocol. For suggested protocol, refer to the online help.

Results

Calculation of Results

The system determines the result using the calculation scheme described in the online help. The system reports results in ng/mL (common units) or µg/L (SI units), depending on the units defined when setting up the assay.

Conversion formula: 1 ng/mL (common units) = 1 µg/L (SI units)

For information about results outside the specified measuring interval, refer to *Measuring Interval*.

Dilutions

The assay measuring interval is 2.00–100.00 ng/mL (µg/L). For information about dilution options used to extend the reportable measuring interval up to 10,000.00 ng/mL (µg/L), refer to the online help.

Samples with CEA levels > 100.00 ng/mL (µg/L) must be diluted and retested to obtain accurate results.

For automated dilutions, ensure that Atellica IM CEA DIL is loaded on the system. Ensure that sufficient sample volume is available to perform the dilution and that the appropriate dilution factor is selected when scheduling the test, as indicated in the table below. Enter a dilution setpoint ≤ 100.00 ng/mL (µg/L).

Sample	Dilution	Sample Volume (µL)
Serum and plasma	1:5	40
Serum and plasma	1:10	40
Serum and plasma	1:50	40
Serum and plasma	1:100	40

Interpretation of Results

Results of this assay should always be interpreted in conjunction with patient's medical history, clinical presentation, and other findings.

Limitations

WARNING

Do not use the Atellica IM CEA assay as a screening test for diagnosis.

NOTE

Do not interpret levels of CEA as absolute evidence of the presence or the absence of malignant disease. Measurements of CEA should always be used in conjunction with other diagnostic procedures, including information from the patient's clinical evaluation.

The concentration of CEA in a given specimen determined with assays from different manufacturers can vary due to differences in assay methods, calibration, and reagent specificity. CEA determined with different manufacturers' assays will vary depending on the method of standardization and antibody specificity.

Patient samples may contain heterophilic antibodies that could react in immunoassays to give falsely elevated or depressed results. This assay is designed to minimize interference from heterophilic antibodies.[12,13]

Expected Values

The reagent formulations used on the Atellica IM Analyzer are the same as those used on the ADVIA Centaur® and ACS:180™ systems. Expected values were established using the ACS:180 system and confirmed by assay comparison. Refer to *Assay Comparison*.

As with all *in vitro* diagnostic assays, each laboratory should determine its own reference interval for the diagnostic evaluation of patient results.[14] Consider these values as guidance only.

Data was obtained as shown in the following table. Serum samples from healthy subjects and patients with various malignant diseases were analyzed. The cancer patients included in this study represented a variety of disease states from active, progressive malignancy to no clinical evidence of disease. The frequency of positive CEA results was significantly lower in patients with no evidence of active disease compared to those with active disease.

	% Distribution of CEA (ng/mL) (µg/L)					
Clinical Condition	**N**	**0–2.5**	**2.6–5.0**	**5.1–10.0**	**10.1–20**	**> 20.0**
Healthy Subject						
Nonsmokers	225	98.2	1.8	0	0	0
Smokers	150	87.3	8.0	4.7	0	0
Cancerous Diseases						
Colorectal	250	37.6	10.8	7.2	6.4	38.0
Lung	158	46.2	15.8	10.8	7.0	20.2
Breast	221	68.3	14.9	7.7	2.3	6.8
Gastric	35	60.0	17.1	8.6	5.7	8.6
Ovarian	35	82.8	11.4	2.9	2.9	0
Pancreatic	43	44.2	20.9	16.3	7.0	11.6
Liver	6	50.0	16.7	0	33.3	0
Lymphoproliferative	15	80.0	20.0	0	0	0
Other[a]	41	75.0	10.0	10.0	5.0	0
Nonmalignant Diseases						
Cirrhosis	53	41.5	13.2	32.1	13.2	0
Other benign liver	5	40.0	20.0	0	40.0	0
Ulcerative colitis	11	90.9	9.1	0	0	0
Benign polyps	23	65.2	21.8	13.0	0	0
Colon and intestinal	15	66.7	20.0	0	13.3	0
Gastrointestinal	21	76.2	14.2	0	4.8	4.8
Breast	53	96.2	0	1.9	0	1.9
Kidney and bladder	12	83.4	8.3	0	8.3	0
Lung	29	69.0	24.1	6.9	0	0
Other[b]	117	86.3	8.5	4.3	0.9	0

[a] Other cancerous diseases include bladder, prostate, esophagus, head and neck, sarcoma, and kidney.

[b] Other nonmalignant diseases include benign uterine, cervical and vaginal, benign ovary, and benign male genital, as well as other benign conditions.

Performance Characteristics

The reagent formulations used on the Atellica IM Analyzer are the same as those used on the ADVIA Centaur and ACS:180 systems. Some performance characteristics for the Atellica IM assay were established using the ADVIA Centaur or ACS:180 systems.

Measuring Interval

2.00–100.00 ng/mL (µg/L).

The lower limit of the measuring interval is defined by the Limit of Quantitation (LoQ). Report results below the measuring interval as < 2.00 ng/mL (µg/L).

When sample results exceed the measuring interval, refer to *Dilutions*.

Specificity

The potential interference of NCA (normal cross-reacting antigen) and NCA2 was tested by adding these antigens to serum pools containing CEA. The level of CEA was then determined.

Cross-Reactant	CEA Value Without Cross-Reactant (ng/mL) (µg/L)	CEA Value With Cross-Reactant (ng/mL) (µg/L)
NCA (500 ng/mL)	2.5	2.5
	23.3	21.8
	71.2	66.1
NCA2 (100 ng/mL)	2.5	2.5
	23.3	22.9
	71.2	62.0

NCA and NCA2 showed minimal interference with the recovery of CEA from the serum samples. Average recovery is > 95%.

Results were established using the ADVIA Centaur system. Assay results obtained at individual laboratories may vary from the data presented.

Detection Capability

Detection capability was determined in accordance with CLSI Document EP17-A2.[15]

Limit of Blank (LoB)	0.50 ng/mL (µg/L)
Limit of Detection (LoD)	1.00 ng/mL (µg/L)
Limit of Quantitation (LoQ)	2.00 ng/mL (µg/L)

The LoB corresponds to the highest measurement likely to be observed for a blank sample with a probability of 95%.

The LoD corresponds to the lowest concentration of carcinoembryonic antigen that can be detected with a probability of 95%.

The LoQ corresponds to the lowest amount of carcinoembryonic antigen in a sample at which the within laboratory CV is ≤ 20%

Precision

Precision was determined in accordance with CLSI Document EP05-A3.[16] Samples were assayed on an Atellica IM Analyzer in duplicate in 2 runs per day for 20 days. The assay was designed to have within-laboratory precision of ≤ 0.22 SD for samples ≤ 2.00 ng/mL (µg/L), ≤ 11% CV for samples from 2.00–5.00 ng/mL (µg/L), and ≤ 10% CV for samples from 5.00–100.00 ng/mL (µg/L). The following results were obtained:

			Repeatability		Within-Laboratory Precision	
Sample Type	**N[a]**	**Mean ng/mL (µg/L)**	**SD[b] ng/mL (µg/L)**	**CV[c] (%)**	**SD ng/mL (µg/L)**	**CV (%)**
Serum A	80	3.12	0.16	5.0	0.19	6.0
Serum B	80	14.00	0.31	2.2	0.47	3.3
Serum C	80	33.35	0.62	1.9	0.96	2.9
Serum D	80	53.97	0.87	1.6	1.47	2.7
Serum E	80	84.81	1.45	1.7	2.20	2.6
Control 1	80	2.12	0.08	3.6	0.12	6.0
Control 2	80	18.76	0.48	2.6	0.61	3.2
Control 3	80	42.24	0.96	2.3	1.21	2.8

[a] Number of samples tested.
[b] Standard deviation.
[c] Coefficient of variation.

Assay results obtained at individual laboratories may vary from the data presented.

Assay Comparison

The Atellica IM CEA assay is designed to have a correlation coefficient of ≥ 0.95 and a slope of 1.0 ± 0.10 compared to the ADVIA Centaur CEA assay. Assay comparison was determined using the Weighted Deming regression model in accordance with CLSI Document EP09-A3.[17] The following results were obtained:

Specimen	**Comparative Assay (x)**	**Regression Equation**	**Sample Interval**	**N[a]**	**r[b]**
Serum	ADVIA Centaur CEA	y = 1.020x - 0.112 ng/mL (µg/L)	2.89–97.65 ng/mL (µg/L)	112	0.997

[a] Number of samples tested.
[b] Correlation coefficient.

For 201 samples in the range of 2.00–78.93 ng/mL (µg/L), the relationship between the ADVIA Centaur CEA assay and the ACS:180 CEA assay is described using ordinary least squares regression by the following equation:

Specimen	**Comparative Assay (x)**	**Regression Equation**	**Sample Interval**	**N[a]**	**r[b]**
Serum	ACS:180 CEA	y = 0.97x + 0.11 ng/mL (µg/L)	2.00–78.93 ng/mL (µg/L)	201	1.00

[a] Number of samples tested.
[b] Correlation coefficient.

Agreement of the assays may vary depending on the study design, comparative assay, and sample population used. Assay results obtained at individual laboratories may vary from the data presented.

Specimen Equivalency

Specimen equivalency was determined with the Deming linear regression model in accordance with CLSI Document EP09-A3.[17] The following results were obtained:

Tube (y) vs. Serum (x)	N[a]	Sample Interval	Slope	Intercept	r[b]
Dipotassium EDTA plasma	65	2.13–91.53 ng/mL (µg/L)	0.97	0.14 ng/mL (µg/L)	1.00
Lithium heparin plasma	47	2.00–91.53 ng/mL (µg/L)	0.99	0.35 ng/mL (µg/L)	1.00

[a] Number of samples tested.
[b] Correlation coefficient.

The assay is designed to have a slope of 0.90–1.10 for alternate tube types versus serum.

Agreement of the specimen types may vary depending on the study design and sample population used. Assay results obtained at individual laboratories may vary from the data presented.

Interferences

Interference testing was performed using the ADVIA Centaur XP system in accordance with CLSI Document EP07-ed3.[18] The following results were obtained:

Substance	Substance Test Concentration	Analyte Concentration ng/mL (µg/L)	Bias (%)
Dipotassium EDTA	9.0 mg/mL	5.78	-0.3
		55.62	4.6
Heparin	75 U/mL	5.83	-0.6
		61.23	0.9

Assay results obtained at individual laboratories may vary from the data presented.

Interference testing was performed in accordance with CLSI Document EP7-A2.[19]

The potential interference of chemotherapeutic agents was tested by adding these agents to serum pools containing CEA. The level of CEA in each of these pools was then determined and normalized to the level without the respective drugs.

Substance	Amount Added (µg/mL)	Mean % Recovery (Spike/Control x 100)
Vincristine	0.70	100.4
Vinblastine	1.20	99.2
Cisplatinum	1.50	97.9
Tamoxifen	133	98.9
Cyclophosphamide	3300	96.9
5-Fluorouracil	360	96.9
Adriamycin	100	96.9
Folinic acid	60	98.4
Mitomycin C	60	96.6

Substance	Amount Added (µg/mL)	Mean % Recovery (Spike/Control x 100)
Methotrexate	4500	98.7
Bleomycin	1300	100.9

Hemolysis, Icterus, and Lipemia (HIL)

Serum specimens that are . . .	Demonstrate ≤ 5% change in results up to . . .
hemolyzed	500 mg/dL of hemoglobin
lipemic	1000 mg/dL of triglycerides
icteric	20 mg/dL of conjugated bilirubin 20 mg/dL of unconjugated bilirubin

Results were established using the ADVIA Centaur system. Assay results obtained at individual laboratories may vary from the data presented.

Dilution Recovery

Five serum samples in the range of 80.18–87.13 ng/mL (µg/L) of CEA were diluted 1:2, 1:4, 1:8, and 1:16 with CEA Diluent and assayed for recovery and parallelism. The recoveries ranged from 108.6%–139.8% with a mean of 123.4%.

Sample	Dilution	Observed (ng/mL) (µg/L)	Expected (ng/mL) (µg/L)	Recovery %
1	—	87.13	—	—
	1:2	49.52	43.57	113.7
	1:4	26.11	21.78	119.9
	1:8	12.97	10.89	119.1
	1:16	6.64	5.45	121.9
	Mean			118.6
2	—	80.18	—	—
	1:2	44.29	40.09	110.5
	1:4	21.76	20.05	108.6
	1:8	11.56	10.02	115.3
	1:16	5.61	5.01	111.9
	Mean			111.6
3	—	86.37	—	—
	1:2	49.91	43.19	115.6
	1:4	28.65	21.59	132.7
	1:8	14.48	10.80	134.1
	1:16	7.39	5.40	136.9

Sample	Dilution	Observed (ng/mL) (µg/L)	Expected (ng/mL) (µg/L)	Recovery %
	Mean			129.8
4	—	85.83	—	—
	1:2	51.62	42.92	120.3
	1:4	28.60	21.46	133.3
	1:8	14.59	10.73	136.0
	1:16	7.50	5.36	139.8
	Mean			132.3
5	—	81.42	—	—
	1:2	48.58	40.71	119.3
	1:4	25.60	20.36	125.8
	1:8	12.64	10.18	124.2
	1:16	6.56	5.09	128.9
	Mean			124.6
Mean				123.4

Results were established using the ADVIA Centaur system. Assay results obtained at individual laboratories may vary from the data presented.

Spiking Recovery

Varying amounts of CEA were added to 7 serum samples with endogenous CEA levels ranging from 0–2.2 ng/mL (µg/L). The amount of CEA that was added varied from 7.0–83.0 ng/mL (µg/L). When compared to the expected value, the measured (recovered) values of CEA averaged 100.8% with a range of 75.5%–135.8%.

Sample	Amount Added (ng/mL) (µg/L)	Observed (ng/mL) (µg/L)	Recovery %
1	—	0.5	—
	7.0	6.5	86.6
	13.0	10.2	75.5
	28.0	28.6	100.5
	55.0	53.7	96.8
	83.0	80.5	96.5
	Mean		91.2
2	—	1.6	—
	7.0	8.3	97.2
	13.0	16.7	114.7
	28.0	31.3	105.9

Sample	Amount Added (ng/mL) (µg/L)	Observed (ng/mL) (µg/L)	Recovery %
	55.0	54.5	96.2
	83.0	81.0	95.8
	Mean		102.0
3	—	0.2	—
	7.0	8.5	118.6
	13.0	12.1	91.4
	28.0	31.4	111.3
	55.0	56.1	101.5
	83.0	79.0	94.9
	Mean		103.5
4	—	0.8	—
	7.0	7.0	90.0
	13.0	11.1	80.7
	28.0	32.6	113.2
	55.0	56.2	100.8
	83.0	82.0	97.9
	Mean		96.5
5	—	0.6	—
	7.0	6.9	91.8
	13.0	18.4	135.8
	28.0	33.1	116.0
	55.0	49.9	89.9
	83.0	104.4	124.9
	Mean		111.7
6	—	0.3	—
	7.0	7.0	95.4
	7.0	12.7	95.7
	13.0	31.5	111.2
	28.0	53.3	96.5
	55.0	78.1	93.8
	Mean		98.5
7	—	0.7	—
	7.0	7.9	102.2

Sample	Amount Added (ng/mL) (µg/L)	Observed (ng/mL) (µg/L)	Recovery %
	13.0	12.2	88.7
	28.0	31.7	110.6
	55.0	60.4	108.5
	83.0	83.6	99.8
	Mean		102.0
Mean			100.8

Results were established using the ADVIA Centaur system. Assay results obtained at individual laboratories may vary from the data presented.

High-Dose Hook Effect

High CEA concentrations can cause a paradoxical decrease in the RLUs (high-dose hook effect). In this assay, patient samples with CEA concentrations as high as 100,000.00 ng/mL (100.00 µg/L) will report > 100.00 ng/mL (µg/L).

Results were established using the Atellica IM Analyzer.

Standardization

The Atellica IM CEA assay is traceable to an internal standard manufactured using highly purified material. Assigned values for calibrators are traceable to this standardization.

Technical Assistance

For customer support, contact your local technical support provider or distributor.

siemens-healthineers.com

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Definition of Symbols

The following symbols may appear on the product labeling:

Symbol	Symbol Title	Source	Symbol	Symbol Title	Source
	Manufacturer	5.1.1[a]	EC REP	Authorized representative in the European Community	5.1.2[a]
	Use-by date	5.1.4[a]	LOT	Batch code	5.1.5[a]
REF	Catalog number	5.1.6[a]		Contains sufficient for <n> tests	5.5.5[a]
	Consult Instructions for Use	5.4.3[a]	 Rev. XX	Version of Instructions for Use	Proprietary
 siemens.com/eifu	Internet URL address to access the electronic instructions for use	Proprietary	Rev. REVISION	Revision	Proprietary

Symbol	Symbol Title	Source	Symbol	Symbol Title	Source
IVD	*In vitro* diagnostic medical device	5.5.1[a]	UDI	Unique Device Identifier	5.7.10[b]
RxOnly	Prescription device (US only)	FDA[c]	CE	CE Marking	EU IVDR[d]
CE XXXX	CE Marking with Notified Body	EU IVDR[d]		Keep away from sunlight	5.3.2[a]
	Temperature limit	5.3.7[a]		Lower limit of temperature	5.3.5[a]
	Upper limit of temperature	5.3.6[a]		Do not freeze	Proprietary
	Do not re-use	5.4.2[a]		This way up	0623[e]
	Recycle	1135[e]		Caution	5.4.4[a]
	Biological risks	5.4.1[a]		Document face up[f]	1952[e]
UNITS C	Common Units	Proprietary	UNITS SI	International System of Units	Proprietary
YYYY-MM-DD	Date format (year-month-day)	N/A	**YYYY-MM**	Date format (year-month)	N/A
	Handheld barcode scanner	Proprietary		Mixing of substances	5657[g]
	Target	Proprietary		Interval	Proprietary
CHECKSUM	Variable hexadecimal number that ensures the Master Curve and Calibrator definition values entered are valid.	Proprietary	MATERIAL	Material	Proprietary
MATERIAL ID	Unique material identification number	Proprietary	CONTROL NAME	Name of control	Proprietary
CONTROL TYPE	Type of control	Proprietary	CAL LOT VAL	Calibrator lot value	Proprietary
CONTROL LOT VAL	Quality control lot value	Proprietary			

[a] International Standard Organization (ISO). ISO 15223-1 Medical Devices- Symbols to be used with medical device labels, labelling and information to be supplied.
[b] ISO 15223-1:2020-04
[c] Federal Register. Vol. 81, No 115. Wednesday, June 15, 2016. Rules and Regulations: 38911.
[d] IVDR REGULATION (EU) 2017/746
[e] International Standard Organization (ISO). ISO 7000 Graphical symbols for use on equipment.
[f] Indicates Assay-eNote
[g] International Electrotechnical Commission (IEC). IEC 60417-1 Graphical symbols for use on equipment – Part 1: Overview and Application

Legal Information

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