



ARCHITECT

SYSTEM

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CEA

REF 7K68

48-5978/R1

B7K6R0

Read Highlighted Changes
Revised September, 2009


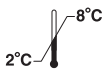


CEA



Customer Service: Contact your local representative or find country specific contact information on www.abbottdiagnostics.com

Package insert instructions must be carefully followed. Reliability of assay results cannot be guaranteed if there are any deviations from the instructions in this package insert.

Key to symbols used

REF	List Number	REAGENT LOT	Reagent Lot
IVD	<i>In Vitro</i> Diagnostic Medical Device	SN	Serial Number
LOT	Lot Number	SAMPLE CUPS	Sample Cups
	Expiration Date	SEPTUM	Septum
	Store at 2-8°C	CONTROL NO.	Control Number
	Consult instructions for use	REACTION VESSELS	Reaction Vessels
	Manufacturer	REPLACEMENT CAPS	Replacement Caps

See **REAGENTS** section for a full explanation of symbols used in reagent component naming.

WARNING: The concentration 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.

CAUTION: United States Federal Law restricts this device to sale and distribution by or on the order of a physician, or to a clinical laboratory; and use is restricted to by or on the order of a physician.

NAME

ARCHITECT CEA (carcinoembryonic antigen)

INTENDED USE

The ARCHITECT CEA assay is a Chemiluminescent Microparticle Immunoassay (CMIA) for the quantitative determination of Carcinoembryonic Antigen (CEA) in human serum and plasma. The ARCHITECT CEA assay is to be used as an aid in the prognosis and management of cancer patients in whom changing concentrations of CEA are observed.

SUMMARY AND EXPLANATION OF TEST

Carcinoembryonic antigen (CEA), first described in 1965 by Gold and Freedman,¹ is a tumor associated antigen. CEA was characterized as a glycoprotein of approximately 200,000 molecular weight with a β -electrophoretic mobility.^{2,3} Subsequent development of a radioimmunoassay (RIA) by Thomson, *et al*⁴ made it possible to detect the very low concentrations of CEA in blood, other body fluids, and also in normal and diseased tissues.⁵⁻⁷ Two years later, Hansen, *et al*⁸ developed a modified RIA for CEA.

The result of clinical studies to date indicate that CEA, although originally thought to be specific for digestive tract cancers, may also be elevated in other malignancies and in some nonmalignant disorders.⁹⁻¹⁵

CEA testing can have significant value in the monitoring of patients with diagnosed malignancies in whom changing concentrations of CEA are observed. A persistent elevation in circulating CEA following treatment is strongly indicative of occult metastatic and/or residual disease.¹⁶⁻²⁰

A persistently rising CEA value may be associated with progressive malignant disease and a poor therapeutic response.²¹⁻²³ A declining CEA value is generally indicative of a favorable prognosis and a good response to treatment.^{21,23-24} Patients who have low pretherapy CEA levels may later show elevations in the CEA level as an indication of progressive disease.²⁵

Clinical relevance of the CEA assay has been shown in the follow-up management of patients with colorectal, gastric, breast, lung, prostatic, pancreatic, and ovarian carcinoma.^{18,24,26-31} Follow-up studies of patients with colorectal, breast, and lung carcinoma suggest that the preoperative CEA level has prognostic significance.³²⁻³⁵

CEA testing is not recommended as a screening procedure to detect cancer in the general population; however, use of the CEA test as an adjunctive test in predicting prognosis and as an aid in the management of cancer patients has been widely accepted.

BIOLOGICAL PRINCIPLES OF THE PROCEDURE

The ARCHITECT CEA assay is a two-step immunoassay to determine the presence of CEA in human serum and plasma, using Chemiluminescent Microparticle Immunoassay (CMIA) technology with flexible assay protocols, referred to as Chemiflex.

In the first step, sample and anti-CEA coated paramagnetic microparticles are combined. CEA present in the sample binds to the anti-CEA coated microparticles. After washing, anti-CEA acridinium-labeled conjugate is added in the second step. Pre-Trigger and Trigger Solutions are then added to the reaction mixture; the resulting chemiluminescent reaction is measured as relative light units (RLUs). A direct relationship exists between the amount of CEA in the sample and the RLUs detected by the ARCHITECT *i** optical system.

For additional information on system and assay technology refer to the ARCHITECT System Operations Manual, Section 3.

* *i* = immunoassay

REAGENTS

Reagent Kit, 100 Tests/500 Tests

NOTE: Some kit sizes are not available in all countries or for use on all ARCHITECT *i* Systems. Please contact your local distributor.

ARCHITECT CEA Reagent Kit (7K68)

- **MICROPARTICLES** 1 or 4 Bottle(s) (6.6 mL for 100 test bottle/ 27.0 mL for 500 test bottle) Anti-CEA (mouse, monoclonal) coated Microparticles in TRIS buffer with protein (bovine) stabilizers. Preservative: Antimicrobial Agents.
- **CONJUGATE** 1 or 4 Bottle(s) (5.9 mL for 100 test bottle/26.3 mL for 500 test bottle) Anti-CEA (mouse, monoclonal) acridinium-labeled Conjugate in phosphate buffer with protein (bovine) stabilizers. Minimum concentration: 0.8 μ g/mL. Preservative: Antimicrobial Agents.

Assay Diluent

ARCHITECT *i* Multi-Assay Manual Diluent (7D82-50)

- **MULTI-ASSAY MANUAL DILUENT** 1 Bottle (100 mL) ARCHITECT *i* Multi-Assay Manual Diluent containing phosphate buffered saline solution. Preservative: Antimicrobial Agent.

Other Reagents

ARCHITECT *i* Pre-Trigger Solution

- **PRE-TRIGGER SOLUTION** Pre-Trigger Solution containing 1.32% (w/v) hydrogen peroxide.

ARCHITECT *i* Trigger Solution

- **TRIGGER SOLUTION** Trigger Solution containing 0.35N sodium hydroxide.

ARCHITECT *i* Wash Buffer

NOTE: Bottle and volume varies based on order.

- **WASH BUFFER** Wash Buffer containing phosphate buffered saline solution. Preservatives: Antimicrobial Agents.

WARNINGS AND PRECAUTIONS

- **IVD**
- For *In Vitro* Diagnostic Use
- Package insert instructions must be carefully followed. Reliability of assay results cannot be guaranteed if there are any deviations from the instructions in this package insert.


Safety Precautions

- **CAUTION:** This product requires the handling of human specimens. It is recommended that all human sourced materials be considered potentially infectious and be handled in accordance with the OSHA Standard on Bloodborne Pathogens³⁶. Biosafety Level 2³⁷ or other appropriate biosafety practices^{38,39} should be used for materials that contain or are suspected of containing infectious agents.
- For product not classified as dangerous per European Directive 1999/45/EC as amended - Safety data sheet available for professional user on request.
- For a detailed discussion of safety precautions during system operation, refer to the ARCHITECT System Operations Manual, Section 8.

Handling Precautions

- Do not use reagent kits beyond the expiration date.
- **Do not mix reagents from different reagent kits.**
- Prior to loading the ARCHITECT CEA Reagent Kit on the system for the first time, the microparticle bottle requires mixing to resuspend microparticles that have settled during shipment. For microparticle mixing instructions, refer to the **PROCEDURE, Assay Procedure** section of this package insert.
- **Septums MUST be used to prevent reagent evaporation and contamination and to ensure reagent integrity. Reliability of assay results cannot be guaranteed if septums are not used according to the instructions in this package insert.**
- To avoid contamination, wear clean gloves when placing a septum on an uncapped reagent bottle.
- Once a septum has been placed on an open reagent bottle, **do not invert the bottle** as this will result in reagent leakage and may compromise assay results.
- Over time, residual liquids may dry on the septum surface. These are typically dried salts which have no effect on assay efficacy.
- For a detailed discussion of handling precautions during system operation, refer to the ARCHITECT System Operations Manual, Section 7.

Storage Instructions

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- The ARCHITECT CEA Reagent Kit must be stored at 2-8°C and may be used immediately after removal from 2-8°C storage.
 - When stored and handled as directed, reagents are stable until the expiration date.
 - The ARCHITECT CEA Reagent Kit may be stored on-board the ARCHITECT *i* System for a maximum of 30 days. After 30 days, the reagent kit must be discarded. For information on tracking on-board time, refer to the ARCHITECT System Operations Manual, Section 5.
 - Reagents may be stored on or off the ARCHITECT *i* System. If reagents are removed from the system, store them at 2-8°C (with septums and replacement caps) in an upright position. For reagents stored off the system, it is recommended that they be stored in their original trays and boxes to ensure they remain upright. **If the microparticle bottle does not remain upright (with a septum installed) while in refrigerated storage off the system, the reagent kit must be discarded. After reagents are removed from the system, initiate a scan to update the on-board stability timer.**

Indications of Reagent Deterioration

When a control value is out of the specified range, it may indicate deterioration of the reagents or errors in technique. Associated test results may be invalid and may require retesting. Assay recalibration may be necessary. For troubleshooting information, refer to the ARCHITECT System Operations Manual, Section 10.

INSTRUMENT PROCEDURE

- The ARCHITECT CEA assay file must be installed on the ARCHITECT *i* System from the ARCHITECT *i* Assay CD-ROM prior to performing the assay. For detailed information on assay file installation and on viewing and editing assay parameters, refer to the ARCHITECT System Operations Manual, Section 2.
- For information on printing assay parameters, refer to the ARCHITECT System Operations Manual, Section 5.
- For a detailed description of system procedures, refer to the ARCHITECT System Operations Manual.

SPECIMEN COLLECTION AND PREPARATION FOR ANALYSIS

- Human serum and plasma collected in heparin (sodium and lithium) or potassium EDTA may be used in the ARCHITECT CEA assay. Follow the tube manufacturer's processing instructions for serum and plasma collection tubes.
- Plasma specimens collected in lithium or sodium heparin have been shown to exhibit an average of 7% to 8% higher results compared to corresponding serum results.
- When serial specimens are being evaluated, the same type of specimen should be used throughout the study.
- The ARCHITECT *i* System does not provide the capability to verify the specimen type. It is the responsibility of the operator to verify the correct specimen types are used in the ARCHITECT CEA assay.
- Use caution when handling patient specimens to prevent cross contamination. Use of disposable pipettes or pipette tips is recommended.
- Do not use grossly hemolyzed specimens.
- For optimal results, inspect all samples for bubbles. Remove bubbles with an applicator stick prior to analysis. Use a new applicator stick for each sample to prevent cross contamination.
- Ensure that complete clot formation in serum specimens has taken place prior to centrifugation. Some specimens, especially those from patients receiving anticoagulant or thrombolytic therapy may exhibit increased clotting time. If the specimen is centrifuged before a complete clot forms, the presence of fibrin may cause erroneous results.
- If testing will be delayed more than 24 hours, serum or plasma should be removed from the clot, serum separator, or red blood cells. Specimens may be stored for up to 7 days at 2-8°C prior to being tested. If testing will be delayed more than 7 days, specimens should be stored/frozen at - 20°C or colder.

- For optimal results, specimens should be free of fibrin, red blood cells, or other particulate matter. **Centrifuge serum and plasma specimens containing fibrin, red blood cells, or particulate matter prior to use to ensure consistency in the results.**
- Multiple freeze-thaw cycles of specimens should be avoided. Specimens must be mixed THOROUGHLY after thawing, by vortexing. Thawed samples containing red blood cells or particulate matter, **or which are hazy or cloudy in appearance** must be centrifuged prior to use to ensure consistency in the results.
- Specimens with obvious microbial contamination should not be used.
- When shipped, specimens must be packaged and labeled in compliance with applicable state, federal, and international regulations covering the transport of clinical specimens and infectious substances. Specimens may be shipped on wet or dry ice. Prior to shipment, specimens should be removed from the clot, serum separator, or red blood cells.
- ARCHITECT CEA Calibrators and Controls should be mixed by gentle inversion prior to use.

PROCEDURE

Materials Provided:

- 7K68 ARCHITECT CEA Reagent Kit

Materials Required but not Provided:

- ARCHITECT *i* System
- ARCHITECT *i* Assay CD-ROM
- 7K68-02 ARCHITECT CEA Calibrators
- 7D82-50 ARCHITECT *i* **MULTI-ASSAY MANUAL DILUENT**
- ARCHITECT *i* **PRE-TRIGGER SOLUTION**
- ARCHITECT *i* **TRIGGER SOLUTION**
- ARCHITECT *i* **WASH BUFFER**
- ARCHITECT *i* **REACTION VESSELS**
- ARCHITECT *i* **SAMPLE CUPS**
- ARCHITECT *i* **SEPTUM**
- ARCHITECT *i* **REPLACEMENT CAPS**
- Pipettes or pipette tips (optional) to deliver the volumes specified on the patient or control order screen.
- For information on materials required for maintenance procedures, refer to the ARCHITECT System Operations Manual, Section 9.

Materials Available but not Provided:

- 7K68-12 ARCHITECT CEA Controls

Assay Procedure

- Before loading the ARCHITECT CEA Reagent Kit on the system for the first time, the microparticle bottle requires mixing to resuspend microparticles that have settled during shipment:
 - Invert the microparticle bottle 30 times.
 - Visually inspect the bottle to ensure microparticles are resuspended. If microparticles are still adhered to the bottle, continue to invert the bottle until the microparticles have been completely resuspended.
 - Once the microparticles have been resuspended, remove and discard the cap. Wearing clean gloves, remove a septum from the bag. Carefully snap the septum onto the top of the bottle.
- **If the microparticles do not resuspend, DO NOT USE. Contact your local Abbott representative.**
- Order tests.
- Load the ARCHITECT CEA Reagent Kit on the ARCHITECT *i* System. Verify that all necessary assay reagents are present. Ensure that septums are present on all reagent bottles.
- The minimum sample cup volume is calculated by the system and is printed on the Orderlist report. No more than 10 replicates may be sampled from the same sample cup. To minimize the effects of evaporation, verify adequate sample cup volume is present prior to running the test.

- Priority: 60 µL for the first CEA test plus 10 µL for each additional CEA test from the same sample cup.
- ≤ 3 hours onboard: 150 µL for the first CEA test plus 10 µL for each additional CEA test from the same sample cup.
- > 3 hours onboard: additional sample volume is required. Refer to the ARCHITECT System Operations Manual, Section 5 for information on sample evaporation and volumes.
- If using primary or aliquot tubes, use the sample gauge to ensure sufficient patient specimen is present.
- To obtain the recommended volume requirements for the ARCHITECT CEA Calibrators and Controls, hold the bottles **vertically** and dispense 5 drops of each calibrator or 4 drops of each control into each respective sample cup.
- Load samples.
 - For information on loading samples, refer to the ARCHITECT System Operations Manual, Section 5.
- Press RUN. The ARCHITECT *i* System performs the following functions:
 - Moves the sample to the aspiration point
 - Loads a reaction vessel (RV) into the process path
 - Aspirates and transfers sample into the RV
 - Advances the RV one position and transfers microparticles into the RV
 - Mixes, incubates and washes the reaction mixture
 - Adds conjugate to the RV
 - Mixes, incubates and washes the reaction mixture
 - Adds Pre-Trigger and Trigger Solutions
 - Measures chemiluminescent emission to determine the quantity of CEA in the sample
 - Aspirates contents of RV to liquid waste and unloads RV to solid waste
 - Calculates the result
- For information on ordering patient specimens, calibrators and controls, and general operating procedures, refer to the ARCHITECT System Operations Manual, Section 5.
- For optimal performance, it is important to follow the routine maintenance procedures defined in the ARCHITECT System Operations Manual, Section 9. If your laboratory requires more frequent maintenance, follow those procedures.

Specimen Dilution Procedures

Specimens with a CEA value exceeding 1500 ng/mL, are flagged with the code ">1500.00" and may be diluted using either the Automated Dilution Protocol or the Manual Dilution Procedure.

- If using the Automated Dilution Protocol, the system performs a 1:10 dilution of the specimen and automatically calculates the concentration of the sample before dilution and reports the result.
- Manual dilutions should be performed as follows:
 - The suggested dilution for ARCHITECT CEA assay is 1:100. An additional 1:10 dilution may be made if needed. It is recommended that dilutions not exceed 1:1000.
 - For a 1:100 dilution, add 20 µL of the patient specimen to 1980 µL of ARCHITECT *i* Multi-Assay Manual Diluent (7D82-50).
 - The operator must enter the dilution factor in the Patient or Control order screen. All assays selected for that order will be diluted. The system will use this dilution factor to automatically calculate the concentration of the sample before dilution and report the result. The dilution should be performed so that the diluted result reads greater than 4 ng/mL.
- For detailed information on ordering dilutions, refer to the ARCHITECT System Operations Manual, Section 5.
- A comparison of the Automated Dilution Protocol to the Manual Dilution Procedure yielded recoveries between 86% and 97%.

Calibration

- To perform an ARCHITECT CEA calibration, test calibrators 1 and 2 in duplicate. A single sample of all levels of CEA controls must be tested to evaluate the assay calibration. Ensure that assay control values are within the concentration ranges specified in the control package insert. Calibrators should be priority loaded.
- Calibration range: 0 - 500 ng/mL.
- The assay protocol allows for the range to be extended to 1500 ng/mL.
- Once an ARCHITECT CEA calibration is accepted and stored, all subsequent samples may be tested without further calibration unless:
 - A reagent kit with a new lot number is used
 - Controls are out of range.
- For detailed information on how to perform an assay calibration, refer to the ARCHITECT System Operations Manual, Section 6.

QUALITY CONTROL PROCEDURES

The recommended control requirement for the ARCHITECT CEA assay is a single sample of all control levels tested once every 24 hours each day of use. If the quality control procedures in your laboratory require more frequent use of controls to verify test results, follow your laboratory-specific procedures. Ensure that assay control values are within the concentration ranges specified in the package insert.

Verification of Assay Claims

For protocols to verify package insert claims, refer to the ARCHITECT System Operations Manual, Appendix B. The ARCHITECT CEA assay belongs to method group 1.

RESULTS

The ARCHITECT CEA assay utilizes a 4 Parameter Logistic Curve fit data reduction method (4PLC, Y weighted) to generate a calibration curve.

Flags

- The default result unit for the ARCHITECT CEA assay is ng/mL.
- Some results may contain information in the Flags field. For a description of the flags that may appear in this field, refer to the ARCHITECT System Operations Manual, Section 5.

LIMITATIONS OF THE PROCEDURE

- Specimens from patients who have received preparations of mouse monoclonal antibodies for diagnosis or therapy may contain human anti-mouse antibodies (HAMA). Such specimens may show either falsely elevated or depressed values when tested with assay kits which employ mouse monoclonal antibodies.^{40,41} ARCHITECT CEA reagents contain a component that reduces the effect of HAMA reactive specimens. Additional clinical or diagnostic information may be required to determine patient status.
- Heterophilic antibodies in human serum can react with reagent immunoglobulins, interfering with *in vitro* immunoassays.⁴² Patients routinely exposed to animals or animal serum products can be prone to this interference and anomalous values may be observed. Additional information may be required for diagnosis.
- The ARCHITECT CEA assay should not be used as a cancer screening test.
- Patients with confirmed carcinoma frequently have a pretreatment CEA level in the same range as healthy individuals. Elevations in circulating CEA levels may be observed in smokers as well as patients with nonmalignant disease. For these reasons, a serum or plasma CEA level, regardless of value, should not be interpreted as absolute evidence for the presence or absence of malignant disease. The CEA level should be used in conjunction with information available from clinical evaluation and other diagnostic procedures.

EXPECTED VALUES

The distribution of ARCHITECT CEA values determined in 1,141 specimens is shown in the following table.*

Distribution of ARCHITECT CEA Values					
Number of Subjects	Percent (%)				
	0 - 3 (ng/mL)	>3 - 5 (ng/mL)	>5 - 10 (ng/mL)	>10 (ng/mL)	
Healthy Subjects					
Smokers	159	74.2	18.2	6.9	0.6
Non-smokers	149	83.2	11.4	5.4	0.0
Total	308	78.6	14.9	6.2	0.3
Nonmalignant Disease					
Ulcerative Colitis	50	72.0	20.0	4.0	4.0
Rectal Polyps	78	83.3	10.3	5.1	1.3
Pulmonary	60	61.7	20.0	13.3	5.0
Cirrhosis	110	47.3	30.0	15.5	7.3
Hepatitis	60	70.0	16.7	11.7	1.7
Renal	20	60.0	15.0	15.0	10.0
Malignant Disease					
Colorectal	150	24.0	10.7	10.7	54.7
Gastric	37	62.2	5.4	10.8	21.6
Pulmonary	110	47.3	19.1	9.1	24.5
Mammary	117	62.4	11.1	10.3	16.2
Ovarian	41	78.0	7.3	2.4	12.2

* Representative data; results in individual laboratories may vary.

In this study, 93.5% of healthy subjects (n=308) had CEA values of 5.00 ng/mL or less.

It is expected that each laboratory establish its own expected reference range for the population of interest.

The distribution table above for malignant disease is derived primarily from patients representing both active (clinical evidence of disease progression) and inactive (no clinical evidence of disease progression) disease states. When changing CEA assay methods in the course of monitoring a patient, additional sequential testing should be carried out to confirm baseline values.

SPECIFIC PERFORMANCE CHARACTERISTICS

Precision

The Architect CEA assay precision is $\leq 8\%$. Precision was determined as described in the Clinical and Laboratory Standards Institute (CLSI, formerly NCCLS) Protocol EP5-T2.⁴³ Five samples, consisting of two serum based panels and three CEA controls, were assayed at three laboratories in replicates of two at two separate times per day for twenty days (n=80 for each sample), using a single lot of reagents and a single calibration. Data from this study are summarized in the following table.*

Reproducibility of ARCHITECT CEA						
Sample	Lab	Mean CEA		Within Run		Total
		(ng/mL)	SD	%CV	SD	%CV
Low Control	1	5.05	0.180	3.6	0.202	4.0
	2	4.79	0.098	2.1	0.178	3.7
	3	4.86	0.110	2.3	0.162	3.3
Medium Control	1	20.17	0.512	2.5	0.641	3.2
	2	19.08	0.515	2.7	0.629	3.3
	3	19.99	0.605	3.0	0.685	3.4
High Control	1	99.45	3.074	3.1	3.182	3.2
	2	93.97	2.082	2.2	2.559	2.7
	3	99.51	2.898	2.9	3.072	3.1

Reproducibility of ARCHITECT CEA

Sample	Lab	Mean CEA		Within Run		Total
		(ng/mL)	SD	%CV	SD	%CV
Panel 1	1	417.34	9.587	2.3	10.483	2.5
	2	395.70	11.313	2.9	13.995	3.5
	3	419.93	11.591	2.8	13.870	3.3
Panel 2	1	1294.72	40.660	3.1	46.508	3.6
	2	1185.03	21.570	1.8	26.286	2.2
	3	1309.28	29.760	2.3	38.030	2.9

* Representative performance data are shown. Results obtained at individual laboratories may vary.

Recovery

Known amounts of CEA were added to normal human serum and plasma samples. The concentration of CEA was determined using the ARCHITECT CEA assay and the resulting percent recovery was calculated.*

Sample Type	Recovery			
	Endogenous Level (ng/mL)	CEA Added (ng/mL)	CEA Observed (ng/mL)	Percent Recovery
Serum				
1	0.86	94.76	91.00	95.1
2	1.07	4.49	5.56	100.0
3	0.94	94.76	94.53	98.8
4	1.11	4.49	5.85	105.6
Average % Recovery: 99.9%				
EDTA				
1	0.81	94.76	91.77	96.0
2	0.70	94.76	92.29	96.7
3	1.10	4.49	5.77	104.0
4	1.72	4.49	6.21	100.0
Average % Recovery: 99.2%				
Heparin				
1	0.93	94.76	94.60	98.8
2	1.26	4.49	6.10	107.8
3	0.92	94.76	95.24	99.5
4	1.17	4.49	5.92	105.8
Average % Recovery: 103.0%				

* Representative data; results in individual laboratories may vary.

$$\% \text{ Recovery} = \frac{\text{Observed (ng/mL)} - \text{Endogenous Level (ng/mL)}}{\text{CEA Added (ng/mL)}} \times 100$$

Analytical Sensitivity

The sensitivity of the ARCHITECT CEA assay was calculated to be better than 0.5 ng/mL at the 95% level of confidence (n = 18 runs). Sensitivity is defined as the concentration at two standard deviations above the mean RLU for the ARCHITECT CEA MasterCheck Level 0 and represents the lowest measurable concentration of CEA that can be distinguished from zero.

Specificity

The specificity of the ARCHITECT CEA assay was determined by testing sera containing the compounds listed below. These compounds showed less than 10% interference in the ARCHITECT CEA assay at the levels indicated.

Test Compound	Test Concentration
Bilirubin	22 mg/dL
Hemoglobin	550 mg/dL
Total Protein	1.8 to 13.2 g/dL
Triglycerides	3300 mg/dL

Carryover

No detectable carryover (less than 12 PPM) was observed when a sample containing 43,630 ng/mL of CEA was assayed.

High Dose Hook

High dose hook is a phenomenon whereby very high level specimens may read within the dynamic range of the assay. For the ARCHITECT CEA assay, no high dose hook effect was observed when samples containing up to approximately 60,000 ng/mL of CEA were assayed.

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