ST AIA-PACK CEA

INTENDED USE

ST AIA-PACK CEA is designed for in vitro diagnostic use only for the quantitative measurement of carcinoembryonic antigen (CEA) in human serum or heparinised plasma on Tosoh AIA System Analysers.

SUMMARY AND EXPLANATION OF TEST

Carcinoembryonic antigen or CEA is a protein-polysaccharide b-globulin with a molecular weight of approximately 200,000 daltons and a sedimentation coefficient of 7S-8S. (1,2,3) It is normally present at very low concentrations in the blood of healthy adults. Although elevated serum CEA levels were originally thought to be specific to colorectal cancer (4,5), a variety of neoplastic and other disease processes cause significant elevation of CEA (6-13). Thus, CEA is used as a tumour marker in the management of patients with colorectal, breast, lung, prostatic, pancreatic, ovarian and other carcinomas, as long as these tumours secrete the CEA moiety. Preoperative CEA levels may be of prognostic value since the level of elevation is correlated with body burden of tumour (8,14,15). Persistent elevation or increasing levels of CEA may indicate the presence of residual or disseminated malignancy (16). Since CEA concentration frequently declines during successful therapy and increases during disease progression, monitoring of serum CEA levels in patients with tumours which produce CEA has been shown to facilitate the clinical management of the disease. Measurement of serum CEA is not recommended as a screening procedure since elevated CEA levels are also seen in a variety of non-neoplastic and benign diseases such as alcoholic cirrhosis, hepatitis, ulcerative colitis, and Crohn's disease (17,18) as well as in heavy cigarette smokers (19).

Likewise, since not all tumours are CEA producing, a serum CEA measurement within the reference intervals found in apparently healthy subjects does not rule out the possibility of the presence of malignant disease.

PRINCIPLE OF THE ASSAY

The ST AIA-PACK CEA is a two-site immunoenzymometric assay which is performed entirely in the ST AIA-PACK CEA test cups. CEA present in the test sample is bound with monoclonal antibody immobilised on a magnetic beads and enzyme-labelled monoclonal antibody in the test cups. The magnetic beads are washed to remove any non-bound enzyme-labelled monoclonal antibodies and then incubated with a fluorogenic substrate, 4-methylumbelliferyl phosphate (4MUP). The amount of enzyme-labelled monoclonal antibody that binds to the beads is in direct proportion to the CEA concentration in the test sample. A standard curve is constructed, and unknown sample concentrations are calculated using this curve.

MATERIAL SUPPLIED

Cat. No. 0025254
ST AIA-PACK CEA
5 trays x 20 test cups

Plastic test cups containing twelve lyophilised magnetic beads coated with anti-CEA mouse monoclonal antibody and 50 µl of anti-CEA mouse monoclonal antibody conjugated to bovine alkaline phosphatase with sodium azide as a preservative.

MATERIALS REQUIRED BUT NOT SUPPLIED

The following materials are required to perform carcinoembryonic antigen analysis using the ST AIA-PACK CEA (Cat. No. 0025254) on Tosoh AIA System Analysers. The following are available separately from Tosoh.

Materials

<table>
<thead>
<tr>
<th>Cat. No.</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>0018539</td>
<td>AIA Nex•IA or AIA-21</td>
</tr>
<tr>
<td>0018540</td>
<td>AIA Nex•IA or AIA-21 LA</td>
</tr>
<tr>
<td>0019836</td>
<td>AIA-1800 ST</td>
</tr>
<tr>
<td>0019837</td>
<td>AIA-1800 LA</td>
</tr>
<tr>
<td>0022100</td>
<td>AIA-2000 ST</td>
</tr>
<tr>
<td>0022101</td>
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<td>0019014</td>
<td>AIA-600 II</td>
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<td>0019328</td>
<td>AIA-600 II BCR</td>
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<td>0022930</td>
<td>AIA-900</td>
</tr>
<tr>
<td>0019945</td>
<td>AIA-360</td>
</tr>
<tr>
<td>0020968</td>
<td>AIA-PACK SUBSTRATE SET II</td>
</tr>
<tr>
<td>0020970</td>
<td>AIA-PACK DETECTOR STANDARDIZATION TEST CUP</td>
</tr>
<tr>
<td>0020971</td>
<td>AIA-PACK SAMPLE TREATMENT CUP</td>
</tr>
<tr>
<td>0020974</td>
<td>AIA-PACK CEA CALIBRATOR SET</td>
</tr>
<tr>
<td>0020554</td>
<td>AIA-PACK CEA ZERO CALIBRATOR</td>
</tr>
<tr>
<td>0020955</td>
<td>AIA-PACK CEA POSITIVE CALIBRATOR</td>
</tr>
<tr>
<td>0020956</td>
<td>AIA-PACK SAMPLE DILUATING SOLUTION</td>
</tr>
<tr>
<td>0020957</td>
<td>AIA-PACK WASH CONCENTRATE</td>
</tr>
<tr>
<td>0020965</td>
<td>AIA-PACK DILUENT CONCENTRATE</td>
</tr>
<tr>
<td>0018581</td>
<td>SAMPLE CUPS</td>
</tr>
<tr>
<td>0018583</td>
<td>PRELOADED PIPETTE TIPS</td>
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<tr>
<td>0018585</td>
<td>PIQUE TIPS</td>
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<tr>
<td>0019215</td>
<td>TIP RACK</td>
</tr>
<tr>
<td>0019216</td>
<td>PRELOADED PIPETTE TIPS</td>
</tr>
<tr>
<td>0022103</td>
<td>PIQUE TIPS</td>
</tr>
</tbody>
</table>

Only materials obtained from Tosoh should be used. Materials obtained elsewhere should not be substituted since assay performance is characterised strictly by Tosoh materials.

WARNINGS AND PRECAUTIONS

1. The ST AIA-PACK CEA is intended for in vitro diagnostic use only.
2. Inspect the packaging and the exterior of the aluminium pouch for any sign of damage before use. If any damages are visible, contact your local TOSOH sales representative.
3. Test cups from different lots or different assays shall not be mixed within a tray.
4. The ST AIA-PACK CEA contains sodium azide, which may react with lead or copper plumbing to form potentially explosive metal azides. When disposing of such reagents, always rinse with large volumes of water to prevent any azide accumulation.
5. Human serum is not used in the preparation of this product; however, since human specimens will be used for samples and other quality control products in the lab may be derived from human serum, please use standard laboratory safety procedures in handling all specimens and controls.
6. Do not use beyond the expiry date.
7. The ST AIA-PACK CEA has been designed so that the high dose “hook effect” will not be a problem for the vast majority of samples. Samples with CEA concentrations between 100 and 20,000 ng/ml will read > 100 ng/ml. The “hook effect” phenomenon may occur at CEA concentrations > 20,000 ng/ml.
8. For safe waste disposal, it is recommended that each laboratory complies with established laboratory procedures and local, state, and federal regulations.
9. After opening, the vial of AIA-PACK CEA SAMPLE DILUTING SOLUTION should be kept tightly sealed with a clean rubber cap. Sealing with dirty material may cause deterioration of the reagent.
10. The remaining sample diluting solution after use should not be mixed with another vial but be discarded to avoid contamination.
11. Serum, dust, metal, or microorganism contamination may cause degradation of reconstituted substrate solution. Store in a clean environment, away from direct sunlight and ultraviolet light.
12. TOSOH recommends that a new pouch of the test cups should be used for calibration.

STORAGE AND STABILITY
All unopened materials will remain stable until the expiry date on the label when stored at the specified temperature.

<table>
<thead>
<tr>
<th>Materials</th>
<th>Cat. No.</th>
</tr>
</thead>
<tbody>
<tr>
<td>2° -8°C:</td>
<td></td>
</tr>
<tr>
<td>ST AIA-PACK CEA</td>
<td>0025254</td>
</tr>
<tr>
<td>AIA-PACK CEA CALIBRATOR SET</td>
<td>0020354</td>
</tr>
<tr>
<td>AIA-PACK CEA SAMPLE DILUTING SOLUTION</td>
<td>0020554</td>
</tr>
<tr>
<td>AIA-PACK SUBSTRATE SET II</td>
<td>0020968</td>
</tr>
<tr>
<td>AIA-PACK WASH CONCENTRATE</td>
<td>0020955</td>
</tr>
<tr>
<td>AIA-PACK DILUENT CONCENTRATE</td>
<td>0020956</td>
</tr>
<tr>
<td>1-30°C:</td>
<td></td>
</tr>
<tr>
<td>AIA-PACK DETECTOR STANDARDIZATION TEST CUP</td>
<td>0020970</td>
</tr>
<tr>
<td>AIA-PACK SAMPLE TREATMENT CUP</td>
<td>0020971</td>
</tr>
</tbody>
</table>

- After opening the aluminium pouch, ST AIA-PACK CEA test cups can be left on-board of the TOSOH AIA System Analyzers (18-25°C) for a maximum of 10 days (10 x 24 hours). When stored over night at 2-8°C, the test cups can be used for up to 30 days (30 cycles of 8 hours on board and 16 hours in the refrigerator). Once the aluminium pouch is opened, the test cups must be used within 30 days.
- AIA-PACK CEA CALIBRATOR SET must be kept tightly sealed and refrigerated at 2-8°C. After opening, the calibrators should be used within 1 day.
- After opening, AIA-PACK CEA SAMPLE DILUTING SOLUTION can be left on-board of the TOSOH AIA System Analyzers (18-25°C) for a maximum of 3 days (3 x 24 hours). When stored over night at 2-8°C, the sample diluting solution can be used for up to 9 days (9 cycles of 8 hours on board and 16 hours in the refrigerator). The sample diluting solution should not be used beyond 90 days after opening, even if it is sealed and stored in the refrigerator.
- Reconstituted substrate solution will remain stable for 3 days at 18°-25°C or 30 days at 2°-8°C.
- Working diluent and wash solutions will remain stable for 30 days at 18°-25°C.
- Reagents should not be used if they appear cloudy or discoloured.

SPECIMEN COLLECTION AND HANDLING
- Serum or heparinised plasma is required for the assay. EDTA and citrated plasma SHOULD NOT BE USED.

- When using serum, a venous blood sample is collected aseptically without additives. Store at 18°-25°C until a clot has formed (usually 15-45 minutes), then centrifuge to obtain the serum specimen for assay.
- When using heparinised plasma, a venous blood sample is collected aseptically with the specified additive. Centrifuge and separate plasma from the packed cells as quickly as possible.
- Inadequate centrifugation or the presence of fibrin or particulate matter in the sample may cause erroneous results.
- Samples containing inhibitors of alkaline phosphatase may cause erroneous results.
- Inspect all samples for air bubbles and foaming. Remove any air bubbles before assay.
- Specimen types should not be used interchangeably during serial monitoring of an individual patient. Measured concentrations may vary slightly between sample types in certain patients.
- Samples may be stored at 2°-8°C for up to 7 days before analysis. If the analysis cannot be performed within 7 days, the sample should be stored frozen at –20°C or below for up to 60 days.
- Repeated freeze-thaw cycles should be avoided. Turbid serum samples or samples containing particulate matter should be centrifuged before testing. Before assaying, slowly bring frozen samples to 18°-25°C and mix gently.
- The sample required for analysis is 100 µl.

PROCEDURE
For the AIA Nex•IA / AIA-21, AIA-600 II, AIA-900, AIA-1800, AIA-2000 and AIA-360, please refer to their Operators’ Manual for detailed instructions.

I. Reagent Preparation
   A. Substrate Solution
      Bring all reagents to 18°-25°C before preparing the working substrate solution. Add one bottle of AIA-PACK SUBSTRATE RECONSTITUENT II to the lyophilised AIA-PACK SUBSTRATE REAGENT II, mix thoroughly to dissolve all solid materials.
   B. Wash Solution
      Add the entire contents of the AIA-PACK WASH CONCENTRATE (100 ml) to approximately 2.0 l of CAP Class I water or the clinical laboratory reagent water (formerly NCCLS Type I) defined by CLSI GP40-A4-AMD guideline, mix well, and adjust the final volume to 2.5 l.
   C. Diluent
      Add the entire contents of the AIA-PACK DILUENT CONCENTRATE (100 ml) to approximately 4.0 l of CAP Class I water or the clinical laboratory reagent water (formerly NCCLS Type I) defined by CLSI GP40-A4-AMD guideline, mix well, and adjust the final volume to 5.0 l.

II. Calibration Procedure
   A. Calibration Curve
      The calibrators for use with the ST AIA-PACK CEA have been standardized on WHO 1st IRP 73/601 (1975).
      The calibration curve for ST AIA-PACK CEA will remain stable for up to 90 days. Calibration stability is monitored by quality control performance and is dependent on proper reagent handling and Tosoh AIA System maintenance in accordance with the manufacturer’s instructions.
      Recalibration may be necessary more frequently if controls are out of the established range for this assay or if certain service procedures are performed (e.g. temperature adjustment, sampling mechanism changes, maintenance of wash probe or detector lamp adjustment or change).

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For further information regarding instrument operation, consult the TOSOH AIA System Operator’s Manual. A sample calibration curve from the AIA-1800 follows and shows the algorithm used to calculate results.

**B. Calibration Procedure**
1. Refer to the appropriate Tosoh AIA System Operators’ Manual for procedural instructions.
2. Verify that both the calibrator lot and concentration numbers have been correctly entered on the software.
3. The AIA-PACK CEA CALIBRATOR SET provided ready for use.
4. Tosoh recommends that all calibrators be run in triplicate.

**C. Calibration Acceptability Criteria**
1. The mean rate for the AIA-PACK CEA ZERO CALIBRATOR should be < 3.0 nmol/(L•s).
2. Since there is a direct relationship between concentration and rate, the rate should rise as concentrations increase.
3. Repeat values should be within a 10% range.

**D. Calibration Review and Acceptance**
1. Review the calibration curve carefully, applying the criteria listed above.
2. Edit the calibration if necessary then accept the calibration.

For further information regarding calibration, consult the Tosoh AIA System Operators’ Manual.

**III. Quality Control Procedure**

**A. Commercially Available Controls**
Commercially available controls shall be run at least once per day. It is recommended that at least two (2) levels of controls, normal and abnormal, be used. Laboratory policy for this particular assay specifies the following:
- **Control Material:** _____________________
- **Frequency:** _____________________
Lot number of control material, acceptable limits, and remedial action to be taken if controls fail to meet laboratory criteria will be found in a separate quality control document kept by the laboratory.

**B. Quality Control Procedure**
1. Assay quality control specimens as instructed in the specific Operators’ Manual for your analyser. In addition, refer to the Tosoh AIA System Operators’ Manual for detailed instructions on defining and editing files.

2. Quality control material to be run with this assay is specified by individual laboratory policy.

**IV. Specimen Processing**

**A. Preparation**
Following the specific instructions in the Operators’ Manual for the analyser, place samples on the instrument appropriately. Barcoded primary tubes as well as sample cups can be run on the AIA Nex•IA / AIA-21, AIA-600 II, AIA-900, AIA-1800, AIA-2000 and AIA-360.

**B. Assay Procedure**
1. Provide a sufficient quantity of ST AIA-PACK CEA test cups for the number of samples to be run.
2. Load patient samples as instructed in the Operators’ Manual and proceed with analysis.

**PROCEDURAL NOTES**
1) Lyophilised substrate must be completely dissolved.
2) Ligand assays performed by the TOSOH AIA System Analyzers require that the laboratory use water designated by the CAP as Class I or by the CLSI as the clinical laboratory reagent water. Water should be tested at least once per month and should be free of particulate matter including bacteria. For further information, consult the CLSI document GP40-A4-AMD, Preparation and Testing of Reagent Water in the Clinical Laboratory; Approved Guideline—Fourth Edition.
3) If a specimen carcinoembryonic antigen concentration is found to be greater than upper limit of the assay range, 100 ng/ml, the specimen should be diluted with the AIA-PACK CEA SAMPLE DILUTING SOLUTION and reassayed in accordance with the Assay Procedure. The recommended dilution for specimens containing more than 100 ng/ml is 10 or 100 fold dilution. It is desirable to dilute the specimen so that the diluted specimen reads between 5 and 100 ng/ml. The dilution factor should be entered on the software. For further information on the dilution of specimens, refer to the Tosoh AIA System Operators’ Manual.
4) The Tosoh AIA System Analyzers can store two different calibration curves for each analyte at one time. Thus, up to two different lots of ST AIA-PACK CEA test cups can be used in the same run.
5) If the assay specifications for this test are not ready on the system software, the specifications must be entered under test code 006.

**CALCULATION OF RESULTS**
The Tosoh AIA System Analyzers perform all sample and reagent handling operations automatically. The Tosoh AIA System Analyzers read the rate of fluorescence produced by the reaction and automatically convert the rate to carcinoembryonic antigen concentration in ng/ml.

For samples requiring dilution, the AIA Nex•IA / AIA-21, AIA-600 II, AIA-900, AIA-1800 and AIA-2000 will automatically perform dilutions and calculate results if the dilution factors are entered on the software. Dilution factors may be entered into the Test File, or pre-defined dilution factors may be selected in Specimen Processing. For detailed information regarding programming dilutions, consult the appropriate TOSOH AIA Operators’ Manual.

**EVALUATION OF RESULTS**

**Quality Control**
In order to monitor and evaluate the precision of the analytical performance, it is recommended that commercially available control samples shall be assayed in accordance with local regulations.

Minimum recommendations for the frequency of running internal control material are:
After calibration, three levels of the internal control are run in order to accept the calibration curve. The three levels of controls are repeated if certain service procedures are performed (e.g., temperature adjustments, sampling mechanism changes, maintenance of the wash probe or detector lamp adjustments or changes). After daily maintenance, at least two levels of the control shall be run in order to verify overall performance of the Tosoh AIA System Analysers.

If one or more control value(s) exceed the acceptable range, it will be necessary to investigate the validity of the calibration curve before reporting patient results. Standard laboratory procedures should be followed in accordance with the strict regulatory agency under which the laboratory operates.

LIMITATIONS

- For diagnostic purposes, results obtained from this assay should be used in conjunction with other data (e.g. symptoms, results of other tests, clinical impressions, therapy, etc.).
- Using ST AIA-PACK CEA, the highest measurable concentration of carcinoembryonic antigen in specimens without dilution is 100 ng/ml, and the lowest measurable concentration in specimens is 0.5 ng/ml (assay sensitivity).
- Although the approximate value of the highest calibrator is 50 ng/ml, the exact concentration may be slightly different. The assay specification, ASSAY RANGE HIGH, should be defined as the upper limit of the assay range, 100 ng/ml.
- Although haemolysis has an insignificant effect on the assay, haemolysed samples may indicate mistreatment of a specimen before assaying and results should be interpreted with caution.
- Lipaemia has an insignificant effect on the assay except in the case of gross lipaemia where spatial interference may occur.
- Specimens from patients taking medicines and/or medical treatment may produce misleading results.
- 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 falsely elevated values when tested for carcinoembryonic antigen.
- Samples from patients under Asfotase Alfa (Genetical Recombination) treatment may cause falsely elevated/decreased results.
- For a fuller understanding of the limitations of this procedure, please refer to the SPECIMEN COLLECTION AND HANDLING, WARNINGS AND PRECAUTIONS, STORAGE AND STABILITY, and PROCEDURAL NOTES sections of this insert sheet.

EXPECTED VALUES

Each laboratory should set a reference interval corresponding to the characteristics of the population being tested. As with all diagnostic procedures, clinical results must be interpreted having due regard to concomitant medications administered to the patient. (20)

I. Reference Ranges

The interval given here was determined in serum samples from 230 apparently healthy Asian individuals. European studies showed that these reference values are also applicable for a European population.

Reference Interval = < 5.8 ng/ml (=< 5.8 µg/l)

II. Conversion Factors

CEA concentrations in this application are in units of ng/ml. The obtained values in ng/mL must be multiplied by 1.0 when converting to values in µg/L.

PERFORMANCE CHARACTERISTICS

ACCURACY

a. Recovery: Three serum pools were spiked with three different levels of CEA and assayed before and after spiking.

<table>
<thead>
<tr>
<th>Sample</th>
<th>Initial CEA Value (ng/ml)</th>
<th>Expected Value (ng/ml)</th>
<th>Measured Value (ng/ml)</th>
<th>Percent Recovery</th>
</tr>
</thead>
<tbody>
<tr>
<td>Serum A1</td>
<td>1.45</td>
<td>24.2</td>
<td>25.6</td>
<td>25.1</td>
</tr>
<tr>
<td>Serum B1</td>
<td>1.95</td>
<td>24.2</td>
<td>26.1</td>
<td>26.8</td>
</tr>
<tr>
<td>Serum C1</td>
<td>2.75</td>
<td>24.2</td>
<td>25.9</td>
<td>28.3</td>
</tr>
<tr>
<td>Serum A2</td>
<td>7.5/10</td>
<td>75.3</td>
<td>74.4</td>
<td>98.8</td>
</tr>
<tr>
<td>Serum B2</td>
<td>7.5/10</td>
<td>75.3</td>
<td>74.4</td>
<td>98.8</td>
</tr>
<tr>
<td>Serum C2</td>
<td>7.5/10</td>
<td>71.6</td>
<td>70.7</td>
<td>98.6</td>
</tr>
</tbody>
</table>

b. Dilution: Three serum samples containing high concentrations of CEA were serially diluted with AIA-PACK CEA SAMPLE DILUTING SOLUTION and assayed.

<table>
<thead>
<tr>
<th>Sample</th>
<th>Dilution Factor</th>
<th>Expected Value (ng/ml)</th>
<th>Measured Value (ng/ml)</th>
<th>Percent Recovery</th>
</tr>
</thead>
<tbody>
<tr>
<td>Serum A2</td>
<td>none</td>
<td>100</td>
<td>100</td>
<td>100</td>
</tr>
<tr>
<td>Serum B2</td>
<td>none</td>
<td>100</td>
<td>100</td>
<td>100</td>
</tr>
<tr>
<td>Serum C2</td>
<td>none</td>
<td>100</td>
<td>100</td>
<td>100</td>
</tr>
</tbody>
</table>

PRECISION

a. Within run precision was determined using three controls in a total of 20 runs. Within each run, one set of duplicates per control was assayed. The mean of each duplicate was used to obtain the pooled standard deviation (SD), which was then used to calculate the coefficient of variation (CV).

<table>
<thead>
<tr>
<th>Sample</th>
<th>Mean Value (ng/ml)</th>
<th>Pooled SD Value (ng/ml)</th>
<th>CV (%)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Serum A3</td>
<td>4.80</td>
<td>0.182</td>
<td>3.8</td>
</tr>
<tr>
<td>Serum B3</td>
<td>18.8</td>
<td>0.570</td>
<td>3.0</td>
</tr>
<tr>
<td>Serum C3</td>
<td>61.1</td>
<td>1.73</td>
<td>2.8</td>
</tr>
</tbody>
</table>
Chemotherapeutic Agents:
Therapeutic concentrations of the following chemotherapeutic agents added to serum or heparinised plasma samples which were then assayed do not interfere with ST AIA-PACK CEA assay: cisplatin, velban, bleomycin, adriamycin, vincristine, methotrexate, 5-fluorouracil, and mitomycin C.

REFERENCES

Sample | Mean (ng/ml) | Pooled SD (ng/ml) | CV (%) |
-------|-------------|------------------|--------|
Serum A3 | 4.80      | 0.198             | 4.1    |
Serum B3 | 18.8       | 0.595             | 3.2    |
Serum C3 | 61.1       | 1.92              | 3.1    |

CORRELATION
The correlation between serum (x) and heparinised plasma (y) on ST AIA-PACK CEA was carried out using 99 patient specimens.

<table>
<thead>
<tr>
<th>Slope</th>
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<tbody>
<tr>
<td>y-Intercept</td>
<td>0.049</td>
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<tr>
<td>Correlation Coefficient</td>
<td>0.983</td>
</tr>
<tr>
<td>Range of Samples</td>
<td>1.3 - 82.6</td>
</tr>
<tr>
<td>Number of Samples</td>
<td>99</td>
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</tbody>
</table>

SPECIFICITY
The following substances were tested for cross-reactivity. Cross-reactivity (%) is the percentage of the compound that will be identified as CEA. If those compounds are present in the specimen at the same concentration as CEA, the final result will be increased by those percentages.

<table>
<thead>
<tr>
<th>Compound</th>
<th>Cross-reactivity (%)</th>
</tr>
</thead>
<tbody>
<tr>
<td>CEA</td>
<td>100</td>
</tr>
<tr>
<td>NCA</td>
<td>&lt; 0.01</td>
</tr>
<tr>
<td>AFP</td>
<td>&lt; 0.01</td>
</tr>
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</table>

SENSITIVITY
The minimum detectable concentration (MDC) of carciinoembryonic antigen is estimated to be 0.5 ng/ml. The MDC is defined as the concentration of CEA that corresponds to the rate of fluorescence which is two standard deviations from the mean rate of fluorescence of 10 repeat determinations by the AIA-PACK CEA ZERO CALIBRATOR.

INTERFERENCE
Interference is defined, for the purposes of this study, with recovery outside of 10% of the known concentration of the specimen after the following substances are added to human specimens.

- Haemoglobin (up to 390 mg/dl), free bilirubin (up to 17 mg/dl) and conjugated bilirubin (up to 18 mg/dl) do not interfere with the assay.
- Lipaemia, as indicated by triglyceride concentration (up to 1,600 mg/dl), does not interfere with the assay.
- Ascorbic acid (up to 20 mg/dl) does not interfere with the assay.
- Protein, as indicated by human albumin concentration (up to 2.5 g/dl), does not interfere with the assay.
- Heparin (up to 100 U/ml) does not interfere with the assay.