AIA-360 Assay Specifications
ST CPEP II Test Code 040

No.	Item	Data
1	Calib. Req	Show
2	Cal 1	0 ng/mL
3	Cal 2	0.5 ng/mL (example)
4	Cal 3	2.0 ng/mL (example)
5	Cal 4	6.0 ng/mL (example)
6	Cal 5	15.0 ng/mL (example)
7	Cal 6	33.0 ng/mL (example)
8	Cal Lot L	
9	Cal Lot R	
10	Unit	ng/mL
11	Smpl. Vol	10
12	Dil. Vol	110
13	Assay L	0.04
14	Assay H	30.00
15	Ref. L	
16	Ref. H	
17	Decimal	2
	Visible only in Test Mode	
18	Test Name	#CPR2
19	Calib. No	6
20	Calib. Mul	3
21	Calib. Equ	13
22	Calib. CV	90
23	Assay Prtl	1
24	Factor1 A	1.000000
25	Factor1 B	0.000000
26	Factor2 A	1.000000
27	Factor2 B	0.000000
28	V. Conc	0.001000
29	G Origin	0.001000

AIA-900 Assay Specifications
ST CPEP II Test Code 040

No.	Item	Data
1	Code	40
2	ACT	1
3	Analyte	#CPR2
4	Lot	***Enter current cal lot no.
5	CAL 1	0 ng/mL
6	CAL 2	0.5 ng/mL (example)
7	CAL 3	2.0 ng/mL (example)
8	CAL 4	6.0 ng/mL (example)
9	CAL 5	15.0 ng/mL (example)
10	CAL 6	33.0 ng/mL (example)
11	Cal lot L	
12	Cal lot R	
13	Unit	ng/mL
14	Decimal	2
15	Assay Low	0.04
16	Assay High	30.00
17	Reference Low	
18	Reference High	
19	Reschedule Low	0.04
20	Reschedule High	30.00
21	Factor A	1
22	Factor B	0
23	Sample Volume	10
24	Diluent Volume	110
25	2 Step reagent dispensing volume	0
26	Calibration code	040
27	CAL. No.	6
28	CAL. MUL.	3
29	CAL. EQU.	13
30	CAL. CV	90
31	DIL. SP1	1
32	DIL. SP2	10
33	DIL. CAL. (Calculation of dil ratio of conc.)	1
34	DIL. CNTL.	1
35	DIL. DO	10
36	DIL. AH.	5
37	DIL. CALC.	1
38	DIL. CODE	040
39	DIL. NAME	#CPR2
40	DIL. PRTY	3
41	PRE. SPVOL (Vol. of pretreated sample)	0
42	PRE. 1VOL (Vol. of pretreatment sol-1)	0
43	PRE. 2 VOL (Vol. of pretreatment sol-2)	0
44	PRE. CODE (pretreated sol. code)	0
45	PRE. NAME (pretreated sol. name)	0
46	Protocol	1
47	SYS. F_A	1.000000
48	SYS. F_B	0
49	V. CONC.	0.001
50	G. ORIGIN	0.001

AIA-2000 Assay Specifications
ST CPEP II Test Code 040

No.	Item	Data
1	Unit	ng/mL
2	Decimal places	2
3	Reference low	
4	Reference high	
5	Reschedule low	0.04
6	Reschedule high	30.00
7	Assay range low	0.04
8	Assay range high	30.00
9	Specimen diluent code	40
10	Specimen diluent name	#CPR2
11	Dilution factor for Sp. 1	1
12	Dilution factor for Sp. 2	10
13	Dilution factor for Control	1
14	Default multiplier for DO	10
15	Default multiplier for >H	5
16	Factor A	1.00000e+000
17	Factor B	0.00000e+000
18	Calibration code	13
19	Calibrator replicates	3
20	Calibrator lot	***Enter current cal. lot no.
21	Calibrator Concentration	
22	Cal - 01	0 ng/mL
23	Cal - 02	0.5 ng/mL (example)
24	Cal - 03	2.0 ng/mL (example)
25	Cal - 04	6.0 ng/mL (example)
26	Cal - 05	15.0 ng/mL (example)
27	Cal - 06	33.0 ng/mL (example)
28		
29		
30		
31		
32		
33		
34	Dilution factor for calibrator	1
35	Calibration period	90
36	Incubation time (10/40)	10
37	Assay protocol	1
38	Specimen volume	10
39	Diluent volume	110
40	Conjugate volume	0
41	Diluted conjugate volume	0
42	Pretreatment	0
43	Pretreatment specimen volume	0
44	Pretreatment Reagent code	0
45	Pretreatment Reagent name	0
46	Pretreatment Reagent 1 volume	0
47	Pretreatment Reagent 2 volume	0
48	System Factor	1.00
49	Calibration Code Check	040
50	Virtual Concentration	0.0
51	Graph Origin	0.0
52	Calculation with Dilution Factor	Yes

C-PEPTIDE II
ST AIA-PACK CPEP II

Name and Intended Use

ST AIA-PACK C-Peptide II is designed for In Vitro Diagnostic Use Only for the quantitative measurement of C-peptide in human serum, heparinized plasma, EDTA plasma, or urine on Tosoh AIA System Analyzers.

Summary and Explanation of Test

C-peptide, a polypeptide 31 amino acids in length, originates in pancreatic B-cells as a metabolically inert by-product in the synthesis of insulin from proinsulin [(1)]. Insulin and C-peptide are released from proinsulin in equimolar concentrations into the portal circulation [(2)]. Therefore, C-peptide levels can serve as an index to insulin secretion [(3,4)]. Where insulin secretion is diminished, as in insulin-dependent diabetes, low C-peptide levels are to be expected. Elevated C-peptide levels may result from increased B-cell activity associated with insulinomas [(4-6).]

Anti-insulin antibodies are commonly found in patients who have undergone insulin therapy. These circulating anti-insulin antibodies may interfere with certain immunoassays for insulin, making it difficult to use as a measure of residual B-cell activity. C-peptide measurement is, therefore, used as an alternative measurement index in this context [(7).]

C-peptide measurement is also used as an additional means of evaluating glucose tolerance tests [(8).]

Principle of the Assay

The ST AIA-PACK C-Peptide II is a two-site immunoenzymometric assay which is performed entirely in the ST AIA-PACK C-Peptide II test cups. C-peptide present in the test sample is bound with monoclonal antibody immobilized on a magnetic solid phase and enzyme-labeled monoclonal antibody in the test cups. The magnetic beads are washed to remove unbound enzyme-labeled antibody and are then incubated with a fluorogenic substrate, 4-methylumbelliferyl phosphate (4MUP). The amount of enzyme-labeled monoclonal antibody that binds to the beads is directly proportional to the C-peptide concentration in the test sample. A standard curve is constructed, and unknown sample concentrations are calculated using this curve.

Material Provided (ST AIA-PACK C-Peptide II, Cat. No. 0025283)

5 trays x 20 test cups (ST AIA-PACK C-PEPTIDE II Test Cup)

Plastic test cups containing lyophilized twelve magnetic beads coated with anti-C-peptide mouse monoclonal antibody and 100 µL of anti-C-peptide mouse monoclonal antibody conjugated to bovine alkaline phosphatase.

Materials Required But Not Provided

The following materials are required to perform C-peptide analysis using the ST AIA-PACK C-Peptide II (Cat. No. 0025283) on the Tosoh AIA System Analyzers. The following are available separately from Tosoh.

Materials		Cat. No.
AIA-SYSTEMS:		
AIA-360		0019945
AIA-900		0022930
AIA-900 9tray Sorter		0022931
AIA-900 19tray Sorter		0022932
AIA-2000 ST		0022100
AIA-2000 LA		0022101
AIA-PACK:		
AIA-PACK Substrate Set II		0020968
AIA-PACK Substrate/Reconstituent		
ST AIA-PACK C-Peptide II Calibrator Set		0025383
Calibrator #1	0 ng/mL	
Calibrator #2	0.5 ng/mL (approx.)	
Calibrator #3	2.0 ng/mL (approx.)	
Calibrator #4	6.0 ng/mL (approx.)	
Calibrator #5	15.0 ng/mL (approx.)	
Calibrator #6	33.0 ng/mL (approx.)	
AIA-PACK C-Peptide Control Set		0025484
AIA-PACK C-Peptide Control Level 1	2 ng/mL (approx)	
AIA-PACK C-Peptide Control Level 2	20 ng/mL (approx)	
ST AIA-PACK C-Peptide II Sample Diluting Solution		0025583
AIA-PACK Wash Concentrate Set		0020955
AIA-PACK Diluent Concentrate Set		0020956
AIA-PACK Detector Standardization Test Cups		0020970
AIA-PACK Sample Treatment Cups		0020971
Sample Cups		0018581
ADDITIONAL REQUIREMENTS: (Except AIA-360)		
Pipette Tips (1000/Pkg)		019215
Tip Rack (Empty)		019216
Preloaded Pipette Tips (96 Tips X 50 Racks)		996010
Preloaded Pipette Tips (96 Tips X 5 Racks)		996005

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

Warnings and Precautions

- The ST AIA-PACK C-Peptide II is intended for in vitro diagnostic use only.
- ℞ only. US Federal law restricts this device to sale by or on the order of a licensed healthcare practitioner.
- Inspect the packaging and the exterior of the aluminum pouch for any sign of damage before use. If any damages are visible, contact Tosoh Technical Support.
- Test cups from different lots or different assays shall not be mixed within a tray.
- After measurement, the ST AIA-PACK C-Peptide II contains sodium azide, which may react with lead or copper plumbing to form potentially explosive metal azides. When disposing of such reagents, always flush with large volumes of water to prevent azide build-up.
- The material derived from human origin 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 origin, please use standard laboratory safety procedures in handling all specimens and controls.
- Do not use beyond the expiration date.
- The ST AIA-PACK C-Peptide II has been designed so that the high dose "hook effect" is not a problem for the vast majority of samples. Serum, heparinized plasma or EDTA plasma samples with C-peptide concentration between 30 and 90 ng/mL will read > 30 ng/mL. On the recommended 10-fold dilution, urine samples with C-peptide concentration between 300 and 900 ng/mL will read > 300 ng/mL. The "hook effect" phenomenon may occur at C-peptide concentrations > 90 ng/mL in serum, heparinized plasma or EDTA plasma, and > 900 ng/mL in urine.
- For safe waste disposal, it is recommended that each laboratory complies with established laboratory procedures and local, state, and federal regulations.
- After opening, the bottle of ST AIA-PACK C-Peptide II Sample Diluting Solution should be kept tightly sealed with a clean cap. Sealing with dirty material may cause deterioration of the reagent.
- The remaining sample diluting solution after use should not be mixed with another bottle but be discarded to avoid contamination.
- 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.
- Tosoh Automated Immunoassays utilizing alkaline phosphatase-based technologies should not be used with samples from patients under Asfotase Alfa treatment.

Storage and Stability

All unopened materials are stable until the expiration date on the label when stored at the specified temperature.

Materials	Cat. No.
Refrigerator Temperature (2 - 8 °C):	
ST AIA-PACK C-Peptide II	0025283
ST AIA-PACK C-Peptide II Calibrator Set	0025383
ST AIA-PACK C-Peptide II Sample Diluting Solution	0025583
AIA-PACK C-Peptide Control Set	0025484
AIA-PACK Substrate Set II	0020968
AIA-PACK Wash Concentrate	0020955
AIA-PACK Diluent Concentrate	0020956
Room Temperature (18 - 25 °C):	
AIA-PACK Detector Standardization Test Cups	0020970
AIA-PACK Sample Treatment Cups	0020971

After opening the aluminum pouch, ST AIA-PACK C-Peptide II test cups can be left on-board of the Tosoh AIA System Analyzers (18 - 25 °C) for a maximum of 7 days (7 x 24 hours). When stored over night at 2 - 8°C, the test cups can be used for up to 21 days (21 cycles of 8 hours on board and 16 hours in the refrigerator). Once the aluminum pouch is opened, even if the test cups are stored in the refrigerator, they must be used within 30 days.

ST AIA-PACK C-Peptide II Calibrator Set must be kept tightly sealed and refrigerated at 2 - 8 °C. After opening or reconstituting, the calibrators should be used within 1 day.

After opening, ST AIA-PACK C-Peptide II Sample Diluting Solution 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 sample diluting solution can be used for up to 30 days (30 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.
AIA-PACK C-Peptide Control Set must be kept tightly sealed and refrigerated at 2 - 8 °C.
After opening or reconstituting, the controls should be used within 14 days.

Reconstituted substrate solution is stable for 3 days at 18 - 25 °C or 30 days at 2 - 8 °C. Working diluent and wash solutions are stable for 30 days at 18 - 25 °C.

Reagents should not be used if they appear cloudy or discolored.

Specimen Collection and Handling

- Serum, heparinized plasma, EDTA plasma, or urine is required for the assay. Citrated plasma SHOULD NOT BE USED.
- No special patient preparation is necessary. When using serum, a venous blood sample is collected aseptically without additives. Store at room temperature (18 - 25 °C) until a clot has formed (usually 15 - 45 minutes), then centrifuge to obtain the serum specimen for assay.
- When using heparinized plasma or EDTA plasma, a venous blood sample is collected aseptically with the designated additive. Centrifuge and separate plasma from the packed cells as soon as possible.

- For urine, collect a 24-hour urine without preservative and keep the sample refrigerated during the collections process. Record the total volume of the collection and use a well-mixed aliquot for analysis. Before assay, clear the sample by filtration or centrifugation.
- Inadequate centrifugation or the presence of fibrin or particulate matter in the sample may cause an erroneous result.
- Samples containing inhibitors of alkaline phosphatase may cause erroneous results.
- Inspect all samples for air bubbles and foaming. Remove any air bubbles prior to 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.
- Serum, heparinized plasma, or EDTA plasma samples may be stored refrigerated at 2 - 8 °C for up to 24 hours prior to analysis. If the analysis cannot be done within 24 hours, the sample should be stored frozen at -20 °C or below for up to 60 days.
- Urine samples may be stored refrigerated at 2 - 8 °C for up to 24 hours prior to analysis. If the analysis cannot be done within 24 hours, the undiluted 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 prior to testing. Prior to the assay, slowly bring frozen samples to 18 - 25 °C and mix gently.
- Urine samples require a 1:10 dilution with the ST AIA-PACK C-Peptide II Sample Diluting Solution prior to analysis. The dilution factor is identified in the test file as Sp.2. The AIA-900 and AIA-2000 will automatically perform these dilutions and calculate the results.
- The sample required for analysis is 10 µL.

Procedure

For the AIA-900, AIA-2000, and AIA-360, please refer to their Operator's Manual for detailed instructions.

1) Reagent Preparation

1a) Substrate Solution

Bring all reagents to room temperature (18 - 25 °C) before preparing the working reagent. Add the entire contents of the AIA-PACK Substrate Reconstituent II (100 mL) to the lyophilized AIA-PACK Substrate Reagent II and mix thoroughly to dissolve the solid material.

1b) 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, mix well, and adjust the final volume to 2.5 L.

1c) 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, mix well, and adjust the final volume to 5.0 L.

2) Calibration

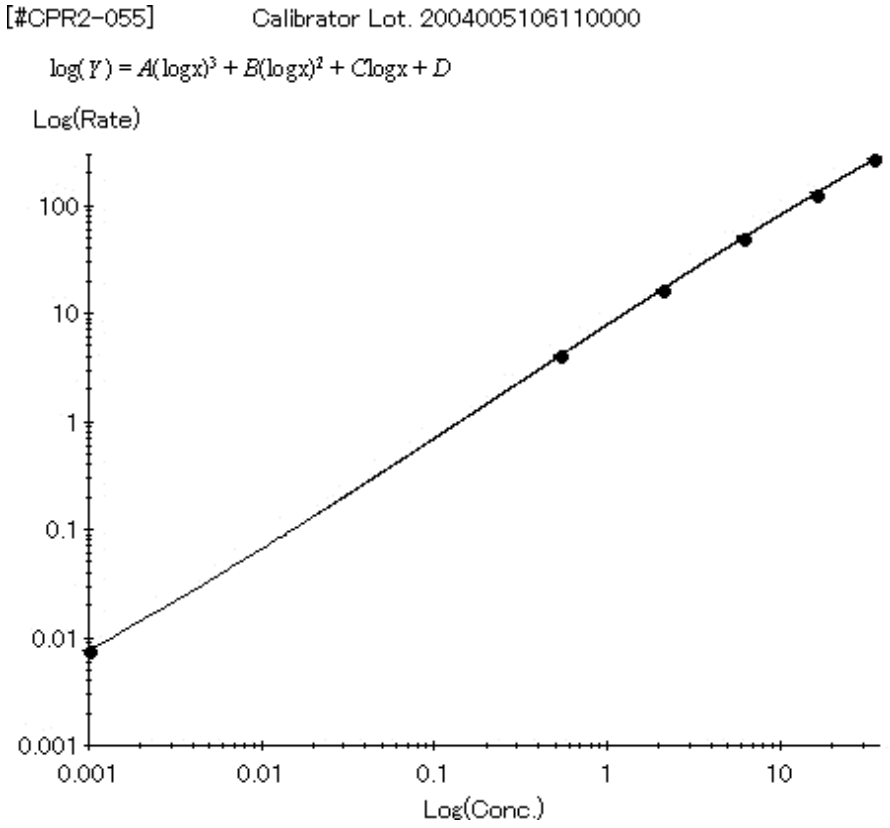
2a) Calibration Curve

The calibrators for use with the ST AIA-PACK C-Peptide II have been standardized against WHO 1st IRP 84/510 (1986).

The calibration curve for the ST AIA-PACK C-Peptide II is 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 according to the manufacturer's instructions.

Recalibration may be necessary more frequently if controls are out of the established range for this assay or when certain service procedures are performed (e.g. temperature adjustment, sampling mechanism changes, maintenance of the wash probe, or detector lamp adjustment or change). For further information regarding instrument operation, consult the Tosoh AIA System Operator's Manual.

A sample calibration curve shows the algorithm used for calculating results. This is an example only. Actual results will vary depending on the instrument type and lot number used. The concentration range of the calibration curve is displayed in 1/10 of assay range in urine specimens. The concentrations of urine specimens are calculated by multiplying the concentrations obtained on the calibration curve with the dilution factor. The AIA-900 and AIA-2000 will automatically calculate the concentrations of urine specimens using the dilution factor and report the results.



2b) Calibration Procedure

Refer to the appropriate Tosoh AIA System Operator's Manual for the procedural instructions.

i) Verify that both the calibrator lot and concentration numbers have been correctly entered into the software.

ii) The ST AIA-PACK C-Peptide II Calibrator (1) is provided ready for use.

iii) The ST AIA-PACK C-Peptide II Calibrator (2) - (6) are lyophilized. Lyophilized calibrators should be reconstituted with 1.0 mL of CAP Class I water or the clinical laboratory reagent water.

iv) Tosoh recommends that all calibrators be run in triplicate.

2c) Calibration Acceptability criteria

i) The mean rate for the ST AIA-PACK C-Peptide II Calibrator (1) should be </= 1.1 mol/(L.s).

ii) Since there is a direct relationship between concentration and rate, the rate should increase as the concentration increases.

iii) The replicate values should be within a 10 % range.

2d) Calibration Review and Acceptance

i) Review the calibration curve carefully, using the criteria listed above.

ii) Edit the calibration if necessary, then accept the calibration.

For further information regarding calibration, consult the Tosoh AIA System Operator's Manual.

3) Quality Control

3a) Commercially Available Controls

Commercially available controls should 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 designates the following:

Control Material: _____
Frequency: _____

Lot number of control material, acceptable limits, and corrective action to be taken if controls do not meet laboratory criteria will be found in a separate quality control document maintained by the laboratory.

3b) Quality Control Procedure

i) Assay quality control specimens as instructed in the specific Operator's Manual for your analyzer. In addition, refer to the AIA System Operator's Manual for detailed instructions on defining and editing the files.

ii) Quality control material to be run with this assay is defined by individual laboratory policy.

4) Specimen Processing

4a) Preparation

Serum, heparinized plasma or EDTA plasma specimens do not require dilution prior to analysis. Urine specimens should be diluted 1:10 with the ST AIA-PACK C-Peptide II Sample Diluting Solution prior to analysis. Either diluted or undiluted patient specimens are

placed in appropriate positions on the Tosoh AIA System Analyzers. For the AIA-360, the urine specimens must be manually diluted in sample cups and the sample cups should be placed on the AIA-360. For further information regarding sample preparation and instrument operation, refer to the SPECIMEN COLLECTION AND HANDLING section and consult the specific Tosoh AIA System Operator's Manual, respectively. Barcoded primary tubes as well as sample cups can be run on the AIA-900 and AIA-2000.

4b) Assay Procedure

i) Ensure a sufficient quantity of ST AIA-PACK C-Peptide II test cups for the number of samples to be run.

ii) Load patient samples as instructed in the Operator's Manual and proceed with analysis. Note: The AIA-900 and AIA-2000 will require AIA-PACK Sample Treatment Cups if onboard dilutions are utilized.

Procedural Notes

1) Lyophilized substrate must be completely dissolved.

2) Ligand assays performed by the Tosoh AIA System Analyzer require that the laboratory use water designated by the CAP Class I or by the clinical laboratory reagent water. Water should be tested at least once per month and should be free of particulate matter including bacteria. The pH of the water should also be routinely tested. 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 C-peptide concentration is found to be greater than 30 ng/mL in serum, heparinized plasma or EDTA plasma, or 300 ng/mL in urine, the specimen should be diluted with the ST AIA-PACK C-Peptide II SAMPLE DILUTING SOLUTION and reassayed according to the Assay Procedure. The recommended dilution for specimens containing greater than 30 ng/mL (serum, heparinized plasma or EDTA plasma) or 300 ng/mL (urine) is a 1:10 dilution. It is desirable to dilute the specimen so that the diluted specimen reads between 0.04 and 30 ng/mL in serum, heparinized plasma or EDTA plasma, or between 0.2 and 300 ng/mL in urine. The dilution factor should be entered into the software. For further information on the dilution of specimens, refer to the Tosoh AIA System Operator's Manual.

4) The Tosoh AIA System Analyzers can store two different calibration curves for each analyte at one time. Therefore, up to two different lots of ST AIA-PACK C-Peptide II test cups can be used during the same run.

5) If the assay specifications for this test are not ready in the system software, the specifications must be entered under test code 040.

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 C-peptide concentration in ng/mL.

For samples requiring dilution, the AIA-900 and AIA-2000 will automatically perform dilutions and calculate results if the dilution factors are entered into the software. For detailed information regarding programming dilutions, consult the appropriate Tosoh AIA System Operator's Manual.

Evaluation of Results

Quality Control

In order to monitor and evaluate the precision of the analytical performance, it is recommended that controls be assayed according to the local regulations.

The minimum recommendations for the frequency of running internal control material are:

- After calibration, at least two levels of the control are run in order to accept the calibration curve.
- The two levels of controls are also repeated when certain service procedures are performed (e.g. temperature adjustment, sampling mechanism changes, maintenance of the wash probe, or detector lamp adjustment or change).
- After daily maintenance, two levels of the control shall be run in order to verify the overall performance of the Tosoh AIA System Analyzers.
- If one or more control value(s) is out of the acceptable range, it is necessary to investigate the validity of the calibration curve before reporting patient results.
- Standard laboratory procedures should be followed in accordance with the regulatory agency under which the laboratory operates.

Limitations of the Procedure

- For diagnostic purposes, the 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 C-Peptide II, the highest measurable concentration of C-peptide in serum, heparinized plasma or EDTA plasma specimens without dilution is 30 ng/mL The lowest measurable concentration in serum, heparinized plasma or EDTA plasma specimens is 0.04 ng/mL (assay sensitivity).
- Using ST AIA-PACK C-Peptide II, the highest measurable concentration of C-Peptide in urine specimens diluted 1:10 with ST AIA-PACK C-Peptide II Sample Diluting Solution corresponds to 300 ng/mL. The lowest measurable concentration in urine specimens diluted 1:10 with ST AIA-PACK C-Peptide II Sample Diluting Solution corresponds to 0.2 ng/mL.
- Although the approximate value of the highest calibrator is 33 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, 30 ng/mL, which corresponds to 300 ng/mL in original urine specimens (dilution factor 10).
- Although hemolysis has an insignificant effect on the assay, hemolyzed samples may indicate mistreatment of a specimen prior to assay and results should be interpreted with caution.

- Lipemia has an insignificant effect on the assay except in the case of gross lipemia where spatial interference may occur.
- Certain medications may interfere with assay performance. Specimens from patients taking medicines and/or medical treatment may show erroneous results. All results should be interpreted with respect to the clinical picture of the patient.
- Samples containing fibrin may exhibit either falsely elevated or falsely decreased results.
- C-peptide concentrations in serum typically increase post-prandially.
- 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 or decreased C-peptide values.
- For a more complete 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 in this insert sheet.

Expected Values

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

Reference Ranges

The interval given here was determined in serum samples from 131 apparently healthy individuals.

Number of Samples (n)	131
Reference Interval	0.69 - 2.45 ng/mL

The reference range of urine samples was verified as 48 to 100 ug/L using the method comparison data and medical decision point analysis.

Conversion Factors

C-peptide 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

1. Accuracy

1a) Recovery

Three serum samples, two plasma samples, and one urine sample were spiked with three different concentration levels of C-peptide and assayed before and after spiking.

Sample	Initial Value (ng/mL)	C-Peptide Added (ng/mL)	Expected Value (ng/mL)	Measured Value (ng/mL)	Percent Recovery (%)
Serum A1	2.05	3.1	5.15	4.8	93.2
	2.05	6.2	8.25	7.53	91.3
	2.05	12.4	14.4	13	89.8
Serum B1	3.16	3.1	6.26	5.93	94.8
	3.16	6.2	9.36	8.9	95.1
	3.16	12.4	15.6	15	96.5
Serum C1	3.14	3.1	6.25	5.87	94
	3.14	6.2	9.35	8.69	92.9
	3.14	12.4	15.5	14.5	93.5
Heparinized	2.63	3.09	5.73	5.4	94.3
plasma A1	2.63	6.18	8.82	7.95	90.2
	2.63	12.4	15	13.7	91.6
EDTA	2.08	3.16	5.24	5.05	96.5
plasma A1	2.08	6.31	8.39	8.01	95.5
	2.08	12.6	14.7	14	95.2
Urine A1	103	26.7	130	131	101.5
	103	53.4	156	160	102.2
	103	107	210	217	103.5

1b) Dilution

Three serum samples, two plasma samples, and one urine sample containing high concentrations of C-peptide were serially diluted with the ST AIA-PACK C-Peptide II Sample Diluting Solution and assayed.

Sample	Dilution Factor	Expected Value (ng/mL)	Measured Value (ng/mL)	Percent Recovery (%)
Serum A2	none	25.8	25.8	100
	7.5/10	19.4	20	103.3
	5.0/10	12.9	13.6	105.1
	2.5/10	6.46	6.99	108.3
	1.0/10	2.58	2.78	107.6
Serum B2	none	25	25	100
	7.5/10	18.8	19.2	102.6
	5.0/10	12.5	13.3	106.3
	2.5/10	6.25	6.76	108.1
	1.0/10	2.5	2.69	107.4
Serum C2	none	27.6	27.6	100
	7.5/10	20.7	21.4	103.2
	5.0/10	13.8	15.2	109.9
	2.5/10	6.89	7.46	108.1
	1.0/10	2.76	2.87	104.1
Heparinized plasma A2	none	25.7	25.7	100
	7.5/10	19.3	19.8	103
	5.0/10	12.8	13.2	103
	2.5/10	6.42	6.69	104.2
	1.0/10	2.57	2.68	104.4
EDTA plasma A2	none	26	26	100
	7.5/10	19.5	19.8	101.4
	5.0/10	13	13.6	104.9
	2.5/10	6.49	6.7	103.2
	1.0/10	2.6	2.65	101.9
Urine A2	none	205	205	100
	7.5/10	154	151	98
	5.0/10	103	101	98.4
	2.5/10	51.3	49.1	95.8
	1.0/10	20.5	21.4	104.5

1c) Linearity:

The linearity for ST AIA-PACK C-Peptide II was determined, based on guidance from CLSI Protocol EP06-A. The linearity was measured on the AIA-360, AIA-900 and AIA-2000 instruments and was demonstrated to be linear from 0.04 to 30 ng/mL in serum, heparinized plasma or EDTA plasma specimens without dilution and from 0.2 to 300 ng/mL in urine specimens diluted 1:10 fold with the ST AIA-PACK C-Peptide II Sample Diluting Solution.

Serum:

Dilution No.	Low : High	Expected Value (ng/mL)	Measured Value (ng/mL)	CV (%)	Recovery (%)
1	Low	0.01	0.01	15.7	100
2	9:01	3.41	3.35	4.2	98.4
3	8:02	6.81	6.51	1.5	95.6
4	7:03	10.21	10.7	0.9	104.8
5	6:04	13.61	14.19	1.1	104.3
6	5:05	17.01	17.76	1.3	104.4
7	4:06	20.41	20.98	2.4	102.8
8	3:07	23.82	24.23	1.7	101.7
9	2:08	27.22	27.65	1.2	101.6
10	1:09	30.62	32.46	1.4	106
11	High Undiluted	34.02	34.02	2.1	100

Heparinized Plasma:

Dilution No.	Low : High	Expected Value (ng/mL)	Measured Value (ng/mL)	CV (%)	Recovery (%)
1	Low	0.01	0.01	14.8	100
2	9:01	3.43	3.28	3.8	95.6
3	8:02	6.85	6.87	1.1	100.3
4	7:03	10.27	10.72	0.6	104.4
5	6:04	13.69	14.07	0.4	102.7
6	5:05	17.12	16.86	0.3	98.5
7	4:06	20.54	20.76	2.8	101.1
8	3:07	23.96	24.36	2.2	101.7
9	2:08	27.38	28.14	1.6	102.8
10	1:09	30.8	31.44	2.2	102.1
11	High Undiluted	34.22	34.22	1.6	100

EDTA Plasma:

Dilution No.	Low : High	Expected Value (ng/mL)	Measured Value (ng/mL)	CV (%)	Recovery (%)
1	Low	0.01	0.01	14.3	100
2	9:01	3.37	3.1	4.1	92.1
3	8:02	6.73	6.35	1.4	94.3
4	7:03	10.09	10.3	2.4	102.1
5	6:04	13.45	14.24	2.3	105.9
6	5:05	16.81	16.57	0.5	98.6
7	4:06	20.17	20.8	1.0	103.1
8	3:07	23.53	23.69	0.6	100.7
9	2:08	26.89	26.75	0.4	99.5
10	1:09	30.25	32.64	0.6	107.9
11	High Undiluted	33.61	33.61	1.9	100

Urine:

Dilution No.	Low : High	Expected Value (ng/mL)	Measured Value (ng/mL)	CV (%)	Recovery (%)
1	Low	0.09	0.09	22.7	100
2	9:01	34.22	31.77	1.1	92.8
3	8:02	68.36	64.39	1.0	94.2
4	7:03	102.49	99.49	1.6	97.1
5	6:04	136.62	137.6	0.5	100.7
6	5:05	170.76	170.14	1.0	99.6
7	4:06	204.89	204.87	2.1	100
8	3:07	239.02	233.72	2.2	97.8
9	2:08	273.15	273.09	0.8	100
10	1:09	307.29	307.66	0.2	100.1
11	High Undiluted	341.42	341.42	2.1	100

2) Precision

2a) Intra-assay precision

The intra-assay (within run) precision was determined using two 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).

Sample	Mean (ng/mL)	Pooled SD (ng/mL)	CV (%)
Serum A3	1.38	0.049	3.5
Serum B3	6.03	0.138	2.3
Serum C3	18.3	0.250	1.4
Heparinized plasma A3	1.63	0.029	1.8
Heparinized plasma B3	6.87	0.120	1.7
Heparinized plasma C3	19.8	0.345	1.7
EDTA plasma A3	1.47	0.037	2.5
EDTA plasma B3	6.78	0.100	1.5
EDTA plasma C3	19.7	0.271	1.4
Urine A3	15.6	0.674	4.3
Urine B3	68.4	1.67	2.4
Urine C3	193.9	5.17	2.7

2b) Total precision

Total precision was determined by the duplicate assay of two controls in 20 separate runs. The means of each run were used to calculate the standard deviation (SD) and coefficient of variation (CV).

Sample	Mean (ng/mL)	Pooled SD (ng/mL)	CV (%)
Serum A3	1.38	0.049	3.6
Serum B3	6.03	0.170	2.8
Serum C3	18.3	0.459	2.5
Heparinized plasma A3	1.63	0.041	2.5
Heparinized plasma B3	6.87	0.150	2.2
Heparinized plasma C3	19.7	0.415	2.1
EDTA plasma A3	1.47	0.047	3.2
EDTA plasma B3	6.78	0.148	2.2
EDTA plasma C3	19.7	0.397	2.0
Urine A3	15.6	0.686	4.4
Urine B3	68.4	1.84	2.7
Urine C3	193.9	5.17	2.7

Control Set Precision

2c) Intra-assay Precision

The intra-assay (within run) precision was determined using two 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).

Sample	Mean (ng/mL)	Pooled SD (ng/mL)	CV (%)
Control 1L	2.24	0.040	1.8
Control 1H	20.81	0.283	1.4
Control 2L	2.37	0.045	1.9
Control 2H	21.29	0.315	1.5
Control 3L	2.30	0.043	1.9
Control 3H	21.23	0.345	1.6

2d) Total Precision

Total precision was determined by the duplicate assay of two controls in 20 separate runs. The means of each run were used to calculate the standard deviation (SD) and coefficient of variation (CV).

Sample	Mean (ng/mL)	Pooled SD (ng/mL)	CV (%)
Control 1L	2.24	0.055	2.5
Control 1H	20.81	0.386	1.9
Control 2L	2.37	0.057	2.4
Control 2H	21.29	0.376	1.8
Control 3L	2.30	0.061	2.7
Control 3H	21.23	0.477	2.2

Correlation

a. The correlation between serum (x) and Na heparinized plasma (y) on the ST AIA-PACK C-Peptide II was carried out using 113 specimens

	Deming	**Regular**
Slope:	1.02 (1.01 to 1.03)	1.03 (1.01 to 1.03)
Intercept:	0.23 (0.18 to 0.28)	0.24 (0.19 to 0.28)
Corr Coef (R):	1.00	
Result Ranges:	0.47 to 28.61 ng/mL	

*95% Confidence Intervals are shown in parentheses

b. The correlation between serum (x) and EDTA Plasma (y) on the ST AIA-PACK C-Peptide II was carried out using 113 specimens.

	Deming	**Regular**
Slope:	1.04 (1.03 to 1.05)	1.04 (1.03 to 1.05)
Intercept:	0.13 (0.06 to 0.19)	1.14 (0.08 to 1.19)
Corr Coef (R):	1.00	
Result Ranges:	0.47 to 28.61 ng/mL	

*95% Confidence Intervals are shown in parentheses

Specificity

The following substances were tested for cross-reactivity. The cross-reactivity (%) is the percent of the compound which will be identified as C-Peptide. If these compounds are present in the specimen at the same concentration as C-Peptide, the final result will be increased by these percentages.

Compound	**Cross-reactivity (%)**
Proinsulin	0.047
Insulin	0.00

LoB, LoD, LoQ

The LoB was determined by 60 measurements of 4 different blank specimens. The LoB was the value at the 95th percentile. In this case LoB was determined to be 0.005 ng/mL.

The LoD was determined by 12 measurements of 10 low level samples. The sample range was chosen to be between LoB and 5XLoB and 3 lots of reagents were utilized. The LoD was determined to be 0.008 ng/mL.

The LOQ was determined by measurements of 10 low level samples and the % CV for each sample calculated. The LoQ was determined to be 0.039 ng/mL.

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.

- Hemoglobin (up to 440 mg/dL), free bilirubin (up to 16 mg/dL), and conjugated bilirubin (up to 18 mg/dL) do not interfere with the assay.
- Lipemia, 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 5 g/dL added to samples from apparently healthy subjects), does not interfere with the assay.
- Heparin (up to 100 U/mL) does not interfere with the assay.
- EDTA•2K (up to 10 mg/mL) does not interfere with the assay.
- Tosoh Automated Immunoassays utilizing alkaline phosphatase-based technologies should not be used with samples from patients under Asfotase Alfa treatment.

References

1. Beischer, W., Proinsulin and C-peptide in Humans. Hormones in Normal and Abnormal Human Tissues Vol 3: 1-43 (1983).
2. Beyer, J., et al., C-Peptide: Its Biogenesis, Structure, Determination and Clinical Significance. Giornale Italiano di Chimica Clinica 4 (Supp.1): 9-22 (1979).
3. Rubenstein, A., et al., Secretion of Proinsulin C-Peptide by Pancreatic by Pancreatic B-cells and Its Circulation in Blood. Nature 224: 697-699 (1969).
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6. Rendall, M., The Expanding Clinical Use of C-Peptide Radioimmunoassay. Acta Diabetological Latine 20: 105-113 (1983).
7. Hoogwerf, B. J., Goetz, F. C., Urinary C-peptide - A Simple Measure of Integrated Insulin Production with Emphasis on Body Size, Diet, and Corticosteroids. J Clin Endocrinol Metab, 56: 60-67 (1983).
8. Kaneko, T., et al., Demonstration of C-Peptide Immunoreactivity in Various Body Fluids and Clinical Evaluation of the Determination of Urinary C-Peptide Immunoreactivity. Endocrinol. Japon., 22: 207-212 (1975).


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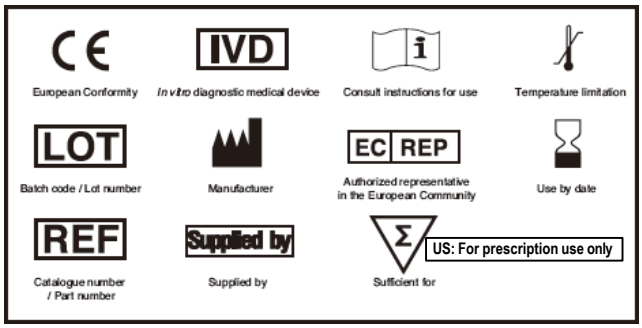
European Conformity
IVD
In vitro diagnostic medical device
Consult instructions for use
Temperature limitation
LOT
Batch code / Lot number
Manufacturer
EC REP
Authorized representative in the European Community
Use by date
REF
Catalogue number / Part number
Supplied by
Supplied by
Σ
US: For prescription use only
Sufficient for

ST AIA-PACK
C-PEPTIDE II CALIBRATOR SET

Intended Use

The ST AIA-PACK C-Peptide II Calibrator Set is intended for In Vitro Diagnostic Use Only for the calibration of the ST AIA-PACK C-Peptide II assay.

Summary and Explanation

The ST AIA-PACK C-Peptide II Calibrator Set contains protein matrix with assigned levels of C-Peptide. Calibration should be performed according to the schedule indicated in the Tosoh AIA System Operator's Manual.

Material Provided (Cat. No. 0025383)

2 x 1 mL ST AIA-PACK C-Peptide II Calibrator (1) 0 ng/mL

Protein matrix containing no detectable concentration of C-peptide with sodium azide as a preservative (ready to use).

2 x 1 mL ST AIA-PACK C-Peptide II Calibrator (2) 0.5 ng/mL (approx.)

ST AIA-PACK C-Peptide II Calibrator (3) 2 ng/mL (approx.)

ST AIA-PACK C-Peptide II Calibrator (4) 6 ng/mL (approx.)

ST AIA-PACK C-Peptide II Calibrator (5) 15 ng/mL (approx.)

ST AIA-PACK C-Peptide II Calibrator (6) 33 ng/mL (approx.)

Protein matrix containing the assigned concentration of C-peptide (described on each vial) (lyophilized).

Warnings and Precautions

- The ST AIA-PACK C-Peptide II Calibrator Set is intended for in vitro diagnostic use only.
- Inspect the packaging and the exterior of the vials for any sign of damage before use. If any damages are visible, contact your local TOSOH sales representative.
- The ST AIA-PACK C-Peptide II Calibrator (1) contains sodium azide, which may react with lead or copper plumbing to form potentially explosive metal azides. When disposing of such reagents, always flush with large volumes of water to prevent azide build-up.
- Although material derived from human origin is not used for these calibrators, it is recommended that this product be handled with the same precautions as used for patient samples.
- Do not use beyond the expiration date.
- For safe waste disposal, it is recommended that each laboratory complies with established laboratory procedures and local, state, and federal regulations.

Preparation and Storage

Bring the calibrators to 18 - 25 °C for use. Using a volumetric pipette or a calibrated adjustable pipette, reconstitute the lyophilized calibrators with 1 mL of CAP Class I water or the clinical laboratory reagent water. Allow the lyophilized material to fully dissolve, then mix the calibrators gently but thoroughly prior to performing the calibration.

Stability

Always store the ST AIA-PACK C-Peptide II Calibrator Set in an upright position at 2 - 8 °C when not in use. When stored unopened and refrigerated at 2 - 8 °C, the Calibrator Set is stable until the expiration date on the label. The calibrators should be used within 1 day of opening or reconstituting, provided the vials are kept tightly sealed and refrigerated at 2 - 8 °C.

Procedure

Refer to the Calibration Procedure in the AIA-PACK section of this analyte application. For additional procedural instructions regarding calibration, refer to the Tosoh AIA System Operator's Manual.

1) Verify that both the calibrator lot and concentrations have been correctly entered into the analyzer software.
2) Add the appropriate amounts of each calibrator to sample cups (refer to the instrument worklist for the amount required in each sample cup).
3) Place the sample cups and the test cups on the analyzer as indicated on the worklist.
4) Tosoh recommends that all calibrators be run in triplicate.

Assignment of Values

The ST AIA-PACK C-Peptide II Calibrator Set contains assigned concentrations of C-peptide. The assigned value is determined on a lot-by-lot basis and is designed to provide an assay calibration range of 0.04 to 30 ng/mL of C-peptide. The calibrators in this set have been standardized against WHO 1st IRP 84/510.

Results

The mean rate for the ST AIA-PACK C-Peptide II Calibrator (1) should be </= 1.1 mol/(L.s).

Since there is a direct relationship between concentration and rate, the rate should increase as the concentration increases.

The replicate values should be within a 10 % range.

Limitations

The ST AIA-PACK C-Peptide II Calibrator Set is designed solely for use with ST AIA-PACK C-Peptide II assay procedures. Although the approximate value of the highest calibrator is 33

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, 30 ng/mL, which corresponds to 300 ng/mL in original urine specimens (dilution factor 10).

References

1. AIA Analyte Application Manual (AAM). Tosoh Bioscience, Inc., Grove City, OH.
2. AIA-System Operator's Manual. Tosoh Bioscience, Inc., Grove City, OH.

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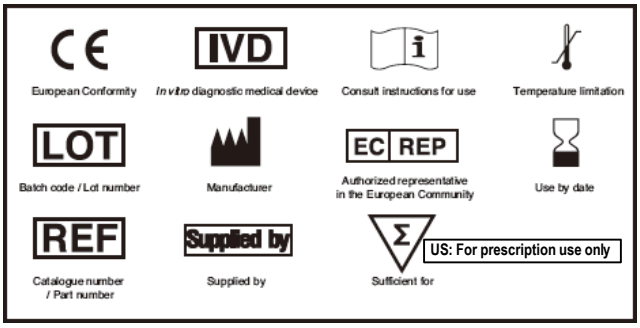


AIA-PACK C-Peptide II
Sample Diluting Solution

Intended Use

The ST AIA-PACK C-Peptide II Sample Diluting Solution is intended for In Vitro Diagnostic Use Only to dilute patient samples.

Summary and Explanation

The AIA-PACK C-Peptide II Sample Diluting Solution contains buffered bovine serum albumin with no detectable concentration of C-Peptide. This Sample Diluting Solution is to be used only with samples that are being tested for C-Peptide concentrations using the ST AIA-PACK C-Peptide II Assays.

Material Provided (Cat. No. 0025583)

4 x 100 mL Sample Diluting Solution

Protein matrix containing no detectable concentration of C-peptide with sodium azide as a preservative.

Warnings and Precautions

- The ST AIA-PACK C-Peptide II Sample Diluting Solution is intended for in vitro diagnostic use only.
- Inspect the packaging and the exterior of the bottles for any sign of damage before use. If any damages are visible, contact your local TOSOH sales representative.
- This material contains sodium azide, which may react with lead or copper plumbing to form potentially explosive metal azides. When disposing of such reagents, always flush with large volumes of water to prevent azide build-up.
- Although material derived from human origin is not used for the sample diluting solution, it is recommended that this product be handled with the same precautions as used for patient samples.
- Do not use beyond the expiration date.
- For safe waste disposal, it is recommended that each laboratory complies with established laboratory procedures and local, state, and federal regulations.
- After opening, the bottle of the sample diluting solution should be kept tightly sealed with a clean cap. Sealing with dirty material may cause deterioration of the reagent.
- The remaining sample diluting solution after use should not be mixed with another bottle but be discarded to avoid contamination.

Preparation of Regents

- The AIA-PACK C-Peptide II Sample Diluting Solution is provided ready to use.
- The sample diluting solution should be used after equilibrating to 18 - 25 °C for about 30 minutes.

Storage and Stability

Always store the ST AIA-PACK C-Peptide II Sample Diluting Solution in an upright position at 2 - 8 °C when not in use. When stored unopened and refrigerated at 2-8 °C, the sample diluting solution is stable until the expiration date on the label. After opening, the sample diluting solution 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 sample diluting solution can be used for up to 30 days (30 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.

Procedure

Refer to the AIA System Operator's Manual for additional procedural instructions regarding sample dilution.

1. Serum, heparinized plasma or EDTA plasma specimens do not require dilution prior to analysis. Urine specimens should be diluted by more than 10 fold with the ST AIA-PACK C-Peptide II Sample Diluting Solution prior to analysis.
2. If a specimen C-peptide concentration is found to be greater than 30 ng/mL in serum, heparinized plasma or EDTA plasma, or 300 ng/mL in urine, the specimen should be diluted with the sample diluting solution and assayed according to the procedure in the insert sheet of the ST AIA-PACK C-Peptide II.
3. The AIA-900 and AIA-2000 will perform dilutions automatically if the dilution factors are entered into the software prior to assaying the diluted sample.
4. The recommended dilution for specimens containing greater than 30 ng/mL (serum, heparinized plasma or EDTA plasma) or 300 ng/mL (urine) is 10 fold dilution. It is desirable to dilute the specimen so that the diluted specimen reads between 0.04 and 30 ng/mL in serum, heparinized plasma or EDTA plasma, or between 0.4 and 300 ng/mL in urine.

Results

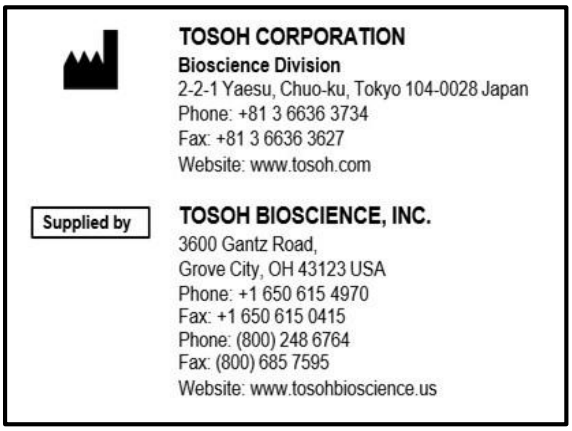
When an auto-dilution is performed, the AIA instrument will calculate the final result.

Limitations

The ST AIA-PACK C-Peptide II Sample Diluting Solution is designed solely for use with ST AIA-PACK C-Peptide II assay procedures

References

1. AIA Analyte Application Manual (AAM) . Tosoh Bioscience, Inc., Grove City, OH.
2. AIA-System Operator's Manual. Tosoh Bioscience, Inc., Grove City, OH.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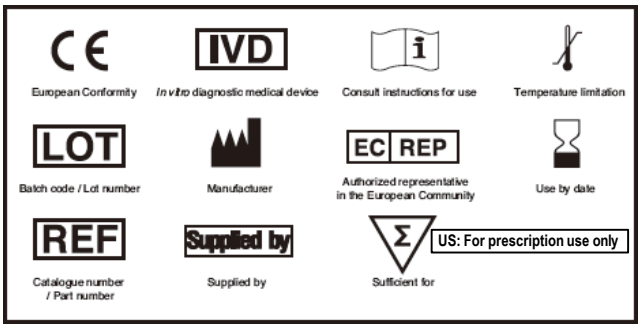

European Conformity
IVD
In vitro diagnostic medical device
Consult instructions for use
Temperature limitation
LOT
Batch code / Lot number
Manufacturer
EC REP
Authorized representative in the European Community
Use by date
REF
Catalogue number / Part number
Supplied by
Σ
Sufficient for
US: For prescription use only

AIA-PACK C-Peptide
Control Set

Intended Use

The AIA-PACK C-Peptide Control Set is intended for In Vitro Diagnostic Use Only for performing quality control procedures with the ST AIA-PACK C-Peptide II assay.

CL AIA-PACK values listed on the Control product labeling (Box and Vials) are for International Use Only and are not intended for use with products in the United States.

Summary and Explanation

The AIA-PACK C-Peptide Control Set contains buffered bovine serum albumin with assigned levels of C-peptide. The C-peptide controls should be run once each day on which C-peptide assays are scheduled.

Material Provided (Cat. No. 0025484)

2 x 2 mL AIA-PACK C-Peptide Control Level 1

Buffered bovine serum albumin containing approximately 2 ng/mL of

C-peptide (Lyophilized). See the vial label for the assigned concentration range.

2 x 2 mL AIA-PACK C-Peptide Control Level 2

Buffered bovine serum albumin containing approximately 20 ng/mL of

C-peptide (Lyophilized). See the vial label for the assigned concentration range.

Warnings and Precautions

- The AIA-PACK C-Peptide Control Set is intended for in vitro diagnostic use only.
- This is an “RX USE” only product.
- Inspect the packaging and the exterior of the vials for any sign of damage before use. If any damages are visible, contact your local TOSOH sales representative.
- The control material has been tested by FDA-approved methods and found negative for the presence of HBsAg, antibody to HIV-1/2 and HCV. Because no test method can offer complete assurance that products derived from human origin will not transmit infectious agents, it is recommended that this product be handled with the same precautions as used for patient samples.
- Do not use beyond the expiration date.
- For safe waste disposal, it is recommended that each laboratory complies with established laboratory procedures and local, state, and federal regulations.

Preparation of Reagents

Bring the controls to 18 - 25 °C for use. Using a volumetric pipette or a calibrated adjustable pipette, reconstitute the lyophilized controls accurately with 2 mL of CAP Class I water or the clinical laboratory reagent water. Allow the lyophilized material to fully dissolve.

Storage and Stability

Always store the AIA-PACK C-Peptide Control Set in an upright position at 2 - 8 °C when not in use. When stored unopened and refrigerated at 2 - 8 °C, the control set is stable until the expiration date on the label. The controls should be used within 14 days of opening or reconstituting, provided the vials are kept tightly sealed and refrigerated at 2 - 8 °C.

Procedure

Refer to the TOSOH AIA System Operator's Manual for additional procedural instructions regarding quality control.

1) Enter control IDs into the AIA-System.
2) Enter the assay request (refer to the specific Operator's Manual for details)
3) Add the appropriate amounts of each control material to sample cups (refer to the specific Operator's Manual for details). Place the sample cups and test cups in the proper positions on the instrument.

Assignment of Values

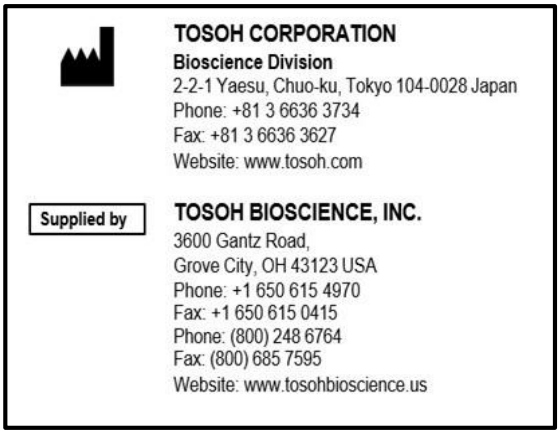
The AIA-PACK C-Peptide Control Set contains assigned concentration range of C-peptide. Control materials were prepared from C-Peptide which was obtained from BACHEM, Product code: H-2470.1000. The assigned range was determined on an AIA 2000 system on a lot-by-lot basis and is designed to provide target control levels of approximately 2 and 20 ng/mL of C-peptide. Since the assay values are dependent upon assay procedures as well as several other factors, each laboratory should establish its own range for the assay procedure being monitored.

Limitations

The AIA-PACK C-Peptide Control Set is designed solely for use with ST AIA-PACK C-Peptide II assay procedures.

References

1. AIA Analyte Application Manual (AAM). Tosoh Bioscience, Inc., Grove City, OH.
2. AIA-System Operator's Manual. Tosoh Bioscience, Inc., Grove City, OH.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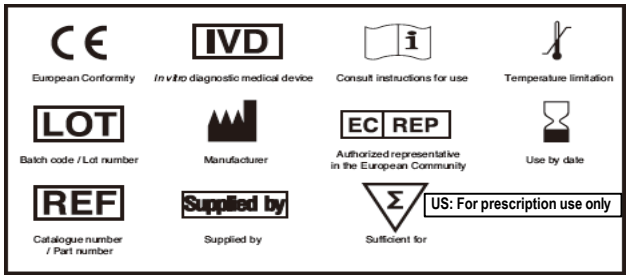
European Conformity
IVD
In vitro diagnostic medical device
Consult instructions for use
Temperature limitation
LOT
Batch code / Lot number
Manufacturer
EC REP
Authorized representative in the European Community
Use by date
REF
Catalogue number / Part number
Supplied by
Supplied by
Sufficient for
US: For prescription use only