AIA-360 Assay Specifications
ST TES Test Code 024

No.	Item	Data
1	Calib. Req	Show
2	Cal 1	0 ng/dL
3	Cal 2	30 ng/dL (example)
4	Cal 3	100 ng/dL (example)
5	Cal 4	350 ng/dL (example)
6	Cal 5	900 ng/dL (example)
7	Cal 6	2200 ng/dL (example)
8	Cal Lot L	
9	Cal Lot R	
10	Unit	ng/dL
11	Smpl. Vol	85
12	Dil. Vol	45
13	Assay L	10
14	Assay H	2200
15	Ref. L	
16	Ref. H	
17	Decimal	1
	Visible only in Test Mode	
18	Test Name	#TES
19	Calib. No	6
20	Calib. Mul	3
21	Calib. Equ	6
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	0.000000
29	G Origin	0.000000

AIA-900 Assay Specifications
ST TES Test Code 024

No.	Item	Data
1	Code	24
2	ACT	1
3	Analyte	#TES
4	Lot	***Enter current cal lot no.
5	CAL 1	0 ng/dL
6	CAL 2	30 ng/dL (example)
7	CAL 3	100 ng/dL (example)
8	CAL 4	350 ng/dL (example)
9	CAL 5	900 ng/dL (example)
10	CAL 6	2200 ng/dL (example)
11	Cal lot L	
12	Cal lot R	
13	Unit	ng/dL
14	Decimal	2
15	Assay Low	10
16	Assay High	2200
17	Reference Low	
18	Reference High	
19	Reschedule Low	10
20	Reschedule High	2200
21	Factor A	1
22	Factor B	0
23	Sample Volume	85
24	Diluent Volume	45
25	2 Step reagent dispensing volume	0
26	Calibration code	24
27	CAL. No.	6
28	CAL. MUL.	3
29	CAL. EQU.	6
30	CAL. CV	90
31	DIL. SP1	1
32	DIL. SP2	1
33	DIL. CAL. (Calculation of dil ratio of conc.)	1
34	DIL. CNTL.	1
35	DIL. DO	1
36	DIL. AH.	5
37	DIL. CALC.	1
38	DIL. CODE	24
39	DIL. NAME	#TES
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
48	SYS. F_B	0
49	V. CONC.	0
50	G. ORIGIN	0

AIA-2000 Assay Specifications
ST TES Test Code 024

No.	Item	Data
1	Unit	ng/dL
2	Decimal places	1
3	Reference low	
4	Reference high	
5	Reschedule low	10
6	Reschedule high	2200
7	Assay range low	10
8	Assay range high	2200
9	Specimen diluent code	24
10	Specimen diluent name	#TES
11	Dilution factor for Sp. 1	1
12	Dilution factor for Sp. 2	1
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	6
19	Calibrator replicates	3
20	Calibrator lot	***Enter current cal. lot no.
21	Calibrator Concentration	
22	Cal - 01	0 ng/dL
23	Cal - 02	30 ng/dL (example)
24	Cal - 03	100 ng/dL (example)
25	Cal - 04	350 ng/dL (example)
26	Cal - 05	900 ng/dL (example)
27	Cal - 06	2200 ng/dL (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	85
39	Diluent volume	45
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
49	Calibration Code Check	024
50	Virtual Concentration	0.0
51	Graph Origin	0.0
52	Calculation with Dilution Factor	Yes

Testosterone
ST AIA-PACK Testosterone

Name and Intended Use

ST AIA-PACK Testosterone is designed for IN VITRO DIAGNOSTIC USE ONLY for the quantitative measurement of testosterone in human serum on specific Tosoh AIA System analyzers. Measurement of testosterone is used to aid in the diagnosis and management of conditions involving excess or deficiency of this androgen.

This device is intended “For Professional Use” only.

Summary and Explanation of Test

Testosterone is one of the major male sex hormones produced by the interstitial cells of Leydig in the testes. The measurement of the total testosterone in serum can provide information to evaluate adrenal and testicular functions. It is useful for the diagnosis of the hypergonadism [1] and hyperpituitarism[2] in men, and hirsutism[3], menstrual disorders[4], and polycystic ovarian syndrome[5] in women. It is also useful for the characterization and follow-up of some cancers such as testicular[6], breast, ovarian, and adrenal tumors[7-9].

Principle of the Assay

The ST AIA-PACK Testosterone is a competitive enzyme immunoassay which is performed entirely in the AIA-PACK. Testosterone present in the test sample competes with enzyme-labeled testosterone for a limited number of binding sites on the testosterone specific monoclonal antibody immobilized on a magnetic solid phase. The magnetic beads are washed to remove unbound enzyme-labeled testosterone and are then incubated with a fluorogenic substrate, 4-methylumbelliferyl phosphate (4MUP). The amount of enzyme-labeled testosterone that binds to the beads is inversely proportional to the testosterone concentration in the test sample. A standard curve is constructed, and unknown sample concentrations are calculated using this curve.

Material Provided (ST AIA-PACK Testosterone, Cat. No. 0025204)

5 trays x 20 test cups (ST AIA-PACK Testosterone Test Cup)

Plastic test cups containing lyophilized magnetic beads coated with anti- testosterone mouse monoclonal antibody and testosterone conjugated to bovine alkaline phosphatase with 0.1% sodium azide as a preservative.

Materials Required But Not Provided

The following materials are not provided but are required to perform testosterone analysis using the ST AIA-PACK Testosterone (Cat. No. 0025204) on specific Tosoh AIA Systems. They 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		
AIA-PACK Testosterone Calibrator Set		0025304
Calibrator #1	0 ng/dL	
Calibrator #2	30 ng/dL (approx.)	
Calibrator #3	100 ng/dL (approx.)	
Calibrator #4	350 ng/dL (approx.)	
Calibrator #5	900 ng/dL (approx.)	
Calibrator #6	2200 ng/dL (approx.)	
AIA-PACK Testosterone Sample Diluting Solution		0025504
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 Testosterone 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 or the vials for any sign of damage before use. If any damages are visible, contact your local Tosoh sales representative.
- Test cups from different lots should not be mixed within a tray.
- The ST AIA-PACK Testosterone 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.
- Human sera 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.
- For safe waste disposal, it is recommended that each laboratory complies with established laboratory procedures and local, state, and federal regulations.
- Do not use beyond the expiration date.
- 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 Testosterone	0025204
AIA-PACK Testosterone Calibrator Set	0025304
AIA-PACK Testosterone Sample Diluting Solution	0025504
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

ST AIA-PACK Testosterone test cups may be stored up to for 24 hours at a room temperature of 18 - 25 °C. Calibrators must be kept tightly sealed and refrigerated at 2 - 8 °C. After opening, calibrators should be used within 7 days. After opening, Sample Diluting Solution is stable for up to

30 days refrigerated at 2 - 8 °C. 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 room temperature (18 - 25 °C). Reagents should not be used if they appear cloudy or discolored.

Specimen Collection and Handling

Serum or heparinized plasma is required for the assay. EDTA and 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 18 - 25 °C until a clot has formed (usually 15 - 45 minutes), then centrifuge to obtain the serum specimen for assay.

To use heparinized plasma, a venous blood sample is collected aseptically with the designated additive. Centrifuge and separate plasma from the packed cells as soon as possible.

Samples may be stored 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.

Repeated freeze-thaw cycles should be avoided. Turbid serum samples or samples containing particulate matter should be centrifuged prior to testing. Prior to assay, slowly bring frozen samples to room temperature (18 - 25 °C) and mix gently.

The sample required for analysis is 85 µL.

Procedure

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 Substrate Reconstituent (100 mL) to the lyophilized Substrate and mix thoroughly to dissolve.

1b) Wash Solution

Add the entire contents of the 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. Prepare Wash Solution at least 24 hours prior to use with this assay.

1c) Diluent

Add the entire contents of the 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. Prepare Diluent Solution at least 24 hours prior use with this assay.

2) Calibration

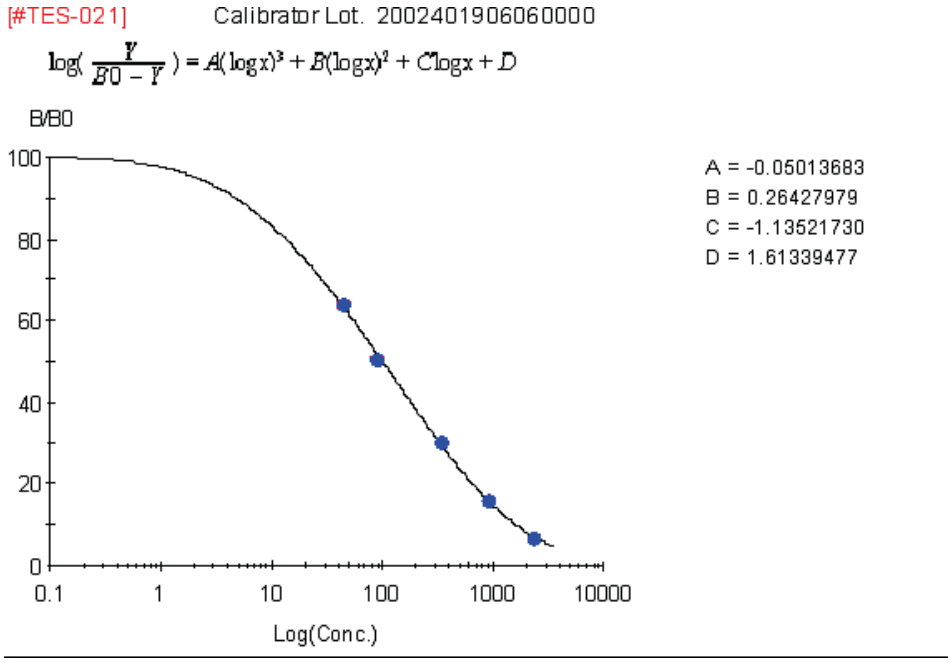
2a) Calibration Curve

The calibrators in this set are prepared gravimetrically and compared to internal reference standards.

The calibration curve for the ST AIA-PACK Testosterone is stable for up to 90 days. Calibration stability is monitored by quality control performance and is dependent on proper reagent handling and 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 if certain service procedures are performed (e.g. temperature adjustment, sampling mechanism changes, or detector lamp adjustment or change). For further information regarding instrument operation, consult the AIA System Operator's Manual.

The sample calibration curve below shows the algorithm used to calculate the results. This is an example only. Actual results will vary depending on the Instrument type and lot number used.



2b) Calibration Procedure

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

i) Verify that the calibrator concentrations listed on the vial labels as well as the calibrator lot numbers have been correctly entered into thesoftware.

ii) Calibrators for ST AIA-PACK Testosterone are provided ready to use. Tosoh recommends that all calibrators be run intriplicate.

2c) Calibration Acceptability criteria

i) Since there is an inverse relationship between concentration and rate, the rates should decrease as the concentration increases.

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

2d) Calibration Review and Acceptance

i) Using the criteria above, review the calibration curve carefully.

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

iii) For further information regarding calibration, consult the 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 the 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

Following specific instructions in the Operator's Manual for the analyzer, place samples on the instrument appropriately.

4b) Assay Procedure

i) Verify a sufficient quantity of ST AIA-PACK Testosterone 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 testosterone concentration is found to be greater than the linearity limit of the assay, 2200 ng/dL; the specimen should be diluted with the AIA-PACK Testosterone Sample Diluting Solution and re-assayed according to the Assay Procedure. The recommended dilution for samples containing greater than 2200 ng/dL is 1:5 or 1:10. It is desirable to dilute the sample so that the diluted sample reads between 200 and 2000 ng/dL. The dilution factor should be entered into the software. For further information on specimen dilution, refer to AIA System Operator's Manual.

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

5) If the assay specifications for this test are not already in the system software, the specifications must be entered under Test Code 024.

Calculation of Results

The AIA Systems perform all sample and reagent handling operations automatically. The AIA Systems read the rate of fluorescence produced by the reaction and automatically convert the rate to testosterone concentration in ng/dL. For samples requiring dilution, the AIA instruments will automatically perform dilutions and calculate results if the dilution factors are entered into the software.

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 be assayed daily.

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

- After calibration, two levels of controls are run in order to accept the calibration curve.
- The two levels of controls are also repeated after calibration 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, at least two levels of the control should be run in order to verify the overall performance of the Tosoh AIA System Analyzers.

If one or more control sample value(s) is out of the acceptable range, it will be necessary to investigate the validity of the calibration curve and the assay results before reporting patient values.

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 Testosterone, the highest concentration of testosterone measurable without dilution is approximately 2200 ng/dL, and the lowest measurable concentration is 10 ng/dL (assay sensitivity).

Although the approximate value of the highest calibrator is 2200 ng/dL, the exact concentration may be slightly different. The assay specification, Assay Range High, should be defined as the upper limit of the assay range, 2200 ng/dL.

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.

Samples from patients who had an injection of fluorescein, which is used in fluorescein fundus angiography, may cause falsely elevated results.

Samples containing fibrin may exhibit either falsely elevated or falsely decreased results. Fibrin must be eliminated in the sample before assay begins.

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.

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 which corresponds 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[10].

Reference Ranges

The interval given here was determined in serum samples from 92 (Male: 62, Female: 30) apparently healthy individuals.

	Number	Ranges (ng/dL)	Average(ng/dL)
Male	62	199 – 1586	485
Female	30	10 – 73.23	32.278

Conversion Factors

Testosterone concentrations in this application are in units of ng/dL. Conversion to SI units of nmol/L may be done using the following equation:

ng/dL × 0.03467 = nmol/L

Performance Characteristics

The following performance characteristics were determined using the Tosoh AIA NexIA Automated Immunoassay Analyzer.

1) Accuracy

1a)Recovery:

Three serum samples were spiked with three different levels of testosterone and assayed before and after spiking.

Sample	Initial Value (ng/dL)	Testosterone Added (ng/dL)	Expected Value (ng/dL)	Measured Value (ng/dL)	Percent Recovery (%)
Serum A	15.1	249.1	264.2	282.9	107.1
	15.1	124.6	139.7	127.5	91.3
	15.1	62.3	77.4	70.9	91.6
Serum B	11.6	228.5	240.1	272.3	113.4
	11.6	114.3	125.9	126.0	100.1
	11.6	57.1	68.7	64.5	93.9
Serum C	12.9	256.0	268.9	272.3	101.3
	12.9	128.0	140.9	130.8	92.8
	12.9	64.0	76.9	65.7	85.4

1b) Dilution:

Three serum samples with high concentrations of testosterone were serially diluted with AIA-PACK Testosterone Sample Diluting Solution and assayed.

Sample	Dilution Factor	Expected Value (ng/dL)	Measured Value (ng/dL)	Percent Recovery (%)
Serum A	none		2096	
	7.5/10	1571	1633	103.9
	5.0/10	1048	1101	105.1
	2.5/10	524	549	104.8
	1.0/10	210	182	86.7
Serum B	none		1989	
	7.5/10	1492	1574	105.5
	5.0/10	995	1100	110.6
	2.5/10	497	550	110.6
	1.0/10	199	182	91.5
Serum C	none		2048	
	7.5/10	1536	1523	99.1
	5.0/10	1024	1122	109.6
	2.5/10	512	581	113.5
	1.0/10	205	193	94.1

1c) Comparative Analysis:

Samples were collected at random. Results from the ST AIA-PACK Testosterone assay (y) were compared to those obtained using another FDA cleared method (x). A total of 71 serum samples were tested in the study.

Slope	**0.9562**
y-intercept	-0.7375 ng/dL
Correlation Coefficient	0.979
Range of Samples (DPC)	7.9 – 1107 ng/dL
Number of Samples (n)	71

2) Precision

2a) Intra-assay precision

The intra-assay (within run) precision coefficient of variation was evaluated in three serum samples by 10 replicate determinations in three different lots of reagent.

Rgt. Lot	Sample	Number of Replicates	Mean (ng/dL)	Standard Deviation (ng/dL)	Coefficient of Variation (%)
BZ12472	Serum A	10	52.0	1.80	3.5
	Serum B	10	800	19.6	2.4
	Serum C	10	1633	45.9	2.8
BZ12473	Serum A	10	53.0	2.79	5.3
	Serum B	10	798	15.4	1.9
	Serum C	10	1558	28.2	1.8
C212474	Serum A	10	61.4	3.19	5.2
	Serum B	10	796	25.9	3.3
	Serum C	10	1503	46.0	3.1

The inter-assay (between run) precision coefficient of variation was evaluated at three different concentrations by analyzing control samples in 20 separate runs.

2b) Inter-assay precision

Sample	Number of Replicates	Mean (ng/dL)	Standard Deviation (ng/dL)	Coefficient of Variation (%)
Serum A	20	88.63	5.31	5.99
Serum B	20	627.16	16.84	2.69
Serum C	20	1402.47	34.82	2.48

Specificity

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

Substance	Concentration added (ng/dL)	Cross-reactivity (%)
Androstenedione	200000	1.71
Aldosterone	160000	0.00
Androsterone	2000000	0.03
Corticosterone	100000	0.01
Cortisol	160000	0.00
Cortisone	160000	0.00
Danazol	4000	0.00
11-Deoxycortisol	20000	0.00
Dexamethasone	160000	0.00
DHEA	5000	0.01
DHEA-sulfate	20000	0.00
5-Dihydrotestosterone	1000	0.81
Esteadiol	200000	0.00
Estrone	10000	0.00
Ethisterone	1000	0.00
Fluoxymesterone	100000	0.00
19-Hydroxyandrostenedione	5000	0.00
Methyltestosterone	600	0.15
Norethindrone	500	0.00
Prednisone	16000	0.03
Progesterone	20000	0.02
Norethynodrel	1000	0.03
Spironolactone	20000	0.01
Triamcinolone	1000	0.00

Sensitivity

The minimal detectable concentration (MDC) of testosterone is estimated to be 10.0 ng/dL. The MDC is defined as that concentration of testosterone which corresponds to the rate of fluorescence that is two standard deviations from the mean rate of fluorescence of 20 replicate determinations of a zero calibrator.

Interference

Interference is defined, for purposes of this study, to be recovery outside of 10% of the known specimen mean concentration. For these studies, interfering substances are added to normal human serum.

- Added hemoglobin (up to 500 mg/dL), conjugated bilirubin (up to 21.1 mg/dL) and free bilirubin (up to 17.0 mg/dL) do not interfere with the assay.
- Lipemia, as indicated by added triglyceride (up to 500 mg/dL) does not interfere with the assay.
- Added albumin (up to 5 mg/mL) does not interfere with the assay.
- Added ascorbic acid (up to 20 mg/dL) does not interfere with theassay.
- Added rheumatoid factor (up to 45 IU/mL) does not interfere with the assay.
- Tosoh Automated Immunoassays utilizing alkaline phosphatase-basedtechnologies should not be used with samples from patients under Asfotase Alfatreatment.

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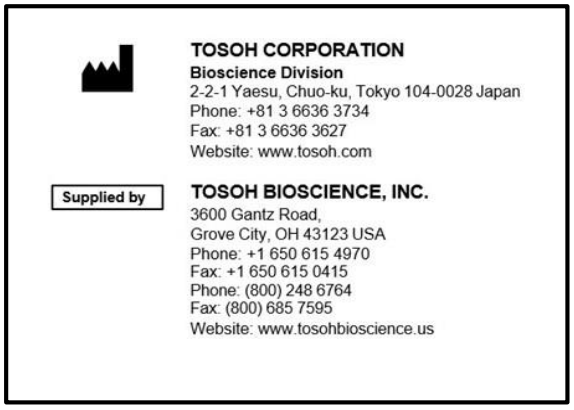
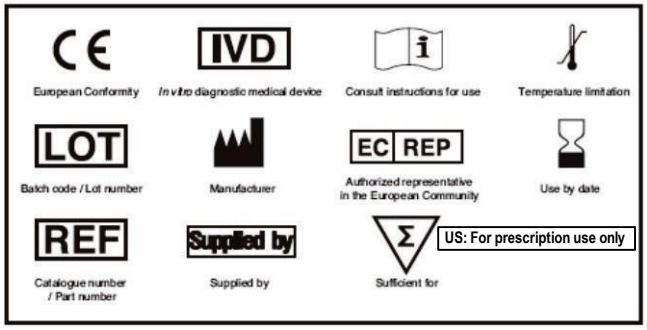




ST AIA-PACK
Testosterone Calibrator Set

Intended Use

The ST AIA-PACK Testosterone Calibrator Set is intended for IN VITRO diagnostic use only for the calibration of the ST AIA-PACK Testosterone Assay.

Summary and Explanation

The ST AIA-PACK Testosterone Calibrator Set contains buffered bovine serum albumin with assigned levels of Testosterone. Calibration should be performed according to the schedule indicated in the AIA System Operator's Manual. The calibrators in this set are prepared gravimetrically and compared to internal reference standards.

Material Provided (Cat. No. 0025304)

2 x 1 mL	Calibrator No. 1	0	ng/dL

Buffered bovine serum albumin containing no detectable concentration of testosterone (0 ng Testosterone/dL), and 0.1% sodium azide as preservative. (Ready to Use)

2 x 1 mL	Calibrator No. 2	30	ng/dL (approx.)
	No. 3	100	ng/dL (approx.)
	No. 4	350	ng/dL (approx.)
	No. 5	900	ng/dL (approx.)
	No. 6	2200	ng/dL (approx.)

Buffered bovine serum albumin containing the assigned concentration of testosterone (described on each vial), and 0.1% sodium azide as a preservative. (Ready to Use)

Warnings and Precautions

- The ST AIA-PACK Testosterone Calibrator Set is for in vitro diagnostic use.
- These materials contain 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 blood is not used for Testosterone Calibrators, it is recommended that this product be handled with the same precautions used for patient samples.
- Do not use beyond the expiration date.

Preparation and Storage

- The ST AIA-PACK Testosterone Calibrator Set is provided ready to use.
- Bring calibrators to room temperature (18 - 25 °C) before use.
- Always store the Calibrator Set in an upright position at 2 - 8 °C when not in use.

Stability

When stored unopened and refrigerated at 2 - 8 °C, the ST AIA-PACK Testosterone Calibrator Set is stable until the expiration date on the label. After opening, the calibrators should be used within 7 days.

Procedure

Refer to the CALIBRATION PROCEDURE in the AIA-PACK section of this analyte application. For additional procedural instructions regarding calibration, refer to the 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 Testosterone Calibrator Set contains assigned concentrations of testosterone. The assigned value is determined on a lot-to-lot basis and is designed to provide an assay calibration range of approximately 0 to 2200 ng/dL of testosterone. The calibrators in this set are prepared gravimetrically and compared to internal reference standards.

Results

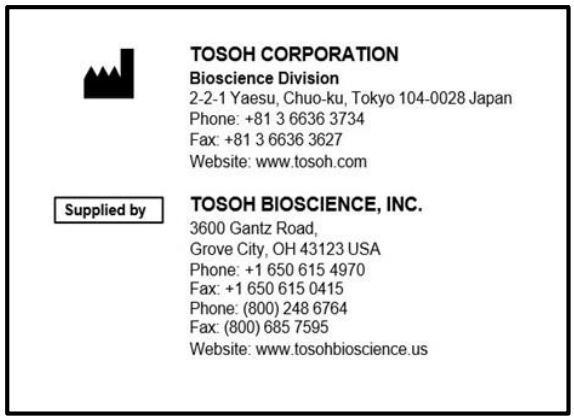
- Since there is an inverse relationship between concentration and rate, the rate should decrease as the concentration increases.
- The replicate values should be within a 10% range.

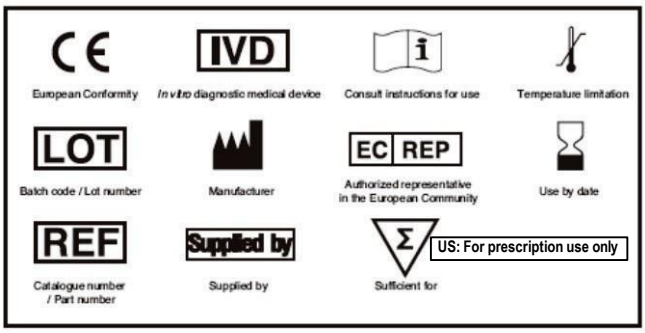
Limitations

The ST AIA-PACK Testosterone Calibrator Set is designed solely for use with ST AIA-PACK 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.





ST AIA-PACK
Testosterone Sample Diluting Solution

Intended Use

The ST AIA-PACK Testosterone Sample Diluting Solution is intended for IN VITRO DIAGNOSTIC USE ONLY to dilute patient samples that have concentrations of Testosterone above the linear range of the assay.

Summary and Explanation

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

Material Provided (Cat. No. 0025504)

4 x 4 mL Sample Diluting Solution

Buffered bovine serum albumin containing no detectable concentration of Testosterone (0 ng/dL), and 0.1% sodium azide as a preservative. (Ready to Use)

Warnings and Precautions

- The ST AIA-PACK Testosterone Sample Diluting Solution is for in vitro diagnostic use.
- These materials contain 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 blood is not used for ST AIA-PACK Testosterone Sample Diluting Solution, it is recommended that this product be handled with the same precautions used for patient samples.
- Do not use beyond the expiration date.

Preparation and Storage

- The ST AIA-PACK Testosterone Sample Diluting Solution is provided ready to use.
- Always store in an upright position at 2 - 8 °C when not in use.

Stability

When stored unopened and refrigerated at 2 - 8 °C, the ST AIA-PACK Testosterone Sample Diluting Solution is stable until the expiration date on the label. After opening, the Sample Diluting Solution is stable for up to 30 days when refrigerated at 2 - 8 °C.

Procedure

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

1. If a specimen is found to contain greater than the linearity limit of approximately 2200 ng/dL, the specimen should be diluted with the Sample Diluting Solution and assayed according to the Procedure in the ST AIA-PACK section of the analyte application.
2. 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.
3. The recommended dilution for serum containing greater than 2200 ng/dL is 1:5 or 1:10. However, it is desirable to dilute the serum samples so that the diluted sample reads between 200 and 2000 ng/dL.

Results

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

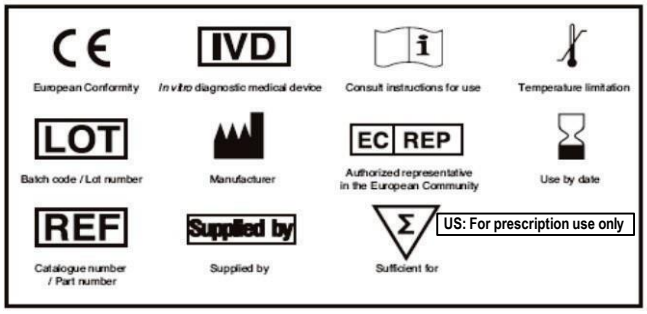
Limitations

The ST AIA-PACK Testosterone Sample Diluting Solution is designed solely for use with AIA-PACK 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.


TOSOH CORPORATION
Bioscience Division
2-2-1 Yaesu, Chuo-ku, Tokyo 104-0028 Japan
Phone: +81 3 6636 3734
Fax: +81 3 6636 3627
Website: www.tosoh.com
Supplied by
TOSOH BIOSCIENCE, INC.
3600 Gantz Road,
Grove City, OH 43123 USA
Phone: +1 650 615 4970
Fax: +1 650 615 0415
Phone: (800) 248 6764
Fax: (800) 685 7595
Website: www.tosohbioscience.us


CE
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