

AIA-360 Assay Specifications

ST AIA-PACK PROG II Test Code 127

No.	Item	Data
1	Calib. Req	SHOW
2	Cal 1	0
3	Cal 2	0.5 (Example)
4	Cal 3	1.5 (Example)
5	Cal 4	5.0 (Example)
6	Cal 5	15 (Example)
7	Cal 6	45 (Example)
8	Cal Lot L	
9	Cal Lot R	
10	Unit	ng/mL
11	Smpl. Vol	75
12	Dil. Vol	75
13	Assay L	0.10
14	Assay H	40
15	Ref. L	
16	Ref. H	
17	Decimal	2

Visible only in Test Mode

18	Test Name	#PR-2
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 AIA-PACK PROG II Test Code 127

No.	Item	
1	Code	127
2	ACT	1
3	Analyte	#PR-2
4	Lot	
5	CAL 1	0
6	CAL 2	0.5 (Example)
7	CAL 3	1.5 (Example)
8	CAL 4	5.0 (Example)
9	CAL 5	15 (Example)
10	CAL 6	45 (Example)
11	Cal lot L	
12	Cal lot R	
13	Unit	ng/mL
14	Decimal	2
15	Assay Low	0.10
16	Assay High	40
17	Reference Low	
18	Reference High	
19	Reschedule Low	0.10
20	Reschedule High	40
21	Factor A	1.000000
22	Factor B	0.000000
23	Sample Volume	75
24	Diluent Volume	75
25	2 Step reagent dispensing volume	0
26	Calibration code	127
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.	4
37	DIL. CALC.	1
38	DIL. CODE	127
39	DIL. NAME	#PR-2
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.	0.000000
50	G. ORIGIN	0.000000

AIA-2000 Assay Specifications

ST AIA-PACK PROG II Test Code 127

No.	Item	
1	Unit	ng/mL
2	Decimal places	2
3	Reference low	
4	Reference high	
5	Reschedule low	0.10
6	Reschedule high	40
7	Assay range low	0.10
8	Assay range high	40
9	Specimen diluent code	127
10	Specimen diluent name	#PR-2
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	1
15	Default multiplier for >H	4
16	Factor A	1.000000
17	Factor B	0.000000
18	Calibration code	6
19	Calibrator replicates	3
20	Calibrator lot	***Enter current cal. lot no.
21	Calibrator Concentration	
22	Cal - 01	0
23	Cal - 02	0.5 (Example)
24	Cal - 03	1.5 (Example)
25	Cal - 04	5.0 (Example)
26	Cal - 05	15 (Example)
27	Cal - 06	45 (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	75
39	Diluent volume	75
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	1.000000
49	Calibration Code Check	127
50	Virtual Concentration	0.0000
51	Graph Origin	0.0000
52	Calculation with Dilution Factor	Yes

PROG II

ST AIA-PACK PROG II

Name and Intended Use

ST AIA-PACK PROG II is designed for In IN VITRO DIAGNOSTIC USE ONLY for the quantitative measurement of progesterone in human serum or heparinized plasma on Tosoh AIA System Analyzers.

Summary and Explanation of Test

Progesterone (pregn-4-ene-3, 20-dione) is a steroid hormone produced mainly by the ovary and adrenal cortex in females and, in lesser amounts, by the adrenal cortex in males (1,2). Progesterone is secreted in small amounts by the ovaries during the follicular phase of the menstrual cycle and increases sharply following ovulation and corpus luteum development (3). Unless pregnancy occurs, a steep decline to follicular levels occurs prior to the next menstrual cycle (4). This pattern provides the rationale for the use of serum progesterone measurement as a reliable method for ovulation detection (5).

Daily progesterone levels are considered the most accurate means for documenting luteal phase defect (6). Measurement of progesterone in blood can also be used to detect and evaluate patients at risk for abortion during the early weeks of gestation (7,8).

Principle of the Assay

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

Material Provided (AIA-PACK PROG II, Cat. No. 0025239)

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

Plastic test cups containing lyophilized twelve magnetic beads with anti-progesterone rabbit polyclonal antibody and 75 µL of progesterone conjugated to bovine alkaline phosphatase with sodium azide as a preservative.

Materials Required But Not Provided

The following materials are required to perform progesterone analysis using the ST AIA-PACK PROG II (Cat. No. 0025239) on the Tosoh AIA System Analyzers. They are available separately from Tosoh.

Materials		Cat. No.
AIA-2000 ST		0022100
AIA-2000 LA		0022101
AIA-900		0022930
AIA-360		0019945
AIA-PACK Substrate Set II		0020968
AIA-PACK Substrate Reagent II		
AIA-PACK Substrate Reconstituent II		
ST AIA-PACK PROG II Calibrator Set		0025339
ST AIA-PACK PROG II Calibrator (1)	0 ng/mL	
ST AIA-PACK PROG II Calibrator (2)	0.5 ng/mL (approx.)	
ST AIA-PACK PROG II Calibrator (3)	1.5 ng/mL (approx.)	
ST AIA-PACK PROG II Calibrator (4)	5.0 ng/mL (approx.)	
ST AIA-PACK PROG II Calibrator (5)	15.0 ng/mL (approx.)	
ST AIA-PACK PROG II Calibrator (6)	45.0 ng/mL (approx.)	
ST AIA-PACK PROG II Sample Diluting Solution		0025539
AIA-PACK Wash Concentrate		0020955
AIA-PACK Diluent Concentrate		0020956
Sample Cups		0018581
AIA-PACK Detector Standardization Test Cup		0020970
AIA-PACK Sample Treatment Cup		0020971

Additional Requirements for AIA-900 and AIA-2000:

Pipette Tips	019215
Tip Rack	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 characterized based strictly on Tosoh materials.

Warnings and Precautions

- The ST AIA-PACK PROG II is intended for in vitro diagnostic use only.
- **Rx** 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 your local Tosoh sales representative.
- Test cups from different lots or different assays shall not be mixed within a tray.
- The ST AIA-PACK PROG 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.
- For safe waste disposal, it is recommended that each laboratory complies with established laboratory procedures and local, state, and federal regulations.
- After opening, the vial of ST AIA-PACK PROG II Sample Diluting Solution should be kept tightly sealed with a clean rubber cap. Sealing with dirty material may cause deterioration of the reagent and could give rise to erroneous results.
- The remaining sample diluting solution after use should not be mixed with another vial 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 PROG II	0025239
ST AIA-PACK PROG II Calibrator Set	0025339
ST AIA-PACK PROG II Sample Diluting Solution	0025539
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 Cup	0020970
AIA-PACK Sample Treatment Cup	0020971

After opening the aluminum pouch, ST AIA-PACK PROG II 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 aluminum pouch is opened, the test cups must be used within 30 days.

ST AIA-PACK PROG II 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, ST AIA-PACK PROG II 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 overnight 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 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 or heparinized 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 heparinized plasma, a venous blood sample is collected aseptically with designated additive. Centrifuge and separate plasma from the packed cells as soon as possible.
- 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.
- Samples may be stored at 2 - 8 °C for up to 7 days prior to analysis. If the analysis cannot be done 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 prior to testing. Prior to assay, bring frozen samples to 18 - 25 °C slowly and mix gently.
- The sample required for analysis is 75 µL.

Procedure

1) Reagent Preparation

1a) Substrate Solution

Bring all reagents to 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

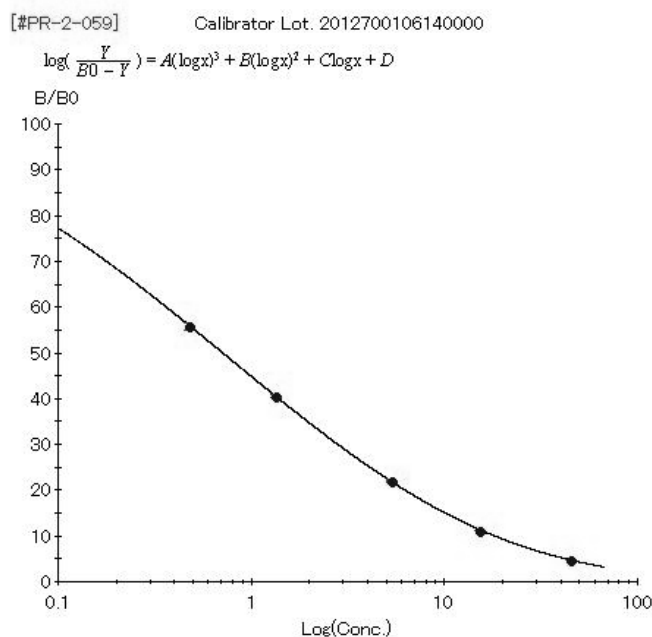
2a) Calibration Curve

The calibrators for use with the ST AIA-PACK PROG II were referred to USP (United States Pharmacopeia) Standard.

The calibration curve for ST AIA-PACK PROG 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 from AIA-2000 follows and shows the algorithm used for calculating results.



2b) Calibration Procedure

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

1. Verify that both the calibrator lot and concentration numbers have been correctly entered into the software.
2. The ST AIA-PACK PROG II Calibrator Set is provided ready for use. Tosoh recommends that all calibrators be run in triplicate.

2c) Calibration Acceptability criteria

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

2d) Calibration Review and Acceptance

1. Review the calibration curve carefully, using the criteria listed above.
2. Edit the calibration if necessary, then accept the calibration.

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

3) Quality Control

3a) Commercially Available Controls

Commercially available controls shall be run at least once per day. It is recommended that at least two 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

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

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

4) Specimen Processing

4a) Preparation

Following the specific instructions in the Operator's Manual for the analyzer, place samples on the instrument appropriately. Barcoded primary tubes as well as sample cups can be run on the AIA-900, AIA-2000 and AIA-360.

4b) Assay Procedure

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

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 progesterone concentration is found to be greater than the upper limit of the assay range, 40 ng/mL, the specimen should be diluted with the ST AIA-PACK PROG II Sample Diluting Solution and reassayed according to the Assay Procedure. The recommended dilution for specimens containing greater than 40 ng/mL is 4 fold dilution. It is desirable to dilute the specimen so that the diluted specimen reads between 2.0 and 20.0 ng/mL. 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 PROG 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 127.

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 progesterone 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 commercially available control samples shall be assayed according to the local regulations.

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

After calibration, two levels of the internal control are run in order to accept the calibration curve. The two levels of controls are 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, at least 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 sample 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 strict 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 PROG II, the highest measurable concentration of progesterone in specimens without dilution is 40 ng/mL, and the lowest measurable concentration in specimens is 0.1 ng/mL (assay sensitivity).

Although the approximate value of the highest calibrator is 45 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, 40 ng/mL.

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.

Specimens from rheumatoid arthritis may interfere with the assay.

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.

Heterophile antibodies are known to interfere in assays of this type. ST AIA-PACK PROG II has been designed to minimize the effects of heterophile antibodies, but interference from high titers cannot be ruled out.

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 (9).

Reference Ranges

The interval given here was determined in serum samples from 294 apparently healthy individuals. European studies showed that these reference values are also applicable for a European population.

Category	n	ranges (ng/mL)
Male	46	≤ 1.36
Female		
Follicular phase	27	≤ 2.05
Luteal phase	28	≤ 22.65
Ovulation phase	30	≤ 19.56
Postmenopausal females	41	≤ 0.48
Pregnant females		
First trimester	42	2.82 – 82.55
Second trimester	40	27.07 – 148.93
Third trimester	40	72.57 – 283.90

Conversion Factors

Progesterone concentrations in this application are in units of ng/mL. The obtained values in ng/mL must be multiplied by 3.18 when converting to values in nmol/L.

Performance Characteristics

1) Linearity

The linearity for ST AIA-PACK PROG II was determined, based on guidance from CLSI Protocol EP06-A. The linearity was measured on the AIA-2000 instrument and has been demonstrated to be linear from 0.1 to 40 ng/mL.

2) Precision

2a) Intra-assay precision

Within-run precision was determined using six 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	1.21	0.0416	3.4
Serum B3	5.94	0.122	2.1
Serum C3	23.3	0.301	1.3
Plasma A3	1.95	0.0618	3.2
Plasma B3	8.47	0.219	2.6
Plasma C3	23.5	0.327	1.4

2b) Total precision

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

Sample	Mean (ng/mL)	Pooled SD (ng/mL)	CV (%)
Serum A3	1.21	0.0491	4.1
Serum B3	5.94	0.156	2.6
Serum C3	23.3	0.467	2.0
Plasma A3	1.95	0.0779	4.0
Plasma B3	8.47	0.258	3.0
Plasma C3	23.5	0.407	1.7

Correlation

The correlations between ST AIA-PACK PROG (x) and ST AIA-PACK PROG II (y) were carried out using (1) 104 serum and (2) 331 heparinized plasma patient specimens, respectively.

	(1)	(2)
Slope	1.09	1.10
y-Intercept	0.102	-0.350
Correlation Coefficient	0.989	0.996
Number of Samples	104	331

Specificity

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

Substance	Concentration After Addition (ng/mL)	Cross-reactivity (%)
Aldosterone	1000	0.01
Androsterone	20000	0.04
Androstenedione	1000	0.01
Chlormadinone acetate	1000	0.01
Corticosterone	9,983	0.001
Cortisol	99,906	0.002
11-deoxycorticosterone	143	0.81
DHEA	100000	0.01
DHEA-S	5,000	0.008
Dydrogesterone	1000	0.01
Estrone	1000	N.D.
Estradiol	1000	N.D.
Estriol	1000	N.D.
Ethinyl-Estradiol	1000	0.04
17 α -hydroxyprogesterone	499	0.26
6 α -methyl-17 α -hydroxy-progesterone acetate	1000	0.58
Medroxyprogesterone	1000	0.01
Norethindrone	1000	0.04
Norethindroneacetate	1000	0.02
D-(-)-Norgestrel	1000	1.99
17-OHP-Caproate	1000	N.D.
5 β -pregnan-3,20-dione	1,986	0.06
5 α -pregnan-3,20-dione	40	3.78
Pregnenolone	125	0.49
Pregnenolone-3-sulfate	1000	N.D.
Testosterone	9,969	0.01

(N.D.: not detectable)

Sensitivity

Limit of Detection: The limit of detection for ST AIA-PACK PROG II was determined, according to CLSI guideline EP17-A2. Blank sample was measured in 60 replicates. Six low level samples were measured in 10 replicates each. As a result, the limit of detection for ST AIA-PACK PROG II was estimated to be 0.05 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 460 mg/dL), free bilirubin (up to 9.1 mg/dL) and conjugated bilirubin (up to 19 mg/dL) do not interfere with the assay.
- Lipemia, as indicated by triglyceride concentration (up to 160 mg/dL) does not interfere with the assay.
- Protein, as indicated by added albumin (up to 0.25 g/dL), does not interfere with the assay.
- Ascorbic acid (up to 20 mg/dL) does not interfere with the assay.
- Heparin (up to 100 U/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

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European Conformity



In vitro diagnostic medical device



Consult instructions for use



Temperature limitation



Batch code / Lot number



Manufacturer

Authorized representative
in the European Community

Use by date

Catalogue number
/ Part number

Supplied by



Sufficient for

US: For prescription use only

ST AIA-PACK PROG II Calibrator Set

Intended Use

The ST AIA-PACK PROG II Calibrator Set is intended for IN VITRO Diagnostic Use Only for the calibration of the ST AIA-PACK PROG II assay.

Summary and Explanation

The ST AIA-PACK PROG II Calibrator Set contains human sera with assigned levels of progesterone. Calibration should be performed according to the schedule indicated in the Tosoh AIA System Operator's Manual.

Material Provided (Cat. No. 0025339)

2 x 1 mL ST AIA-PACK PROG II Calibrator (1)	0	ng/mL
Protein matrix containing no detectable concentration of PROG with sodium azide as a preservative (ready for use).		
2 x 1 mL ST AIA-PACK PROG II Calibrator (2)	0.5	ng/mL (approx.)
ST AIA-PACK PROG II Calibrator (3)	1.5	ng/mL (approx.)
ST AIA-PACK PROG II Calibrator (4)	5.0	ng/mL (approx.)
ST AIA-PACK PROG II Calibrator (5)	15	ng/mL (approx.)
ST AIA-PACK PROG II Calibrator (6)	45	ng/mL (approx.)
Human serum containing the assigned concentration of progesterone (described on each vial) with sodium azide as a preservative (ready for use).		

Warnings and Precautions

- The ST AIA-PACK PROG II Calibrator 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.
- 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.
- The calibrator material has been tested by FDA-approved method and found negative for the presence of HBsAg and antibody to HIV-1 and HCV. Because no test method can offer complete assurance that the products derived from human blood 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 and Storage

Bring the calibrators to 18 - 25 °C for use. Always store the ST AIA-PACK PROG II 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 Calibrator Set is stable until the expiration date on the label. The calibrators should be used within 24 hours (1 day) of opening 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.

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

Assignment of Values

The ST AIA-PACK PROG II Calibrator Set contains assigned concentrations of progesterone. The assigned value is determined on an AIA 2000 system on a lot-by-lot basis and is designed to provide an assay calibration range of 0.1 to 40 ng/mL of progesterone. The calibrators for use with the ST AIA-PACK PROG II were referred to through the USP (United States Pharmacopeia) Standard.

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 $\leq 10\%$ range.

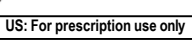
Limitations

The ST AIA-PACK PROG II Calibrator Set is designed solely for use with ST AIA-PACK PROG II assay procedures. Although the approximate value of the highest calibrator is 45 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, 40 ng/mL.

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

ST AIA-PACK PROG II Sample Diluting Solution

Intended Use

The ST AIA-PACK PROG II Sample Diluting Solution is intended for In Vitro Diagnostic Use Only to dilute patient samples with concentrations of progesterone above the upper limit of the assay range.

Summary and Explanation

The AIA-PACK PROG II Sample Diluting Solution contains human serum with no detectable concentration of Progesterone (PROG II). This Sample Diluting Solution is to be used only with samples that are being tested for PROG II concentrations using the ST AIA-PACK PROG II assay.

Material Provided (Cat. No. 0025539)

4 x 4 mL ST AIA-PACK PROG II Sample Diluting Solution
Human serum with sodium azide as a preservative.

Warnings and Precautions

- The ST AIA-PACK PROG II Sample Diluting Solution 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.
- 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.
- The sample diluting solution has been tested by FDA-approved method and found negative for the presence of HBsAg and antibody to HIV-1/2 and HCV. Because no test method can offer complete assurance that the 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.
- After opening, the vial of the sample diluting solution should be kept tightly sealed with a clean rubber cap. Sealing with dirty material may cause deterioration of the reagent and could give rise to erroneous results.
- The remaining sample diluting solution after use should not be mixed with another vial but be discarded to avoid contamination.

Preparation

The ST AIA-PACK PROG II Sample Diluting Solution is provided ready for 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 PROG II Sample Diluting Solution in an upright position. 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 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.

Procedure

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

- If a specimen progesterone concentration is found to be greater than the upper limit of the assay range, 40 ng/mL, the specimen should be diluted with the ST AIA-PACK PROG II Sample Diluting Solution and assayed according to the Procedure in the insert sheet of the ST AIA-PACK PROG II.
- 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.
- The recommended dilution for specimens containing greater than 40 ng/mL is 4 fold dilution. It is desirable to dilute the specimen so that the diluted specimen reads between 2.0 and 20.0 ng/mL.

Results

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

Limitations

The ST AIA-PACK PROG II Sample Diluting Solution is designed solely for use with ST AIA-PACK PROG 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



In vitro diagnostic medical device



Consult instructions for use



Temperature limitation



Batch code / Lot number



Manufacturer



Authorized representative in the European Community



Use by date



Catalogue number / Part number



Supplied by



Sufficient for