AIA-360 Assay Specifications
ST E2 Test Code 029

No.	Item	Data
1	Calib. Req	Show
2	Cal 1	0 pg/mL
3	Cal 2	40 pg/mL (example)
4	Cal 3	100 pg/mL (example)
5	Cal 4	500 pg/mL (example)
6	Cal 5	1000 pg/mL (example)
7	Cal 6	3250 pg/mL (example)
8	Cal Lot L	
9	Cal Lot R	
10	Unit	pg/mL
11	Smpl. Vol	75
12	Dil. Vol	50
13	Assay L	25.0
14	Assay H	3000
15	Ref. L	
16	Ref. H	
17	Decimal	1

Visible only in Test Mode

18	Test Name	#E2
19	Calib. No	6
20	Calib. Mul	3
21	Calib. Equ	6
22	Calib. CV	90
23	Assay Prtl	1
24	Factor1 A	2.980000
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 E2 Test Code 029

No.	Item	Data
1	Code	29
2	ACT	1
3	Analyte	#E2
4	Lot	***Enter current cal lot no.
5	CAL 1	0 pg/mL
6	CAL 2	40 pg/mL (example)
7	CAL 3	100 pg/mL (example)
8	CAL 4	500 pg/mL (example)
9	CAL 5	1000 pg/mL (example)
10	CAL 6	3250 pg/mL (example)
11	Cal lot L	
12	Cal lot R	
13	Unit	pg/mL
14	Decimal	1
15	Assay Low	25
16	Assay High	3000
17	Reference Low	
18	Reference High	
19	Reschedule Low	25
20	Reschedule High	3000
21	Factor A	1
22	Factor B	0
23	Sample Volume	75
24	Diluent Volume	50
25	2 Step reagent dispensing volume	0
26	Calibration code	29
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	21
39	DIL. NAME	E2
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	2.98
48	SYS. F_B	0
49	V. CONC.	0
50	G. ORIGIN	0

AIA-2000 Assay Specifications
ST E2 Test Code 029

No.	Item	Data
1	Unit	pg/mL
2	Decimal places	1
3	Reference low	
4	Reference high	
5	Reschedule low	25
6	Reschedule high	3000
7	Assay range low	25
8	Assay range high	3000
9	Specimen diluent code	21
10	Specimen diluent name	E2
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	10
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 pg/mL
23	Cal - 02	40 pg/mL (example)
24	Cal - 03	100 pg/mL (example)
25	Cal - 04	500 pg/mL (example)
26	Cal - 05	1000 pg/mL (example)
27	Cal - 06	3250 pg/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	75
39	Diluent volume	50
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	**2.98**
49	Calibration Code Check	029
50	Virtual Concentration	0.0
51	Graph Origin	0.0
52	Calculation with Dilution Factor	Yes

Estradiol
ST AIA-PACK E2

Name and Intended Use

ST AIA-PACK E2 is designed for IN VITRO DIAGNOSTIC USE ONLY for the quantitative measurement of Estradiol (E2) in human serum and heparinized plasma on specific Tosoh AIA System analyzers.

Summary and Explanation of Test

Estradiol (1,3,5(10)-estratriene-3, 17ß-diol; E2) is a steroid hormone produced mainly by the ovary in females and, in lesser amounts, by the testes in males.[1] In non-pregnant subjects there is cyclic variation in the concentration of E2 with the highest concentrations occurring just prior to ovulation.[2,3] In the first half of the menstrual cycle, follicle stimulating hormone (FSH) accelerates follicular development and E2 secretion. Rapid secretion of E2 imposes a positive feedback influence upon the pituitary gland, resulting in the release of luteinizing hormone (LH) from the pituitary, and ovulation begins.[4]

The measurement of E2 simultaneously with FSH and LH levels can provide information to evaluate ovary function.[5] In males, E2 measurements are used for investigating feminizing syndromes such as gynaecomastia.[6]

Principle of the Assay

The ST AIA-PACK E2 is a competitive enzyme immunoassay which is performed entirely within the AIA-PACK. Estradiol present in the test sample competes with enzyme-labeled estradiol for a limited number of binding sites on a estradiol-specific antibody immobilized on magnetic beads. The beads are washed to remove the unbound enzyme labeled estradiol and are then incubated with a fluorogenic substrate, 4-methylumbelliferyl phosphate (4MUP). The amount of enzyme labeled estradiol that binds to the beads is inversely proportional to the estradiol concentration in the test sample. A standard curve using a range of known standard concentrations is constructed and unknown estradiol concentrations are calculated using this curve.

Material Provided (ST AIA-PACK E2, Cat. No. 0025274)

5 trays x 20 test cups (ST AIA-PACK E2 Test Cup)

Plastic test cups containing lyophilized magnetic beads with anti-E2 rabbit polyclonal antibody and estradiol 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 Estradiol analysis using the ST AIA-PACK E2 (Cat. No. 0025274) 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		
ST AIA-PACK E2 Calibrator Set		0025374
Calibrator #1	0 pg/mL	
Calibrator #2	40 pg/mL (approx.)	
Calibrator #3	100 pg/mL (approx.)	
Calibrator #4	500 pg/mL (approx.)	
Calibrator #5	1000 pg/mL (approx.)	
Calibrator #6	3250 pg/mL (approx.)	
AIA-PACK E2 Sample Diluting Solution		0020574
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 E2 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 E2 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 E2	0025274
ST AIA-PACK E2 Calibrator Set	0025374
AIA-PACK E2 Sample Diluting Solution	0020574
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 E2 test cups may be stored for up to 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 24 hours. After opening, Sample Diluting Solution is stable for up to 90 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 75 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 the solid material.

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.

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.

2) Calibration

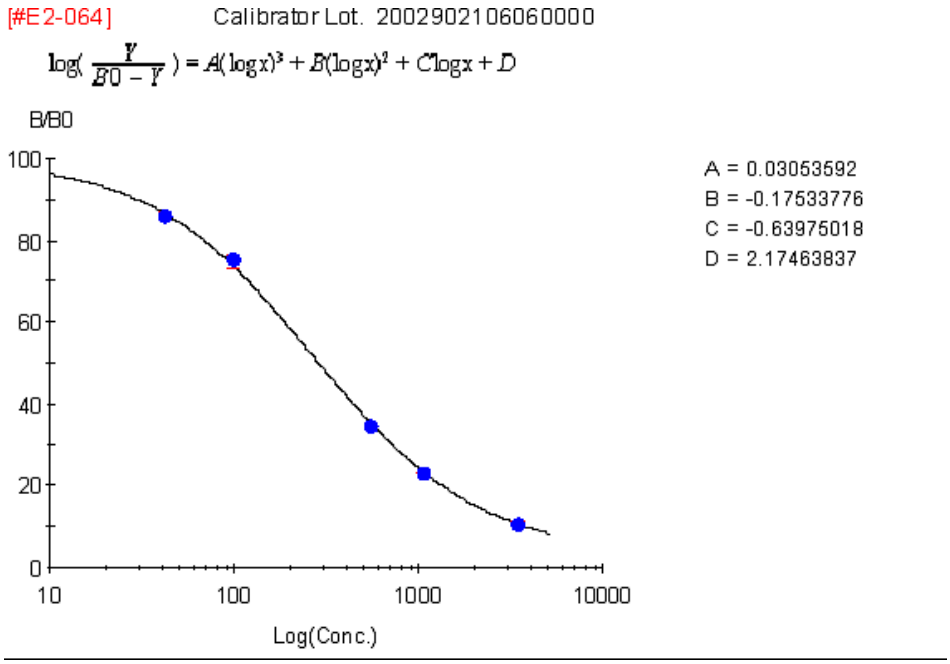
2a) Calibration Curve

The calibrators for use with the ST AIA-PACK E2 are prepared gravimetrically and are compared to internal reference standards.

The calibration curve for the ST AIA-PACK E2 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 both the calibrator lot and concentrations have been correctly entered into the software.

ii) Calibrators for ST AIA-PACK E2 are in liquid form and need no reconstitution. Tosoh recommends that all calibrators be run in triplicate.

2c) Calibration Acceptability criteria

i) The mean rate for the zero calibrator should be < 3.0 nM/sec.

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

iii) 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 specific 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

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

4b) Assay Procedure

i) Ensure a sufficient quantity of ST AIA-PACK E2 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 serum or plasma specimen Estradiol concentration is found to be greater than the linearity limit of the assay, 3000 pg/mL; the specimen should be diluted with the AIA-PACK E2 Sample Diluting Solution and re-assayed according to the Assay Procedure. The recommended dilution for samples containing greater than 3000 pg/mL is 1:10. It is desirable to dilute the serum or plasma sample so that the diluted sample reads between 100 and 500 pg/mL. The dilution factor should be entered into the software. For further information on the dilution of specimens, refer to the 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 E2 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 029.

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 estradiol concentration in pg/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 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 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 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 E2, the highest concentration of estradiol measurable without dilution is approximately 3000 pg/mL, and the lowest measurable concentration is 25 pg/mL (assay sensitivity).

Although the approximate value of the highest calibrator is 3250 pg/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, 3000 pg/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 patients with hyperbilirubinemia may yield falsely elevated results.

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.[7]

Reference Ranges

The intervals given here were determined in serum samples from 142 apparently healthy individuals.

Category	Samples	pg/mL	pmol/L
Male	28	<25 - 75 pg/mL	(73 - 275 pmol/L)
Ovulating Female	90		
Follicular phase	30	<25 - 84 pg/mL	(81 - 308 pmol/L)
Mid-cycle	36	198 - 693 pg/mL	(727 - 2543 pmol/L)
Luteal phase	24	190 - 270 pg/mL	(697 - 991 pmol/L)
Postmenopausal Female	24	32 - 73 pg/mL	(117 - 268 pmol/L)

Conversion Factors

Estradiol concentrations in this application are in units of pg/mL. Conversion to SI units of pmol/L may be made using the following equation:

pmol E2/L = pg E2/mL x 3.67

Performance Characteristics

1) Accuracy

1a) Recovery:

Three serum pools were spiked with three different levels of estradiol and assayed before and after spiking.

Sample	Initial Value (pg/mL)	E2 Added (pg/mL)	Expected Value (pg/mL)	Measured Value (pg/mL)	Percent Recovery (%)
Serum A	48.3	540.8	589.1	543.1	92.2
	48.3	1081.5	1129.8	1086.0	96.1
	48.3	2163.1	2211.4	2269.8	102.6
Serum B	43.6	507.6	551.3	533.8	96.8
	43.6	1015.3	1058.9	1099.6	103.8
	43.6	2030.6	2074.2	2077.4	100.2
Serum C	91.0	501.2	592.2	588.4	99.4
	91.0	1002.3	1093.4	1073.3	98.2
	91.0	2004.6	2095.7	2082.7	99.4

1b) Dilution:

Three serum samples containing high concentrations of estradiol were serially diluted with E2 Sample Diluting Solution and assayed.

Sample	Dilution Factor	Expected Value (pg/mL)	Measured Value (pg/mL)	Percent Recovery (%)
Serum A	none		2495.6	
	7.5/10	1871.7	1762.9	94.2
	5.0/10	1247.8	1210.6	97.0
	2.5/10	623.9	629.9	101.0
	1.0/10	249.6	277.9	111.3
Serum B	none		2378.7	
	7.5/10	1784.1	1712.6	96.0
	5.0/10	1189.4	1131.8	95.2
	2.5/10	594.7	563.5	94.8
	1.0/10	237.9	244.6	102.8
Serum C	none		2277.5	
	7.5/10	1708.1	1696.9	99.3
	5.0/10	1138.7	1077.0	94.6
	2.5/10	569.4	552.2	97.0
	1.0/10	227.7	238.7	104.8

2) Precision

2a) Intra-assay precision

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

Sample	Mean (pg/mL)	Pooled SD (pg/mL)	Coefficient of Variation (%)
Control A	110.2	6.70	6.1
Control B	301.9	10.13	3.4
Control C	747.3	19.72	2.6

2b) Inter-assay precision

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

Sample	Number of Replicates	Mean (pg/mL)	Standard Deviation (pg/mL)	Coefficient of Variation (%)
Control A	20	114.1	10.19	8.9
Control B	20	308.2	15.13	4.9
Control C	20	756.8	31.84	4.2

2c) Total precision

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

Sample	Mean (pg/mL)	Standard Deviation (pg/mL)	Coefficient of Variation (%)
Control A	110.2	10.07	9.1
Control B	301.9	16.67	5.5
Control C	747.3	28.60	3.8

Specificity

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

Compound	Cross-reactivity (%)
Estradiol	100.0
17α-Estradiol	0.04
Estriol	1.1
Progesterone	<0.001
Hydrocortisone	<0.001
Testosterone	<0.001
17α-Ethynylestradiol	2.3
Estrone	7.2
β-Estradiol-17β-D-glucuronide	0.010
17β-Estradiol-3- glucuronide-17-sulfate	0.003
17β-Estradiol-3-sulfate	0.31

Sensitivity

The minimal detectable concentration (MDC) of Estradiol is estimated to be 25 pg/mL. The MDC is defined as that concentration of E2 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.

- Added hemoglobin (up to 427 mg/dL), free bilirubin (up to 17 mg/dL) and conjugated bilirubin (up to 1.9 mg/dL) do not interfere with the assay.
- Lipemia, as indicated by added triglyceride (up to 833 mg/dL), does not interfere with the assay.
- Protein, as indicated by added albumin (up to 12 g/dL), does not interfere with the assay.
- Ascorbic acid (up to 20 mg/dL) 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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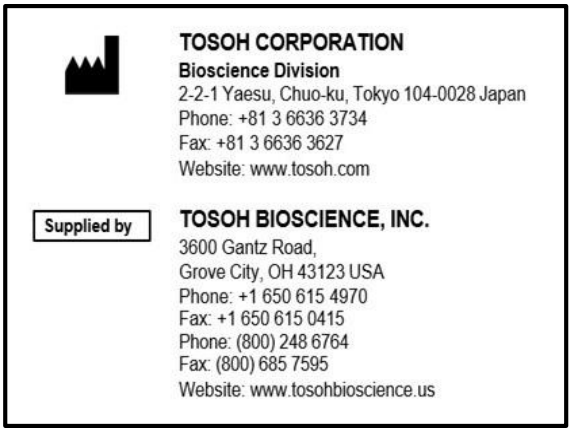
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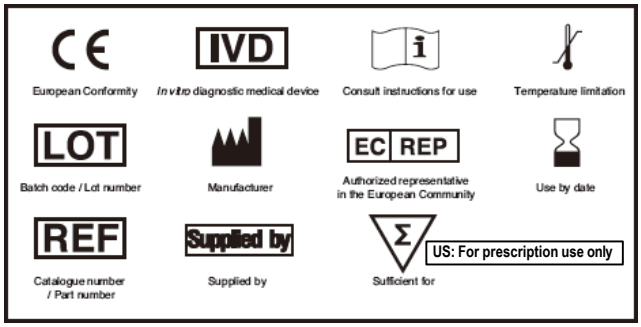
European Conformity
IVD
In vitro diagnostic medical device
Consult instructions for use
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Use by date
REF
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Supplied by
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Sufficient for
US: For prescription use only

ST AIA-PACK
E2 Calibrator Set

Intended Use

The ST AIA-PACK E2 Calibrator Set is intended for IN VITRO DIAGNOSTIC USE ONLY for the calibration the ST AIA-PACK E2 Assay.

Summary and Explanation

The ST AIA-PACK E2 Calibrator Set contains human serum with assigned levels of estradiol (E2). 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 are compared to internal reference standards.

Material Provided (Cat. No. 0025374)

2 x 1 mL	Calibrator	No. 1	0	pg/mL

Human serum containing no detectable concentration of E2 (0 pg E2/mL), and 0.1% sodium azide as a preservative. (ready to use)

2 x 1 mL	Calibrator	No. 2	40	pg/mL (approx.)
		No. 3	100	pg/mL (approx.)
		No. 4	500	pg/mL (approx.)
		No. 5	1000	pg/mL (approx.)
		No. 6	3250	pg/mL (approx.)

Human serum containing the assigned concentration of E2 (described on each vial), and 0.1% sodium azide as a preservative. (ready to use)

Warnings and Precautions

- The ST AIA-PACK E2 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.
- Human sera used in the preparation of this product has been tested by FDA cleared methods and found negative for the presence of HBsAg and antibody to HIV-1 and HCV. Because no test method can offer complete assurance that 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.

Preparation and Storage

- The ST AIA-PACK E2 Calibrators are provided ready to use.
- Bring calibrator to room temperature (18 ° - 25 °C) for 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 E2 Calibrator Set is stable until the expiration date on the label. After opening, the calibrators should be used within 24 hours.

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 E2 Calibrator Set contains assigned concentrations of estradiol. The assigned value is determined on a lot-to-lot basis and is designed to provide an assay calibration range of approximately 0 to 3250 pg/mL of Estradiol. The Calibrator Set has been prepared gravimetrically and is compared to internal reference standards.

Results

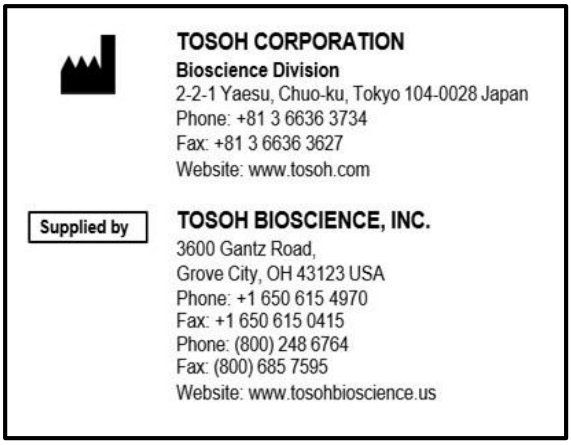
- Since there is an inverse relationship between concentration and rate, the rates should decrease as the concentration increases.
- The replicate values should be within a 10% range.

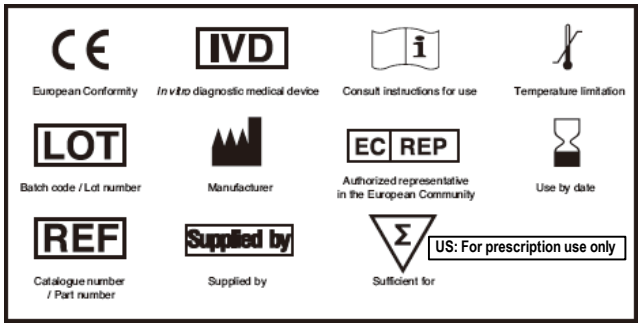
Limitations

The ST AIA-PACK E2 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.





AIA-PACK
E2 Sample Diluting Solution

Intended Use

The AIA-PACK E2 Sample Diluting Solution is intended for IN VITRO DIAGNOSTIC USE ONLY to dilute patient samples that have concentrations of estradiol above the linear range of the assay.

Summary and Explanation

The AIA-PACK E2 Sample Diluting Solution contains human serum with no detectable concentration of estradiol (E2). This Sample Diluting Solution is to be used only with samples that are being tested for estradiol concentrations using the AIA-PACK E2 assay or the ST AIA-PACK E2 assay.

Materials Provided (Cat. No. 0020574)

4 x 4 mL	Sample Diluting Solution Human serum containing no detectable concentration of Estradiol (0 pg E2/mL), and 0.1% sodium azide as a preservative.

Warnings and Precautions

- The AIA-PACK E2 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.
- Human sera used in the preparation of this product has been tested by FDA cleared methods and found negative for the presence of HBsAg and antibody to HIV-1 and HCV. Because no test method can offer complete assurance that 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.

Preparation and Storage

- The AIA-PACK E2 Sample Diluting Solution is provided ready to use.
- Always store the Sample Diluting Solution in an upright position at 2 - 8 °C when not in use.

Stability

When stored unopened and refrigerated at 2 - 8 °C, the AIA-PACK E2 Sample Diluting Solution is stable until the expiration date on the label. After opening, the Sample Diluting Solution is stable for up to 90 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 3000 pg/mL, the specimen should be diluted with the Sample Diluting Solution and assayed according to the procedure in the 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 or plasma containing greater than 3000 pg/mL is 1:10. However, it is desirable to dilute the serum or plasma samples that contain more than 3000 pg E2/mL so that the diluted sample reads between 100 and 500 pg E2/mL.

Results

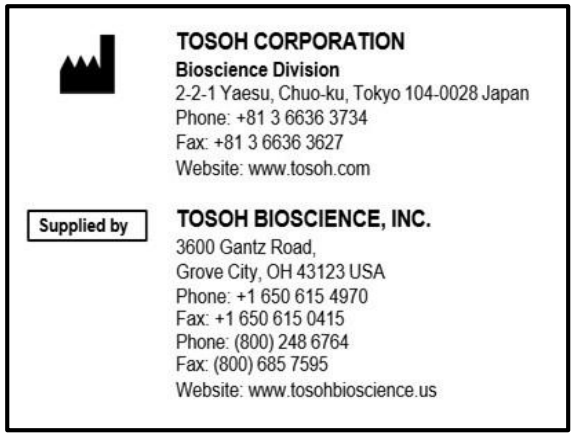
When an auto-dilution is performed, the AIA instrument will calculate the final result.

Limitations

The AIA-PACK E2 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.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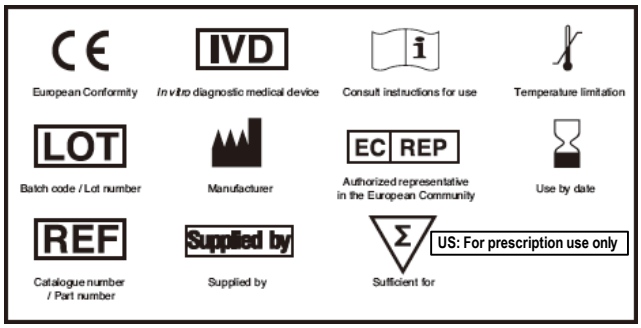
IVD
European Conformity
In vitro diagnostic medical device
Consult instructions for use
Temperature limitation
LOT
Batch code / Lot number
Manufacturer
EC REP
Authorized representative in the European Community
Use by date
REF
Catalogue number / Part number
Supplied by
Supplied by
Sufficient for
US: For prescription use only