AIA-360 Assay Specifications
ST bHCG Test Code 071

No.	Item	Data
1	Calib. Req	Show
2	Cal 1	0 mIU/mL
3	Cal 2	200 mIU/mL (example)
4		
5		
6		
7		
8	Cal Lot L	
9	Cal Lot R	
10	Unit	mIU/mL
11	Smpl. Vol	50
12	Dil. Vol	100
13	Assay L	0.5
14	Assay H	400.0
15	Ref. L	
16	Ref. H	
17	Decimal	1
	Visible only in Test Mode	
18	Test Name	#bHCG
19	Calib. No	2
20	Calib. Mul	3
21	Calib. Equ	1
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 bHCG Test Code 071

No.	Item	Data
1	Code	71
2	ACT	1
3	Analyte	#B-HCG
4	Lot	***Enter cal. lot no.
5	CAL 1	0 mIU/mL
6	CAL 2	200 mIU/mL (example)
7		
8		
9		
10		
11	Cal lot L	
12	Cal lot R	
13	Unit	mIU/mL
14	Decimal	1
15	Assay Low	0.5
16	Assay High	400
17	Reference Low	
18	Reference High	
19	Reschedule Low	0.5
20	Reschedule High	400
21	Factor A	1
22	Factor B	0
23	Sample Volume	50
24	Diluent Volume	100
25	2 Step reagent dispensing volume	0
26	Calibration code	35
27	CAL. No.	2
28	CAL. MUL.	3
29	CAL. EQU.	1
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	10
36	DIL. AH.	5
37	DIL. CALC.	1
38	DIL. CODE	35
39	DIL. NAME	B-HCG
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 bHCG Test Code 071

No.	Item	Data
1	Unit	mIU/mL
2	Decimal places	1
3	Reference low	
4	Reference high	
5	Reschedule low	0.5
6	Reschedule high	400.0
7	Assay range low	0.5
8	Assay range high	400.0
9	Specimen diluent code	35
10	Specimen diluent name	bHCG
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	100
15	Default multiplier for >H	10
16	Factor A	1.00000e+000
17	Factor B	0.00000e+000
18	Calibration code	1
19	Calibrator replicates	3
20	Calibrator lot	***Enter cal. lot no.
21	Calibrator Concentration	
22	Cal - 01	0 mIU/mL
23	Cal - 02	200 mIU/mL (example)
24		
25		
26		
27		
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	50
39	Diluent volume	100
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	035
50	Virtual Concentration	0.0
51	Graph Origin	0.0
52	Calculation with Dilution Factor	Yes

Total Beta HCG
ST AIA-PACK bHCG

Name and Intended Use

ST AIA-PACK bHCG is designed for IN VITRO DIAGNOSTIC USE ONLY for the quantitative measurement of Human Chorionic Gonadotropin (total beta HCG) in human serum or plasma on specific Tosoh AIA System analyzers.

Summary and Explanation of Test

Human chorionic gonadotropin (HCG) is a glycoprotein which, like LH, FSH and TSH consists of alpha and beta chains. It contains approximately 30% carbohydrate by weight.[1] The alpha chains are virtually identical in all four hormones, whereas the beta chains are different and determine both the specific biological activity and immunological characteristics of each hormone.[2,3] In the case of HCG, however, the amino acid sequence of the beta chain displays a considerable degree of homology with that of LH[4], making it difficult to achieve the required assay specificity based on conventional antibody techniques. The use of monoclonal antibody technology has made it possible to produce an essentially unlimited supply of antibody of precisely defined specificity.

HCG is produced by the placenta shortly after implantation[5-7] and increases at a geometric rate until it reaches a peak near the end of the first trimester. This makes it an excellent marker for the confirmation of pregnancy and/or monitoring its course thereafter when necessary.[5,8] Other conditions associated with elevated serum or plasma HCG concentrations are neoplasms of trophoblastic and non-trophoblastic origin.[9-12]

Clinical applications of the HCG beta assay as a tumor marker include the diagnosis and management of hydatidiform mole and choriocarcinoma.[13] The HCG beta assay is a valuable tool also in the diagnosis, staging and management of patients with testicular and ovarian germ-cell tumors.[14] Ectopic production of HCG beta has been reported in cases such as carcinoma of the stomach, liver, pancreas, breast and in multiple myeloma and melanoma.[15]

Principle of the Assay

The ST AIA-PACK bHCG is a two-site immunoenzymometric assay for the intact HCG molecule and beta subunit which is performed entirely in the AIA-PACK. Intact HCG molecule and beta subunit present in the test sample are bound with monoclonal antibody immobilized on a magnetic solid phase, and then a distinctly different antigenic site on the beta subunits is bound with enzyme-labeled monoclonal antibody in the AIA-PACK. The magnetic beads are washed to remove unbound enzyme-labeled monoclonal antibody and are then incubated with a fluorogenic substrate 4-methylumbelliferyl phosphate (4MUP). The amount of enzyme-labeled monoclonal antibody that binds to the beads is directly proportional to the bHCG concentration in the test sample.

Material Provided (ST AIA-PACK bHCG, Cat. No. 0025261)

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

Plastic test cups containing lyophilized magnetic beads coated with anti-bHCG mouse monoclonal antibody and mouse monoclonal antibody (to human bHCG) 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 Total Beta HCG analysis using the ST AIA-PACK bHCG (Cat. No. 0025261) 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 bHCG Calibrator Set	0020361
Calibrator Zero 0 mIU/mL	
Positive 200 mIU/mL (approx.)	
AIA-PACK bHCG Sample Diluting Solution	0020561
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 bHCG 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 bHCG 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.
- The ST AIA-PACK bHCG has been designed so that the high dose “hook effect” is not a problem for the vast majority of samples. Samples with bHCG concentrations between 400 and 40,000 mIU/mL will read > 400 mIU/mL. The “hook effect” phenomenon may occur at bHCG concentrations > 40,000 mIU/mL.
- 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 bHCG	0025261
AIA-PACK bHCG Calibrator Set	0020361
AIA-PACK bHCG Sample Diluting Solution	0020561
AIA-PACK bHCG Calibration Verification/Linearity Test Set	0020661
AIA-PACK Substrate Set II	0020968
AIA-PACK Wash Concentrate	0020955
AIA-PACK Diluent Concentrate	0020956

Room Temperature (18 - 25 °C):

Detector Standardization Test Cups	0020970
Sample Treatment Cups	0020971

ST AIA-PACK bHCG 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 50 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

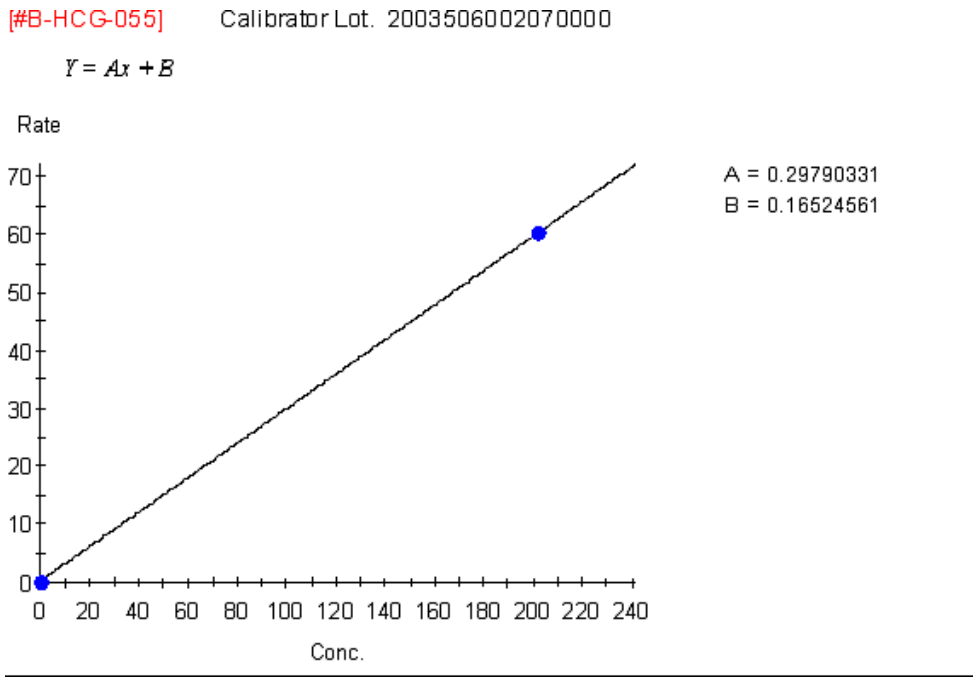
2a) Calibration Curve

The calibrators for use with the ST AIA-PACK bHCG have been standardized against WHO 3rd IS 75/537 (1975).

The calibration curve for the ST AIA-PACK bHCG 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

1. Refer to the appropriate AIA System Operator's Manual for procedural instructions.
2. Verify that the calibrator concentrations listed on the vial labels as well as the calibrator lot numbers have been correctly entered into the software.
3. Calibrators for ST AIA-PACK bHCG are provided ready to use. Tosoh recommends that all calibrators be run in triplicate.

2c) Calibration Acceptability criteria

1. The mean rate for the zero calibrator should be < 3.0 nM/sec.
2. Since there is a direct relationship between concentration and rate, the rates should increase as the concentration increases.
3. The replicate values should be within a 10% range.

2d) Calibration Review and Acceptance

1. Using the criteria above, review the calibration curve carefully.
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 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

1. 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.
2. 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

1. Ensure a sufficient quantity of ST AIA-PACK bHCG test cups for the number of samples to be run.
2. 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 Total Beta HCG concentration is found to be greater than the linearity limit of the assay, 400 mIU/mL, the specimen should be diluted with the bHCG Sample Diluting Solution and reassayed according to the Assay Procedure. The recommended dilution for samples containing greater than 400 mIU/mL is 1:10 or 1:100. It is desirable to dilute the serum or plasma sample so that the diluted sample reads between 5 and 400 mIU/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 bHCG 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 071.

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 Total Beta HCG concentration in mIU/mL.

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 bHCG, the highest concentration of Total Beta HCG measurable without dilution is 400 mIU/mL, and the lowest measurable concentration is 0.5 mIU/mL (assay sensitivity).

Although the approximate value of the highest calibrator is 200 mIU/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, 400 mIU/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 who have received preparations of mouse monoclonal antibodies for diagnosis or therapy may contain human anti-mouse antibodies (HAMA). Such specimens may show falsely elevated values when tested for Total Beta HCG.

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.[16]

Reference Ranges

bHCG is not normally detected in the serum or plasma of healthy men and healthy non-pregnant women by ST AIA-PACK bHCG. Serum or plasma bHCG concentrations < 5.0 mIU/mL are considered negative.

Pregnant women normally attain serum or plasma bHCG concentrations up to 50 mIU/mL in the first week. A maximum is reached by the end of the first trimester.

Expected bHCG Concentrations During Pregnancy (5-7)

Gestational Age	mIU/mL
1 week	5 - 50
2 weeks	40 - 1,000
3 weeks	100 - 5,000
4 weeks	600 - 10,000
5 - 6 weeks	1,500 - 100,000
7 - 8 weeks	16,000 - 200,000
2 - 3 months	12,000 - 300,000
2nd trimester	24,000 - 55,000
3rd trimester	6,000 - 48,000

Performance Characteristics

1) Accuracy

1a) Recovery:

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

Sample	Initial Value (mIU/mL)	bHCG Added (mIU/mL)	Expected Value (mIU/mL)	Measured Value (mIU/mL)	Percent Recovery (%)
Serum A1	0.00	75.85	75.85	73.66	97.1
	0.00	151.71	151.71	143.02	94.3
	0.00	303.42	303.42	285.52	94.1
Serum B1	0.00	75.85	75.85	73.17	96.5
	0.00	151.71	151.71	148.62	98.0
	0.00	303.42	303.42	293.95	996.9
Serum C1	3.41	75.85	79.26	80.20	101.2
	3.41	151.71	155.12	155.94	100.5
	3.41	303.42	306.82	309.27	100.8

1b) Dilution:

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

Sample	Dilution Factor	Expected Value (mIU/mL)	Measured Value (mIU/mL)	Percent Recovery (%)
Serum A2	none		356.83	
	7.5/10	267.62	273.25	102.1
	5.0/10	178.41	183.24	102.7
	2.5/10	89.21	93.38	104.7
	1.0/10	35.68	37.92	106.3
Serum B2	none		366.29	
	7.5/10	274.72	279.60	101.8
	5.0/10	183.15	190.81	104.2
	2.5/10	91.57	96.50	105.4
	1.0/10	36.63	38.97	106.4
Serum C2	none		380.87	
	7.5/10	285.65	289.26	101.3
	5.0/10	190.43	196.94	103.4
	2.5/10	95.22	98.27	103.2
	1.0/10	38.09	40.89	107.4

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 (mIU/mL)	Pooled SD (mIU/mL)	Coefficient of Variation (%)
Control A3	4.19	0.063	1.5
Control B3	83.89	1.000	1.2
Control C3	206.09	2.654	1.3

2b) Inter-assay precision

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

Sample	Number of Replicates	Mean (mIU/mL)	Standard Deviation (mIU/mL)	Coefficient of Variation (%)
Control A3	20	4.11	0.09	2.1
Control B3	20	82.60	1.55	1.9
Control C3	20	203.66	4.66	2.3

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 the standard deviation (SD) and coefficient of variation (CV).

Sample	Mean (mIU/mL)	Standard Deviation (mIU/mL)	Coefficient of Variation (%)
Control A3	4.19	0.121	2.9
Control B3	83.89	1.822	2.2
Control C3	206.09	5.125	2.5

Specificity

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

Compound	Cross-reactivity (%)
ßHCG	100
hTSH	0
hFSH	0.30
hLH	0

Sensitivity

The minimal detectable concentration (MDC) of Total Beta HCG is estimated to be 0.5 mIU/mL. The MDC is defined as that concentration of bHCG 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 390 mg/dL), free bilirubin (up to 17 mg/dL) and conjugated bilirubin (up to 19 mg/dL) do not interfere with the assay.
- Lipemia, as indicated by added triglyceride (up to 1,600 mg/dL), does not interfere with the assay.
- Protein, as indicated by added albumin (up to 5 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.

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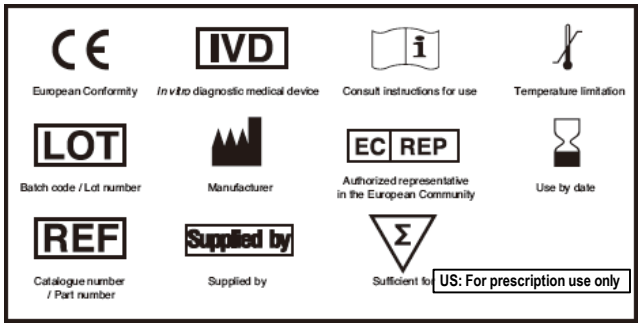
TOSOH CORPORATION
Bioscience Division
2-2-1 Yaesu, Chuo-ku, Tokyo 104-0028 Japan
Phone: +81 3 6636 3734
Fax: +81 3 6636 3627
Website: www.tosoh.com
Supplied by
TOSOH BIOSCIENCE, INC.
3600 Gantz Road,
Grove City, OH 43123 USA
Phone: +1 650 615 4970
Fax: +1 650 615 0415
Phone: (800) 248 6764
Fax: (800)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

AIA-PACK
bHCG Calibrator Set

Intended Use

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

Summary and Explanation

The AIA-PACK bHCG Calibrator Set contains human serum with assigned levels of Beta HCG. Calibration should be performed according to the schedule indicated in the AIA System Operator's Manual. The calibrators in this set have been standardized against WHO 3rd IS 75/537 (1975).

Material Provided (Cat. No. 0020361)

2 x 1 mL Zero Calibrator

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

2 x 1 mL Positive Calibrator

Human serum containing the assigned concentration of bHCG (approximately 200 mIU bHCG/mL, described on each vial) and 0.1% sodium azide as preservative (ready to use).

Warnings and Precautions

- The AIA-PACK bHCG 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 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 AIA-PACK bHCG 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.

Calibration

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 AIA-PACK bHCG Calibrator Set contains assigned concentrations of Beta HCG. The assigned value is determined on a lot-to-lot basis and is designed to provide an assay calibration range of approximately 0.0 to 400.0 mIU/mL of Total Beta HCG. The calibrators in this set have been standardized against WHO 3rd IS 75/537 (1975).

Results

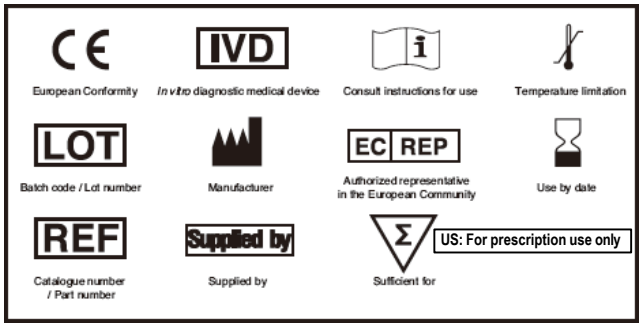
- The mean rate for the zero calibrator should be < 3.0 nM/sec.
- Since there is a direct relationship between concentration and rate, the rates should increase as the concentration increases.
- The replicate values should be within a 10% range.

Limitations

The AIA-PACK bHCG Calibrator Set 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.



AIA-PACK
bHCG Sample Diluting Solution

Intended Use

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

Summary and Explanation

The AIA-PACK bHCG Sample Diluting Solution contains human serum with no detectable concentration of Beta HCG. This Sample Diluting Solution is to be used only with samples that are being tested for Total Beta HCG concentrations using the ST AIA-PACK bHCG assay.

Material Provided (Cat. No. 0020561)

4 x 4 mL	Sample Diluting Solution Human serum containing no detectable concentration of Beta HCG (0 mIU bHCG/mL), and 0.1% sodium azide as a preservative.

Warnings and Precautions

1. The AIA-PACK bHCG Sample Diluting Solution is for in vitro diagnostic use.
2. 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.
3. Human sera used in the preparation of this product has been tested by FDA approved 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.
4. Do not use beyond the expiration date.

Preparation and Storage

- The AIA-PACK bHCG 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 ST AIA-PACK bHCG 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 400 mIU/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 containing greater than 400 mIU/mL is 1:10 or 1:100. However, it is desirable to dilute the serum or plasma samples that contain more than 400 mIU bHCG/mL so that the diluted sample reads between 5 and 400 mIU bHCG/mL.

Results

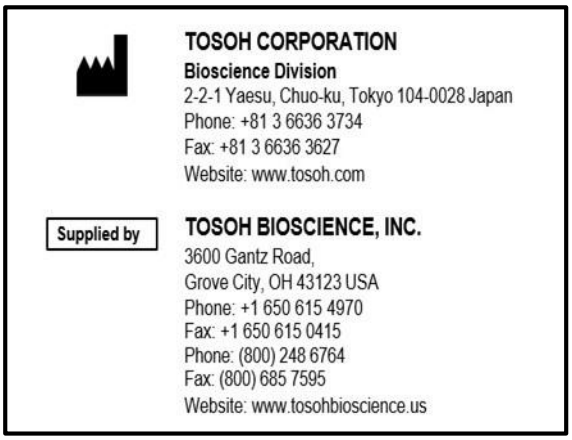
When an auto-dilution is performed, the AIA instrument will calculate the final result.

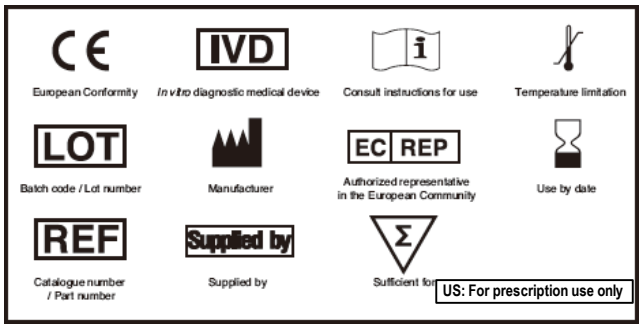
Limitations

The AIA-PACK bHCG 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


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

AIA-PACK
bHCG Calibration Verification/Linearity Test Set

Intended Use

The AIA-PACK bHCG Calibration Verification/Linearity Test Set is intended for IN VITRO diagnostic use only for the verification of the calibration and linearity of the ST AIA-PACK bHCG Assay.

Summary and Explanation

The AIA-PACK bHCG Calibration Verification/Linearity Test Set can be used as part of a quality assurance program to assist in complying with various regulatory requirements under which an institution may operate. Specific guidelines for the acceptability of data are determined by the institution in conformance with these requirements. Good laboratory practices stipulate using different materials for calibration and quality control purposes. Calibration Verification Materials should be analyzed as unknown test samples according to the directions stated in the AIA System Operator's Manual.

Material Provided (Cat. No. 0020661)

2 x 4 mL	Sample Diluting Solution (SDS) Human serum containing no detectable concentration of bHCG (0 mIU bHCG/mL), and 0.1% sodium azide as a preservative. (Ready to Use)
2 x 2 mL	Calibration Verification Material (CVM) Human serum containing the assigned concentration of bHCG (approximate upper linearity limit of 400 mIU bHCG/mL described on each vial) and 0.1% sodium azide as a preservative. (Ready to Use)

Warnings and Precautions

- The AIA-PACK bHCG Calibration Verification/Linearity Test 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 materials, 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 approved 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 his product be handled with the same precautions as used for patient samples.
- Do not use beyond the expiration date.

Preparation and Storage

- The Calibration Verification Material and Sample Diluting Solution are provided ready to use.
- The materials should be at room temperature (18 - 25 ^{o}C) prior to use.
- Always store the Calibration Verification/Linearity Test Set 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 bHCG Calibration Verification/Linearity Test Set is stable until the expiration date on the label. After opening, the materials should be used within 24 hours.

Procedure

The frequency of performing calibration verification and linearity of the ST AIA-PACK bHCG assay is established by each institution in accordance with its quality assurance program and appropriate regulatory requirements. For additional procedural instructions regarding auto dilution, refer to the AIA System Operator's Manual.

Manual Dilutions

1. Make the desired dilutions of the Calibration Verification Material with Sample Diluting Solution and mix well. A sufficient amount should be made to assay each diluted sample in triplicate.
2. Program the instrument to run each of the prepared dilutions three times.
3. Add the appropriate amounts of each diluted sample to sample cups (refer to the instrument worksheet for the amount required in each sample cup).
4. Verify the appropriate amount of test cups for the assay.
5. Load sample cups on the instrument as instructed in the AIA System Operator's Manual.
6. Start the assay.
7. Record the values obtained on the appropriate forms and calculate the desired statistics.

Assignment of Values

The Calibration Verification Material contains an assigned concentration of Beta HCG. The assigned value is determined on a lot-to-lot basis and is designed to approximate the upper linear range of the assay. The Calibration Verification Material has been standardized against WHO 3rd IS 75/537 (1975).

Results

- Make a determination of the acceptability of the data according to the specific guidelines established by your institution which satisfy the regulatory requirements under which your institution operates. If results do not meet your specifications, please initiate corrective action, as appropriate, or contact Tosoh Bioscience, Inc. for assistance.
- Retain test records in the laboratory in a designated location for future reference.

Limitations

The AIA-PACK bHCG Calibration Verification/Linearity Test Set is designed solely for use with AIA-PACK assay procedures. The ST AIA-PACK bHCG Calibration Verification/Linearity Test Set will only verify linearity between the established sensitivity of the assay and the value of analyte level listed on the Calibration Verification Material label.

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.