AIA-360 Assay Specifications
ST TSH Test Code 072

No.	Item	Data
1	Calib. Req	Show
2	Cal 1	0 µIU/mL
3	Cal 2	0.2 µIU/mL (example)
4	Cal 3	5.0 µIU/mL (example)
5	Cal 4	25.0 µIU/mL (example)
6	Cal 5	50.0 µIU/mL (example)
7	Cal 6	100.0 µIU/mL (example)
8	Cal Lot L	
9	Cal Lot R	
10	Unit	µIU/mL
11	Smpl. Vol	100
12	Dil. Vol	50
13	Assay L	0.03
14	Assay H	100
15	Ref. L	
16	Ref. H	
17	Decimal	2

Visible only in Test Mode

18	Test Name	#TSH
19	Calib. No	6
20	Calib. Mul	3
21	Calib. Equ	13
22	Calib. CV	90
23	Assay Prtl	1
24	Factor1 A	1.000000
25	Factor1 B	0.000000
26	Factor2 A	1.000000
27	Factor2 B	0.000000
28	V. Conc	0.001000
29	G Origin	0.010000

AIA-900 Assay Specifications
ST TSH Test Code 072

No.	Item	Data
1	Code	72
2	ACT	1
3	Analyte	#TSH
4	Lot	***Enter current cal lot no.
5	CAL 1	0 μIU/mL
6	CAL 2	0.2 μIU/mL (example)
7	CAL 3	5.0 μIU/mL (example)
8	CAL 4	25.0 μIU/mL (example)
9	CAL 5	50.0 μIU/mL (example)
10	CAL 6	100.0 μIU/mL (example)
11	Cal lot L	
12	Cal lot R	
13	Unit	uIU/mL
14	Decimal	2
15	Assay Low	0.03
16	Assay High	100
17	Reference Low	
18	Reference High	
19	Reschedule Low	0.03
20	Reschedule High	100
21	Factor A	1
22	Factor B	0
23	Sample Volume	100
24	Diluent Volume	50
25	2 Step reagent dispensing volume	0
26	Calibration code	50
27	CAL. No.	6
28	CAL. MUL.	3
29	CAL. EQU.	13
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	50
39	DIL. NAME	TSH3G
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.	0.001
50	G. ORIGIN	0.01

AIA-2000 Assay Specifications
ST TSH Test Code 072

No.	Item	Data
1	Unit	µIU/mL
2	Decimal places	2
3	Reference low	
4	Reference high	
5	Reschedule low	0.03
6	Reschedule high	100
7	Assay range low	0.03
8	Assay range high	100
9	Specimen diluent code	50
10	Specimen diluent name	TSH3G
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	13
19	Calibrator replicates	3
20	Calibrator lot	***Enter current cal lot no.
21	Calibrator Concentration	
22	Cal - 01	0 µIU/mL
23	Cal - 02	0.2 µIU/mL (example)
24	Cal - 03	5.0 µIU/mL (example)
25	Cal - 04	25.0 µIU/mL (example)
26	Cal - 05	50.0 µIU/mL (example)
27	Cal - 06	100.0 µIU/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	100
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	1
49	Calibration Code Check	050
50	Virtual Concentration	0.001
51	Graph Origin	0.010
52	Calculation with Dilution Factor	Yes

Thyroid Stimulating Hormone
ST AIA-PACK TSH

Name and Intended Use

ST AIA-PACK TSH is designed for IN VITRO DIAGNOSTIC USE ONLY for the quantitative measurement of Thyroid Stimulating Hormone (TSH) in human serum or heparinized plasma on specific Tosoh AIA System analyzers.

Summary and Explanation of Test

Thyroid Stimulating Hormone, (TSH or thyrotropin) is a glycoprotein hormone secreted by the anterior pituitary gland. When feedback suppression of the pituitary is reduced by a reduced production of thyroid hormones (T4 and T3), the TSH rises in an attempt to increase thyroid hormone production. This rise occurs while the patient is still asymptomatic and thus is an early and very sensitive indication of hypothyroidism.[1-5] TSH is also controlled by the hypothalamic peptide, thyrotropin releasing hormone (TRH).

Accurate determination of serum TSH is the most useful and sensitive test for primary hypothyroidism, where serum thyroid hormone concentrations are depressed and serum TSH concentrations are significantly elevated. Serum TSH determinations may also be used to differentiate between pituitary (secondary) and hypothalamic (tertiary) hypothyroidisms.[6-9] Through the use of monoclonal antibody technology which provides the necessary specificity and sensitivity, the usefulness of TSH determination in the diagnosis of hyperthyroidism distinguished from euthyroidism has been well established.[10,11]

Principle of the Assay

The ST AIA-PACK TSH is a two-site immunoenzymometric assay which is performed entirely in the AIA-PACK test cups. TSH present in the test sample is bound with monoclonal antibody immobilized on a magnetic solid phase and enzyme-labeled monoclonal antibody in the AIA-PACK test cups. 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 TSH concentration in the test sample. A standard curve is constructed, and unknown sample concentrations are calculated using this curve.

Material Provided (ST AIA-PACK TSH, Cat. No. 0025294)

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

Plastic test cups containing lyophilized magnetic beads coated with anti-TSH mouse monoclonal antibody and mouse monoclonal antibody (to human TSH) 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 Thyroid Stimulating Hormone analysis using the ST AIA-PACK TSH (Cat. No. 0025294) 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 TSH 3rd Gen Calibrator Set	0020394
Calibrator #1 0 µIU/mL	
Calibrator #2 0.2 µIU/mL (approx.)	
Calibrator #3 5.0 µIU/mL (approx.)	
Calibrator #4 25.0 µIU/mL (approx.)	
Calibrator #5 50.0 µIU/mL (approx.)	
Calibrator #6 50.0 µIU/mL (approx.)	
AIA-PACK TSH 3rd Gen Sample Diluting Solution	0020594
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 TSH 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 TSH 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 TSH has been designed so that the high dose "hook effect" is not a problem for the vast majority of samples. Samples with TSH concentrations between 100 and 5,000 μIU/mL will read > 100 μIU/mL. The "hook effect" phenomenon may occur at TSH concentrations > 5,000 μIU/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.

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 TSH	0025294
AIA-PACK TSH 3rd-Gen Calibrator Set	0020394
AIA-PACK TSH 3rd-Gen Sample Diluting Solution	0020594
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 TSH test cups may be stored at room temperature 18 - 25 °C for up to 24 hours. Calibrators must be kept tightly sealed and refrigerated at 2 - 8 °C. After opening, calibrators should be used within 7 days. After opening, Sample Diluting Solution is stable for 90 days in the refrigerator 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 100 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

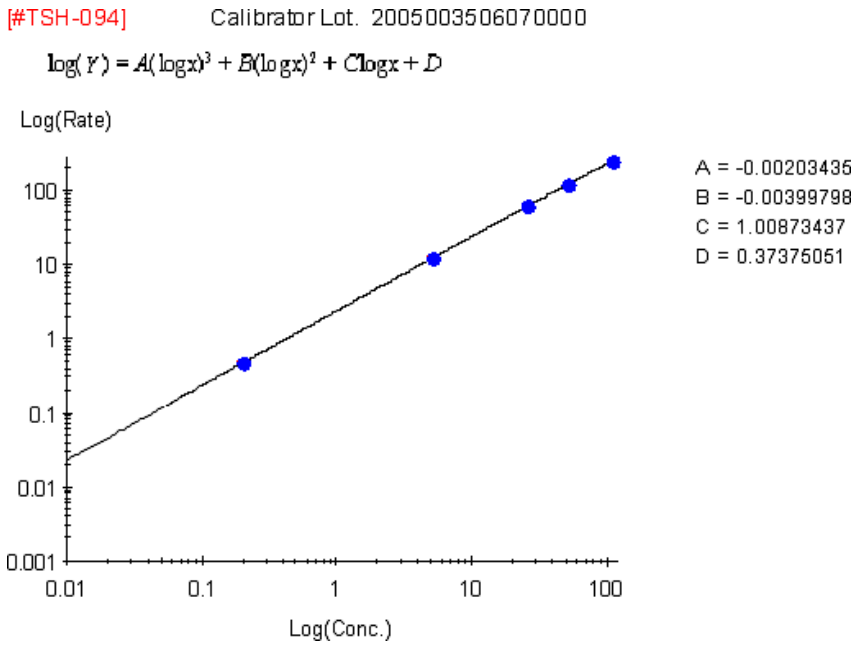
2a) Calibration Curve

The calibrators for use with the ST AIA-PACK TSH have been standardized against WHO 2nd IRP 80/558 (1983).

The calibration curve for the ST AIA-PACK TSH 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 concentration numbers have been correctly entered into the software.

ii) Calibrators for ST AIA-PACK TSH are provided ready to use. 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 a direct relationship between concentration and rate, the rates should increase as the concentration increases.

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

2d) Calibration Review and Acceptance

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

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

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 appropriately.

4b) Assay Procedure

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

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

Procedural Notes

1. Lyophilized Substrate must be completely dissolved.
2. Ligand assays performed by the Tosoh AIA System Analyzer require that the laboratory use water designated by the CAP Class I or by the clinical laboratory reagent water. Water should be tested at least once per month and should be free of particulate matter including bacteria. The pH of the water should also be routinely tested. For further information, consult the CLSI document GP40-A4-AMD, Preparation and Testing of Reagent Water in the Clinical Laboratory; Approved Guideline - Fourth Edition.
3. If a specimen Thyroid Stimulating Hormone concentration is found to be greater than the linearity limit of the assay, 100 μIU/mL; the specimen should be diluted with the AIA-PACK TSH 3rd-Gen Sample Diluting Solution and re-assayed according to the Assay Procedure. The recommended dilution for samples containing greater than 100 μIU/mL is 1:10. It is desirable to dilute the sample so that the diluted sample reads between 10 and 100 μIU/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 TSH 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 072.

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 Thyroid Stimulating Hormone concentration in μIU/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 TSH, the highest concentration of Thyroid Stimulating Hormone measurable without dilution is approximately 100 μIU/mL, and the lowest measurable concentration is 0.03 μIU/mL (assay sensitivity).

Although the approximate value of the highest calibrator is 100 μIU/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, 100 μIU/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 Thyroid Stimulating Hormone.

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.[12]

Reference Ranges

The interval given here was determined in serum samples from 127 apparently healthy individuals. The samples were tested for TgAb and TPOAb in addition to TSH.

Reference interval (including all 127 specimens) = 0.5 – 5.8 μIU/mL

Reference interval (107 specimens after excluding samples with high TgAb and TPOAb)

= 0.6 – 4.8 μIU/mL

Performance Characteristics

1) Accuracy

1a) Recovery:

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

Sample	Initial Value (μIU/mL)	TSH Added (μIU/mL)	Expected Value (μIU/mL)	Measured Value (μIU/mL)	Percent Recovery (%)
Serum A	1.7	20.7	22.4	23.0	102.7
	1.7	41.4	43.1	45.3	105.1
	1.7	82.7	84.4	91.0	107.8
Serum B	1.4	20.7	22.1	21.3	96.4
	1.4	41.4	42.8	44.8	104.7
	1.4	82.7	84.1	90.7	107.8
Serum C	1.4	20.7	22.1	24.2	109.5
	1.4	41.4	42.8	48.8	114.0
	1.4	82.7	84.1	89.6	106.5

1b) Dilution:

Three serum samples containing high concentrations of TSH were serially diluted with AIA-PACK TSH 3rd-Gen Sample Diluting Solution and assayed.

Sample	Dilution Factor	Expected Value (μIU/mL)	Measured Value (μIU/mL)	Percent Recovery (%)
Serum A2	none		98.6	
	7.5/10	73.9	72.8	98.5
	5.0/10	49.3	49.4	100.2
	2.5/10	24.6	24.4	99.2
Serum B2	none		103.6	
	7.5/10	77.7	75.3	96.9
	5.0/10	51.8	51.6	99.7
	2.5/10	25.9	25.9	100.0
Serum C2	none		104.0	
	7.5/10	78.0	76.4	97.9
	5.0/10	52.0	51.2	98.5
	2.5/10	26.0	26.3	101.2

1c) Comparative Analysis:

50 serum samples were analyzed with the ST AIA-PACK TSH assay and another commercially available TSH assay. The statistics, presented below, demonstrate good correlation between these two methods.

Slope	1.048
y-intercept	0.054 μIU/mL
Correlation Coefficient	0.998
Range of Samples	0.3 - 56.0 μIU/mL
Number of Samples (n)	50

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.

Sample	Mean (μIU/mL)	Pooled SD (μIU/mL)	Coefficient of Variation (%)
Serum A3	2.19	0.064	2.9
Serum B3	8.26	0.192	2.3
Serum C3	80.63	2.016	2.5

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 over 20 days.

Sample	Number of Replicates	Mean (μIU/mL)	Standard Deviation (μIU /mL)	Coefficient of Variation (%)
Serum A3	20	2.09	0.077	3.7
Serum B3	20	7.99	0.0.26	3.3
Serum C3	20	78.88	2.743	3.5

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 (μIU/mL)	Standard Deviation (μIU/mL)	Coefficient of Variation (%)
Serum A3	2.19	0.110	5.0
Serum B3	8.26	0.399	4.8
Serum C3	80.63	3.577	4.4

Specificity

The following substances were tested for cross-reactivity. The cross-reactivity (%) is expressed in terms of the percentage of each substance which will be measure as thyroid stimulating hormone.

Compound	Cross-reactivity (%)
TSH	100
HCG	<0.01
FSH	<0.01
LH	0.17
HGH	<0.01

Sensitivity

Analytical sensitivity

The minimal detectable concentration (MDC) of Thyroid Stimulating Hormone is estimated to be 0.03 μIU/mL. The MDC is defined as that concentration of TSH which corresponds to the rate of fluorescence that is two standard deviations from the mean rate of fluorescence of 30 replicate determinations of a zero calibrator.

Functional sensitivity

TSH assay functional sensitivity has been defined as the TSH concentration at which the interassay coefficient of variation equals 20%, using the interassay precision profile.[13] Functional sensitivity for the ST AIA-PACK TSH assay was determined to be 0.009 μIU/mL by assaying 10 replicates of one sample over 4 weeks on the AIA NexIA.

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 1600 mg/dL), does not interfere with the assay.
- Ascorbic acid (up to 20 mg/dL) does not interfere with the assay.

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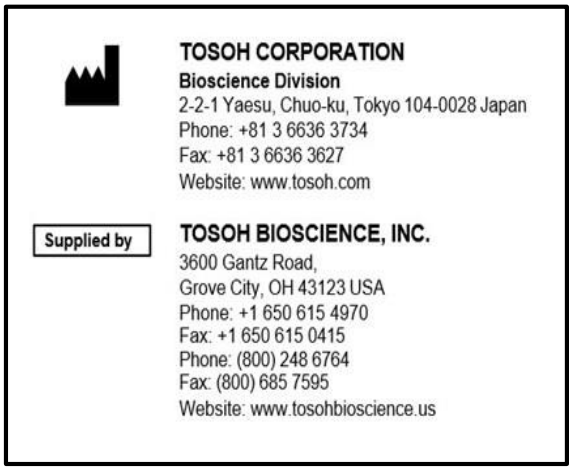
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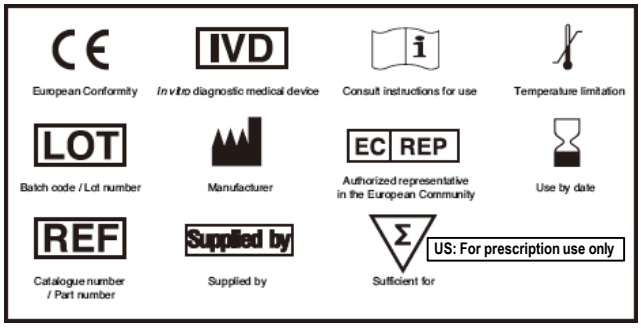

IVD
European Conformity
In vitro diagnostic medical device
Consult instructions for use
Temperature limitation
LOT
Batch code / Lot number
Manufacturer
EC REP
Authorized representative in the European Community
Use by date
REF
Catalogue number / Part number
Supplied by
Supplied by
Sufficient for
US: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

AIA-PACK
TSH 3rd-Gen Calibrator Set

Intended Use

The AIA-PACK TSH 3rd-Gen Calibrator Set is intended for IN VITRO diagnostic use only for the calibration of the ST AIA-PACK TSH Assay and the AIA-PACK TSH 3rd-Gen Assay.

Summary and Explanation

The AIA-PACK TSH 3rd-Gen Calibrator Set contains a bovine protein matrix with assigned levels of Thyroid Stimulating Hormone. 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 2nd IRP 80/558 (1983).

Material Provided (Cat. No. 0020394)

2 x 1 mL	Calibrator	No. 1	0.0	μIU/mL

A bovine protein matrix containing no detectable concentration of TSH (0 μIU TSH/mL), and 0.1% sodium azide as preservative.(Ready to Use)

2 x 1 mL	Calibrator	No. 2	0.2	μIU/mL (approx.)
		No. 3	5.0	μIU/mL (approx.)
		No. 4	25.0	μIU/mL (approx.)
		No. 5	50.0	μIU/mL (approx.)
		No. 6	100.0	μIU/mL (approx.)

A bovine protein matrix containing the assigned concentration of TSH (described on each vial) and 0.1% sodium azide as preservative. (Ready to Use)

Warnings and Precautions

- The AIA-PACK TSH 3rd-Gen Calibrator Set is for in vitro diagnostic use.
- These materials contain sodium azide, which may react with lead or copper plumbing to form potentially explosive metal azides. When disposing of such reagents, always flush with large volumes of water to prevent azide build-up.
- Although material derived from human blood is not used for TSH 3rd-Gen calibrators, it is recommended that this product be handled with the same precautions as used for patient samples.
- Do not use beyond the expiration date.

Preparation and Storage

- The AIA-PACK TSH 3rd-Gen Calibrators are provided ready to use.
- Bring calibrator to room temperature (18 - 25 °C) before use.
- Always store the Calibrator Set in an upright position at 2 - 8 °C when not in use.

Stability

When stored unopened and refrigerated at 2 - 8 °C, the AIA-PACK TSH 3rd-Gen Calibrator Set is stable until the expiration date on the label. After opening, the calibrators should be used within 7 days.

Procedure

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

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

Assignment of Values

The AIA-PACK TSH 3rd-Gen Calibrator Set contains assigned concentrations of Thyroid Stimulating Hormone. The assigned value is determined on a lot-to-lot basis and is designed to provide an assay calibration range of approximately 0 to 100 μIU/mL of Thyroid Stimulating Hormone. The calibrators in this set have been standardized against WHO 2nd IRP 80/558 (1983).

Results

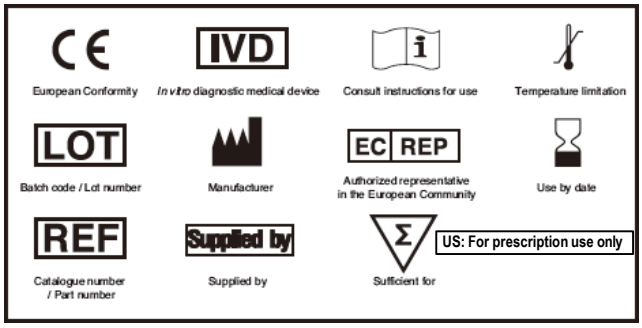
- The mean rate for the zero calibrator should be <3.0 nM/sec.
- Since there is a direct relationship between concentration and rate, the rates should increase as the concentration increases.
- The replicate values should be within a 10% range.

Limitations

The AIA-PACK TSH 3rd-Gen 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
TSH 3rd-Gen Sample Diluting Solution

Intended Use

The AIA-PACK TSH 3rd-Gen Sample Diluting Solution is intended for IN VITRO DIAGNOSTIC USE ONLY to dilute patient samples that have concentrations of Thyroid Stimulating Hormone above the linear range of the assay.

Summary and Explanation

The AIA-PACK TSH 3rd-Gen Sample Diluting Solution contains a bovine protein matrix with no detectable concentration of Thyroid Stimulating Hormone. This Sample Diluting Solution is to be used only with samples that are being tested for Thyroid Stimulating Hormone concentrations using the ST AIA-PACK TSH assay or the AIA-PACK TSH 3rd-Gen assay.

Materials Provided (Cat. No. 0020594)

4 x 4mL	Sample Diluting Solution A bovine protein matrix containing no detectable concentration of thyroid stimulating hormone (0 μIU TSH/mL), and 0.1% sodium azide as a preservative.

Warnings and Precautions

- The AIA-PACK TSH 3rd-Gen Sample Diluting Solution is for IN VITRO diagnostic use.
- These materials contain sodium azide which may react with lead or copper plumbing to form potentially explosive metal azides. When disposing of such reagents, always flush with large volumes of water to prevent azide build-up.
- Although material derived from human blood is not used for TSH 3rd-Gen Sample Diluting Solution, it is recommended that this product be handled with the same precautions as used for patient samples.
- Do not use beyond the expiration date.

Preparation and Storage

- The AIA-PACK TSH 3rd-Gen 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 TSH 3rd-Gen Sample Diluting Solution is stable until the expiration date on the label. After opening, the Sample Diluting Solution is stable for 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 100 μIU/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 a sample containing greater than 100 uIU/mL is 1:10 or 1:100. However, it is desirable to dilute the samples that contain more than 100 μIU TSH/mL so that the diluted sample reads between 10 and 100 μIU/mL.

Results

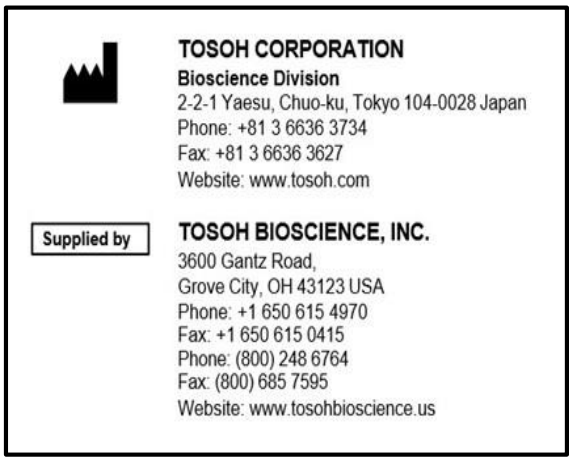
When an auto-dilution is performed, the AIA instrument will calculate the final result.

Limitations

The AIA-PACK TSH 3rd-Gen 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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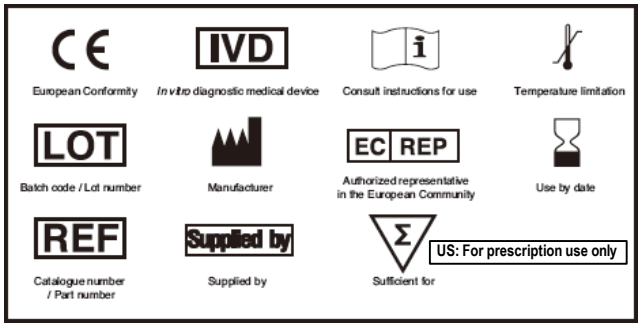
IVD
European Conformity
In vitro diagnostic medical device
Consult instructions for use
Temperature limitation
LOT
Batch code / Lot number
Manufacturer
EC REP
Authorized representative in the European Community
Use by date
REF
Catalogue number / Part number
Supplied by
Supplied by
Sufficient for
US: For prescription use only