AIA-360 Assay Specifications
ST TT3 Test Code 074

No.	Item	Data
1	Calib. Req	Show
2	Cal 1	0 ng/mL
3	Cal 2	0.5 ng/mL (example)
4	Cal 3	1.0 ng/mL (example)
5	Cal 4	2.0 ng/mL (example)
6	Cal 5	4.0 ng/mL (example)
7	Cal 6	8.0 ng/mL (example)
8	Cal Lot L	
9	Cal Lot R	
10	Unit	ng/mL
11	Smpl. Vol	25
12	Dil. Vol	125
13	Assay L	0.20
14	Assay H	8.0
15	Ref. L	
16	Ref. H	
17	Decimal	2

Visible only in Test Mode

18	Test Name	#TT3
19	Calib. No	6
20	Calib. Mul	3
21	Calib. Equ	6
22	Calib. CV	90
23	Assay Prtl	1
24	Factor1 A	1.000000
25	Factor1 B	0.000000
26	Factor2 A	1.000000
27	Factor2 B	0.000000
28	V. Conc	0.000000
29	G Origin	0.000000

AIA-900 Assay Specifications
ST TT3 Test Code 074

No.	Item	Data
1	Code	74
2	ACT	1
3	Analyte	#TT3
4	Lot	***Enter current cal lot no.
5	CAL 1	0 ng/mL
6	CAL 2	0.5 ng/mL (example)
7	CAL 3	1.0 ng/mL (example)
8	CAL 4	2.0 ng/mL (example)
9	CAL 5	4.0 ng/mL (example)
10	CAL 6	8.0 ng/mL (example)
11	Cal lot L	
12	Cal lot R	
13	Unit	ng/mL
14	Decimal	2
15	Assay Low	0.2
16	Assay High	8.0
17	Reference Low	
18	Reference High	
19	Reschedule Low	0.2
20	Reschedule High	8.0
21	Factor A	1
22	Factor B	0
23	Sample Volume	25
24	Diluent Volume	125
25	2 Step reagent dispensing volume	0
26	Calibration code	43
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	43
39	DIL. NAME	TT3
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 TT3 Test Code 074

No.	Item	Data
1	Unit	ng/mL
2	Decimal places	2
3	Reference low	
4	Reference high	
5	Reschedule low	0.20
6	Reschedule high	8.0
7	Assay range low	0.20
8	Assay range high	8.0
9	Specimen diluent code	43
10	Specimen diluent name	TT3
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	4
15	Default multiplier for >H	4
16	Factor A	1.00000e+000
17	Factor B	0.00000e+000
18	Calibration code	6
19	Calibrator replicates	3
20	Calibrator lot	***Enter current cal. lot.no.
21	Calibrator Concentration	
22	Cal - 01	0 ng/mL
23	Cal - 02	0.5 ng/mL (example)
24	Cal - 03	1.0 ng/mL (example)
25	Cal - 04	2.0 ng/mL (example)
26	Cal - 05	4.0 ng/mL (example)
27	Cal - 06	8.0 ng/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	25
39	Diluent volume	125
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	043
50	Virtual Concentration	0.0
51	Graph Origin	0.0
52	Calculation with Dilution Factor	Yes

Triiodothyronine
ST AIA-PACK TT3

Name and Intended Use

ST AIA-PACK TT3 is designed for IN VITRO DIAGNOSTIC USE ONLY for the quantitative measurement of Total Triiodothyronine (TT3) in human serum or heparinized plasma on specific Tosoh AIA System analyzers.

Summary and Explanation of Test

Triiodothyronine (T3) and thyroid hormone, (thyroxine; T4), regulate a variety of biochemical processes throughout the body.[1] The majority of T3 in circulation is produced enzymatically by monodeiodination of T4 in the peripheral tissues, rather than from direct secretion from the thyroid gland.[2] Approximately one-third of all T4 secreted is deiodinated to yield T3.[3]

Serum T3 measurements can be a valuable component of a thyroid-function screening panel in diagnosing certain disorders of thyroid function in addition to conditions caused by iodide deficiency. Assays for T3 are valuable in early detection of hyperthyroidism and for monitoring the efficacy of treatment for thyroid disorders [4]. A normal T3 value in the presence of an elevated T4 and/or Free T4 (FT4) level may also help to rule out hyperthyroidism.[5]

Principle of the Assay

The ST AIA-PACK TT3 is a competitive enzyme immunoassay which is performed entirely within the AIA-PACK. Triiodothyronine, which is displaced from its binding proteins by ANS (8-anilino-1-naphthalene sulfonic acid), and free T3 present in the test sample compete with enzyme-labeled T3 for a limited number of binding sites on a T3 specific antibody immobilized on magnetic beads. The beads are washed to remove the unbound enzyme-labeled T3 and are then incubated with a fluorogenic substrate, 4-methylumbelliferyl phosphate (4-MUP). The amount of enzyme labeled T3 that binds to the beads is inversely proportional to the T3 concentration in the test sample. A standard curve using a range of known standard concentrations is prepared and unknown T3 concentrations are calculated using this curve.

Material Provided (ST AIA-PACK TT3, Cat. No. 0025282)

5 trays x 20 test cups (ST AIA-PACK TT3 Test Cup)

Plastic test cups containing lyophilized magnetic beads with anti-T3 sheep monoclonal antibody, T3 conjugated to bovine alkaline phosphatase and ANS (8-anilino-1-naphthalene sulfonic acid) with 0.1% sodium azide as a preservative.

Materials Required But Not Provided

The following materials are not provided but are required to perform Triiodothyronine analysis using the ST AIA-PACK TT3 (Cat. No. 0025282) 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 TT3 Calibrator Set		0020382
Calibrator #1	0 ng/mL	
Calibrator #2	0.5 ng/mL (approx.)	
Calibrator #3	1.0 ng/mL (approx.)	
Calibrator #4	2.0 ng/mL (approx.)	
Calibrator #5	4.0 ng/mL (approx.)	
Calibrator #6	8.0 ng/mL (approx.)	
AIA-PACK TT3 Sample Diluting Solution		0020582
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 TT3 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 TT3 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 TT3	0025282
AIA-PACK TT3 Calibrator Set	0020382
AIA-PACK TT3 Sample Diluting Solution	0020582
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 TT3 test cups may be 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 of 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 of 18 - 25 °C and mix gently.

The sample required for analysis is 25 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

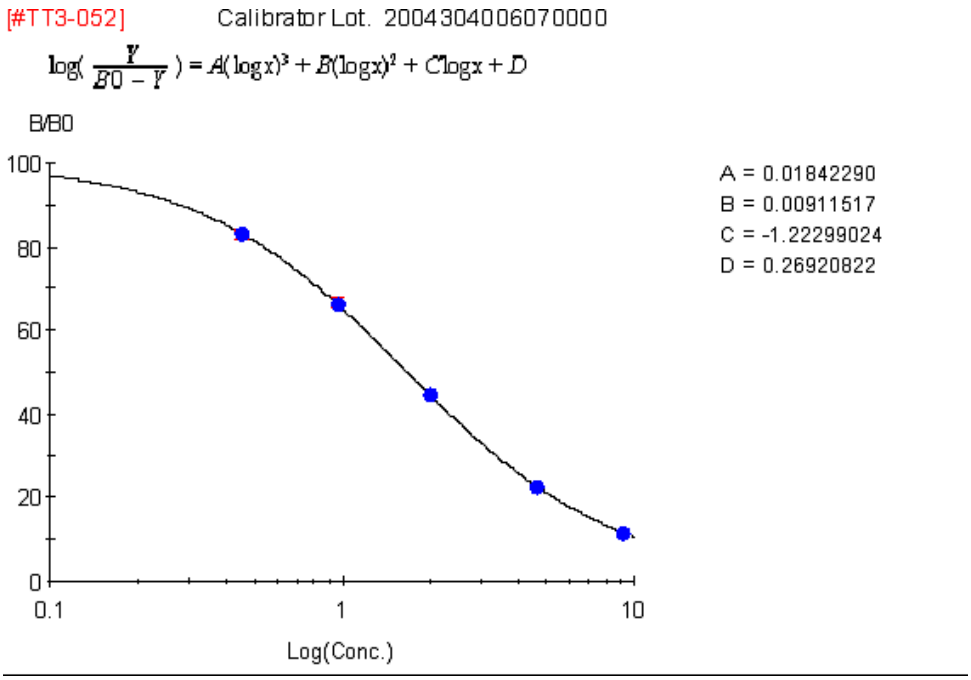
2a) Calibration Curve

The calibrators for use with the ST AIA-PACK TT3 are prepared gravimetrically and are compared to internal reference standards.

The calibration curve for the ST AIA-PACK TT3 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 Systems 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 TT3 are provided ready to use. Tosoh recommends that all calibrators be run in triplicate.

2c) Calibration Acceptability criteria

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

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

2d) Calibration Review and Acceptance

i) 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 TT3 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 T3 concentration is found to be greater than the linearity limit of the assay, 8.0 ng/mL; the specimen should be diluted with the AIA-PACK TT3 Sample Diluting Solution and re-assayed according to the Assay Procedure. The recommended dilution for samples containing greater than the concentration of the highest calibrator is 1:4. It is desirable to dilute the sample so that the diluted sample reads between 1.0 and 4.0 ng/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 TT3 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 074.

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 T3 concentration in ng/mL.

For samples requiring dilution, the AIA-900 and AIA-2000 will automatically perform dilutions and calculate results if the dilution factors are entered into the software. For detailed information regarding programming dilutions, consult the appropriate 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 TT3, the highest concentration of T3 measurable without dilution is approximately 8.0 ng/mL, and the lowest measurable concentration is 0.20 ng/mL (assay sensitivity).

The exact linearity of the ST AIA-PACK TT3 depends on the particular lot of calibrator in use. Although the approximate value of the highest calibrator is 8.0 ng/mL, the exact concentration may be slightly different. The assay specification, Assay Range High, should be defined as the upper limit of the assay range, 8.0 ng/mL.

Although hemolysis has an insignificant effect on the assay, hemolyzed samples may indicate mistreatment of a specimen prior to assay and results should be interpreted with caution.

Lipemia has an insignificant effect on the assay except in the case of gross lipemia where spatial interference may occur.

Using the ST AIA-PACK TT3, specimens with extremely high serum albumin levels will exhibit falsely decreased T3 results, and specimens with extremely low serum albumin levels will exhibit falsely increased T3 results. In RIA procedures, effect of abnormal serum albumin concentrations also occurs, but low concentrations cause falsely decreased results and elevated concentrations of serum albumin yield falsely increased results. This opposite effect of albumin concentration may be noticed during correlation studies.

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.

Specimens from patients under treatment with Diclofenac sodium and Mefenamic acid may demonstrate falsely elevated results.

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. Patients undergoing thyroid replacement therapy with triiodothyronine may show elevated levels of total T3 as measured by the assay. Patients undergoing thyroid replacement therapy with thyroxine may show negligible elevation in levels of total T3 consistent with the specificity profile of the assay. Samples from patients undergoing thyroid replacement therapy should be monitored using a panel of thyroid assays including an assay for thyroid stimulating hormone.6 As with all diagnostic procedures, clinical results must be interpreted with regard to concomitant medications administered to the patient.[7]

Reference Ranges

The interval given here was determined in serum samples from 304 apparently healthy individuals.

Reference Interval = 0.70 - 1.70 ng/mL (70 - 170 ng/dL)

Performance Characteristics

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

1) Accuracy

1a) Recovery

Recovery: Three serum pools were spiked with three different levels of T3 and assayed before and after spiking.

Sample	Initial Value (ng/mL)	T3 Added (ng/mL)	Expected Value (ng/mL)	Measured Value (ng/mL)	Percent Recovery (%)
Serum A1	0.58	1.31	1.89	1.88	99.5
	0.58	2.62	3.20	3.21	100.3
	0.58	5.24	5.82	5.85	100.5
Serum B1	0.80	1.31	2.11	2.03	96.2
	0.80	2.62	3.42	3.32	97.1
	0.80	5.24	6.05	5.79	95.7
Serum C1	1.86	1.31	3.18	3.17	99.7
	1.86	2.62	4.49	4.42	98.4
	1.86	5.24	7.11	7.05	99.2

1b) Dilution:

Three serum samples containing high concentrations of T3 were serially diluted with AIA-PACK TT3 Sample Diluting Solution and assayed.

Sample	Dilution Factor	Expected Value (ng/mL)	Measured Value (ng/mL)	Percent Recovery (%)
Serum A2	none		6.93	
	7.5/10	5.20	5.68	109.2
	5.0/10	3.47	4.00	115.3
	2.5/10	1.73	2.06	119.1
Serum B2	none		5.28	
	7.5/10	3.96	4.19	105.8
	5.0/10	2.64	2.78	105.3
	2.5/10	1.32	1.44	109.1
Serum C2	none		6.65	
	7.5/10	4.99	5.28	105.8
	5.0/10	3.32	3.86	116.3
	2.5/10	1.66	1.95	117.5

1c) Comparative Analysis:

Samples were collected at random. Results from the ST AIA-PACK TT3 assay (y) were compared to those obtained using the AIA-PACK TT3 assay (x). A total of 49 serum samples were tested in the study. The statistics, presented below, demonstrate good correlation between these two methods.

Slope	1.02
y-intercept	0.12 ng/mL
Correlation Coefficient	0.9959
Range of Samples	0.843 – 5.267 ng/mL
Number of Samples (n)	49

1) Precision

1a) 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 (ng/mL)	Pooled SD (ng/mL)	Coefficient of Variation (%)
Serum A3	0.71	0.027	3.8
Serum B3	1.72	0.040	2.3
Serum C3	3.72	0.090	2.4

1b) Inter-assay precision

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

Sample	Number of Replicates	Mean (ng/mL)	Standard Deviation (ng/mL)	Coefficient of Variation (%)
Serum A3	20	0.73	0.050	6.8
Serum B3	20	1.72	0.066	3.8
Serum C3	20	3.72	0.138	3.7

1c) 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 (ng/mL)	Standard Deviation (ng/mL)	Coefficient of Variation (%)
Serum A3	0.71	0.044	6.2
Serum B3	1.72	0.063	3.7
Serum C3	3.72	0.119	3.2

Specificity

The following substances were tested for cross-reactivity. The cross-reactivity (%) is the percent of the compound which will be identified as T3. If these compounds are present in the specimen at the same concentration as T3, the final result will be increased by these percentages.

Compound	Cross-reactivity (%)
L-Triiodothyronine (L-T3)	100.00
D-Triiodothyronine (D-T3)	125.00
L-Thyroxine (L-T4)	0.15
D-Thyroxine (D-T4)	0.07
3, 3', 5'-Triiodothyronine	0.30
3, 5-Diiodo-L-tyrosine	<0.001

Sensitivity

The minimal detectable concentration (MDC) of T3 is estimated to be 0.20 ng/mL. The MDC is defined as that concentration of T3 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 410 mg/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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2). Braverman L., Ingbar, S. and Sterling, K., 1970, Conversion of Thyroxine to Triiodothyronine in Normal Human Subjects. Science, 169:1099-1100.

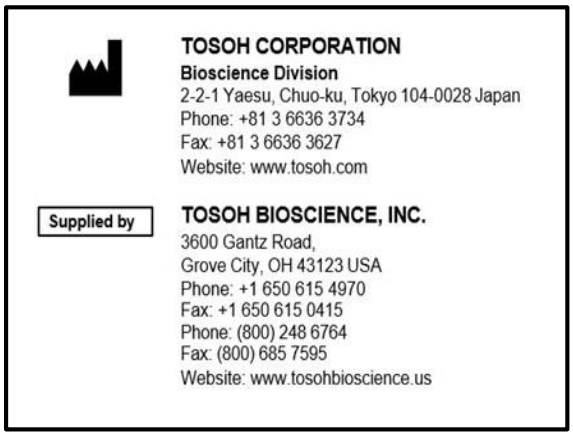
3). Felig, P., Baxter, J., Brodaus, A. and Frohman, L. (eds), 1987, Endocrinology and Metabolism (2nd ed). pp. 389-409.

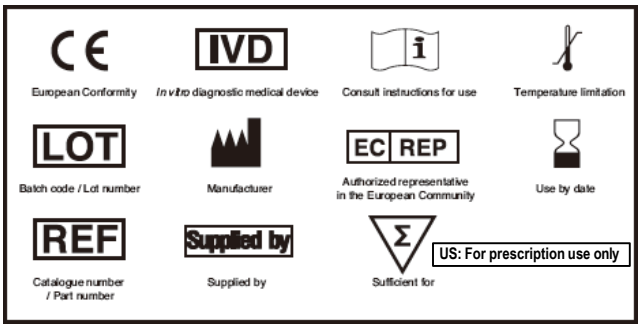
4). Howanitz, J., Howanity, P. and Henry, J., Evaluation of Endocrine Function, in Henry, J. (ed), 1991, Clinical Diagnosis and Management by Laboratory Methods (18th ed). pp. 308-320.

5). Larsen, P., 1972, Triiodothyronine: Review of Recent Studies of Its Physiology and Pathophysiology in Man. Metabolism 21: 1073-1092.

6). Abuid, J., Larsen, P., 1974, Triiodothyronine and Thyroxine in Hyperthyroidism: Comparison of the Acute Changes During Therapy with Antithyroid Agents. Journal of Clinical Investigations 54: 201-208.

7). Young, D., 1990, Effects of Drugs on Clinical Laboratory Tests. 3rd Edition, Washington, DC, American Association for Clinical Chemistry Press.





AIA-PACK
TT3 Calibrator Set

Intended Use

The AIA-PACK TT3 Calibrator Set is intended for IN VITRO DIAGNOSTIC USE ONLY for the calibration the ST AIA-PACK TT3 Assays.

Summary and Explanation

The AIA-PACK TT3 Calibrator Set contains human serum with assigned levels of triiodothyronine (T3). Calibration should be performed according to the schedule indicated in the AIA System Operator's Manual. The calibrators in this set are prepared gravimetrically and compared to internal reference standards.

Materials Provided (Cat. No. 0020382)

2 x 1 mL	Calibrator	No. 1	0 ng/mL	
	Human serum containing no detectable concentration of T3 (0 ng T3/mL), and 0.1% sodium azide as a preservative. (Ready to Use)			
2 x 1 mL	Calibrator	No. 2	0.50 ng/mL	(approx.)
		No. 3	1.00 ng/mL	(approx.)
		No. 4	2.00 ng/mL	(approx.)
		No. 5	4.00 ng/mL	(approx.)
		No. 6	8.00 ng/mL	(approx.)
	Human serum containing the assigned concentration of T3 (described on each vial), and 0.1% sodium azide as a preservative. (Ready to Use)			

Warnings and Precautions

- The AIA-PACK TT3 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 AIA-PACK TT3 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 TT3 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 AIA-PACK TT3 Calibrator Set contains assigned concentrations of T3. The assigned value is determined on a lot-to-lot basis and is designed to provide an assay calibration range of approximately 0 to 8.0 ng/mL of T3. The calibrators in this set are prepared gravimetrically and are compared to internal reference standards.

Results

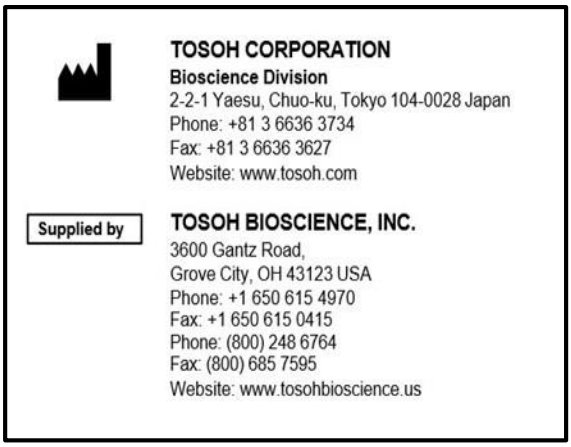
- Since there is an inverse relationship between concentration and rate, the rates should decrease as the concentration increases.
- The replicate values should be within a 10% range.

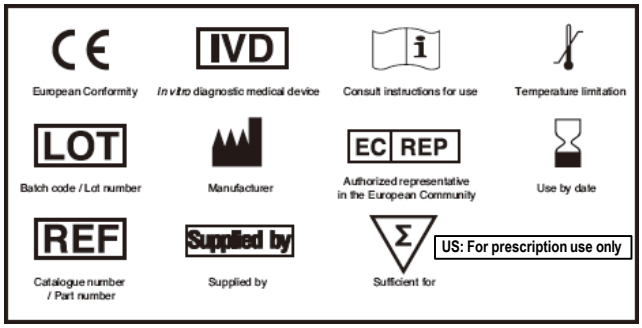
Limitations

The AIA-PACK TT3 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
T3 Sample Diluting Solution

Intended Use

The AIA-PACK TT3 Sample Diluting Solution is intended for IN VITRO DIAGNOSTIC USE ONLY to dilute patient samples that have concentrations of triiodothyronine (T3) above the linear range of the assay.

Summary and Explanation

The AIA-PACK TT3 Sample Diluting Solution contains human serum with no detectable concentration of T3. This Sample Diluting Solution is to be used only with samples that are being tested for T3 concentrations using the ST AIA-PACK TT3 Assays.

Materials Provided (Cat. No. 0020582)

4 x 4 mL	Sample Diluting Solution Human serum containing no detectable concentration of T3 (0 ng T3/mL), and 0.1% sodium azide as a preservative.

Warnings and Precautions

- The AIA-PACK TT3 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 TT3 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 TT3 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 8.0 ng/mL, the specimen should be diluted with the Sample Diluting Solution and assayed according to the Assay 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 specimen containing greater than 8.0 ng/mL is 1:4. However, it is desirable to dilute the samples that contain more than 8.0 ng T3/mL so that the diluted sample reads between 1.0 and 4.0 ng T3/mL.

Results

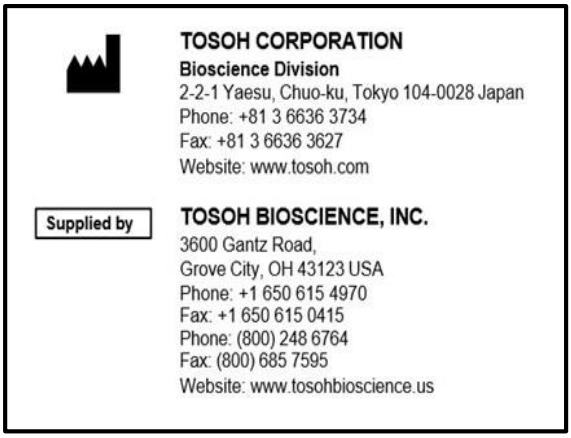
When an auto-dilution is performed, the AIA instrument will calculate the final result.

Limitations

The AIA-PACK TT3 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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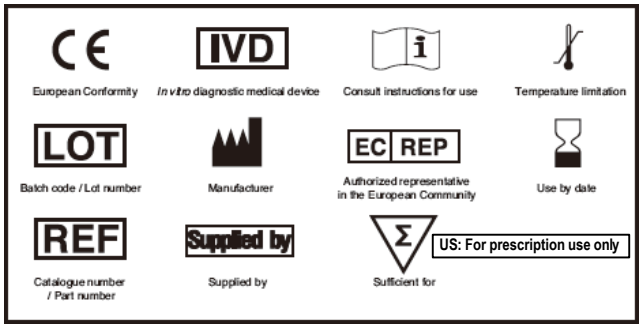
IVD
European Conformity
In vitro diagnostic medical device
Consult instructions for use
Temperature limitation
LOT
Batch code / Lot number
Manufacturer
EC REP
Authorized representative in the European Community
Use by date
REF
Catalogue number / Part number
Supplied by
Supplied by
Sufficient for
US: For prescription use only