AIA-360 Assay Specifications
ST MYO Test Code 096

No.	Item	Data
1	Calib. Req	Show
2	Cal 1	0 ng/mL
3	Cal 2	50 ng/mL (example)
4	Cal 3	250 ng/mL (example)
5	Cal 4	500 ng/mL (example)
6	Cal 5	750 ng/mL (example)
7	Cal 6	1200 ng/mL (example)
8	Cal Lot L	
9	Cal Lot R	
10	Unit	ng/mL
11	Smpl. Vol	10
12	Dil. Vol	140
13	Assay L	2.0
14	Assay H	1000
15	Ref. L	
16	Ref. H	
17	Decimal	1
	Visible only in Test Mode	
18	Test Name	MYO
19	Calib. No	6
20	Calib. Mul	3
21	Calib. Equ	10
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 MYO Test Code 096

No.	Item	Data
1	Code	96
2	ACT	1
3	Analyte	MYO
4	Lot	***Enter current cal lot no.
5	CAL 1	0 ng/mL
6	CAL 2	50 ng/mL (example)
7	CAL 3	250 ng/mL (example)
8	CAL 4	500 ng/mL (example)
9	CAL 5	750 ng/mL (example)
10	CAL 6	1200 ng/mL (example)
11	Cal lot L	
12	Cal lot R	
13	Unit	ng/mL
14	Decimal	1
15	Assay Low	2.0
16	Assay High	1000
17	Reference Low	
18	Reference High	
19	Reschedule Low	2.0
20	Reschedule High	1000
21	Factor A	1
22	Factor B	0
23	Sample Volume	10
24	Diluent Volume	140
25	2 Step reagent dispensing volume	0
26	Calibration code	96
27	CAL. No.	6
28	CAL. MUL.	3
29	CAL. EQU.	10
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	96
39	DIL. NAME	MYO
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 MYO Test Code 096

No.	Item	Data
1	Unit	ng/mL
2	Decimal places	1
3	Reference low	
4	Reference high	
5	Reschedule low	2.0
6	Reschedule high	1000
7	Assay range low	2.0
8	Assay range high	1000
9	Specimen diluent code	96
10	Specimen diluent name	MYO
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	10
19	Calibrator replicates	3
20	Calibrator lot	***Enter current cal. lot no.
21	Calibrator Concentration	
22	Cal - 01	0 ng/mL
23	Cal - 02	50 ng/mL (example)
24	Cal - 03	250 ng/mL (example)
25	Cal - 04	500 ng/mL (example)
26	Cal - 05	750 ng/mL (example)
27	Cal - 06	1200 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	10
39	Diluent volume	140
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	096
50	Virtual Concentration	0.0
51	Graph Origin	0.0
52	Calculation with Dilution Factor	Yes

MYOGLOBIN
ST AIA-PACK Myoglobin

Name and Intended Use

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

Summary and Explanation of Test

Myoglobin is an oxygen-binding heme protein of low molecular weight (17,800) that is found in both cardiac and skeletal muscle. Myoglobin is released from the muscle cells and appears in the circulation after injury to the skeletal muscles or myocardium (e.g. acute myocardial infarction or AMI), surgery, exercise, or myopathies.[1]

In AMI, damaged myocardial tissue leads to elevated myoglobin above normal levels within [2-3] hours after onset of symptoms, reaching peak levels at 6 to 9 hours, and returning to the normal range by 24 hours.[2] This rapid elevation of myoglobin in the circulation has lead to its usefulness for the early diagnosis and monitoring of AMI. [3-5] Increases in myoglobin concentration following thrombolytic treatment act as an early predictor of infarct reperfusion.[6-8] Successful reperfusion of a blocked coronary artery is indicated by myoglobin levels which peak between 30 minutes and 2 hours following thrombolytic therapy.

Principle of the Assay

The ST AIA-PACK Myoglobin is a two-site immunoenzymometric assay which is performed entirely in the AIA-PACK. Myoglobin 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. 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 myoglobin concentration in the test sample. A standard curve is constructed, and unknown sample concentrations are calculated using this curve.

Material Provided (ST AIA-PACK Myoglobin, Cat. No. 0025297)

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

Plastic test cups containing lyophilized magnetic beads coated with anti- myoglobin mouse monoclonal antibody and mouse monoclonal antibody (to human myoglobin) 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 myoglobin analysis using the ST AIA-PACK Myoglobin (Cat. No. 0025297) 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 ST Myoglobin Calibrator Set		0025397
Calibrator #1	0 ng/mL	
Calibrator #2	50 ng/mL (approx.)	
Calibrator #3	250 ng/mL (approx.)	
Calibrator #4	500 ng/mL (approx.)	
Calibrator #5	750 ng/mL (approx.)	
Calibrator #6	1200 ng/mL (approx.)	
AIA-PACK ST Myoglobin Sample Diluting Solution		0025597
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 Myoglobin 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 or different assays shall not be mixed within a tray.
- The ST AIA-PACK Myoglobin 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 Myoglobin has been designed so that the high dose “hook effect” is not a problem for the vast majority of samples. Samples with myoglobin concentrations between 1000 and 20,000 ng/mL will read > 1000 ng/mL. The “hook effect” phenomenon may occur at myoglobin concentrations > 20,000 ng/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 Myoglobin	0025297
AIA-PACK ST Myoglobin Calibrator Set	0025397
AIA-PACK ST Myoglobin Sample Diluting Solution	0025597
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

AIA-PACK test cups may be stored for 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 7 days. After opening, Sample Diluting Solution is stable for up to 7 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, EDTA or heparinized plasma is required for the assay. 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.

If using EDTA or 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.

Specimen types should not be used interchangeably during the serial monitoring of an individual patient, since measured concentrations may vary among sample types.

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.

Prior to analysis, ensure that the sample is free from fibrin.

The sample required for analysis is 10 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

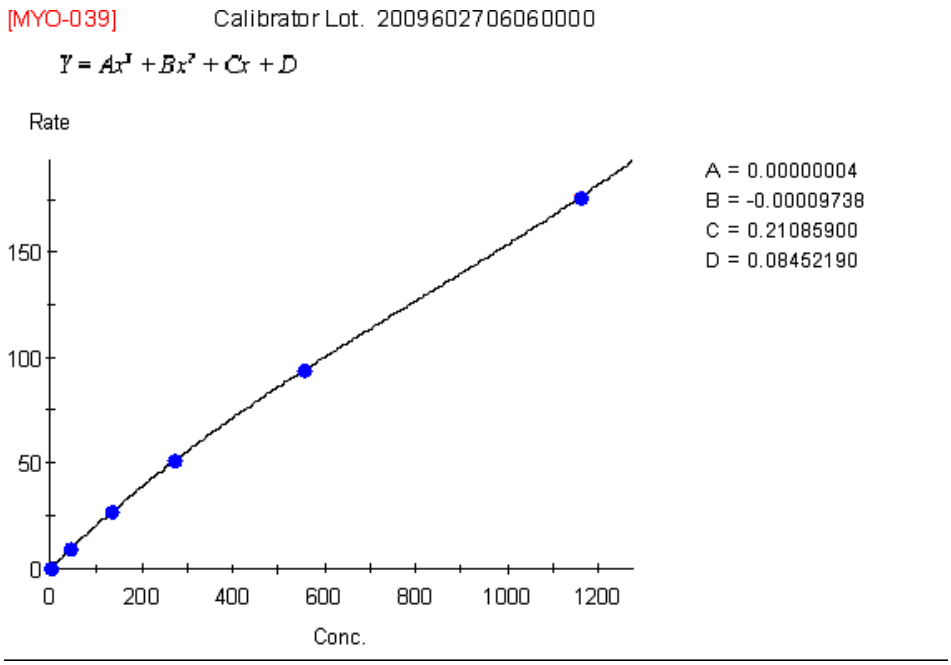
2a) Calibration Curve

The calibrators in this set are prepared gravimetrically and compared to internal reference standards.

The calibration curve for the ST AIA-PACK Myoglobin 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) The ST AIA-PACK Myoglobin CALIBRATOR (1) is provided ready for use.

iii) The ST AIA-PACK Myoglobin CALIBRATOR (2) - (6) are lyophilized. Lyophilized calibrators should be reconstituted with 1.0 mL of CAP Class I water or the clinical laboratory reagent water.

iv) 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 Myoglobin 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 myoglobin concentration is found to be greater than the linearity limit of the assay, 1000 ng/mL; the specimen should be diluted with the AIA-PACK ST MYO 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 1:10 or 1:100. It is desirable to dilute the sample so that the diluted sample reads between 5 and 1000 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 Myoglobin 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 096.

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 myoglobin 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. Dilution factors may be entered when programming the specimens in Assay Monitor.

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 Myoglobin, the highest concentration of myoglobin measurable without dilution is approximately 1000 ng/mL, and the lowest measurable concentration is 2.0 ng/mL (assay sensitivity).

Although the approximate value of the highest calibrator is 1200 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, 1000 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.

Samples containing fibrin may exhibit either falsely elevated or falsely decreased results.

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 myoglobin.

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 and the sample type being used. As with all diagnostic procedures, clinical results must be interpreted with regard to concomitant medications administered to the patient.[9] Myoglobin results should be used in conjunction with the total clinical presentation of the patient.

Reference Ranges

The interval given here was determined in serum samples from 153 apparently healthy individuals.

Reference Interval = 11.6 - 73.0 ng/mL

Heparinized plasma samples may yield results up to 20% lower in observed Myoglobin values as compared to serum ST AIA-PACK Myoglobin values. Therefore, it is recommended that different sample types not be mixed when performing repeat or serial testing on the same patient. A separate reference interval should be established for each sample type.

Performance Characteristics

The following performance characteristics were determined using the Tosoh AIA NexIA Automated Immunoassay Analyzer. The AIA-systems demonstrate equivalent performance.

1) Accuracy

1a) Recovery:

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

Sample	Initial Value (ng/mL)	Myoglobin Added (ng/mL)	Expected Value (ng/mL)	Measured Value (ng/mL)	Percent Recovery (%)
Serum A	57.4	30.6	88.0	86.6	98.4
	57.4	61.1	119.0	117.0	98.3
	57.4	122.0	179.0	182.0	102.0
Serum B	38.8	19.0	57.8	56.5	97.8
	38.8	38.0	76.8	75.0	97.7
	38.8	76.0	115.0	111.0	96.5
Serum C	35.1	27.7	62.8	61.4	97.8
	35.1	55.4	90.5	85.0	93.9
	35.1	111.0	146.0	137.0	93.8

1b) Dilution:

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

Sample	Dilution Factor	Expected Value (ng/mL)	Measured Value (ng/mL)	Percent Recovery (%)
Serum A	none		113.0	
	7.5/10	84.4	86.9	103.0
	5.0/10	56.3	56.9	101.0
	2.5/10	28.1	28.9	103.0
	1.0/10	11.3	10.8	95.8
Serum B	none		347.0	
	7.5/10	260.0	257.0	99.0
	5.0/10	173.0	171.0	98.7
	2.5/10	86.7	84.5	97.5
	1.0/10	34.7	33.6	96.8
Serum C	none		375.0	
	7.5/10	281.0	284.0	101.0
	5.0/10	187.0	182.0	97.0
	2.5/10	93.7	95.9	102.0
	1.0/10	37.5	37.7	101.0

1c) Comparative Analysis

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

Slope	**1.02**
y-intercept	1.89 ng/mL
Correlation Coefficient	0.996
Range of Samples	29.5 - 1186 ng/mL
Number of Samples (n)	83

2) Precision

2a) Intra-assay precision

The intra-assay (within run) precision coefficient of variation was evaluated in three control samples by 10 replicate determinations.

Sample	Number of Replicates	Mean (ng/mL)	Standard Deviation (ng/mL)	Coefficient of Variation (%)
Sample A	10	32.6	0.52	1.6
Sample B	10	110.0	3.04	2.8
Sample C	10	930.0	26.20	2.8

2b) Inter-assay precision

The inter-assay (between run) precision coefficient of variation was evaluated at three different concentrations by analyzing control samples in 30 separate runs.

Sample	Number of Replicates	Mean (ng/mL)	Standard Deviation (ng/mL)	Coefficient of Variation (%)
Sample A	30	31.4	1.40	4.4
Sample B	30	113.0	4.65	4.1
Sample C	30	971.0	43.30	4.5

Specificity

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

Compound	Cross-reactivity (%)
Hemoglobin	0.0

Sensitivity

The minimal detectable concentration (MDC) of myoglobin is estimated to be 2.0 ng/mL. The MDC is defined as that concentration of myoglobin 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 470 mg/dL), conjugated bilirubin (up to 22.8 mg/dL) and free bilirubin (up to 20.9 mg/dL) do not interfere with the assay.
- Lipemia, as indicated by added triglyceride (up to 2,340 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.
- Tosoh Automated Immunoassays utilizing alkaline phosphatase-based technologies should not be used with samples from patients under Asfotase Alfa treatment.

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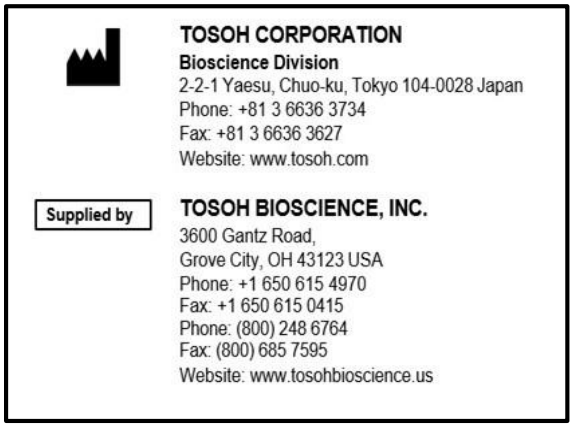

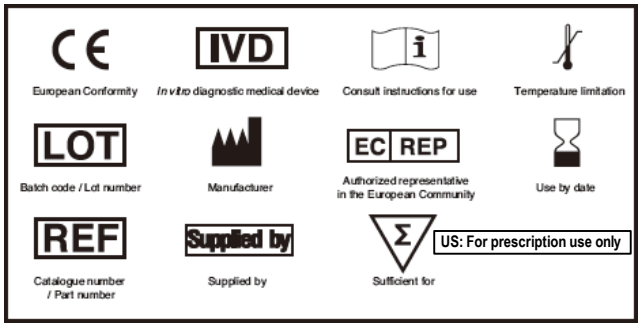

AIA-PACK
ST Myoglobin Calibrator Set

Intended Use

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

Summary and Explanation

The ST AIA-PACK Myoglobin Calibrator Set contains buffered bovine serum albumin with assigned levels of myoglobin. 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.

Material Provided (Cat. No. 0025397)

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

Buffered bovine serum albumin containing no detectable concentration of myoglobin (0 ng MYO/mL), and 0.1% sodium azide as preservative. (Ready for Use)

2 x 1 mL	Calibrator No. 2	50	ng/mL (approx.)
	No. 3	250	ng/mL (approx.)
	No. 4	500	ng/mL (approx.)
	No. 5	750	ng/mL (approx.)
	No. 6	1200	ng/mL (approx.)

Buffered bovine serum albumin containing the assigned concentration of myoglobin (described on each vial), and 0.1% sodium azide as a preservative. (Lyophilized)

Warnings and Precautions

- The ST AIA-PACK Myoglobin 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 Myoglobin 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

- Using a volumetric pipette or a calibrated adjustable pipette, reconstitute the lyophilized calibrators accurately with 1.0 mL of CAP Class I water or the clinical laboratory reagent water.
- Bring calibrator to room temperature (18 - 25 °C) for use.
- Always store the Calibrator Set in an upright position at 2 - 8 °C when not in use.

Stability

When stored unopened and refrigerated at 2 - 8 °C, the ST AIA-PACK Myoglobin 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 ST AIA-PACK Myoglobin Calibrator Set contains assigned concentrations of myoglobin. The assigned value is determined on a lot-to-lot basis and is designed to provide an assay calibration range of approximately 0 to 1200 ng/mL of myoglobin. The calibrators in this set are prepared gravimetrically and compared to internal reference standards.

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.

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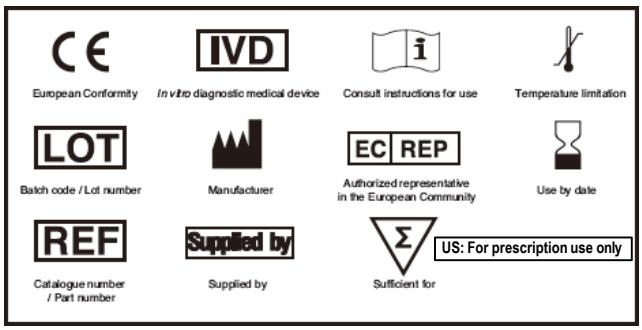
Limitations

The ST AIA-PACK Myoglobin 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
ST Myoglobin Sample Diluting Solution

Intended Use

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

Summary and Explanation

The ST AIA-PACK Myoglobin Sample Diluting Solution contains buffered bovine serum albumin with no detectable concentration of Myoglobin. This Sample Diluting Solution is to be used only with samples that are being tested for Myoglobin concentrations using the ST AIA-PACK Myoglobin assay.

Material Provided (Cat. No. 0025597)

4 x 4 mL	Sample Diluting Solution Buffered bovine serum albumin containing no detectable concentration of Myoglobin (0 ng MYO/mL), and 0.1% sodium azide as a preservative.

Warnings and Precautions

- The ST AIA-PACK Myoglobin 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 MYO 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 ST AIA-PACK Myoglobin 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 Myoglobin Sample Diluting Solution is stable until the expiration date on the label. After opening, the Sample Diluting Solution is stable for up to 7 days when refrigerated 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 1200 ng/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 specimen containing greater than 1000 ng/mL is 1:10 or 1:100. However, it is desirable to dilute the samples so that the diluted sample reads between 5 and 1000 ng/mL.

Results

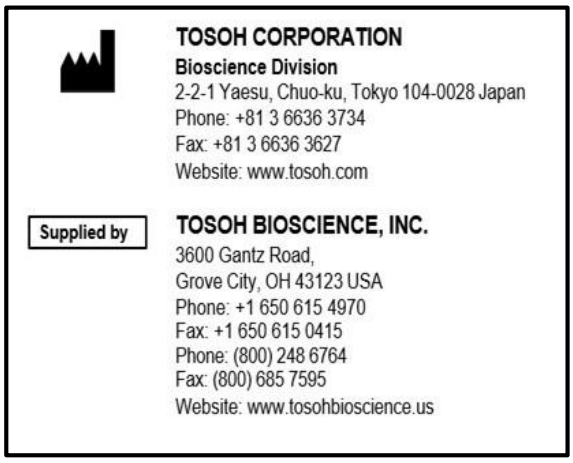
When an auto-dilution is performed, the AIA-instrument will calculate the final result.

Limitations

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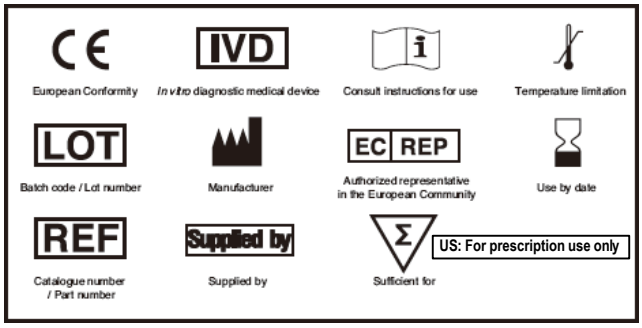
CE
European Conformity
IVD
In vitro diagnostic medical device
Consult instructions for use
Temperature limitation
LOT
Batch code / Lot number
Manufacturer
EC REP
Authorized representative in the European Community
Use by date
REF
Catalogue number / Part number
Supplied by
Supplied by
Σ
Sufficient for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