



TOSOH

Tosoh Bioscience, Inc.

AIA-360[®]

TRAINING MANUAL



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Version: 1

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Disclaimer:

The AIA-360 software is a product intended for international distribution. Certain AIA-PACK Analytes referenced in this manual should not be construed as available for sale or use in all markets.

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Tab 1**INTRODUCTION****Training Objectives:**

The AIA-360 Training Program is an integrated on-going approach designed to provide optimum use of the instrument for analysis. The training includes routine operation, calibration, maintenance, troubleshooting and assistance with Method Validation studies required by CLIA '88.

In addition to this Training Manual, the AIA-360 Quick Reference Guide (part number 260010) is provided as a resource for performing routine operation and maintenance of the AIA-360 analyzer.

When you have completed the AIA-360 training, you will be able to do the following:

- Explain the assay principles for both sandwich and competitive assays
- Prepare any necessary reagents
- Perform basic instrument operation and calibration
- Perform maintenance procedures
- Set and change assay specifications
- Troubleshoot
- Perform method validation studies

Tab 1**INTRODUCTION****WELCOME TO TOSOH BIOSCIENCE, INC.**

Congratulations on your decision to choose the AIA-360 Immunoassay Analyzer!

**TOSOH BIOSCIENCE, INC.
MISSION STATEMENT**

Tosoh Bioscience, Incorporated is a provider of high quality in vitro diagnostics products and services.

Our mission is to establish recognition as a leader in technology and customer support within the healthcare industry.

Our first priority is to anticipate and satisfy customer needs through a companywide commitment to partnerships, value and continuous improvement.

These goals will be achieved through the teamwork, dedication, and creativity of each Tosoh Bioscience employee.

TOSOH CORPORATION, JAPAN

Tosoh Corporation, started in 1925, is one of the top Japanese chemical companies, supplying specialty chemicals, scientific instrumentation and electronic materials to many of the world's leading manufacturers of consumer goods.

A few of the many products manufactured by Tosoh Corporation are:

- High performance liquid chromatography systems
- Fully automated immunoassay analyzers
- Petrochemicals
- Organic Chemicals
- Ceramic Materials

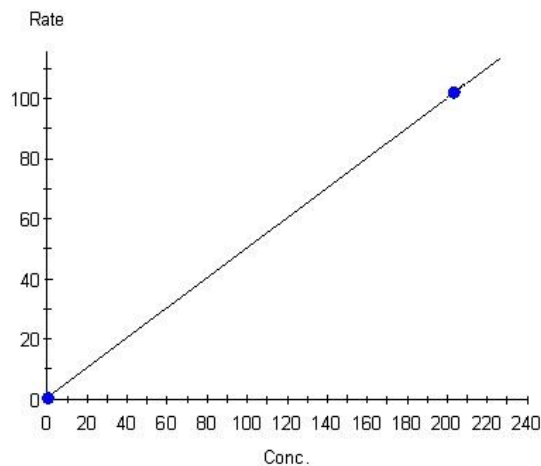
Tab 2**IMMUNOASSAY PRINCIPLES*****LEARNING OBJECTIVES***

At the conclusion of this module, the participant will be able to:

- Explain Immunoassay Principles
- Describe key points on assay principle/test cup diagram
- Describe assay pattern of a one-step sandwich reaction process
- Describe assay pattern of a one-step competitive reaction process
- Identify Sandwich and Competitive assays from the AIA test menu

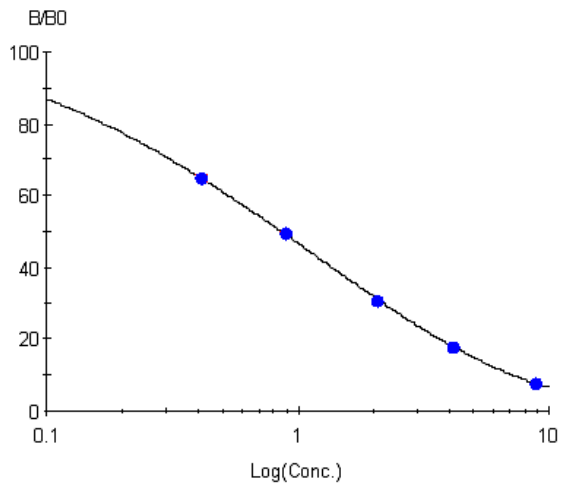
Tab 2**IMMUNOASSAY PRINCIPLES****One Step Sandwich Assay (IEMA Immunoenzymometric Assay):**

- Designed for high molecular weight analytes, i.e., TSH, PRL, FER
- Two types of antibodies are used in this assay: an antibody bound to the bead and a second antibody labeled with alkaline phosphatase in the conjugate.
- The antigen (analyte) binds to the immobilized antibody on the bead. The enzyme-labeled antibody (conjugate) binds to a different site on the antigen than the bead-bound antibody. Since both antibodies bind to the same antigen, this is referred to as the antigen-antibody “sandwich.”
- Excess antibody is bound to the bead so that the formation of the antigen-antibody complexes is not limited by the concentration of the analyte.
- Fluorescence (enzyme reaction) is directly proportional to the concentration of the analyte.
- Curves are usually linear and AFP, BHCG, CEA, FER, FSH, PAP, PRL and PA use two calibrators. Sandwich assays that use a 6-point calibration are ACTH, BMG, CA125, CA19-9, 27.29, CK-MB, CPEPII, cTnI2, Cystatin-C, HGH, IgEII, iPTH, IRI, LHII, MYO, SHBG and TSH.
- The calibration curve is expressed as rate vs. concentration.



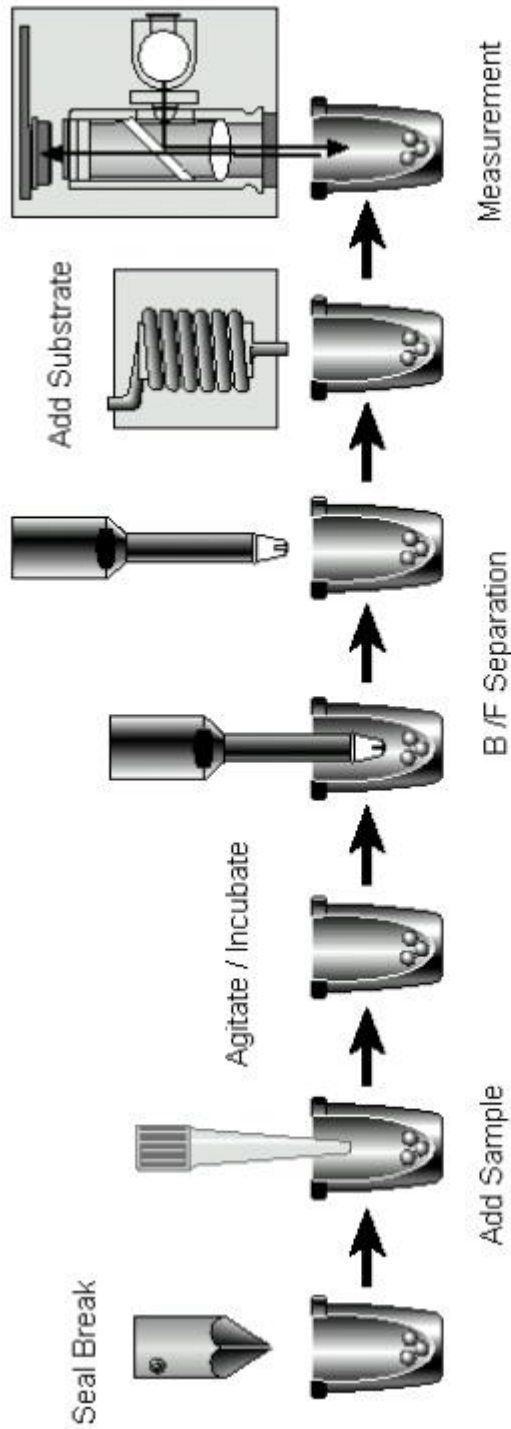
Tab 2**IMMUNOASSAY PRINCIPLES****Competitive Binding Assay**

- Designed for low molecular weight analytes, i.e. CORT, DHEA-S, E2, HCY, TT3, T4, FT3, FT4, PR-2, PR-3 and Testosterone.
- Antigen in the sample and the enzyme labeled antigen compete for a limited amount of antibody binding sites on the bead.
- Fluorescence (enzyme reaction) is indirectly proportional to the concentration of the analyte.
- Competitive binding assays require 6 calibrators. T-U, a modified competitive binding assay, requires only 2 calibrators.
- Because the residual enzyme activity decreases exponentially in relation to the amount of antigen in the sample, the concentration of the analyte is calculated using a log-logit function.



Tab 2

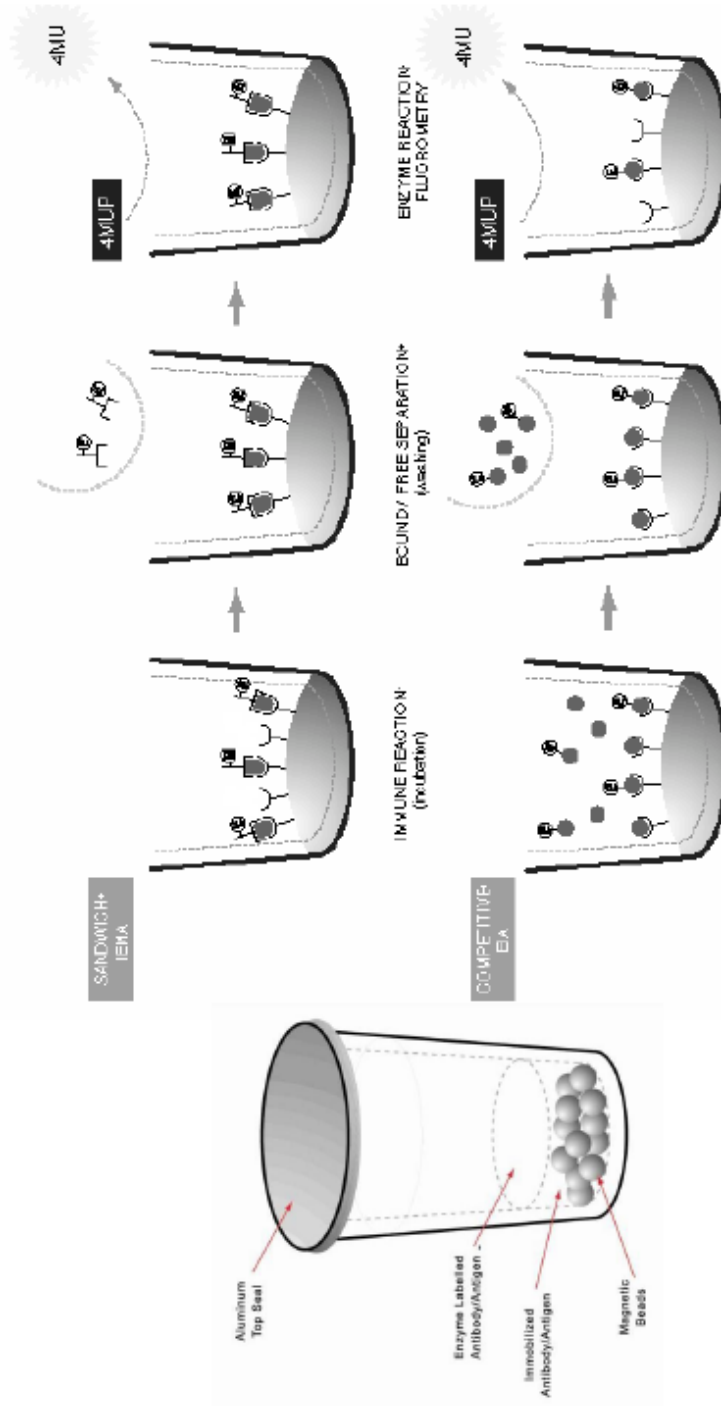
IMMUNOASSAY PRINCIPLES



AIA Reaction Scheme

Tab 2

IMMUNOASSAY PRINCIPLES



AIA-Systems Assay Principles

Tab 2

IMMUNOASSAY PRINCIPLES

ANALYTES	ASSAY TYPE
TUMOR MARKERS	
ST AFP	Sandwich
ST CA 125	Sandwich
ST CA 19-9	Sandwich
ST 27.29	Sandwich
ST CEA	Sandwich
ST PA (PSA)	Sandwich
CARDIAC MARKERS	
ST CKMB	Sandwich
ST Myoglobin	Sandwich
ST cTnI 2nd Gen (Troponin I)	Sandwich
ANEMIA MARKERS	
ST FER (Ferritin)	Sandwich
METABOLIC	
ST CORT (Cortisol)	Competitive
ST HGH (Human Growth Hormone)	Sandwich
KIDNEY MARKERS	
ST CysC (Cystatin C)	Sandwich
ST BMG (β_2 Microglobulin)	Sandwich
ST iPTH	Sandwich
DIABETES ASSAYS	
ST C-Peptide II	Sandwich
ST IRI (Insulin)	Sandwich
ADDITIONAL ANALYTES	
ST ACTH	Sandwich
ST HCY (Homocysteine)	Competitive
ST IgE II	Sandwich
ST PAP (Prostatic Acid Phosphatase)	Sandwich
THYROID HORMONES	
ST T4	Competitive
ST TT3	Competitive
ST TSH	Sandwich
ST FT3 (Free T3)	Competitive
ST FT4 (Free T4)	Competitive
ST TU (T-Uptake)	Competitive

Tab 2

IMMUNOASSAY PRINCIPLES

REPRODUCTIVE HORMONES	
ST β HCG	Sandwich
ST FSH	Sandwich
ST LH II	Sandwich
ST PRL (Prolactin)	Sandwich
ST E2 (Estradiol)	Competitive
ST PR-2 (Progesterone)	Competitive
ST PR-3 (Progesterone)	Competitive
ST Testosterone	Competitive
ST DHEA-S	Competitive
ST SHBG (Sex Hormone-Binding Globulin)	Sandwich

Tab 2

IMMUNOASSAY PRINCIPLES

**QUIZ**

1. Name the two types of immunoassay principles discussed in this module.

2. What information is read off the dot pattern on the top of the test cup?

- a. Expiration date & lot number
- b. Lot number & test code
- c. Expiration date & test code

3. What are the two components that are added to the bead prior to being placed in the test cup?

- a. Antigen & ferrite
- b. Antibody & ferrite
- c. Conjugate & oxygen

4. In a sandwich assay, the concentration is directly proportional to the amount of fluorescence.

True

False

5. In a competitive assay, the zero calibrator has the lowest rate of fluorescence.

True

False

6. TSH is a competitive assay.

True

False

Tab 3 REAGENT PREPARATION & LABORATORY SAFETY**LEARNING OBJECTIVES**

At the conclusion of this module, the participant will be able to:

- Prepare all of the common reagents used on the AIA-360
- Define the stability of the reagents
- Define the stability of the calibration curve
- Define which assays can use both serum and urine
- Explain laboratory safety precautions

Tab 3 REAGENT PREPARATION & LABORATORY SAFETY

This section provides preparation instructions and stability specifications for the common reagents, calibrators, calibration verification sets, sample diluting solutions and samples.

All assays utilize the same, substrate, diluent and wash. The sample diluting solutions, calibration/verification materials, and calibrators are specific for each analyte. Some assays have pretreatment reagent and control material. Once opened, please refer to the Analyte Application Manual (AAM) for reagent stability information which can be downloaded with the AIA-360 Operator's Manual at www.diagnostics.us.tosohbioscience.com/support/document-download.

Note: Notification inside the package insert of all AIA-Test Pack reagents states that **ALL** customers in the United States should refer to the Analyte Application Manual (AAM), **not the package insert**, for FDA cleared wording and claims on current analyte specifications, reagent preparation instructions and expiration dates. This also applies to ALL customers receiving product from the United States.

REAGENT

PREPARATION & STABILITY

Substrate II

- 2 sets per box
- Bring to room temp. before reconstituting
- Add 1 bottle of reconstituent to 1 bottle of lyophilized powder
- Mix thoroughly by swirling contents and let stand until completely dissolved
- Uses 200 μ L per sample
- On-board stability is 3 days
- Stable for 30 days in the refrigerator at 2-8°C
- Label with expiration date after preparation
- Do not mix fresh substrate with substrate that is about to expire (High Blank flag could occur)

Diluent

- 4 x 100 mL bottles/box
- Fill 500 mL reservoir with approximately 300 mL of CAP Class I water or the clinical laboratory reagent water
- Add 10 mL of diluent concentrate and q.s. (bring the volume up to) 500 mL with water (graduations are on the side of the diluent reservoir)
- Mix vigorously
- Stable for 30 days at room temperature
- Label with expiration date after preparation
- Prepare the diluent 24 hours prior to usage, to allow equilibration of the pH

Wash

- 4 x 100 mL bottles/box
- Fill 1-liter reservoir with approximately 800 mL of CAP Class I water or the clinical laboratory reagent water
- Add 40 mL of wash concentrate and q.s. (bring the volume up to) 1.0 liter with water (graduations are on the side of the wash reservoir)
- Mix vigorously
- Stable for 30 days at room temperature
- Label with expiration date after preparation
- Prepare the wash 24 hours prior to usage, to allow equilibration of the pH

Tab 3 REAGENT PREPARATION & LABORATORY SAFETY

<u>REAGENT</u>	<u>PREPARATION & STABILITY</u>
Test Cups (AIA-360 uses only the ST AIA-PACKS)	<ul style="list-style-type: none"> • ST reagents are packaged in 100 test kits, 5 trays/kit, 20 cups/tray • Most test cups are stable up to 24 hours at room temperature Refer to Stability Chart • Stable until expiration date at 2-8°C
Calibrators	<ul style="list-style-type: none"> • 2 sets per box; some analytes have two calibrators and others have 6 calibrators • Some calibrators are liquid and may be used directly from the bottle; others are lyophilized and need to be reconstituted • Most calibrators should be used within 24 hours of opening or reconstituting, provided vials are kept tightly sealed and refrigerated at 2-8°C. Some opened calibrators are stable for 7 days • Refer to the Analyte Application Manual (AAM) for reconstitution instructions and stability information
Calibration Verification/Linearity Standards	<ul style="list-style-type: none"> • 2 sets per box (SDS + high sample) • Two 2 mL bottles of Calibration Verification Material • Two 4 mL bottles of Sample Diluting Solution • Opened CVM should be used within 24 hours provided vials are kept tightly sealed and refrigerated at 2-8°C • CVM is protein-based serum containing the assigned concentration of the approximate upper linearity limit for the specific analyte being tested
Sample Diluting Solution (SDS)	<ul style="list-style-type: none"> • Four 4.0 mL or four 100 mL bottles of SDS • For most assays, SDS may be used directly from the bottle. See the Analyte Application Manual (AAM) for complete information • Once opened, most SDS is stable at 2-8°C for 90 days Refer to Stability Chart • SDS is protein-based serum containing no detectable concentration of the specific analyte being tested
Standardization Cups	<ul style="list-style-type: none"> • 200 test kits, 10 trays/kit, 20 cups/tray • Use one test cup during daily maintenance for lamp check and substrate background reading • Stable at room temperature
Pretreatment Reagent	<ul style="list-style-type: none"> • One assay, HCY, requires a pretreatment step • Pretreatment reagents are buffered protein solutions • Refer to the Analyte Application Manual (AAM) for instructions and stability information
Control Material	<ul style="list-style-type: none"> • Available for some assays • Control material is buffered protein or buffered bovine serum albumin • Refer to the Analyte Application Manual (AAM) for instructions and stability information

Tab 3 REAGENT PREPARATION & LABORATORY SAFETY

General Precautions

Although this section refers to sample handling, observe the same precautions when handling calibrators, controls, proficiency testing samples, etc. as when handling samples.

Refer to the Analyte Application Manual (AAM) for any assay specific precautions.

Serum / Plasma

Always follow good laboratory practices when handling samples.

Serum or plasma may be used for most AIA-PACKS. 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 testing. Please refer to the Analyte Application Manual (AAM) for the specimen type.

Samples may be stored refrigerated (2-8°C) for up to 24 hours prior to analysis. If analysis cannot be performed within 24 hours, the sample should be stored frozen at or below -20°C for up to 60 days. Repeated freeze-thaw cycles should be avoided. Please refer to the Analyte Application Manual (AAM) for detailed collection and handling information.

Turbid samples or samples containing particulate matter should be centrifuged before testing. Prior to assay, bring frozen samples to room temperature slowly and mix gently.

Human serum/plasma samples should be handled and disposed of as if potentially infectious.

Urine

Urine should be collected in a container to which no preservatives have been added. Once collected, follow the directions found in the Analyte Application Manual (AAM) for pH adjustment, if necessary.

Human urine samples should be handled and disposed of as if potentially infectious.

Currently, BMG and CPEP are the only assays cleared for urine specimens.

Sample Dilution

- BMG requires either a 1:51 (serum/plasma) or a 1:5 (urine) dilution with BMG Sample Diluting Solution prior to analysis.
- 27.29 requires a 1:21 (serum/plasma) dilution with 27.29 Sample Diluting Solution prior to analysis.
- CPEP requires a 1:10 (urine) dilution with CPEP Sample Diluting Solution prior to analysis.
- CysC requires a 1:25 (serum/plasma) dilution with CysC Sample Diluting Solution prior to analysis.
- SHBG requires a 1:20 (serum/plasma) dilution with SHBG Sample Diluting Solution prior to analysis.

NOTE: The AIA-360 cannot perform online dilutions. All dilutions must be performed offline before assaying. HCY requires an offline sample pretreatment prior to analysis. Refer to Manual Procedures in this manual or the Analyte Application Manual for specific instructions.

Tab 3 REAGENT PREPARATION & LABORATORY SAFETY

Miscellaneous

Remove any bubbles from the top of the sample tube or sample cup. The level sensor will detect air and could cause a short sample error.

Check the sample for fibrin or other particulate matter that may clog the sample probe. Remove the fibrin or centrifuge the specimen prior to analysis.

The minimum sample requirement (dead volume) for a properly spun primary tube is 500 uL. The dead volume in a sample cup is 100 uL.

Clean up all spills immediately and disinfect the area.

Major Points

Current scientific evidence indicates that HIV is not spread by common everyday casual contact. It is transmitted through sexual contact or exposure to infected blood or body fluids.

Cases of transmission in the laboratory or health care environment have been the result of needlesticks or direct exposure to infected fluids to the mucous membranes of the mouth, nose and eyes, or broken skin.

The precautions listed below are for the protection from infectious pathogens, such as HIV and the hepatitis B virus.

Precautions

- Always wear gloves, a laboratory coat and protective eye wear.
- Always dispose of these items before leaving the laboratory.
- Always wash hands thoroughly. Wash hands after removing your laboratory coat and gloves.
- Never recap needles and “sharps”.
- Never smoke, apply cosmetics, eat, drink, or store food in the laboratory area.
- Always use biological safety cabinets whenever a procedure could generate droplets or aerosols.
- Skin disorders or open lesions create higher risk and should always be covered.
- Place all specimens of blood and body fluids in well-constructed containers with secure lids to prevent leaking.
- Never mouth pipette.
- After a spill of blood or body fluids, decontaminate the laboratory surfaces with an appropriate chemical disinfectant such as 10% bleach solution.
- Routinely decontaminate equipment which may come in contact with blood or body fluids with a chemical disinfectant such as 10% bleach solution.
- Always dispose of blood and body fluids and materials contaminated with blood and body fluids as a biohazard waste according to your standard operating procedures and/or local regulations.

Tab 3 REAGENT PREPARATION & LABORATORY SAFETY

ST AIA-PACK STABILITY

Code	Analyte	Test Cup (18-25°C)	Calibrator (2-8°C)	SDS (2-8°C)	Curve Stability	Control (2-8°C)	Pretreatment (2-8°C)
91	ST 27.29	24 hours	7 days	7 days**	90 days		
106	ST ACTH	24 hours	24 hours	90 days	90 days	7 days	
14	ST AFP	24 hours	24 hours	90 days	90 days		
71	ST bHCG	24 hours	24 hours	90 days	90 days		
65	ST BMG	24 hours	24 hours	90 days	90 days		
26	ST CA 125	24 hours	24 hours	90 days	90 days		
15	ST CA 19-9	24 hours	7 days	90 days	90 days		
06	ST CEA	24 hours	24 hours	90 days	90 days		
78	ST CKMB	24 hours	24 hours	90 days	90 days		
67	ST CORT	24 hours	7 days	90 days	90 days		
40	ST CPEP II	7 days	24 hours	30 days**	90 days	14 days	
102	ST CysC	24 hours	24 hours	7 days**	90 days		
79	ST DHEA-S	24 hours	24 hours	90 days	90 days		
29	ST E2	24 hours	24 hours	90 days	90 days		
64	ST FER	24 hours	24 hours	90 days	90 days		
68	ST FSH	24 hours	24 hours	90 days	90 days		
76	ST FT3	24 hours	24 hours	NA	90 days		
75	ST FT4	24 hours	24 hours	NA	90 days		
97	ST HCY	24 hours	24 hours	9 days**	90 days	14 days	24 hours
66	ST HGH	24 hours	7 days	90 days	90 days		
77	ST IgE II	24 hours	7 days	7 days	90 days		
58	ST IRI	24 hours	7 days	90 days	90 days		
39	ST LH II	24 hours	24 hours	7 days	90 days		
96	ST MYO	24 hours	7 days	7 days	90 days		
27	ST PAP	24 hours	7 days	90 days	90 days		
41	ST PRL	24 hours	24 hours	90 days	90 days		
127	ST PR-2	10 days	24 hours	9 days**	90 days		
123	ST PR-3	24 hours	24 hours	9 days**	90 days		
52	ST iPTH	24 hours	24 hours	7 days**	90 days	7 days	
28	ST PA	24 hours	24 hours	90 days	90 days		
124	ST SHBG	7 days	24 hours	30 days**	90 days		
74	ST TT3	24 hours	24 hours	90 days	90 days		
73	ST T4	24 hours	24 hours	90 days	90 days		
24	ST TES	24 hours	7 days	30 days	90 days		
72	ST TSH	24 hours	7 days	90 days	90 days		
20	ST TU	24 hours	24 hours	NA	90 days		
93	ST cTnl 2	24 hours	24 hours	30 days	30 days		

**The Sample Diluting Solution (SDS) can be used for up to 90 days provided that:

- 1) It is used for manual dilutions only.
- 2) The bottles are kept tightly sealed and stored at 2-8°C immediately after use.

Tab 3

REAGENT PREPARATION & LABORATORY SAFETY**ST AIA-PACK SPECIMEN TYPE
CHART**

Code	Analyte	Serum	Heparinized Plasma	EDTA Plasma	Urine
91	ST 27.29	X	X		
106	ST ACTH			X	
14	ST AFP	X	X		
71	ST bHCG	X	X		
65	ST BMG	X	X		X
26	ST CA 125	X	X		
15	ST CA 19-9	X	X		
06	ST CEA	X	X		
78	ST CKMB	X	X		
67	ST CORT	X	X		
40	ST CPEP II	X	X	X	X
102	ST CysC	X	X	X	
79	ST DHEA-S	X	X	X	
29	ST E2	X	X		
64	ST FER	X	X		
68	ST FSH	X	X		
76	ST FT3	X	X		
75	ST FT4	X	X		
97	ST HCY	X	X	X	
66	ST HGH	X	X		
77	ST IgE II	X	X		
58	ST IRI	X	X		
39	ST LH II	X	X		
96	ST MYO	X	X	X	
27	ST PAP	X	X		
41	ST PRL	X	X		
127	ST PR-2	X	X		
123	ST PR-3	X	X		
52	ST iPTH	X		X	
28	ST PA	X	X		
124	ST SHBG	X	X		
74	ST TT3	X	X		
73	ST T4	X	X		
24	ST TES	X	X		
72	ST TSH	X	X		
20	ST TU	X	X		
93	ST cTnl 2		X		

Tab 3

REAGENT PREPARATION & LABORATORY SAFETY



QUIZ

1. List the three common reagents used on the AIA-360.

2. How many days can the substrate be stored at room temperature?

a. 3 days b. 7 days c. 30 days

3. List two laboratory safety items that must be worn during sample handling.

4. Which analyte can use either serum or urine?

a. BHCG
b. BMG
c. PA

5. What should be used to routinely decontaminate an instrument after a blood spill?

a. Ethanol
b. 10% Bleach
c. Distilled water

6. The reagent test cups are stable at room temperature for 14 days.

True False

7. SDS that has been opened is stable for one year from date of manufacture.

True False

8. The calibration curve for Troponin is stable for 90 days.

True False

Tab 4**SYSTEM OVERVIEW*****LEARNING OBJECTIVES***

At the conclusion of this module, the participant will be able to:

- Explain the sizes of primary tubes and sample cups that can be loaded on the AIA-360
- Explain the total number of tests that can be processed per sample
- Explain the total number of sample positions on the AIA-360
- Explain the system specifications
- Explain the time required for the first result to print

Tab 4**SYSTEM OVERVIEW****System Configuration and Control****System Configuration:**

The AIA-360 Automated Immunoassay System consists of one bench-top module, external common reagents and liquid waste reservoir.

Computer Control: The AIA-360 analyzer is controlled by an internal CPU and slave microprocessors.

The AIA-360 system software, consisting of simple user interface and analyzer control software is loaded into system RAM via a Smart Media card (flash ROM) or USB drive. If the PC loses power, reloading of the system software is not necessary.

Interface Specifications:

The AIA-360 can be interfaced with a host computer system (LIS) via an RS232C serial interface. Complete, detailed interface specifications for communication with a host computer (LIS) are provided in the AIA-360 Operator's Manual.

Operation and Features**Calibration:**

Calibrations are performed using the AIA-PACK Calibrator Sets. Up to 6 calibrator concentrations can be run for each analyte.

For the currently available test menu, most ST AIA-PACK sandwich assays exhibiting a linear calibration response use two calibrator concentrations, while those exhibiting a non-linear calibration response use six calibrator concentrations (with the exception of T-Uptake). In the ST AIA-PACK competitive binding assays, six calibrator concentrations are routinely used. All reagent test cup lot calibrations, except for cTnI 2nd Gen, are stable for a period of 90 days. The calibration curve for cTnI 2nd Gen is stable for a period of 30 days.

Two calibration curves can be stored for each analyte. This allows the operator to use two test cup lots of the same analyte simultaneously, permitting efficient test cup lot management.

Inventory Management:

Inventory of the substrate is input manually and maintained automatically by the system software. The bulk common reagents (wash and diluent) are monitored continuously by liquid level sensors. Reagents may be added as necessary without interrupting work in process.

Assay Requests:

Assay requests are registered automatically using a combination of an internal barcode reader and a cup reader. Specimen identification can be manually programmed for non-barcode tubes and sample cups.

Tab 4

SYSTEM OVERVIEW

Sampling:

The AIA-360 carousel accepts four different common primary draw tube sizes; 13 mm X 75 mm, 13 mm X 100 mm, 16 mm X 75 mm and 16 mm X 100 mm. In addition to primary draw tubes, sample cups (Hitachi-type, available from Tosoh-P/N: 018581) can be used. The carousel can be loaded with any combination of primary tubes and sample cups.

The carousel contains 25 specimen/sample cup positions on the lower ring and 25 test cup positions on the upper ring. A maximum of 4 analytes can be loaded for each sample.

The barcode scanner is able to decode four common barcode formats simultaneously.

Note: Pressing the blue START key on the instrument initiates the start of an assay run. **Holding down the START key for ~3 seconds will send an abort request** to abort the assay in progress. This is useful if you realize a mistake was made in loading the carousel and you need to quickly terminate the assay.

Samples may be processed continuously. A sample can be removed from the carousel as soon as the tube emerges from the processing area. Sampling progress is tracked on the Assay Monitor screen.

The AIA-360 employs two sensors (contact capacitance and pressure/vacuum) to determine the presence, volume, and integrity of the sample in each primary tube or sample cup. The total required sample volume depends upon the type and number of analytes to be run. Sample volumes range from 10 μL to 100 μL , with a maximum total volume (sample plus diluent) not to exceed 200 μL . The approximate dead volume in properly centrifuged primary tubes is 500 μL ; the approximate dead volume in AIA-360 sample cups is 100 μL .

DO NOT USE THE BD FALCON 13x100 mm TUBE ON THE AIA-360.

This tube measures 13 mm near the top, just below the threads used to secure the screw-on cap. However, the diameter of the tube at the bottom is only 11.5 mm.

The tapered bottom may cause the sample probe to crash.



DO NOT USE SAMPLE CUP ADAPTERS IN TUBES

The use of adapters increases the height and causes the instrument to treat it as a tube. This can cause the sample probe to crash.

DO NOT USE 12x75 mm TUBES

12x75 mm tubes will not fit correctly on the AIA-360 carousel. With usage the tubes may fit loosely and result in a probe crash.

Tab 4**SYSTEM OVERVIEW****Reaction:**

Specimen and diluent are added to the ST AIA-PACK test cup. This antigen-antibody reaction mixture is incubated at 37°C for 10 minutes. All AIA-PACK common reagents (diluent, wash and substrate) are preheated to 37°C. The solid phase carriers (magnetic beads) are then washed and substrate (4-MUP) is dispensed.

Fluorescent Measurement:

After dispensing the 4-MUP substrate, changes in fluorescent intensity are measured. The concentrations are calculated based on a predetermined calibration. Multiple equations are calculated by the AIA-360, with a unique equation required for each analyte.

Waste Disposal:

Solid waste (test cup) is manually removed. Liquid waste is collected in a 1 L container, monitored by a liquid level sensor. When the liquid waste reaches the approximate volume of 0.8 L, an audible alarm will sound to alert the operator that the liquid waste needs to be emptied.

Reports:

The first result will be output to the printer in real-time in ~20 minutes. After the initial lag time, a result is output every 100 seconds.

After appropriate operator review, all or part of the results may be transmitted to a host computer system (LIS).

Required Utilities:

The AIA-360 analyzer requires a standard dedicated AC outlet rated at 115 VAC \pm 10%, 15 amps, 60 cycles.

Tab 4

SYSTEM OVERVIEW

System Specifications

Assay principle	Fluorescence enzyme immunoassay (FEIA)
Processing method	Automated continuous random access
Processing capacity	Max. 36 tests/hr.
Sample volumes	10 to 100 μ L
Sample clog detection	Pressure detection
Measuring conditions	Reaction temperature: 37°C Antigen-antibody reaction time: 10 min.
Detection method	Fluorescent detection
Sample capacity	Max. 25
Reagent loading capacity	Max. 25
Tests for each sample	Max. 4
Sample tubes or cups	13 x 75 mm, 13 x 100 mm, 16 x 75 mm, 16 x 100 mm; 2 mL sample cups (Hitachi type, P/N: 018581 available from Tosoh)
Specimen barcodes	CODE39, CODE128, ITF and NW-7
External output	RS-232C
Power	AC100-240V, 50/60Hz, 250VA
External dimensions	16 in. (W) x 16 in. (D) x 21 in. (H)
Weight	61 lbs.
Temperature	15 to 30°C
Humidity	40 to 80% (no condensation)

Tab 4**SYSTEM OVERVIEW****QUIZ**

1. The following primary tubes or sample cups can be used on the AIA-360: Circle all that are applicable.
 - a. 13 mm X 75 mm
 - b. 12 mm X 75 mm
 - c. 13 mm X 100 mm
 - d. BD Falcon 13 mm X 100 mm tubes
 - e. 16 mm X 75 mm
 - f. 16 mm X 100 mm
 - g. Samples Cups
 - h. Sample Cup adapters

2. What is the incubation time for the assays on the AIA-360?

3. What is the maximum number of analytes for each specimen that can be assayed on the AIA-360?

Tab 5

OPERATION

LEARNING OBJECTIVES

The AIA-360 Quick Reference Guide is used during operator training. Users should refer to the Quick Reference Guide for daily operation.

At the conclusion of this module and with the aid of the AIA360 Quick Reference Guide, the participant will be able to:

- Start the Instrument and perform Daily Check
- Perform Calibration
- Review and accept calibrations
- Delete Calibration curves when required
- Assay specimens and review results
- Shutdown the instrument

Tab 5**OPERATION****Curves and Flags:**

Refer to Flags and Error codes in Tab #8 – Troubleshooting.

Curve designations are shown on the CALIB. REVIEW SCREEN. Refer to the Quick Reference Guide to view this screen.

Curve Designations:

“**A**” – Curve has been accepted.

“**P**” – Curve has rate data but has not been accepted.

“**V**” – Curve is void (past 30 or 90-day stability). This status will be shown for 60 days after the expiration of the calibration curve.

“-” – Curve is void beyond 60 days of expiration.

Tab 5**OPERATION****QUIZ**

1. What is the purpose of performing a Daily Check?
2. How many calibrations can you perform at the same time?
3. How many calibration curves can be stored for the same lot number?
4. Using the screen; show how to review calibrations and what do the symbols A, P and V stand for?
5. What is the solution that replaces the substrate at the time of shut down?
6. What does a CV flag indicate?

Tab 6**MAINTENANCE****LEARNING OBJECTIVES**

At the conclusion of this module, the participant will be able to:

- Explain the daily maintenance procedure
- Explain the weekly maintenance procedure
- Explain the monthly maintenance procedure
- Explain the six-month maintenance procedure

Tab 6

MAINTENANCE

Proper maintenance of the AIA-360 is one of the most important aspects of a complete Quality Assurance program.

Completing the required maintenance procedures minimizes down time, provides records for inspection and accreditation, provides assistance in the definition and isolation of problems, and maintains optimal instrument and assay performance.

Daily Maintenance

Daily Check

Refer to the Quick Reference Guide, “Start-Up” for detailed instructions.

End of Day

Perform System Shutdown. Refer to the Quick Reference Guide, “Shutdown” for detailed instructions.

Weekly Maintenance

If the substrate line is dirty, the substrate blank becomes higher causing an HB flag.

1. Replace the substrate bottle with a bottle of 70% ethanol or 70% Isopropyl alcohol*.
2. Under SPECIAL MENU, press MAINT to access the Maintenance Screen.
3. Select ‘6: REPLACE SUBSTRATE’. Perform this step three times.

Monthly Maintenance

To prevent contamination, Tosoh Bioscience recommends regular cleaning of the wash and diluent reservoirs and the sampling area. At a minimum, the reservoirs should be cleaned quarterly.

1. Clean the sampling area with a neutral detergent. You may also use 70% ethanol or 70% Isopropyl alcohol*. The **SAMPLE FEED** key on the control panel can be used to advance the carousel as needed.
2. Remove and empty the wash and diluent reservoirs. Clean the diluent and wash reservoirs with a 1:100 solution of common household bleach. Rinse multiple times with CAP Class I water or the clinical laboratory reagent water to avoid any residual bleach that could mix with the diluent or wash solutions and affect the reaction. Refill with fresh wash or diluent and reinstall.

As Needed Maintenance

Clean instrument surfaces with a neutral detergent. 70% ethanol or 70% Isopropyl alcohol* may also be used for cleaning.

*70% ethanol or 70% Isopropyl alcohol is recommended. Methyl alcohol should not be part of the compound, as over time, methanol can damage certain components of the analyzer.

Tab 6**MAINTENANCE****Six-Month Maintenance**

Clean the diluent and wash lines to ensure consistency of results.

It is recommended to clean the diluent and wash lines and the diluent and wash solution bottles on the same day.

This procedure takes about an hour to perform.

1. Pour about a liter of distilled water and 10 mL of household bleach into a clean reservoir.
2. Remove the tubes from the diluent and wash solution bottles and detach the filters from the tube ends.
3. Put the ends of the diluent and wash lines into the bleach solution prepared in step 1.
4. Under SPECIAL MENU, press MAINTEN to access the Maintenance screen.
5. Select "3: PRIME SAMPLER DILUENT" to flush bleach through the diluent line. Perform this step five times.
6. Next, select "5: PRIME BF WASHER" on the same screen to flush the bleach solution through the wash line. Perform this step five times.
7. Pour about a liter of CAP Class I or the clinical laboratory reagent water into another clean reservoir and place the tube ends into this reservoir. Make sure the liquid level sensors are washed well to remove any residual bleach solution.
8. Let the tubes sit in the CAP Class I or the clinical laboratory reagent water for about five minutes before priming.
9. Select "3: PRIME SAMPLER DILUENT" to flush water through the diluent line to remove any residual bleach solution. Perform this step five times.
10. Select "5: PRIME BF WASHER" on the same screen to flush water through the wash line to remove any residual bleach solution. Perform this step five times.

Note: Steps 5-10 should be performed as quickly as possible to minimize the exposure of the metallic sensors to the bleach solution. Perform each priming step in succession.

11. Prepare fresh diluent and wash solution and add to the clean diluent and wash solution bottles. Attach new filters to the diluent and wash line tube ends and put them into each bottle.
12. Repeat Steps 5 and 6 to flush the fresh diluent and wash solutions.
13. Perform a Daily Check prior to running the analyzer.

Tab 6**MAINTENANCE****QUIZ**

1. How often should the diluent and wash lines be cleaned?
 - a. Weekly
 - b. Monthly
 - c. Every 6 months

2. What maintenance procedures should be performed if a HB flag occurs?
 - a. Daily Check
 - b. Shutdown
 - c. 6-month maintenance
 - d. Weekly

Tab 7**SPECIFICATION ADJUSTMENT PROCEDURE****LEARNING OBJECTIVES**

At the conclusion of this module, the participant will be able to:

- Start the instrument in TEST MODE
- Access the TEST FILE
- Adjust the Assay Specifications

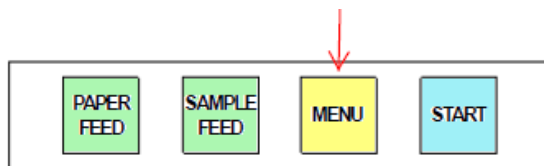
Tab 7

SPECIFICATION ADJUSTMENT PROCEDURE

The assay test files may need to be adjusted to meet U.S. requirements or to add additional analytes. Carefully follow the directions below to perform these modifications or additions.

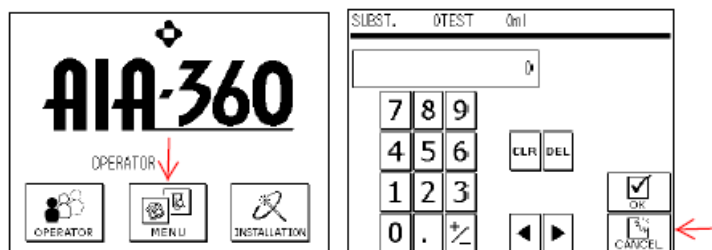
1. **Before beginning, be sure you have these instructions and the AIA-360 Assay Specifications Sheet printed and easily accessible.**

While the AIA-360 is turned off, hold down the **MENU** key on the keypad (located below the touch screen) and then turn on the power to the instrument. Continue to hold down the MENU key until the words TEST MODE appear in the upper right of the screen. This will put the instrument in TEST MODE.

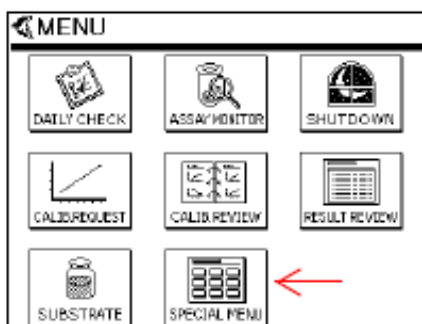


(Menu key on the keypad)

2. After a second beep sound (within 5 - 10 seconds), the opening screen will be shown. Press **MENU** on the touch screen. The screen will display the substrate input screen. Press **CANCEL**. The instrument will begin initialization. This will take approximately 30 seconds.



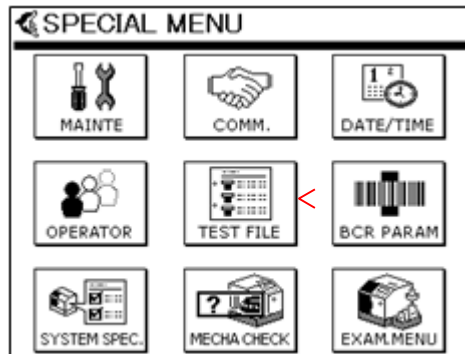
3. After the initialization is complete, press **SPECIAL MENU** on the **MENU** screen.



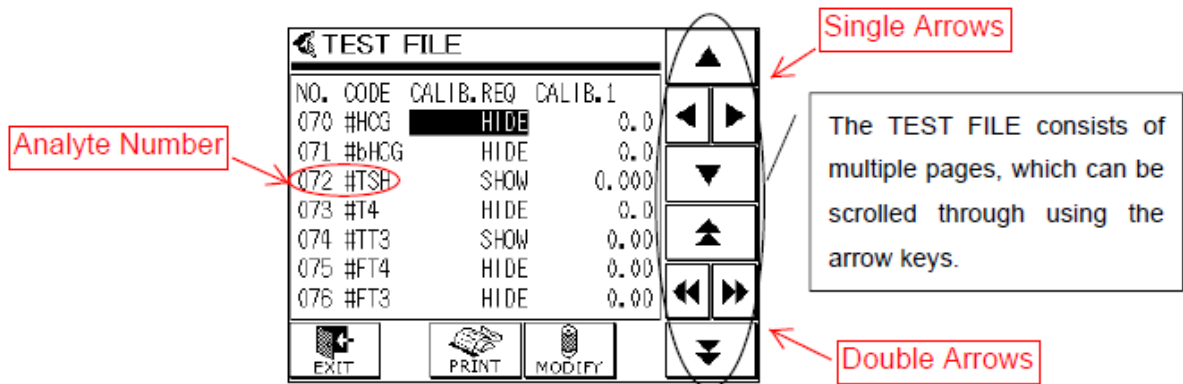
Tab 7

SPECIFICATION ADJUSTMENT PROCEDURE

4. Press **TEST FILE** on the **SPECIAL MENU** screen.



5. Using the arrows on the keypad, scroll to the analyte number of the test being added. Refer to the AIA-360 Assay Specifications Sheet. Single arrows will scroll line by line and double arrows will scroll page by page.



6. After locating the analyte number that corresponds with the assay specification sheet, press **MODIFY** to change from **HIDE** to **SHOW** to activate the analyte.

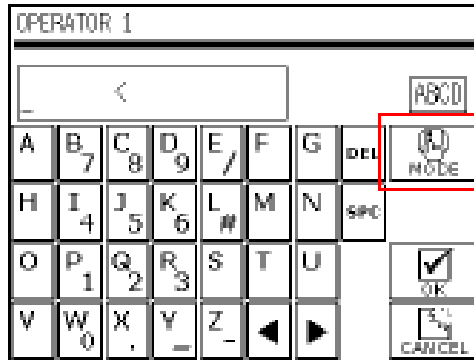
Note: The Test File screen may not appear as shown in the image in step 5. The analyte code may also need to be updated.

7. Use the right **single** arrow key to move to the next parameter to be updated. Use the AIA-360 Assay Specifications Sheet.
8. To change the parameter setting, press **MODIFY**. Press **CLR** to delete the current value. Enter the new value from the AIA-360 Assay Specifications Sheet. Press **OK** to confirm changes.
9. Repeat steps 7 and 8 for each parameter specification adjustment. Continue to use the **single** right arrow key to scroll right until all of the parameters on the AIA-360 Assay Specifications Sheet are updated.




Tab 7

SPECIFICATION ADJUSTMENT PROCEDURE

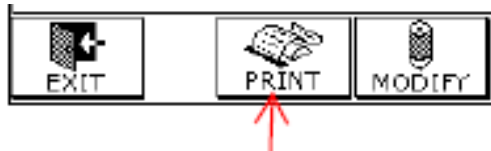
Note: For some parameters, lower case letters and special symbols are required. Use **MODE** to switch between capital letters, lower case letters and numbers. For special symbols use the numbers' mode.



Pressing the  icon displays the following content.

 Alphabet (uppercase)  Alphabet (lowercase)
 Numerals

10. For assays requiring a dilution (27.29, Cystatin C and SHBG), enter the dilution factor in the **FACTOR 2 A** column to automatically multiply the patient and control results. Enter **21** for 27.29, **25** for Cystatin C and **20** for SHBG.
11. After all parameters are updated; press **PRINT** to print the test file. Save the printout for your records.



12. Press **EXIT** to return to the **SPECIAL MENU** screen to save any changes.
13. Power the system off and on to return to the regular mode.

Important: Changes made to the instrument test file may also need to be made to your LIS system. Check with your LIS vendor to determine if this is necessary. Please consult Tosoh Technical Support at 800-248-6764 for more information on specification adjustment.

Tab 7

SPECIFICATION ADJUSTMENT PROCEDURE

U.S. Assay Specifications for Analytes Available on the AIA-360

Test Code	Analyte	Sample Volume*	Assay L	Assay H
91	ST 27.29	20 µl**	0.1	19.1 U/mL
106	ST ACTH	50 µl	2.0	2000 pg/mL
14	ST AFP	25 µl	1.0	400 ng/mL
71	ST BHCG	50 µl	0.5	400 mIU/mL
65	ST BMG	15 µl**	0.002	0.4 mg/L
26	ST CA125	100 µl	2.0	1000 U/mL
15	ST CA19-9	50 µl	1.0	400 U/mL
06	ST CEA	100 µl	0.5	100 ng/mL
78	ST CKMB	50 µl	0.5	500 ng/mL
67	ST CORT	10 µl	0.2	60 µg/dL
40	ST CPEP II	10 µl	0.04	30 ng/mL
102	ST CysC	10 µl**	0.004	0.32 mg/L
79	ST DHEA-S	10 µl	2.0	1000 ug/dL
29	ST E2	75 µl	25	3000 pg/mL
64	ST FER	20 µl	3.0	1000 ng/mL
68	ST FSH	50 µl	1.0	200 mIU/mL
76	ST FT3	50 µl	0.5	25 pg/mL
75	ST FT4	10 µl	0.1	8 ng/mL
97	ST HCY	10 µl***	0.5	50 µmol/L
66	ST HGH	75 µl	0.07	45 ng/mL
77	ST IgE II	10 µl	3.0	4000 IU/mL
58	ST IRI	50 µl	0.5	320 µU/mL
39	ST LH II	40 µl	0.2	200 mIU/mL
96	ST MYO	10 µl	2.0	1000 ng/mL
28	ST PA	20 µl	0.05	100 ng/mL
27	ST PAP	75 µl	0.2	40 ng/mL
41	ST PRL	30 µl	1.0	200 ng/mL
127	ST PR-2	75 µl	0.1	40 ng/mL
123	ST PR-3	30 µl	0.1	40 ng/mL
52	ST iPTH	75 µl	1.0	2000 pg/mL
124	ST SHBG	15 µl**	0.01	12.5 nmol/L
73	ST T4	10 µl	0.5	24 µg/dL
24	ST TES	85 µl	10	2200 ng/dL
72	ST TSH	100 µl	0.03	100 µIU/mL
74	ST TT3	25 µl	0.2	8 ng/mL
20	ST TU	10 µl	10	60 tu
93	ST cTnl 2	50 µl	0.06	115 ng/mL

All analytes available on the AIA-360 have a 90-day calibration stability, except Troponin I which is 30 days.

*Test file volume.

** See Manual Procedures for dilution volume and protocol.

***See Manual Procedures for pretreatment volume and protocol.

Tab 7

SPECIFICATION ADJUSTMENT PROCEDURE

**QUIZ**

1. Which key is held down to start the instrument in TEST MODE?
2. What is the assay high for AFP?
3. What is the assay low for FT4?
4. What is the assay high for cTnl2?
5. Assay results requiring manual dilution will automatically be multiplied by the correct dilution factor.

True

False

Tab 8**TROUBLESHOOTING****LEARNING OBJECTIVES**

At the conclusion of this module, the participant will be able to:

- Troubleshoot problems on the AIA-360

Always call Tosoh Technical Support to report a problem

Phone: 800-248-6764

Fax: 877-898-9883

Have the following information ready before your call:

1. Account Number
2. Account Name
3. Serial Number of the Instrument
4. Lot Number of the Reagents
5. Daily Check print-out
6. Control values

Tab 8

TROUBLESHOOTING

Result and Error Flags

The various types of error flags listed in the table below are assigned to assay results to indicate the type of error that has occurred.

Flag	Description	Rate	Result
SE	System Error	No	No
ME	Matching Error	No	No
AE	Test Code Detection Error	No	No
NB	Seal Break Failure	No	No
WU	Washing Incomplete	No	No
WS	Wash Shortage	No	No
BS	Substrate Shortage	No	No
SS	Short Sample	No	No
SC	Sample Clog Detected	No	No
LE	Lot Detection Error	No	No
DO	Detector Over Range	No	No
IM	Specimen ID Mismatch	No	No
DS	Diluent Solution Shortage	No	No
SP	Sampling Prevented	No	No
MF	Mechanical Failure	No	No
NC	No Calibration	Yes	No
CE	Calculation Error	Yes	No
<L	Lower Than Assay Range	Yes	No
>H	Higher Than Assay Range	Yes	No
DL	Lamp Intensity Low	Yes	No
IO	Temperature Over Range	Yes	Yes
HB	High Substrate Background	Yes	Yes
CV	Calibration Void	Yes	Yes
MA	Test Cup Matching Error	Yes	Yes
L	Lower Than Reference Range	Yes	Yes
H	Higher Than Reference Range	Yes	Yes
LL	Lamp Low	Yes	Yes

Tab 8

TROUBLESHOOTING

Flag Definitions and Corrective Measures

Flag	Definition	Cause	Resolution
SE	System error	Test run aborted due to mechanical malfunction, power loss, or operator intervention	Note specific error message. Contact Tosoh Technical Support
ME	Matching error	Analyte error	Check reagent cup. Only short-time (ST) assays can be run on the AIA-360
AE	Analyte error	Analyzer unable read test cup dot pattern	Repeat test, make sure test cup foil is dry and unwrinkled
SP	Sampling prevented	Specimen processing interrupted	Repeat test. Check diluent and wash solution supply
NB	No break	Test cup seal not punctured	Repeat test
WU	Wash unsuccessful	Poor B/F probe dispense or wash aspiration	B/F probe may be dirty or clogged. Contact Tosoh Technical Support
WS	Wash shortage	1. Shortage of wash solution 2. Level sensor wires loose 3. Wash concentrate not properly diluted	1. Refill wash reservoir 2. Reconnect sensor wires 3. Make fresh wash solution
BS	Substrate shortage	Shortage of Substrate	Replenish Substrate and update volume on Substrate screen
SS	Short sample	Shortage of sample detected	Repeat test with adequate sample volume. Sample should be free of bubbles
SC	Sample clot	Sample clot detected by sample probe	Repeat test with fresh fibrin free sample
LE	Lot error	Analyzer unable to read lot number dot pattern	Repeat test, make sure test cup foil is dry and unwrinkled
DO	Detector over range	Very high concentration of an analyte in a sample	Repeat test using an appropriate dilution
IM	Specimen ID mismatch	Mismatch between a requested specimen ID and read specimen ID by the internal barcode reader	Repeat assay after checking the barcode label and sample order
DS	Diluent Solution Shortage	Indicates inability to conduct assay operation due to diluent shortage	Replenish diluent
SP	Waste Bottle Full	Indicates inability to conduct assay operation due to waste full	Empty the waste bottle
MF	Mechanical Failure while sampling	Indicate mechanical failure while sampling	Check for other error codes while sampling. Contact Tosoh Technical Support
NC	No calibration	1. Test cup lot not calibrated 2. Calibration not accepted 3. Calibration is void beyond 60 days of expiration of the curve.	1. Calibrate test cup lot being used 2. Accept calibration in Calibration Review screen. Recalculate results in Result Review screen

Tab 8

TROUBLESHOOTING

Flag	Definition	Cause	Resolution
CE	Calculation error	Assay rate is less than the rate of the lowest calibrator	1. If a single result, repeat test. Obtain new specimen if possible 2. If multiple results, contact Tosoh Technical Support
<L	Less than low	Result less than assay range	Review result
>H	Greater than high	Result higher than assay range	Repeat test using an appropriate dilution
DL	Detector low	1. Out of substrate, or running with cleaning solution 2. Low detector lamp intensity	1. Replenish substrate, perform Daily Check 2. Contact Tosoh Technical Support
IO	Temperature error	Temperature exceeded acceptable range	Contact Tosoh Technical Support if problem persists
HB	High background	Abnormally high background due to substrate separation	1. Repeat Daily Check with freshly reconstituted substrate 2. Substrate lines may be dirty. Contact Tosoh Technical Support
CV	Calibration void	1. Valid calibration period of 30 or 90 days expired 2. This flag will appear for 60 days after the curve has expired.	Recalibrate, accept curve, and then recalculate results in Result Review
MA	Matching error	Analyte error	Check reagent cup. Only short-time (ST) assays can be run on the AIA-360
L	Low result	Result lower than reference range	Review result
H	High result	Result higher than reference range	Review result
LL	Lamp Low	Indicates intensity of Detector lamp. If sufficient: OK If insufficient: LL	Run Daily Check Contact Tosoh Technical Support

Tab 8

TROUBLESHOOTING

Analyzer Error Codes

All analyzer error code numbers are associated with a particular system, operation, or communication function.

An error number, problem, problem cause, and possible problem solution will be displayed whenever an error occurs.

Error codes which suggest solutions beyond the scope of the operator should be referred to Tosoh Technical Support.

When an error occurs, an audible alarm will sound, and the error message will be displayed on the screen and output to the printer. The operator should take appropriate action and press OK on the screen.

When an assay is started soon after turning the power switch on, if the incubator has not reached the appropriate temperature, Error Message No. 3003 is displayed, and the assay may not be started.

No.	Error Message	Meaning	Troubleshooting
3003	WAITING FOR TEMPERATURE	Waiting for the temperature to rise.	Wait until the temperature rises to correct temperature.

If one of Error Messages No. 3017 to 3020 is displayed, the assay is suspended. If a reaction is in progress, however, the assay continues. Take the appropriate action in accordance with the displayed message and restart the assay. After all the ongoing assays end, perform the corresponding troubleshooting and press the START key to restart assays.

No.	Error Message	Meaning	Troubleshooting
3017	SUBSTRATE LOW	Insufficient substrate.	After confirming that 'ASSAY' displayed on the upper right of the ASSAY MONITOR screen changes to 'STOP', replace the enzyme substrate with new one and press the START key to restart assay operation.
3018	WASTE TANK FULL	The waste tank is full.	After confirming that 'ASSAY' displayed on the upper right of the ASSAY MONITOR screen changes to 'STOP', empty the waste tank and press the START key to restart assay operation.
3019	WASHER LOW	Insufficient wash solution.	After confirming that 'ASSAY' displayed on the upper right of the ASSAY MONITOR screen changes to 'STOP', replace the wash solution with new one and press the START key to restart assay operation.
3020	DILUENT LOW	Insufficient diluent.	After confirming that 'ASSAY' displayed on the upper right of the ASSAY MONITOR screen changes to 'STOP', replace the diluent with new one and press the START key to restart assay operation

Tab 8

TROUBLESHOOTING

Operating Errors

No.	Error message	Description	Troubleshooting
0001	FILE SYSTEM ERROR	The external recording medium could not be initialized.	Use other media or contact Tosoh local representative.
0002	MAIN PROGRAM OPEN ERROR	The main program cannot be read.	Use other media or contact Tosoh local representative.
0003	MAIN PROGRAM FORMAT ERROR	The file format of the main program is incorrect.	Use other media or contact Tosoh local representative.
0004	SLAVE PROGRAM OPEN ERROR	The slave program cannot be read.	Use other media or contact Tosoh local representative.
0005	SLAVE PROGRAM FORMAT ERROR	The file format of the slave program is incorrect.	Use other media or contact Tosoh local representative.
0006	TOUCH PANEL PROGRAM OPEN ERROR	The touch panel program cannot be read.	Use other media or contact Tosoh local representative.
0007	INSTALLATION OPEN ERROR	The image data cannot be read.	Use other media or contact Tosoh local representative.
0008	INSTALLATION FORMAT ERROR	The format of the image data file is incorrect.	Use other media or contact Tosoh local representative.
0009	INSUFFICIENT STANDARD CUP	No standard cup is loaded for the daily check.	Load a standard cup on reagent cup holder No.1 and repeat.
0010	TWO CALIBRATION CURVES CONFIRMED	Calibration curves of two lots have already been confirmed.	Delete a calibration curve before accept a new one.
0011	SAME LOT CALIBRATION CURVE	Calibration curves have already been confirmed for the same lot.	Delete the old calibration curve before accept a new one.
0012	CALIBRATION NOT ENOUGH	There is insufficient data to calculate calibration curves.	Repeat the calibration.
0013	CALCULATION ERROR	Calculation error of the calibration curve.	Repeat the calibration.
0014	CALIBRATION DATA ZIGZAG	The calibration curve rates are not in ascending order.	Repeat the calibration.
0015	TOO MANY CALIBRATION DATA	The calibration curve data is abnormal.	Repeat the calibration.
0016	CALIBRATION DATA MINUS RATE	Logarithm calculation of calibration curve failed.	Repeat the calibration.
0017	TOMAS DATA WRITE ERROR	Unable to write external recording medium.	Use other media or contact Tosoh local representative.

Tab 8

TROUBLESHOOTING

Communication-related errors

No.	Error message	Description	Troubleshooting
1001	UNABLE TO SEND TO SLAVE	FIFO has become full during transmission to the slave.	Turn the power off and on again. If this problem reoccurs, contact Tosoh local representative.
1002	UNABLE TO RECEIVE FROM SLAVE	A communication error occurred during transmission to the slave.	Turn the power off and on again. If this problem reoccurs, contact Tosoh local representative.
1003	RECEIVE DATA ERROR FROM T.PANEL	A communication error occurred during reception from the touch panel.	Turn the power off and on again. If this problem reoccurs, contact Tosoh local representative.
1004	TRANSMISSION TO T.PANEL TIMED OUT	A timeout error occurred during reception from the touch panel.	Turn the power off and on again. If this problem reoccurs, contact Tosoh local representative.
1005	BARCODE ERROR	A barcode communication error occurred.	Turn the power off and on again. If this problem reoccurs, contact Tosoh local representative.
1006	ASTM PARITY ERROR	A parity error occurred in ASTM communication.	Check the communication settings and cable.
1007	ASTM FRAME ERROR	An ASTM communication frame error occurred.	Check the communication settings and cable.
1008	ASTM OVERRUN ERROR	ASTM communication overrun error	Check the communication settings and cable.
1009	ASTM BUFFER FULL	The ASTM communication buffer has become full.	Check the communication settings and cable.
1011	ASTM RETRY ERROR	An ASTM communication retry error occurred.	Check the communication settings and cable.
1012	ASTM SEND TIMEOUT	A send timeout event occurred in ASTM communication.	Check the communication settings and cable.
1013	ASTM RECEIVE TIMEOUT	A receive timeout error occurred in ASTM communication.	Check the communication settings and cable.
1014	ASTM NO RESPONSE	No response was received in ASTM communication.	Check the communication settings and cable.

Tab 8

TROUBLESHOOTING

Control related errors

No.	Error message	Description	Troubleshooting
2001	RTC POWER ON CLEAR	An internal clock backup error occurred.	Reset the date and time. If this problem reoccurs, contact Tosoh local representative.
2002	TESTCUP READ ERROR	The test cup read error occurred.	If this problem reoccurs frequently, contact Tosoh local representative
2003	TESTCUP READ ERROR	The test cup position error occurred at the detector calibration.	Set the test cup to a right position.
2004	DET CALIB. TESTCUP READ ERROR	The test cup read error at the detector calibration.	Set the STD cup to a right position.
2005	DET CALIB. DIVIDE BY ZERO	Data error at the detector calibration.	Check the conditions, Repeat the detector calibration.
2006	DET CALIB. DATA VARIANCE ERROR	Data variance error at the detector calibration.	Check the conditions, Repeat the detector calibration.
2007	DET CALIB. ABNORMAL DAT A	Data abnormal error at the detector calibration.	Check the conditions, Repeat the detector calibration.
2008	DET CALIB. SUBSTRATE HB	The background intensity of substrate is high.	Replace the new substrate
2009	BF PROBE LIQUID SENSOR ERROR	Liquid detection error in BF probe.	Contact Tosoh local representative.
2010	SAMPLE LEVEL FAILURE	A liquid detection open-circuit error occurred at the sample nozzle.	Contact Tosoh local representative.
2011	AIR DETECTED [SAMPLE]	There is no contact with the liquid surface after sample suction.	Contact Tosoh local representative.
2012	AIR DETECTED [DILUENT]	There is no contact with the liquid after diluent suction.	Contact Tosoh local representative.
2013	SAMPLE LEVEL DETECTION ERROR	The liquid surface cannot be detected even at the bottom of the sample cup or the blood sample tube.	Contact Tosoh local representative.
2014	SAMPLE SHORTAGE DETECTED	Insufficient sample.	Prepare enough volume of specimen.
2015	BF PROBE PURGE FAILURE	Purging by the BF probe is abnormal.	Clean up the wash probe tip or replace it. Contact Tosoh local representative.
2016	BFPROBE SUCTION FAILURE	Suction by the BF probe is abnormal.	Contact Tosoh local representative.
2017	SUBSTRATE PURGE FAILURE	The substrate was not purged normally.	Check for insufficient substrate.

Tab 8

TROUBLESHOOTING

Monitor-related errors

No.	Error message	Description	Troubleshooting
3001	PRINTER PAPER END	No paper is loaded in the printer.	Load paper in the printer.
3002	PRINTER HEADUP	The printer head has gone up.	Lower the printer head.
3003	WAITINGFOR TEMPERATUR E	Waiting for the temperature to rise.	Wait until the temperature rises to correct temperature.
3004	TEMPERATURE TIMEOUTED	A timeout error occurred while waiting for the temperature to rise.	Turn the power off and on again. If this problem reoccurs, contact Tosoh local representative.
3005	TURN TABLE TEMPERATURE LOW	The turntable temperature is below the lower limit.	Turn the power off and on again. If this problem reoccurs, contact Tosoh local representative.
3006	WASHER TEMPERATURE LOW	The wash solution temperature is below the lower limit.	Turn the power off and on again. If this problem reoccurs, contact Tosoh local representative.
3007	SUBSTRATE TEMPERATURE LOW	The substrate temperature is below the lower limit.	Turn the power off and on again. If this problem reoccurs, contact Tosoh local representative.
3008	TURN TABLE TEMPERATURE HIGH	The turntable temperature is above the upper limit.	Turn the power off and on again. If this problem reoccurs, contact Tosoh local representative.
3009	WASHER TEMPERATURE HIGH	The wash solution temperature is above the target temp.	Turn the power off and on again. If this problem reoccurs, contact Tosoh local representative.
3010	SUBSTRATE TEMPERATURE HIGH	The substrate temperature is above the upper limit.	Turn the power off and on again. If this problem reoccurs, contact Tosoh local representative.
3011	TURN TABLE TEMP. MALFUNCTION	The turntable temperature sensor disconnection occurred.	Turn the power off and on again. If this problem reoccurs, contact Tosoh local representative.
3012	WASHER TEMP. MALFUNCTION	The wash solution temperature sensor disconnection occurred.	Turn the power off and on again. If this problem reoccurs, contact Tosoh local representative.
3013	SUBSTRATE TEMP. MALFUNCTION	The substrate temperature disconnection error occurred.	Turn the power off and on again. If this problem reoccurs, contact Tosoh local representative.
3014	TURN TABLE TEMP. LIMIT	The turntable temperature is above the upper limit.	Turn the power off and on again. If this problem reoccurs, contact Tosoh local representative.
3015	WASHER TEMP. LIMIT	The wash solution temperature reach the upper limit.	Turn the power off and on again. If this problem reoccurs, contact Tosoh local representative.

Tab 8

TROUBLESHOOTING

Monitor-related errors

No.	Error message	Description	Troubleshooting
3016	SUBSTRATE TEMP. LIMIT	The substrate temperature is above the upper limit.	Turn the power off and on again. If this problem reoccurs, contact Tosoh local representative.
3017	SUBSTRATE LOW	Insufficient substrate.	Replace the enzyme substrate.
3018	WASTE TANK FULL	The waste tank is full.	Empty the waste tank.
3019	WASHER LOW	Insufficient wash solution.	Replenish the wash solution.
3020	DILUENT LOW	Insufficient diluent.	Replenish the diluent.
3021	LEAK SENSOR S701 DETECTED	Leakage sensor S701 activated.	Contact Tosoh local representative.
3022	LEAK SENSOR S702 DETECTED	Leakage sensor S702 activated.	Contact Tosoh local representative.
3023	PM DUE	Periodic Maintenance due.	Contact Tosoh local representative.
3024	PM REQUIRED	Periodic Maintenance is required.	Contact Tosoh local representative.

Actuator-related errors

No.	Error message	Description	Troubleshooting
4001	TURN TABLE HOME SENSOR	The turntable motor home sensor remains activated.	Turn the power off and on again. If this problem reoccurs, contact Tosoh local representative.
4002	TURN TABLE HOME NOT FOUND	The home position of the turntable motor cannot be detected.	Turn the power off and on again. If this problem reoccurs, contact Tosoh local representative.
4003	TURN TABLE HOME OVERRUN	The turntable motor overran on the home side.	Turn the power off and on again. If this problem reoccurs, contact Tosoh local representative.
4004	TURN TABLE SLIP	The turntable motor slipped.	Turn the power off and on again. If this problem reoccurs, contact Tosoh local representative.
4005	TURN TABLE ACCELL	The acceleration/deceleration table of the turntable motor was incorrectly set.	Turn the power off and on again. If this problem reoccurs, contact Tosoh local representative.
4006	TURN TABLE S106	The turntable anti-rotation sensor is activated.	Check that the blood sample tube is in contact with the sensor.
4007	MIXER HOME SENSOR	The mixer motor home sensor remains activated.	Turn the power off and on again. If this problem reoccurs, contact Tosoh local representative.
4008	MIXER HOME NOT FOUND	The home position of the mixer motor cannot be detected.	Turn the power off and on again. If this problem reoccurs, contact Tosoh local representative.

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TROUBLESHOOTING

Actuator-related errors

No.	Error message	Description	Troubleshooting
4009	MIXER HOME OVERRUN	The mixer motor overran on the home side.	Turn the power off and on again. If this problem reoccurs, contact Tosoh local representative.
4010	MIXER SLIP	The mixer motor slipped.	Turn the power off and on again. If this problem reoccurs, contact Tosoh local representative.
4011	MIXER ACCELL	The acceleration/deceleration table of the mixer motor was incorrectly set.	Turn the power off and on again. If this problem reoccurs, contact Tosoh local representative.
4012	SPEC.SY HOME SENSOR	The specimen syringe motor home sensor remains activated.	Turn the power off and on again. If this problem reoccurs, contact Tosoh local representative.
4013	SPEC.SY HOME NOT FOUND	The home position of the specimen syringe motor cannot be detected.	Turn the power off and on again. If this problem reoccurs, contact Tosoh local representative.
4014	SPEC.SY HOME OVERRUN	The specimen syringe motor overran on the home side.	Turn the power off and on again. If this problem reoccurs, contact Tosoh local representative.
4016	SPEC.SY ACCELL	The acceleration/deceleration table of specimen syringe motor was incorrectly set.	Turn the power off and on again. If this problem reoccurs, contact Tosoh local representative.
4017	SPEC.SY CLOG DETECTED	Specimen clog was detected.	The item is not assayed. Repeat assay.
4018	SPEC.Z-AXIS HOME SENSOR	The specimen Z-axis motor home sensor remains activated.	Turn the power off and on again. If this problem reoccurs, contact Tosoh local representative.
4019	SPEC.Z-AXIS HOME NOT FOUND	The home position of the specimen Z-axis motor cannot be detected.	Turn the power off and on again. If this problem reoccurs, contact Tosoh local representative.
4020	SPEC.Z-AXIS HOME OVERRUN	The specimen Z-axis motor overran on the home side.	Turn the power off and on again. If this problem reoccurs, contact Tosoh local representative.
4022	SPEC.Z-AXIS ACCELL	The acceleration/deceleration table of the specimen Z-axis motor was incorrectly set.	Turn the power off and on again. If this problem reoccurs, contact Tosoh local representative.
4023	SPEC.R-AXIS HOME SENSOR	The specimen R-axis motor home sensor remains activated.	Turn the power off and on again. If this problem reoccurs, contact Tosoh local representative.
4024	SPEC.R-AXIS HOME NOT FOUND	The home position of the specimen R-axis motor cannot be detected.	Turn the power off and on again. If this problem reoccurs, contact Tosoh local representative.
4025	SPEC.R-AXIS HOME OVERRUN	The specimen R-axis motor overran on the home side.	Turn the power off and on again. If this problem reoccurs, contact Tosoh local representative.

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TROUBLESHOOTING

Actuator-related errors

No.	Error message	Description	Troubleshooting
4027	SPEC.R-AXIS ACCELL	The acceleration/deceleration table of the specimen R-axis motor was incorrectly set.	Turn the power off and on again. If this problem reoccurs, contact Tosoh local representative.
4028	SPEC.T-AXIS HOME SENSOR	The specimen θ -axis motor home sensor remains activated.	Turn the power off and on again. If this problem reoccurs, contact Tosoh local representative.
4029	SPEC.T-AXIS HOME NOT FOUND	The home position of the specimen θ -axis motor cannot be detected.	Turn the power off and on again. If this problem reoccurs, contact Tosoh local representative.
4030	SPEC.T-AXIS HOME OVERRUN	The specimen θ -axis motor overran on the home side.	Turn the power off and on again. If this problem reoccurs, contact Tosoh local representative.
4032	SPEC.T-AXIS ACCELL	The acceleration/deceleration table of the specimen θ -axis motor was incorrectly set.	Turn the power off and on again. If this problem reoccurs, contact Tosoh local representative.
4033	SEAL BREAK HOME SENSOR	The seal breaker motor home sensor remains activated.	Turn the power off and on again. If this problem reoccurs, contact Tosoh local representative.
4034	SEAL BREAK HOME NOT FOUND	The home position of the seal breaker motor cannot be detected.	Turn the power off and on again. If this problem reoccurs, contact Tosoh local representative.
4035	SEAL BREAK HOME OVERRUN	The seal breaker motor overran on the home side.	Turn the power off and on again. If this problem reoccurs, contact Tosoh local representative.
4037	SEAL BREAK ACCELL	The acceleration/deceleration table of the seal breaker motor was incorrectly set.	Turn the power off and on again. If this problem reoccurs, contact Tosoh local representative.
4038	WASH.PROBE HOME SENSOR	The BF probe motor home sensor remains activated.	Turn the power off and on again. If this problem reoccurs, contact Tosoh local representative.
4039	WASH.PROBE HOME NOT FOUND	The home position of the BF probe motor cannot be detected.	Turn the power off and on again. If this problem reoccurs, contact Tosoh local representative.
4040	WASH.PROBE HOME OVERRUN	The BF probe motor overran on the home side.	Turn the power off and on again. If this problem reoccurs, contact Tosoh local representative.
4042	WASH.PROBE ACCELL	The acceleration/deceleration table of the BF probe motor was incorrectly set.	Turn the power off and on again. If this problem reoccurs, contact Tosoh local representative.
4043	WASH.SY HOME SENSOR	The BF syringe motor home sensor remains activated.	Turn the power off and on again. If this problem reoccurs, contact Tosoh local representative.

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TROUBLESHOOTING

Actuator-related errors

No.	Error message	Description	Troubleshooting
4044	WASH.SY HOME NOT FOUND	The BF syringe motor home position cannot be detected.	Turn the power off and on again. If this problem reoccurs, contact Tosoh local representative.
4045	WASH.SY HOME OVERRUN	The BF syringe motor overran on the home side.	Turn the power off and on again. If this problem reoccurs, contact Tosoh local representative.
4047	WASH.SY ACCELL	The acceleration/deceleration table of the BF syringe motor was incorrectly set.	Turn the power off and on again. If this problem reoccurs, contact Tosoh local representative.
4048	SUBST.SY HOME SENSOR	The substrate syringe motor home sensor remains activated.	Turn the power off and on again. If this problem reoccurs, contact Tosoh local representative.
4049	SUBST.S HOME NOT Y FOUND	The substrate syringe motor home position cannot be detected.	Turn the power off and on again. If this problem reoccurs, contact Tosoh local representative.
4050	SUBST.SY HOME OVERRUN	The substrate syringe motor overran on the home side.	Turn the power off and on again. If this problem reoccurs, contact Tosoh local representative.
4052	SUBST.SY ACCELL	The acceleration/deceleration table of the substrate syringe motor was incorrectly set.	Turn the power off and on again. If this problem reoccurs, contact Tosoh local representative.
4053	SEAL BREAK POS. SENSOR	The seal breaking position sensor is faulty.	Turn the power off and on again. If this problem reoccurs, contact Tosoh local representative.

Tab 8

TROUBLESHOOTING

System-related errors

No.	Error message	Description	Troubleshooting
5001	INTERNAL ERROR	Internal program error.	Turn the power off and on again. If this problem reoccurs, contact Tosoh local representative.
5002	NO RESPONSE FROM SLAVE	Slave response not detected error.	Turn the power off and on again. If this problem reoccurs, contact Tosoh local representative.
5003	SLAVE COMMAND ERROR	Slave command error.	Turn the power off and on again. If this problem reoccurs, contact Tosoh local representative.
5004	SLAVE FIFO ERROR	Slave FIFO error.	Turn the power off and on again. If this problem reoccurs, contact Tosoh local representative.
5005	MAIN PROGRAM ERASE TIMED OUT	Main program erase timeout.	Turn the power off and on again. If this problem reoccurs, contact Tosoh local representative.
5006	MAIN PROGRAM WRITE ERROR	Main program write error.	Turn the power off and on again. If this problem reoccurs, contact Tosoh local representative.
5007	MAIN PROGRAM COMPARE ERROR	Main program compare error.	Turn the power off and on again. If this problem reoccurs, contact Tosoh local representative.
5008	MAIN PROGRAM NOT INSTALLED	Main program not found.	Contact Tosoh local representative.
5009	SLAVE PROGRAM ERASE TIMED OUT	Slave program erase timeout.	Turn the power off and on again. If this problem reoccurs, contact Tosoh local representative.
5010	SLAVE PROGRAM WRITE ERROR	Slave program write error.	Turn the power off and on again. If this problem reoccurs, contact Tosoh local representative.
5011	SLAVE PROGRAM COMPARE ERROR	Slave program compare error.	Turn the power off and on again. If this problem reoccurs, contact Tosoh local representative.
5012	SLAVE PROGRAM NOT INSTALLED	Slave program not found.	Contact Tosoh local representative.
5013	INSTALLATION ERASE TIMED OUT	Image data erase timeout.	Turn the power off and on again. If this problem reoccurs, contact Tosoh local representative.
5014	INSTALLATION WRITE ERROR	Image data write error.	Turn the power off and on again. If this problem reoccurs, contact Tosoh local representative.
5015	INSTALLATION COMPARE ERROR	Image data compare error.	Turn the power off and on again. If this problem reoccurs, contact Tosoh local representative.
5016	INSTALLATION NOT INSTALLED	Image data not found.	Contact Tosoh local representative.

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TROUBLESHOOTING

System-related errors

No.	Error message	Description	Troubleshooting
5017	PRINTER HARD ERROR	Printer hardware error.	Turn the power off and on again. If this problem reoccurs, contact Tosoh local representative.
5018	ASSAY ABORTED	Measurement terminated.	Repeat assay.
5019	DETECTOR CALIB. ABORTED	Detector calibration aborted.	Check the conditions, Repeat the detector calibration.
5020	DETECTOR TASK ERROR	Detector calibration task execution error.	Turn the power off and on again. If this problem reoccurs, contact Tosoh local representative.
5021	TURNTABLE TASK ERROR	Turntable task execution error.	Turn the power off and on again. If this problem reoccurs, contact Tosoh local representative.
5022	SPECIMEN TASK ERROR	Specimen arm task execution error.	Turn the power off and on again. Send the printed error report to Tosoh local representative.
5023	SEALBREAK TASK ERROR	Seal break task execution error.	Turn the power off and on again. If this problem reoccurs, contact Tosoh local representative.
5024	CCD TASK ERROR	Cup read task execution error.	Turn the power off and on again. If this problem reoccurs, contact Tosoh local representative.
5025	SUBTRATE TASK ERROR	Substrate task execution error.	Turn the power off and on again. If this problem reoccurs, contact Tosoh local representative.
5026	WASHER TASK ERROR	BF washing task execution error.	Turn the power off and on again. If this problem reoccurs, contact Tosoh local representative.
5027	DRAIN TASK ERROR	Drain task execution error.	Turn the power off and on again. If this problem reoccurs, contact Tosoh local representative.
5029	CSUM ERROR (PARAM)	Control parameter checksum error.	Turn the power off and on again and check the parameters. If this problem reoccurs, contact Tosoh local representative.
5030	CSUM ERROR (REAGENT)	Test file checksum error.	Turn the power off and on again and check the test file and calibration curve. If this problem reoccurs, contact Tosoh local representative.

Tab 8
TROUBLESHOOTING***System-related errors***

No.	Error message	Description	Troubleshooting
5031	CSUM ERROR (RESULT)	Assay result checksum error.	Turn the power off and on again. If this problem reoccurs, contact Tosoh local representative.
5032	CSUM ERROR (ERRLOG)	Error log checksum error.	Turn the power off and on again. If this problem reoccurs, contact Tosoh local representative.
5033	CSUM ERROR (OPERATION LIST)	Operation log checksum error.	Turn the power off and on again. If this problem reoccurs, contact Tosoh local representative.
5034	TESTFILE FLASH COMPARE ERROR	Test file data write compare error.	Turn the power off and on again. If this problem reoccurs, contact Tosoh local representative.
5035	MUTEX LOCK UNLOCK ERROR	Control variable acquisition error for sample dispensing task.	Send the printed error report to Tosoh local representative.

Tab 8**TROUBLESHOOTING****QUIZ**

1. What is the hotline number for Tosoh Technical Support?
2. What will you do in the event of a 2016 error?
3. What will you do when you see a HB flag?
4. What will you do if you see a 3021 error?

Tab 9

MANUAL PROCEDURES

This section contains manual dilution protocols and Homocysteine pretreatment instructions.

Tab 9

MANUAL PROCEDURES

Tosoh AIA-360 Manual Dilution Protocol**Recommended Protocol for Results >H**

Add the volume of sample and sample diluting solution (SDS) to a sample cup and mix well. Ensure there are no air bubbles on the surface of the liquid.

Dilution	Sample Volume	SDS Volume
1:5	50 µL	200 µL
1:10	50 µL	450 µL
1:20	20 µL	380 µL
1:25	10 µL	240 µL
1:50	10 µL	490 µL
1:100	20 µL of a 1:5	380 µL
1:250	50 µL of a 1:50	200 µL

Suggested dilutions for BHCG

Gestational Age	mIU/mL	Dilution
1 week	5-50	None
2 weeks	40-1,000	1:5
3 weeks	100-5,000	1:20
4 weeks	600-10,000	1:25
5-6 weeks	1,500-100,000	1:50 1:250

Recommended Protocol for ST 27.29, ST BMG, ST CysC and ST SHBG

Analyte	Dilution	Sample Volume	SDS Volume
ST 27.29	1:21	10 µL	200 µL
ST BMG	1:51	10 µL	500 µL
ST CysC	1:25	10 µL	240 µL
ST SHBG	1:20	10 µL	190 µL

NOTE: Specimens may be diluted further if the original dilution yields a value of >H (see example below).

Example: 1:21 dilution is >H for ST 27.29 (further dilution using 1:5):

Use 50 µL of the 1:21 dilution for sample volume.

Use 200 µL of SDS.

The final dilution factor is calculated as follows:

21 (original factor) multiplied by 5 (2nd dilution factor) = 105 (final dilution factor to be used in result calculation)

When manually calculating results, remember to multiply all final results by the correct dilution factor.

If you would like the analyzer to automatically apply the dilution factor, see the Specification Adjustment Procedure (this procedure is only applicable if you are running one sample type for BMG).

Tab 9**MANUAL PROCEDURES****ST Homocysteine Pretreatment Instructions**

All samples (calibrators, controls, plasma and serum) require pretreatment prior to assaying on the AIA-360.

1. Bring all pretreatment reagents to 18-25°C.
2. Using a volumetric pipette or a calibrated adjustable pipette, reconstitute the lyophilized ST AIA-PACK Homocysteine Pretreatment-1 with 5mL of the ST AIA-PACK Homocysteine Pretreatment-2. Allow the material to fully dissolve.
3. Pipette 200µL of the reconstituted Pretreatment-1 into a disposable tube.
4. Pipette 40µL of the sample (calibrator, control, plasma or serum) into each tube.
5. Cover the tubes and mix well using a vortex mixer.
6. Incubate the sample for 30 minutes at 18-25°C.
7. Transfer all of the pretreated samples into sample cups.
8. Place the sample cups on the instrument with the HCY test cups.
Note: The pretreated samples should be assayed within 2 hours after completion of the pretreatment procedure. The pretreated samples should not be stored frozen.
9. Press Start.

The AIA-PACK Homocysteine Control Set is provided ready for use. The control set is stable until the expiration date on the label when stored at 2-8°C. Once opened the AIA-PACK Homocysteine Control Set is stable for 14 days at 2-8°C.

This section contains the following items:

- CLIA/COLA FAQs
- Barcode Specifications
- Record Keeping Forms
- AIA-360 Maintenance Log
- Analyte Summary Sheets
- List of Supplies/Parts
- Training Evaluation
- Training Checklist
- Quiz answers

Tab 10

MISCELLANEOUS

CLIA/COLA FAQs

1. What is the protocol for Method Validations Studies?

The three performance tests listed below are required for CLIA compliance. Each laboratory has to establish its own protocol to comply with CLIA/COLA regulations.

Section 493.1253 Standard: Establishment and verification of performance specifications.

Each laboratory that introduces an unmodified, FDA cleared, or approved test system must do the following before reporting patient test results:

- i) Demonstrate that it can obtain performance specifications comparable to those established by the manufacturer for the following performance characteristics:
 - a. Accuracy
 - b. Precision
 - c. Reportable range of test results for the test system.
- ii) Verify that the manufacturer's reference intervals (normal values) are appropriate for the laboratory's patient population.

2. How does the user satisfy the requirements for testing accuracy?

In order to satisfy the requirements for accuracy, the user needs to calibrate the assay he/she plans to run and run two levels of commercially available control samples.

1. Calibrate the assays that are going to be run. Refer to the calibration section of the Quick Reference Guide to obtain a detailed description of how to order and load the calibration material. The calibration curves will be necessary to determine the results for the control material and patient samples. After the calibration curves have been accepted, proceed to the next step.
2. Run all levels of the appropriate control material with the appropriate test cups. Press MENU on the keypad. Press ASSAY MONITOR, load the samples onto the carousel and press START. When analysis is complete, verify the results with the ranges on the package insert. If one or more control sample value(s) is out of range, it is necessary to investigate the validity of the calibration curve before reporting patient results.

3. How often should controls be assayed?

In order to monitor and evaluate the accuracy of the analytical performance, it is recommended that two levels of commercially available control samples be assayed daily. If one or more control sample value(s) is out of range, it is necessary to investigate the validity of the calibration curve before reporting patient results. Laboratories with multiple shifts may assay controls during every shift depending on the laboratory protocol.

CLIA/COLA FAQs**4. What is precision and how can the user check for precision?**

Precision is the reproducibility of an assay and is measured by running a specimen multiple times. Precision can be checked at a single level or across several levels. Each laboratory should establish its own protocol for verifying precision. The criterion used by Tosoh Bioscience, Inc. for reproducibility (%CV) is 10%.

The specimens used to determine assay precision must be similar to routine patient specimens. To verify the manufacturer's claim, specimens should have values that are within the stated linear range on the analyte specification sheet.

Coefficient of variation is calculated using the following equation:

$$CV = (SD) (100) \div \text{Mean}$$

The %CV is dependent upon the sample concentration and is inversely proportional to the concentration. If the sample concentration is high, then the %CV can be low. If the sample concentration is low, then the %CV can be high.

For inter-run precision, it is recommended by CLSI that a minimum of 20 operating days is necessary to properly reflect the true precision of the instrument.

5. How many points are required to complete a precision study?

The objective of the precision study is to verify the manufacturer's claim for performance characteristics of the assay. Each laboratory has to establish its own protocol for the precision study. Precision studies can be performed using a control material or pooled specimens.

Intra-assay precision can be checked by assaying the control or specimen material multiple times (e.g. 20 times) in the same run. Compare the %CVs with the manufacturer's claim. Each laboratory should use its own protocol (e.g. Lab X may assay control material 8 times and calculate the CV while Lab Y may assay the serum specimen 10 times to calculate the %CV).

Inter-assay precision can be checked by assaying the control or specimen material for several days (20 days recommended by CLSI). For example, Lab. X may calculate the Inter-assay precision using control values over 7 days while Lab Y may assay a serum specimen for 10 days and calculate the %CV.

6. Can the laboratory use the manufacturer's reference range?

It is recommended by CLIA/COLA regulations that each laboratory verifies the manufacturer's reference range by performing its own reference range study.

Reference range is dependent on patient demographics. Each laboratory should establish a reference range suited to its patient population.

Tab 10

MISCELLANEOUS

CLIA/COLA FAQs

7. What is Reportable Range?

Reportable range studies are required by CLIA regulations to substantiate the accuracy of the assay throughout the laboratory's reportable range. This study requires analysis of at least two replicates of two concentrations (low and high). Tosoh Bioscience prefers to assay 3 concentrations, low, high and a midpoint. Each laboratory should establish its own protocol.

Tosoh Bioscience, Inc. manufactures Calibration Verification Material (CVM) for all 2-point sandwich assays. This material has approximately twice the analyte concentration of Calibrator 2 (P Calibrator) and is used to substantiate the reportable range for 2-point assays. Calibrators are used for 6-point assays.

A Tosoh Bioscience representative will perform the following protocol for the reportable range study during instrument installation unless the laboratory provides their own protocol.

For 2-point assays, run the following three specimens:

1. Sample Diluting Solution (SDS) included in the CVM package or Calibrator 1
2. Calibrator 2 or a 50% dilution of the CVM
3. Calibration Verification Material

For 6-point assays, run the following three specimens:

1. Calibrator 1
2. Calibrator 5 (or the calibrator that is closest to the midpoint of the assay range)
3. Calibrator 6 (or the calibrator that is closest to the upper limit of the assay range)

Instructions:

1. Analyze each specimen at least in duplicate.
2. Calculate the mean.
3. Calculate the percent recovery:
 - Divide the mean of the replicates by the expected mean x 100
 - Percent recovery should be between 90 -110%

Other sources of material suitable for calibration verification include:

1. Previously tested patient specimens of at least three concentrations that cover the low, middle and upper end of the reportable range
2. Calibration verification materials purchased from a vendor

8. What is the difference between Calibration Verification and Reportable Range?

Refer to #7 above for reportable range.

Calibration verification follows the same procedure as reportable range. According to CLIA, calibration verification requires analysis of three concentrations; high, low and a midpoint. Reportable range on the other hand requires analysis of only the high and low concentrations. Each laboratory should follow its own protocol.

Calibration verification is required only for 2-point assays. Reportable range is required for both 2-point and 6-point assays

Reportable range is performed only at installation or addition of a new analyte. Calibration verification is performed every six months for analytes with less than three calibrators.

Tab 10

CLIA/COLA FAQs

MISCELLANEOUS

9. What are the requirements for performing correlation between two different systems?

The ideal way to perform correlation studies is by analyzing the same samples on two instruments using the following criteria:

Specimen Requirements

Specimens should be fresh serum, not QC material or standards.
Previously frozen specimens should be simultaneously analyzed on both instruments.
Analyte concentrations should cover the entire range of linearity.

NOTE: IF SPECIMENS ARE NOT ANALYZED SIMULTANEOUSLY, A FALSE BIAS MAY OCCUR WHEN COMPARING THE RESULTS OF THE TWO METHODS. THE CORRELATION COEFFICIENT WILL NOT CHANGE, BUT THE SLOPE MAY VARY DUE TO EVAPORATION, FREEZE THAW CYCLES, AND ANALYTE INSTABILITY.

Interpretation of Results

Examine the data for obvious errors.
Calculate the mean of the replicates for each concentration.
Compare the expected results and observed results.
Calculate the percent recovery using linear regression analysis.

S = SLOPE: The slope of a line is a proportionality constant indicating change in y units to a change in x units. The ideal value of the slope is 1.000. Deviations from this value are taken as estimates of proportional systematic error.

Y = INTERCEPT: Defined as the point at which the linear regression line intersects the y-axis when $x = 0$. The ideal value of the intercept is 0 meaning that the standard curve goes through the origin. Deviation from the origin is an indication of constant error and is expressed in units of concentration.

The CORRELATION COEFFICIENT (r) is used to help judge how well two independent groups of measurements tend to agree on a scale between -1 and $+1$. When $r = 1$, the agreement is perfect; when $r = 0$, the data are random; and when $r = -1$, the agreement is perfectly inverse. A perfect correlation does not mean that the quantitative answers are identical; only that the **relationship** is constant and predictable.

10. How many points are required to complete a correlation study?

Laboratories collect samples to complete a correlation study. It is very important to assay samples that cover the entire range to get a better perspective. The more samples used, the better assessment of correlation exists. For example, 20 samples provide more data points than 10 and therefore provide a better correlation assessment. Each laboratory should follow their established protocol.

While performing correlations it is always better to compare the reference range used for the two methods. The objective of a correlation study is to check the clinical impact of a new methodology. Different methods may produce different results, but may not affect the clinical decision. It is always recommended to verify the manufacturer's reference range before performing the correlation study.

11. Is the manufacturer's representative required to perform the method validation studies?

Method validation studies are the laboratory's responsibility. Manufacturer representatives usually assist in performing these studies. It is recommended to share your protocol for the method validation with the manufacturer's representative. In the event that you haven't established a protocol you may choose to use the manufacturer's method. Remember it is your laboratory that will be inspected by CLIA/COLA! Your laboratory has to comply with these regulations.

12. How often does the lab have to perform method validation studies?

Controls should be run daily. Some laboratories may choose to run controls for each shift.

Precision, accuracy and reportable range should be performed when introducing a new instrument or analyte. Calibration verification should be performed every 6 months on all analytes that have less than three calibrators.

The laboratory should also check for accuracy and precision after a major repair. The laboratory should follow its own protocol for checking accuracy and precision.

Note: If not supplied a protocol by the laboratory, TBI uses its own protocol for method validation studies. This is available in the Method Validation Binder.

Tab 10

MISCELLANEOUS

BARCODE SPECIFICATIONS

The following section outlines the barcode specifications for use on primary sample tubes.

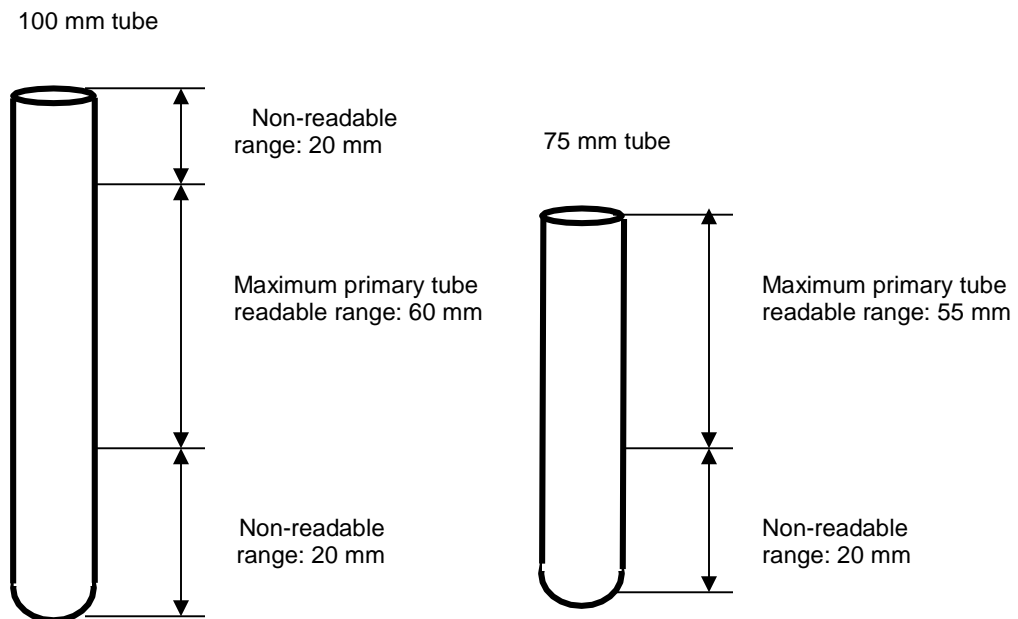
Barcode Label Specifications

Applicable barcodes
element width
PCS

CODE128, NW7, CODE39, ITF Minimum
0.191 (0.254 or higher recommended)
0.5 or higher (white reflectance 75%)

Barcode Read Range

The internal barcode reader is unable to read the bottom 20 mm portion of the tube. Apply barcode labels to ensure effective label reading. The barcode effective read range is designated as shown below.



Tab 10

MISCELLANEOUS

BARCODE SPECIFICATIONS

Maximum Number of Readable Barcode Digits

	Code		Element width (narrow)	Max. no. readable digits	
				75 mm	100 mm
1	CODE128		0.191 (min.)	16	16
2			0.254 (norm.)		
3	NW7	C/D: no (check digit)	0.191 (min.)	16	
4			0.254 (norm.)	14	
5		C/D: yes	0.191 (min.)	16	
6			0.254 (norm.)	13	
7	CODE39	C/D: no	0.191 (min.)	16	
8			0.254 (norm.)	10	
9		C/D: yes	0.191 (min.)	16	
10			0.254 (norm.)	9	
11	ITF	C/D: no	0.191 (min.)	16	
12			0.254 (norm.)		
13		C/D: yes	0.191 (min.)		
14			0.254 (norm.)		

NOTE: The number of readable digits may be limited for CODE39 and NW7 depending on the conditions when using 75 mm tubes.

Effective barcode read range may decrease depending on the quality of the barcode label used.

Tab 10

MISCELLANEOUS

AIA-360 Substrate Background Information Chart

Month _____ Year _____

Day	Oper. Init.	Substrate Replacement	4MU BG	4MU BG Value	Lamp Intensity	BG Sample	BG Ref	Subst. Smp	Subst. Ref
1									
2									
3									
4									
5									
6									
7									
8									
9									
10									
11									
12									
13									
14									
15									
16									
17									
18									
19									
20									
21									
22									
23									
24									
25									
26									
27									
28									
29									
30									
31									

Tab 10

MISCELLANEOUS

AIA-360 Common Reagent Log: Substrate II

Lot #	Expiration Date	Date Received	Date Reconstituted	Date Put On Instrument

Tab 10

MISCELLANEOUS

AIA-360 Common Reagent Log: Diluent

Lot #	Expiration Date	Date Received	Date Reconstituted	Date Put On Instrument



TOSOH

TOSOH AIA-360 Maintenance Log


Month:

Year

Daily	1	2	3	4	5	6	7	8	9	10	11	12	13	14	15	16	17	18	19	20	21	22	23	24	25	26	27	28	29	30	31
Empty carousel																															
Empty liquid waste reservoir																															
Check diluent and wash fluids, replace as needed																															
Replace alcohol with substrate																															
Check paper supply; replace if necessary																															
Record results from Daily Check (Substrate Background)																															
Check control recovery																															
End of day, replace substrate with 70% ethanol or 70% isopropyl alcohol																															
Operator Initials																															
Weekly	1	2	3	4	5	6	7	8	9	10	11	12	13	14	15	16	17	18	19	20	21	22	23	24	25	26	27	28	29	30	31
Clean substrate line with 70% ethanol or 70% isopropyl alcohol																															
Operator Initials																															
Monthly	1	2	3	4	5	6	7	8	9	10	11	12	13	14	15	16	17	18	19	20	21	22	23	24	25	26	27	28	29	30	31
Clean sample area with 70% ethanol or 70% isopropyl alcohol																															
Clean diluent and wash reservoirs with 1:100 dilution of common household bleach (aqueous hypochlorite)																															
Rinse reservoirs with CAP Class 1 or clinical laboratory water																															
Operator Initials																															
6 Months	1	2	3	4	5	6	7	8	9	10	11	12	13	14	15	16	17	18	19	20	21	22	23	24	25	26	27	28	29	30	31
Clean diluent and wash tubing lines																															
Replace filters for diluent and wash bottles																															
Operator Initials																															
As Needed	1	2	3	4	5	6	7	8	9	10	11	12	13	14	15	16	17	18	19	20	21	22	23	24	25	26	27	28	29	30	31
Clean instrument surfaces after any spills																															
Operator initials																															

Calibrate all analytes according to manufacturer's guidelines. Refer to the individual assay's Analyte Application.

Please refer to the AIA-360 Operator's Manual for detailed procedures.

 TOSOH	TOSOH AIA®-PACK ANALYTE SUMMARY				
	Assay Type	Sample Volume	Assay Range	Reference Range (Normal Range)	Calibrator Values
METABOLIC					Liquid (Ready to Use)
ST CORT (Cortisol)	Competitive	10 µL	0.2 - 60 µg/dL	AM: 10.4 - 26.4 µg/dL	0, 0.6, 2.0, 6.0, 20.0, 60.0 µg/dL
ST HGH (Human Growth Hormone)	IEMA	75 µL	0.07 - 45 ng/mL	Male: ≤5.0 ng/mL, Female: ≤10.0 ng/mL	0, 1.9, 3.8, 11.3, 22.6, 49.7 ng/mL
CARDIAC MARKERS					
ST CKMB	IEMA	50 µL	0.5 - 500 ng/mL	<5.8 ng/mL	0, 10, 20, 100, 200, 500 ng/mL
ST Myoglobin	IEMA	10 µL	2.0 - 1000 ng/mL	11.6 - 73.0 ng/mL	0, 50, 250, 500, 750, 1200 ng/mL
ST cTnI 2nd Gen (Troponin I)	IEMA	50 µL	0.06 - 115 ng/mL	Cutoff range is 0.31 - 0.64 ng/mL See Analyte Application for more details	0, 0.5, 5, 15, 45, 120 ng/mL
ST BNP	IEMA	50 µL	4.0 - 2000 pg/mL	Cutoff is 100 pg/mL	0, 15, 40, 150, 600, 2300 pg/mL
ANEMIA MARKERS					
ST FER (Ferritin)	IEMA	20 µL	3.0 - 1000 ng/mL	Males: 18 - 45 yrs: 22 - 340 ng/mL, >45 yrs: 22 - 415 ng/mL Females: 18-45 yrs: 6 - 115 ng/mL, >45 yrs: 15 - 200 ng/mL	0, 500 ng/mL
B12 (Vitamin B12)*	Competitive	200 µL**	50 - 2000 pg/mL	230 - 1050 pg/mL	0, 100, 250, 500, 1000, 2100 pg/mL
FOL (Folate)*	Competitive	160 µL**	0.5 - 20 ng/mL	3 - 16 ng/mL	0, 1.0, 2.5, 5.0, 10, 20 ng/mL
RFOL (RBC Folate)*	Competitive	50 µL**	0.62 - 24 or 30.3 - 1173 ng/mL after final calculation	3.4 - 10.3 ng/mL 148.3 - 531.1 ng RBC folate/mL – after final calculation	0, 3.25, 6.5, 13.5, 25, 44 ng/mL
ADDITIONAL ANALYTES					
ST IgE II	IEMA	10 µL	3.0 - 4000 IU/mL	5.8 - 216 IU/mL	0, 50, 300, 1000, 2500, 4000 IU/mL
ST PAP (Prostatic Acid Phosphatase)	IEMA	75 µL	0.2 - 40 ng/mL	<1.5 ng/mL	0, 20 ng/mL
ST ACTH	IEMA	50 µL	2.0 - 2000 pg/mL	7.4 - 64.3 pg/mL	0, 15, 50, 300, 800, 2200 pg/mL
ST HCY (Homocysteine)	Competitive	40 µL**	0.5 - 50 µmol/L	6.6 - 17.8 µmol/L	0, 2, 4, 8, 15, 55 µmol/L
ST Vitamin D*	Competitive	60 µL**	4.0 - 120 ng/mL	Deficient: <20 ng/mL, Insufficient: <30 ng/mL Sufficient: 30 - 100 ng/mL, Toxic: >100 ng/mL	0, 10, 20, 40, 80, 165 ng/mL


LBL-00001 V3

* Not available on the AIA®-360

** Sample volume needed for pretreatment (Off-line pretreatment on the AIA®-360)

Notes:

- RBC folate is rated as highly complex according to CLIA complexity rating.
- All assays have 90-day calibration stability except for B12, Folate and Troponin.
- Specimen type is serum or heparinized plasma except for iPTH which is serum or EDTA plasma. Specimen type for ACTH and BNP is EDTA plasma. Specimen type for RBC Folate is heparin or EDTA whole blood. Specimen type for B12, Folate, HCG and TSH3G is serum.
- Listed calibrator values are approximate; the exact calibrator concentrations are printed on each calibrator vial label.
- Each laboratory should determine a reference interval which corresponds to the characteristics of the population being tested.

 TOSOH	TOSOH AIA [®] -PACK ANALYTE SUMMARY				
	Assay Type	Sample Volume	Assay Range	Reference Range (Normal Range)	Calibrator Values
REPRODUCTIVE HORMONES					Liquid (Ready to Use)
ST β HCG	IEMA	50 μ L	0.5 - 400 mIU/mL	<5.0 mIU/mL	0, 200 mIU/mL
ST HCG	IEMA	50 μ L	0.5 - 400 mIU/mL	<5.0 mIU/mL	0, 200 mIU/mL
ST FSH	IEMA	50 μ L	1.0 - 200 mIU/mL	Male: 1.0 - 42.5 mIU/mL Female Ovulating: Follicular Phase: 2.7 - 15.4 mIU/mL Peak: 3.9 - 22.0 mIU/mL, Luteal phase: 1.0 - 14.4 mIU/mL Postmenopausal: 25.0 - 160.0 mIU/mL	0, 100 mIU/mL
ST LH II	IEMA	40 μ L	0.2 - 200 mIU/mL	Male: 1.7 - 11.2 mIU/mL Female Ovulating: Follicular Phase: 1.7 - 13.3 mIU/mL Peak: 4.1 - 68.7 mIU/mL, Luteal phase: 0.5 - 19.8 mIU/mL Postmenopausal: 14.4 - 62.2 mIU/mL	0, 5, 20, 50, 100, 200 mIU/mL
ST PRL (Prolactin)	IEMA	30 μ L	1.0 - 200 ng/mL	Male: 3.3 - 20.8 ng/mL Female: Premenopausal: 2.1 - 47.6 ng/mL, Postmenopausal: 0 - 41.4 ng/mL	0, 100 ng/mL
ST E2 (Estradiol)	Competitive	75 μ L	25 - 3000 pg/mL	Male: <25 - 75 pg/mL Female Ovulating: Follicular phase: <25 - 83.7 pg/mL Peak: 197.6 - 693.1 pg/mL, Luteal phase: 189.9 - 269.7 pg/mL Postmenopausal Female: 32.1 - 73.1 pg/mL	0, 40, 100, 500, 1000, 3200 pg/mL
ST PROG II (Progesterone)	Competitive	75 μ L	0.1 - 40 ng/mL	Male: \leq 1.36 ng/mL Female: Follicular phase: \leq 2.05 ng/mL Ovulation phase: \leq 19.56 Luteal phase: \leq 22.65 ng/mL Postmenopausal: \leq 0.48 ng/mL	0, 0.5, 1.5, 5.0, 15.0, 45.0 ng/mL
ST PROG III (Progesterone)	Competitive	30 μ L	0.1 - 40 ng/mL	Male: \leq 0.88 ng/mL Female: Follicular phase: 0.11 - 0.95 ng/mL Luteal phase: 1.65 - 22.04 ng/mL Postmenopausal: \leq 0.90 ng/mL	0, 0.5, 1.5, 5.0, 15.0, 45.0 ng/mL
ST Testosterone	Competitive	85 μ L	10 - 2200 ng/dL	Male: 199 - 1586 ng/dL Female: 10 - 73.2 ng/dL	0, 30, 100, 350, 900, 2200 ng/dL
ST DHEA-S	Competitive	10 μ L	2.0 - 1000 ug/dL	Males: <20 yrs: 35.35 - 819.22 ug/dl, 20-29 yrs: 84.04 - 570.75 ug/dL, 30-39 yrs: 105.9 - 445.1 ug/dL, 40-49 yrs: 65.7-488.4 ug/dL, 50-59 yrs: 77.4 - 364.8 ug/dL Females: <20 yrs: 20.91 - 349.95, 20-29 yrs: 50.67 - 413.78 ug/dL, 30-39 yrs: 71.4 - 208.1 ug/dL, 40-49 yrs: 33.8-303.4 ug/dL, 50-59 yrs: 40.8 - 222.0 ug/dL	0, 5, 12, 60, 300, 1200 ug/dL
ST SHBG	IEMA	15 μ L	0.01 - 12.5 nmol/L or 0.2 - 250 nmol/L after dilution factor*	Males: 21-49 yrs: 12-64 nmol/L, \geq 50 yrs: 18-99 nmol/L** Females (pre-menopausal \geq 21 years): 19-131 nmol/L** Females (post-menopausal): 15-170 nmol/L**	0, 0.1, 0.3, 1.25, 6.25, 15 nmol/L


LBL-00001 V3

* All samples are diluted 1:20

** See AIA Analyte Application Manual for calculation of free androgen index (%FAI)

Notes:

- RBC folate is rated as highly complex according to CLIA complexity rating.
- All assays have 90-day calibration stability except for B12, Folate and Troponin.
- Specimen type is serum or heparinized plasma except for iPTH which is serum or EDTA plasma. Specimen type for ACTH and BNP is EDTA plasma. Specimen type for RBC Folate is heparin or EDTA whole blood. Specimen type for B12, Folate, HCG and TSH3G is serum.
- Listed calibrator values are approximate; the exact calibrator concentrations are printed on each calibrator vial label.
- Each laboratory should determine a reference interval which corresponds to the characteristics of the population being tested.

 TOSOH	TOSOH AIA®-PACK ANALYTE SUMMARY				
	Assay Type	Sample Volume	Assay Range	Reference Range (Normal Range)	Calibrator Values
THYROID					Liquid (Ready to Use)
ST T4	Competitive	10 µL	0.5 - 24 µg/dL	4.0 - 11.0 µg/dL	0, 0.75, 3, 6, 12, 24 µg/dL
ST TT3	Competitive	25 µL	0.2 - 8 ng/mL	0.7 - 1.7 ng/mL	0, 0.5, 1.0, 2.0, 4.0, 8.0 ng/mL
ST TSH	IEMA	100 µL	0.03 - 100 µIU/mL	0.5 - 5.8 µIU/mL No exclusion criteria 0.6 - 4.8 µIU/mL Excluded samples with a high TPOAb and TgAb	0, 0.2, 5.0, 25, 50, 100 µIU/mL
TSH3G*	IEMA	100 µL	0.01 - 100 µIU/mL	0.5 - 5.8 µIU/mL No exclusion criteria 0.6 - 4.8 µIU/mL Excluded samples with a high TPOAb and TgAb	0, 0.2, 5.0, 25, 50, 100 µIU/mL
ST FT3 (Free T3)	Competitive	50 µL	0.5 - 25 pg/mL	2.0 - 4.9 pg/mL	0, 1.5, 3.0, 6.0, 12.0, 25 pg/mL
ST FT4 (Free T4)	Competitive	10 µL	0.1 - 8 ng/dL	0.75 - 1.54 ng/dL	0, 0.4, 1.0, 2.5, 4.0, 9.0 ng/dL
ST TU (T-Uptake)	Competitive	10 µL	10 - 60 tu	25 - 38 tu	25, 45 tu
TPOAb*	2-step IEMA	10 µL	0.16 - 20.0 IU/mL or 8.0 - 1020 IU/mL after dilution factor**	<10.1 IU/mL	0, 0.5, 2.0, 4, 10, 20 IU/mL
TgAb*	2-step IEMA	50 µL	0.24 - 40.0 IU/mL or 12.0 - 2040 IU/mL after dilution factor**	<28.7 IU/mL	0, 2, 4, 10, 20, 40 IU/mL
DIABETES					
ST C-Peptide II	IEMA	10 µL	0.04 - 30 ng/mL	Serum: 0.69 - 2.45 ng/mL Urine: 48 - 100 µg/L	0, 0.5, 2.0, 6.0, 15.0, 33.0 ng/mL
ST IRI (Insulin)	IEMA	50 µL	0.5 - 320 µU/mL	<17.0 µU/mL	0, 20, 40, 80, 160, 320 µU/mL

LBL-00001 V3

* Not available on the AIA®-360

** All samples are diluted 1:51

Notes:

- RBC folate is rated as highly complex according to CLIA complexity rating.
- All assays have 90-day calibration stability except for B12, Folate and Troponin.
- Specimen type is serum or heparinized plasma except for iPTH which is serum or EDTA plasma. Specimen type for ACTH and BNP is EDTA plasma. Specimen type for RBC Folate is heparin or EDTA whole blood. Specimen type for B12, Folate, HCG and TSH3G is serum.
- Listed calibrator values are approximate; the exact calibrator concentrations are printed on each calibrator vial label.
- Each laboratory should determine a reference interval which corresponds to the characteristics of the population being tested.



TOSOH AIA[®]-PACK ANALYTE SUMMARY

	Assay Type	Sample Volume	Assay Range	Reference Range (Normal Range)	Calibrator Values
TUMOR MARKERS					Liquid (Ready to Use)
ST AFP	IEMA	25 µL	1.0 - 400 ng/mL	<5.63 ng/mL	0, 200 ng/mL
ST CA 125	IEMA	100 µL	2.0 - 1000 U/mL	<35 U/mL	0, 10, 30, 125, 500, 1000 U/mL
ST CA 19-9	IEMA	50 µL	1.0 - 400 U/mL	<47.0 U/mL See Analyte Application for more details	0, 25, 50, 100, 200, 400 U/mL
ST 27.29	IEMA	20 µL	0.1 - 19.05 U/mL or 2.1 - 400 U/mL after dilution factor*	Cutoff is 37.7 U/mL	0, 0.2, 2.5, 5.0, 10, 20 U/mL
ST CEA	IEMA	100 µL	0.5 - 100 ng/mL	Non-Smokers: ≤7.2 ng/mL, Smokers: ≤14.5 ng/mL	0, 50 ng/mL
ST PA (PSA)	IEMA	20 µL	0.05 - 100 ng/mL	0 - 4.0 ng/mL	0, 50 ng/mL
KIDNEY MARKERS					
ST BMG (β ₂ Microglobulin)	IEMA	15 µL	0.002 - 0.4 mg/L or 0.102 - 20.4 mg/L after dilution factor**	Serum: <2.7 mg/L, Urine: <0.3 mg/L	0.0, 0.015, 0.05, 0.15, 0.30, 0.40 mg/L
ST Cystatin C	IEMA	10 µL	0.004 - 0.32 mg/L or 0.1 - 8.0 mg/L after dilution factor***	0.50 - 1.16 mg/L	0, 0.01, 0.04, 0.08, 0.16, 0.35 mg/L
ST iPTH	IEMA	75 µL	1.0 pg/mL - 2000 pg/mL	8.2 - 83.5 pg/mL	0, 15, 50, 200, 800, 2200 pg/mL

LBL-00001 V3

* All samples are diluted 1:21

** All samples are diluted 1:51

*** All samples are diluted 1:25

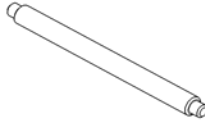

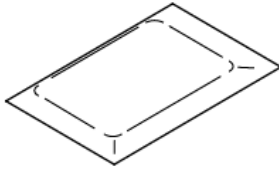

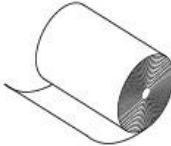

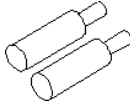

Notes:

- RBC folate is rated as highly complex according to CLIA complexity rating.
- All assays have 90-day calibration stability except for B12, Folate and Troponin.
- Specimen type is serum or heparinized plasma except for iPTH which is serum or EDTA plasma. Specimen type for ACTH and BNP is EDTA plasma. Specimen type for RBC Folate is heparin or EDTA whole blood. Specimen type for B12, Folate, HCG and TSH3G is serum.
- Listed calibrator values are approximate; the exact calibrator concentrations are printed on each calibrator vial label.
- Each laboratory should determine a reference interval which corresponds to the characteristics of the population being tested.

Tab 10

MISCELLANEOUS

SUPPLIES/PARTS




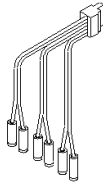

Part No.	Part Name and Specifications	Schematic Diagram	# Included
0019510	AIA-360 PRINTER PAPER ROD		1
0020107	PROBE TIP		6/pack
0020970	DETECTOR STANDARDIZATION CUP STD CUP		200/box
0018581	SAMPLE CUPS		1000/pouch
0019563	PRINTER PAPER 60 mm × 42 mm		10 rolls/box
0019398	WASTE BOX		1
0018585	WASH & DILUENT BOTTLE FILTERS		10/pouch
0018619	BOTTLE 30mL		1

Tab 10

MISCELLANEOUS

SUPPLIES/PARTS

For analyzers with plug socket connection from the level sensor leads to the bottles. Note that parts for analyzers with plug socket connections cannot be interchanged with parts from analyzers with screw type level sensor connections.





Part No.	Part Name and Specifications	Schematic Diagram	No. Included
0021068	WASH SOLUTION BOTTLE: with label 1000 mL		1
0021067	DILUENT BOTTLE: with label 500 mL		1
0021069	WASTE BOTTLE: with label 1000 mL		1
0021138	LEVEL SENSOR LEADS		1
0021207	RUBBER STOPPER		1

Tab 10

MISCELLANEOUS

SUPPLIES/PARTS

For analyzers with screw type connection from the level sensor leads to the bottles. Note that parts for analyzers with screw type connections cannot be interchanged with parts from analyzers with plug socket level sensor connections.

Part No.	Part Name and Specification	Schematic Diagram	No. Included
0024686	DILUENT BOTTLE: with label 500 mL Part Name: (DILUENT BOTTLE-2 WITH LABEL)		1
0024687	WASH SOLUTION BOTTLE: with label 1000 mL Part Name: (WASTE BOTTLE-2 WITH LABEL)		1
0024688	WASTE BOTTLE: with label 1000 mL Part Name: (WASTE BOTTLE-2 WITH LABEL)		1
0024317	LEVEL SENSOR LEADS Part Name: (LEAD WIRE OF LEVEL SENSOR-2) * with screws		1

SUPPLIES/PARTS**Ordering Consumables**

Any consumable part or reagent that is required for use is only to be purchased from Tosoh for use on Tosoh equipment. Use of consumables/expendables not supplied by Tosoh will void the analyzer warranty. Only Tosoh parts or reagents can be used with a Tosoh Analyzer. The consumable parts can be ordered from Tosoh Bioscience, Inc. in any of the following ways:

- Via telephone by calling Tosoh Bioscience, Inc. Customer Operations at 866-527-3587, 8:30 a.m. to 7:30 p.m. EST Mon-Fri
- Via FAX at 800-685-7595.
- Via mail by sending an order to:
Tosoh Bioscience, Inc. Customer
Service Department
3600 Gantz Road
Grove City, OH 43123-1895
- Via email to bioscienceorders@tosoh.com

Tab 10

MISCELLANEOUS

AIA-360 TRAINING EVALUATION

Name (print): _____ Date: _____

Facility: _____ Account: _____

Address: _____ City & State: _____

Training Date: _____ Instructor: _____

We want your opinion!

Now that you have completed the Tosoh Bioscience, Inc. System Training, we would like to know how you felt about it. Your comments and suggestions are crucial for assessing and improving the quality of this Training Program. Please take a few moments to give us your honest evaluation of the training. We sincerely thank you for your comments.

SYSTEM: AIA-360

1. Please rate the training content:	Excellent	Good	Fair	Poor
Overall training	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Organization of material	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Presentation of information	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Level of information presented	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Training Manual	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Quick Reference Guide	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>

Comments: _____

Tab 10

MISCELLANEOUS

AIA-360 TRAINING EVALUATION

2. Please rate your training instructor. After reading each statement, circle an appropriate response from 1 to 4.

This training instructor:	Strongly Agree		Strongly Disagree	
had a thorough knowledge of the subject	4	3	2	1
had good technical ability	4	3	2	1
had good presentation skills	4	3	2	1
was well prepared and organized	4	3	2	1
answered all my questions	4	3	2	1
made the training environment relaxed and informative	4	3	2	1
seemed genuinely interested in whether or not I learned	4	3	2	1

Comments: _____

3. What did you like best about the training?

Comments: _____

4. What did you like least about the training?

Comments: _____

Tab 10

MISCELLANEOUS

AIA-360 TRAINING EVALUATION

5. Please rate your level of understanding of the following operations:

	Excellent	Good	Fair	Poor
Calibration	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Sample Processing	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Software Screens	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Printing Results	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Maintenance	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Troubleshooting	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>

6. Overall, compared to other similar training seminars held by other companies in this industry, this seminar was:

- Excellent
 Good
 Fair
 Poor

Why: _____

Customer's signature: _____ Date: _____

Tab 10

MISCELLANEOUS

AIA-360 TRAINING CHECKLIST

NAME: _____ DATE: _____

FACILITY: _____ Account #: _____

ADDRESS: _____ City & State: _____

I UNDERSTAND AND/OR HAVE PERFORMED THE FOLLOWING:

- Daily Startup
 Programming control material and samples
 Printing a sample list
 Loading samples and reagents on the carousel
 Printing results
 Performing assay calibration procedures
 Performing system maintenance
- Daily
 Monthly
 As needed
- Setting and changing assay specifications
 Setting and changing the system specifications
 Performing routine troubleshooting procedures
 Significance and resolution of a High Substrate Blank
 Reagents and supplies: preparation, handling, storage and stability
 Performing reportable range studies
 Performing correlation studies
 Performing precision studies
 Review of AIA-AAM
 Review of Operator's manual
 Safety procedures in dealing with the AIA-360
 Requesting technical and instrument assistance
 How to order reagents, expendable supplies

CUSTOMER'S SIGNATURE: _____ DATE: _____

TRAINER'S SIGNATURE: _____ DATE: _____

Tab 10

MISCELLANEOUS

QUIZ ANSWERS

Tab # 2 Immunoassay Principles

1. Name the two types of immunoassay principles discussed in this module.

Sandwich

Competitive

2. What information is read off the dot pattern on the top of the test cup?

- a. Expiration date & lot number
b. Lot number & test code
 c. Expiration date & test code

3. What are the two components that are added to the bead prior to being placed in the test cup?

- a. Antigen & ferrite
b. Antibody & ferrite
 c. Conjugate & oxygen

The ferrite particles provide the magnetic property to the bead and the antibody is used to bind to the Antigen (Analyte) in the serum. For example, TSH test cup will have Anti-TSH antibody and ferrite on the bead.

4. In a sandwich assay, the concentration is directly proportional to the amount of fluorescence.

True

False

5. In a competitive assay, the zero calibrator has the lowest rate of fluorescence.

True

False

6. TSH is a competitive assay.

True

False

Tab 10

QUIZ ANSWERS

MISCELLANEOUS

Tab # 3 Reagent Preparation and Laboratory Safety

1. List the three common reagents used on the AIA-360.

_____ Wash _____ Diluent _____ Substrate _____

2. How many days can the substrate be stored at room temperature?

a. 3 days b. 7 days **c. 30 days**

3. List two laboratory safety items that must be worn during sample handling.

_____ Labcoat and Gloves _____

4. Which analyte can use either serum or urine?

a. BHCG
b. BMG
c. PA

5. What should be used to routinely decontaminate an instrument after a blood spill?

a. Ethanol
b. 10% Bleach
c. Distilled water

6. The reagent test cups are stable at room temperature for 14 days.

True **False**

7. SDS that has been opened is stable for one year from date of manufacture.

True **False**

8. Calibration curve for Troponin is stable for 90 days.

True **False**

Tab 10**MISCELLANEOUS****QUIZ ANSWERS****Tab # 4 System Overview**

1. The following primary tubes or sample cups can be used on the AIA-360: Circle all that are applicable.
 - a. 13 mm X 75 mm
 - b. 12 mm X 75 mm
 - c. 13 mm X 100 mm
 - d. BD Falcon 13 mm X 100 mm tubes
 - e. 16 mm X 75 mm
 - f. 16 mm X 100 mm
 - g. Samples Cups
 - h. Sample Cups with adapter

2. What is the incubation time for the assays on the AIA-360?
10 minutes.

3. What is the maximum number of analytes for each specimen that can be assayed on the AIA-360?
Four.

Tab 10

MISCELLANEOUS

QUIZ ANSWERS

Tab # 5 Operation

1. What is the purpose of performing a Daily Check?

The Daily check is performed to check if the substrate and detector are working fine. Flags in the daily check will indicate problems with substrate background.

2. How many calibrations can you perform at the same time?

One can perform one 6-point and one 2-point calibration OR four 2-point calibration.

3. How many calibration curves can be stored for the same lot number?

One.

4. Using the screen; show how to review calibrations and what do the symbols A, P and V stand for?

“**A**” – Curve has been accepted.

“**P**” – Curve has rate data but has not been accepted.

“**V**” – Curve is void (past 30 or 90-day stability). This status will be shown for 60 days after the expiration of the calibration curve.

5. What is the solution that replaces the substrate at the time of shut down?

70% ethanol or 70% isopropyl alcohol

6. What does a CV flag indicate?

A CV flag indicates that the curve is void beyond the 30 or 90-day expiration. One has to perform a new calibration and recalculate the results.

Tab 10**MISCELLANEOUS****QUIZ ANSWERS****Tab # 6 Maintenance**

1. How often should the diluent and wash lines be cleaned?
 - a. Weekly
 - b. Monthly**
 - c. Every 6 months

2. What maintenance procedure should be performed if a HB flag occurs?
 - a. Daily Check
 - b. Shutdown
 - c. 6-month maintenance
 - d. Weekly**

Tab 10**MISCELLANEOUS****QUIZ ANSWERS****Tab # 7 Specification Adjustment Procedure**

1. Which key do you hold down to start the instrument in Test Mode?

Power on the AIA-360 while holding down the MENU key on the keypad (located below the touch screen). Hold down the MENU key until a beep sounds. This will put the instrument in TEST MODE.

2. What is the assay high for AFP?

400 ng/mL

3. What is the assay low for FT4?

0.1 ng/dL

4. What is the assay high for cTnl2?

115 ng/mL

5. Assay results requiring manual dilution will automatically be multiplied by the correct dilution factor.

True, if the correct dilution factor is entered in the **FACTOR 2 A** column in the assay test file.

QUIZ ANSWERS**Tab # 8 Troubleshooting**

1. What is the hotline number for Tosoh Technical Support?

Tosoh Technical Support
Phone: 800-248-6764
Fax: 877-898-9883

2. What will you do in the event of a 2016 error?

Turn the system OFF and ON. Then perform Installation Wizard. If this does not resolve, call Tosoh Technical Support.

3. What will you do when you see a HB flag?

Repeat Daily Check with freshly reconstituted substrate.
If this does not resolve, Substrate lines may be dirty. Contact Tosoh Technical Support.

4. What will you do if you see a 3021 error?

3021 error indicates a leak in the system. Inspect for leaks and call Tosoh Technical Support.