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Section: Serology Manual	Subject Title: AxSYM System	
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**AXSYM SYSTEM FOR HBsAg, HBsAb, HBeAg, HBeAb, HBcAb-IgM, HBcAbTotal,
HAV-IgM, HCVAb, CMV IgG, HIV-1/2, Rubella IgG**

I. Introduction

The Abbott AxSYM System is a fully automated random access analyser that utilizes an enzyme-linked immunoreacting substance (antibody, antigen or hapten) adsorbed onto microparticles to detect the primary interaction of antibody or antigen. The reaction mixture is transferred to an inert glass fibre matrix to which the microparticles bind irreversibly. The immune complex on the glass fibre matrix is detected by alkaline phosphatase-labelled conjugate.

II. Specimen Collection and Processing

Blood is collected (5 mL for adult and 1 mL for neonates) in a serum separator tube, Sodium heparin tube, Sodium citrate tube, ACD tube, CPDA-1 tube or EDTA tube. Sample is centrifuged (3,000 g x 10 minutes) and the serum is stored refrigerated until testing. After testing is completed, specimens are stored at -70⁰C for 10 years for bone marrow and bone bank patients and 3 months for other patients.

III. Procedure

Reagents

Reagents, calibrator and control packs for the assays are stored refrigerated. All other reagents are stored at room temperature, except MUP (Solution 1) which is stored refrigerated. Once MUP solution is opened, it is only good for 2 weeks.

AxSYM Operation

[A] Daily Maintenance

- 1) Check inventory and waste containers. Flush tubings.
- 2) Scan reagent packs. Add additional reagent packs and calibrate (if necessary) sufficient for the days work.
- 3) Probe clean to be done at the end of the shift.
- 4) Initial the maintenance log book.

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[B] Assay Procedure for Patient Sample (Primary tube)

- 1) Check that label on tube contains ordered tests as per the requisition and the name on the label matched the name on the tube. The bar code label is centered and vertical on the tube.
- 2) Remove the cap. Check for and remove any bubbles in the serum. Ensure that the level of serum is adequate.
- 3) Load the samples and place the segments in the sample carousel.
- 4) Load the appropriate assay reagents in the reagent carousel. (Remember to open reagent bottle #4 on the reagent pack, if present).

[C] Assay Procedure for Patient Sample (Sample cup)

- 1) From the MAIN MENU, select "ORDERLIST",select F6 "Patient".
- 2) Scan LIS #, type in "Name",and then press "TAB".
- 3) Type S/P location of the sample cup.
- 4) Select F6 - "ADD", continue the above steps for the next sample cup.
- 5) Select F1 - "EXIT" once all the patients have been entered.
- 6) Print the displayed orderlist using the PRINT KEY. Verify sample cups are in correct location.
- 7) Load the samples.
- 8) Check for bubbles in the sample and place the segments in the sample carousel.
- 9) Load the appropriate assay reagents in reagent carousel. (Remember to open reagent bottle #4 on the reagent pack, if present).
- 10) PRESS "RUN".

[D] Assay Procedure for Control Sample

- 1) From the MAIN MENU, select "ORDERLIST".
- 2) Select F5 - control.
- 3) Select the assay for the control by touchscreen.
- 4) Type in the location of the control sample S/P.
- 5) Select positive/or negative control by touchscreen.
- 6) Select F6 - "ADD". Continue for next control follow.
- 7) Select F1 - "EXIT" Repeat control for next assay or Press "ABBOTT LOGO" TO "MAIN MENU".
- 8) Review the displayed orderlist. To print the orderlist, select the PRINT KEY.
- 9) Load the control samples.

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- 10) Check for bubbles in the sample and place the segments in the sample carousel.
- 11) Load the appropriate assay reagents in reagent carousel. (Remember to open reagent bottle #4 on the reagent packs, if present).
- 12) Press "RUN".

INDEX CALIBRATION: HBsAg, HBeAg, HBeAb, HBcAb-IgM, HBcAb-Total, HAV IgM Ab, HCVAb, HIV-1/2

Index Calibration procedure requires only one sample cup. Check required volume on printed orderlist.

- 1) Order Cal from the MAIN MENU, select "ORDERLIST".
- 2) Select F4 - "CAL".
- 3) Select the assay to be calibrated using the touch screen.
- 4) The S/P is automatically assigned. Change the S/P location if necessary.
- 5) Enter reagent lot number and expired date (found on bottle).
- 6) Press F6 - "ADD".
- 7) Press Abbott logo (a) if no other assay calibration is required.
- 8) Print the displayed orderlist using the "PRINT KEY".
- 9) Mix the calibrator and place appropriate volume in the sample cup.
- 10) Check for bubbles in the sample and place the segments in the sample carousel.
- 11) Load the appropriate assay reagents in reagent carousel. (Remember to open reagent bottle #4 on the reagent pack, if present).
- 12) Press "RUN".

MASTER CALIBRATION: HBsAb, CMV IgG Ab, Rubella IgG Ab

Master calibration requires two calibrators in separate S/P locations. Check required volume on printed orderlist.

- 1) From the MAIN MENU, select "STORED RESULTS".
- 2) Select calibration review.
- 3) Select F4 - NEW LOT.
- 4) Enter the master curve information by selecting - F4 "SCAN CURVE".
- 5) Scan the bar code label, top and bottom.
- 6) Select F6 - SAVE.
- 7) Master Cal is performed through the calibration orders and calibration type screen.

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- 8) Go to the MAIN MENU, select "ORDERLIST".
- 9) Select F4 - Cal.
- 10) Select the assay to be calibrated by using the touchscreen.
- 11) The S/P for two master cal samples is automatically assigned. Change the S/P location if necessary.
- 12) Enter master cal lot number and expiry date (number on box).
- 13) Make sure calibration type is Master Cal, if not enter "MASTER CAL" by touchscreen.
- 14) Select F6 - "ADD".
- 15) Select F1 "ABBOTT LOGO" if no further request is needed.
- 16) Print the displayed orderlist using the "PRINT KEY".
- 17) Dispense master calibrators into two sample cups. AUSAB calibrators must be microcentrifuged for 10 minutes on maximum speed before using.
- 18) Check for bubbles in the samples and place the segments in the sample carousel.
- 19) Load the appropriate assay reagent in the reagent carousel. (Remember to open reagent bottle #4 on the reagent pack, if present).
- 20) Press "RUN".

[E] Daily Clean-up Procedure

- 1) Ensure that all reagents have been removed and scanned.
- 2) Clean probe.

[F] Weekly Maintenance

- 1) MEIA & FPIA Verification
- 2) Clean sample segments and sample cup adaptors.
- 3) Clean matrix cell & processing carousels.
- 4) Clean air filters.
- 5) Clean outside of probes
- 6) Clean wash cups/ waste stations.
- 7) Clean dispenser nozzles and baseplate.
- 8) Flush pumps and syringes.
- 9) Weekly Archive patient results (must be performed before 1,500 records).

[G] Monthly Maintenance

- 1) Tubing decontamination.

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IV. Results

Results should be sorted and viewed by S/P to ensure that all tests were completed then resorted and printed.

- 1) From the MAIN MENU, select "RESULTS".
- 2) Select F5 - SORT.
- 3) Select "S/P" by touchscreen, "OK".
- 4) Scroll down the list checking that every S/P with a sample has a result.
- 5) Select F5-SORT.
- 6) Select "SID" OK. Once sorted, select F2-Select All and PRINT.
- 7) Select "Print a listing of all selected results", "OK" using touchscreen to activate printing.
- 8) After successful printing of results, select F3 "Release Results". "Are you sure? - Yes".
- 9) Check print-out for low level positive CMV, Rubella and enter the low level message in the LIS. Check for reactive HB_sAg, HB_cAb, HCVAb, HIV 1/2, for which repeat testing or reflex testing may be necessary.
- 10) Initial and give print-out to senior technologist for verifying.

Note:

HB_cAb: Repeat all reactive results for HB_cAb. After repeat testing complete.
Select the appropriate result for 8HBC test from keypad in LIS.
(Exception: HB_cAb reflex testing (8HBC2) performed on HB_sAg reactive sample for which HB_cAb (8HBC) was not originally ordered as outlined below.

HB_sAg: Perform reflex confirmatory testing and HB_cAb on all reactive HB_sAg samples except for patients with previously confirmed positive HB_sAg.
Preliminary report of stat requests will be phoned as "presumptive positive".

2 Reporting Results

i) **HB_sAg Assay Cut-off: >2.0 S/N**

Reactive and confirmed, HB_cAb reactive: POSITIVE

Reactive and previously confirmed positive: POSITIVE

Reactive and non-confirmed: Negative

HB_sAg S/N	HB_cAb Result	Action Required
≤2	+ or -	Report: Negative
2-5	+	Send to PHL
>5 -10	+	Perform Confirmatory Testing
2 – 10	-	Send to PHL
>10	-	Perform Confirmatory Testing
>10	+ S/CO <0.2	Report: Positive
>10	+ S/CO >0.2	Perform Confirmatory Testing

ii) **HB_sAb Assay Cut-off: >10.0 IU/mL**

Reactive: POSITIVE

Negative: Negative

iii) **HB_cAb Assay Cut-off: <1.0 S/CO**

Repeatable reactive: POSITIVE

Non-reactive: Negative

Non-repeatable reactive: NEGATIVE*

iv) **HB_eAb Assay Cut-off: >1.0 S/CO**

Reactive: POSITIVE

Negative: Negative

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v) HBeAg Assay Cut-off: >1.0 S/N

Reactive: POSITIVE, repeat specimen with value of >1.0 and <10.

Negative: Negative

vi) HBcAb-IgM Assay Cut-off: >0.80 Index

Reactive: POSITIVE

Negative: Negative

vii) HBcAb-Total Assay Cut-off: <1.0 S/CO

Reactive: POSITIVE

Negative: Negative

Non-repeatable reactive: NEGATIVE*

viii) HAV-IgM Assay Cut-off: >1.20 index

Reactive: POSITIVE

Grey-zone Reactive 0.8 - 1.2 Index: Inconclusive. Please send repeat specimen.

Non-reactive: Negative

ix) HCV Ab Assay Cut-off: >1.0 S/CO

1. If S/CO > 10, reflex to 8HCA2. Report positive if repeatably reactive.
2. If S/CO < 10, enter in the LIS as "To PHL @ MOHC". Send to PHL next day. Preliminary report of STAT testing will be phoned as "Presumptive Positive".

Grey-zone 1.6-2.0 S/N: NON-REACTIVE

Non-reactive: NON-REACTIVE

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x) CMV IgG Antibody Cut-off: >15 AU/mL

Positive (>25 AU/ml) : POSITIVE
 Positive (15-25 AU/mL): POSITIVE (Low Level)
 Negative (< 15 AU/ml): Negative

xi) Rubella IgG Antibody Cut-off: >10.0 IU/mL

Positive (>15 IU/mL): POSITIVE
 Positive (10-15 IU/mL): POSITIVE (Low Level)
 Greyzone (5-9.9 IU/mL): Negative
 Negative: Negative

xii) HIV 1/2 Assay

*Reactive: Enter in the LIS as "TO PHL". Send to PHL next day for confirmation.

Negative: Negative

*Review with Charge Technologist before reporting.

VI. Quality Control

Abbott Controls:

Positive and negative controls must be run for the following assays once per 8 hour shift:
 HCV Ab , CMV Ab, and Rubella IgG, .

Positive and negative controls must be run for the following assays once per 24 hour shift:
 HBsAg, HBsAb, HAV IgM, HBeAg, HBeAb and HIV ½

Results are verified by a senior technologist and filed in AXSYM printout log.

External Controls:

Run Positive External Control with each new reagent lot.

Accurun 5100 is for :HBsAg, HIV ½, HBcore Ab,HCV Ab, and CMV IgG

Accurun 51 is for HBeAg, HbcIgM, and HAVIgM

Accurun 52 is for AUSAB, and HBeAb

Accurun 140 for Rubella IgG

Viroclear is used as negative control for all except Rubella IgG

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All stock Accuruns are stored at -70°C freezer (MIFTJ).

External Controls are verified by a senior technologist and filed in External QC binder.

If any external control result is wrong, the test is invalid. Inform Charge/senior technologist, and repeat testing.

CAP, QMP-LS, and LCDC provide external proficiency testings

Calibrations:

Run calibration for each new reagent lot or when control(s) fail.

Failed QC:

Test is invalid without satisfactory QC results.

- a. Do not release reagent lot for use pending resolution of QC error.
- b. Inform charge/senior technologist.
- c. Record in Reagent Log Chart, Instrument Maintenance Log if microscope/incubator is involved in the failure (and Incident Report if necessary).
- d. Re-run failed control materials in parallel to fresh controls to evaluate the QC material itself.
- e. If the re-run shows the old QC material still fails and fresh QC is satisfactory, the error may be attributed to the old QC material itself and the reagent is satisfactory.
- f. If the re-run shows both the old and fresh QC materials fail (or other QCs not satisfactory), the error may be attributed to the reagent then the reagent cannot be released for use.

VII. Reference

AXSYM operational manual and manufacturer's package insert for the appropriate assay.

(Abbott Laboratories, Diagnostics Division, Abbott Park IL 60064, USA)