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Section: Serology Manual	Subject Title: Hepatitis Virus Serology	
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HEPATITIS VIRUS SEROLOGY

Although there are many infectious causes of hepatitis, the majority are caused by hepatitis A, B and C viruses. Acute Hepatitis A is diagnosed by detection of IgM antibodies. Anti-HAV IgM becomes positive just before the development of clinical hepatitis and remains positive for at least 4 months after infection. There is no chronic carrier state for Hepatitis A. Detection of total antibodies to Hepatitis A indicates immunity due to either past infection or immunization.

Hepatitis B is diagnosed by either detecting hepatitis B surface antigen (HBsAg) which indicates the presence of infectious virus, (HBcAb-IgM) **or** Anti-hepatitis B surface antibodies (HBsAb) which indicate immunity due to either past infection or immunization. Anti-hepatitis B core IgM antibodies indicate acute infection and HBcAb-Total indicates previous or current infection. HBsAg should be cleared within 6 months of acute infection. Persistence of HBsAg beyond 6 months is consistent with chronic hepatitis B infection. Some of these tests may occasionally be performed on a STAT basis because of concern regarding transmission of the virus to a susceptible individual following exposure (i.e. needlestick, newborn) to infected blood/body fluids and the need to prevent the disease by administering vaccine and/or immunoglobulin.

Hepatitis due to the delta virus is rare in Canada. It only occurs in association with patients who are positive for hepatitis B surface antigen. Requests for this virus should be forwarded to the Public Health Laboratory.

Hepatitis C (HCV) is a blood borne virus closely associated with blood transfusion and intravenous drug use. The presence of antibodies to HCV indicates that an individual may have been infected with HCV, may harbour infectious HCV and\or may be capable of transmitting HCV infection. The following requests will be handled in our laboratory:

Hepatitis B surface antigen	HBsAg
Hepatitis B surface antibody	HBsAb
Hepatitis B core antibody	HBcAb
Hepatitis B e antigen	HBeAg ¹
Hepatitis B e antibody	HBeAb ¹
Hepatitis A IgM antibody	HAV-IgM ²
Hepatitis A Total antibody	HAV-IgG

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<sup>Note: 1) These tests will be performed on request only if the patient is HBsAg positive.
2) Perform only HAV-IgM if type of Hepatitis A test is not specified.</sup>

Table 1	Tests perfo	rmed as ner	· designated	categories
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	Test Performed			
Clinical Category	HBsAg	HBsAb	HAV-IgM	HCVAb
Hepatitis B Screen	Х			
Hepatitis A Screen			Х	
Hepatitis B Immune Status		Х		
Needlestick				
- Patient (source)	Х			Х
- Staff (exposed)		Х		Х
Pre/postnatal				
- Mother	Х			
Hepatitis Screen	Х		Х	Х

For additional requests within the above categories, consult with the charge technologist or medical microbiologist. In the absence of one of the above clinical categories, do the tests as requested.

Clinical setting	Serum tested	Time frame from exposure to report	Days of week	Call- back
Neonate	Mother	< 12 hours	A 11	No ¹
Neonate D			All	
Prenatal	Mother	< 12 hours	All	No
Needlestick/ mucosal exposure ²	See below	< 72 hours	All	No ¹
Renal dialysis	Patient	< 12 hours	All	No ¹

Table 2. Guidelines for STAT Testing

1) May require call back on weekends if time from exposure to reporting exceeds 12 hours. Must be approved by microbiologist on-call.

2) Perform HBsAg and HCVAb on the source. Test HBsAb and HCVAb on the employee. Whichever of these arrives first is to be tested STAT. If both arrive at the same time, test both simultaneously. If the source HBsAg is positive, test the employee STAT. If the source is negative, test employee in the next routine run.

HUMAN IMMUNODEFICIENCY VIRUS(HIV) ½ SEROLOGY

HIV testing will be done on patient (source) involved in' Needle Stick Incident' as 'STAT', so appropriate prophylaxis can be given in case it is positive. It is also done for transplant patients (donor & recipient). Two tubes of blood should be received. If the result is positive, send the unopened tube to PHL. The positive result will be reported as 'sent to PHL for confirmation'. Specimen will be sent out as 'STAT' the next working day to PHL. Put specimen with PHL HIV form in a separate brown bag, clearly marked as 'STAT'. Call 416-340-6022 to inform PHL HIV lab that this specimen is coming as 'STAT', and ask to call result to Lab when it is available.

Daily Maintenance:

- 1. Empty Waste Containers first thing in the morning or at the end of the day. Open the Waste and Supply Center Doors (<u>DO NOT OPEN THIS DOOR WHEN THE</u> AXSYM IS RUNNING), then open the Interior Waste Door :
 - a. Remove Consumable waste
 - i. Remove biohazard bag from the consumable waste container and dispose it into Biohazard waste box.
 - ii. Place a new biohazard bag in the container.
 - b. Remove Liquid Waste
 - i. Hold down the tubing to the Liquid Waste Container while pressing the metal tab on the side of the clip.
 - ii. Remove the Liquid Waste Container.
 - iii. Transfer liquid waste into decontamination containers near the sinks. Fill container with 4/5 full of waste and 1/5 full of Javex. Label date on the lid.
 - iv. Rinse container with a little bit of Javex, and then lots of H₂O. Wipe dry outside of container.
 - v. Reattach the tubing by pressing the tubing assembly until it locks into place.

Close the Interior Waste Door, and close the Waste and Supply Center Doors.

- 2. Update Waste Levels:
 - a. Select Inventory from the Main Menu.
 - b. Select F4- Waste.
 - c. Select F3- Empty Waste.
 - d. Select F6- Save.
 - e. Exit to Main Menu.

- 3. Update Matrix cells and Bulk Solutions:
 - a. Matrix Cells:
 - i. Visually check inventory level.
 - ii. If level is around or less than 100, add a box by removing the plastic cover, and the paper tabs in the middle of the box. Place the box between the plastic walls at the top of the Matrix Cell Hopper. Rest the box ends firmly on the roll bars and apply pressure to the center of the box. The Matrix cells pour into the Hopper. Make sure that no Matrix Cells lie sideways.
 - iii. Update inventory:
 - 1. Select Inventory in Main Menu.
 - 2. Select F2- Matrix cell.
 - 3. Select F3- Add a box.
 - 4. Select F6-Save.
 - 5. Exit to Main Menu.
 - b. Bulk Solutions:
 - i. Open Waste and Supply Center Doors:
 - 1. Remove the bulk solution that you are replacing.
 - 2. Load the replacement solution bottle and screw on the cap.
 - 3. Close the Waste and Supply Center Doors.
 - ii. Update inventory:
 - 1. Select Inventory from Main Menu.
 - 2. Select F5- Bulk Solutions
 - 3. Select F2- Replace Solution 1
 - F4- Replace Solution 3
 - F5- Replace Solution 4
 - 4. F6- Save, Exit to Main Menu.
- 4. Flushing Pumps and Syringes:

Select Maintenance from the Main Menu.

Select Prime and Flush.

Enter 1 under sampling syringe flush and Processing syringe flush.

Select F2- Perform Maint.

Check for leaks or bubbles in the tubings.

Exit to Main Menu.

- 5. After loading all reagent packs, press F5-Scan pack,
 - Press 'Inventory'.

Press F3-'Reagent Load List'. Check to see how many tests are left in each reagent pack. To print a copy, Press 'Alt' and 'PRINT' at the same time.

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- 6. Scan reagent packs at the end of the day:
 - a. Remove all Reagent Packs.
 - b. Select F5- scan pack from Main Menu.
- 7. Probe Clean at the end of the day :
 - a. Select Maintenance from the Main Menu.
 - b. Select Probe Clean. Follow instructions on the screen.
 - c. Load two Reaction Cells at the designated locations on the Reaction Vessel Carousel.
 - d. Pipette 1 ml of TEAH(Probe Clean Solution) into both the buffer and predilution wells of both Reaction Vessels.
 - e. Select OK.
 - f. When finished, exit to Main Menu.
- 8. Archive new results of the week on Friday.

Weekly Maintenance :

- 1. Replace and cleaning Air Heater Inlet Filter.
- 2. Replace and cleaning Card Cage Air Filter.
- 3. Cleaning Sampling Probe.
- 4. Cleaning Processing Probe.
- 5. Cleaning Sampling Wash Station.
- 6. Cleaning Processing Wash Station.
- 7. Cleaning Dispenser Nozzles.
- 8. Flushing Pumps and Syringes.
- 9. Cleaning Processing Carousel.
- 10. Cleaning Matrix Cell Carousel.
- 11. MEIA Verification.
- 12. FPIA Verification.
- 13. Cleaning Segments and Sample Cup Adapters.

Remove Cell Hopper, and lift Processing Center Cover.

1. Replace and Cleaning Air Heater Inlet Filter:

The Air Heater Inlet Air Filter is located on the left hand side and near the back of the AXSYM.

Lift filter up and replace with a clean filter in the filter slot.

Clean the dirty filter under running tap water in the opposite direction of the airflow arrows. Shake off excess water and air-dried.

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Replace and Cleaning Card Cage Air Filter
 Open the Card Cage Access Panel located on the left side of the system.
 Remove the Card Cage Filter.
 Place the spare filter in the filter slot.
 Install the Card Cage Access Panel.
 Clean the dirty filter under running tap water in the opposite direction of the airflow arrows. Shake off excess water and air-dried.

Select Maintenance from Main Menu. Select PRIME AND FLUSH. Select F6- Raise probes. Open the sampling Pipette Cover.

- Cleaning Sampling Probe

 Moisten a cotton swab with Deionized H2O.
 Wipe the Sampling probe several times.
 Moisten a cotton swab with 95 % Ethanol.
 Wipe the Sampling probe several times.
 Moisten a cotton swab with Deionized H2O.
 Wipe the Sampling probe several times.
 Moisten a cotton swab with Deionized H2O.
 Wipe the Sampling probe several times.
 Visually check the probe for damage.
- 4. Cleaning Processing Probe: Moisten a cotton swab with Deionized H₂O. Wipe the Processing probe several times. Moisten a cotton swab with 95 % Ethanol. Wipe the Processing probe several times. Moisten a cotton swab with Deionized H₂O. Wipe the Processing probe several times. Visually check the probe for damage.
- 5. Cleaning Sampling Wash Station: Remove the Wash Station.
 Rinse the Wash Station with Deionized H₂O.
 Rinse the Wash Station with 95 % Ethanol.
 Rinse the Wash Station with Deionized H₂O.
 Clean the inside and outside of the Wash Station with a cotton swab moistened with Deionized H₂O to remove any salt buildup.
 Reinstall the Wash Station.

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- 6. Cleaning Processing Wash Station: Remove the Wash Station. Rinse the Wash Station with Deionized H₂O. Rinse the Wash Station with 95 % Ethanol. Rinse the Wash Station with Deionized H₂O. Clean the inside and outside of the Wash Station with a cotton swab moistened with Deionized H₂O to remove any salt buildup. Reinstall the Wash Station. Home Probes.
- 7. Cleaning Dispenser Nozzles:

Remove the Bulk Solution 1 Dispenser by pulling olive-green lever toward you (\downarrow) . Lift the Dispenser to inspect the nozzle for buffer deposits.

Moisten a cotton swab with Deionized H_2O and clean the outside of the nozzle and the surrounding collar.

Inspect the nozzle for obstruction.

Reinstall the Dispenser by lifting the black clip to vertical position.(should hear 'click'). Check the Dispenser position. Make sure that the Dispenser sits properly, not on a raised position.

Remove the Bulk Solution 3 Dispenser by Dispenser by pulling olive-green lever toward you (\downarrow) .

Lift the Dispenser to inspect the nozzle for buffer deposits.

Moisten a cotton swab with Deionized H_2O and clean the outside of the nozzle and the surrounding collar.

Inspect the nozzle for obstruction.

Reinstall the Dispenser by sliding the metal hinge pin on the right end of the Dispenser into the openings on the base. Lower the left end into the circular opening of the base plate. Check the Dispenser position. Make sure that the Dispenser sits properly, not on a raised position.

 Flushing Pumps and Syringes: Select Prime and Flush Enter 1 under sampling syringe flush and Processing syringe flush. Select F2- Perform Maint. Check for leaks or bubbles in the tubings. Exit to Main Menu.

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9. Cleaning Processing Carousel:

Remove the Processing Carousel Cover by unscrewing the two thumbscrews.

Grasp Processing Carousel Motor Handle, push back and hold open.

Remove by tilting Carousel and pulling up, careful not to hit the probe.

Clean the carousel and the surrounding area with lint-free tissue moistened with water. Inspect the clips on the under side of the carousel for broken pieces/loose connections. Dry the Carousel with Lint free tissue.

Reinstall the Carousel by grasping the Processing Carousel Motor Handle, push back and hold open.

Place the rim of the Carousel in the V-wheel located under the Carousel Motor Housing. Tilt the Carousel downward and fit the rim into the two front V-wheels. Careful not to hit the probe.

Reinstall the Processing Carousel Cover by tightening the two thumbscrews.

10. Cleaning the Matrix Carousel:

Remove the Matrix Cell Carousel Access Panel.

Remove the Air Deflector.

Select F2- Shutdown from the Main Menu.

Verify that Shutdown was selected, select OK.

Turn the power switch to OFF. Once power is off, make sure that it is off for at least 5 minutes before turning AXSYM back 'ON'.

Rotate the Carousel so that the red dot is facing you.

Remove the Carousel by pushing back on the Carousel, tilting down and pulling out. Clean the carousel and the surrounding area with lint-free tissue moistened with water. Inspect the clips on the under side of the carousel for broken pieces/loose connections. Dry the Carousel with Lint free tissue.

Reinstall the Carousel by holding the carousel with the red dot facing you, and fit the rim of the carousel into the rear V-wheel and push in towards the spring-loaded V-wheel.

Tilt up and fit the rim of the carousel into the front V-wheels.

Manually rotate Carousel to ensure proper positioning.

Reinstall Air Deflector. Reinstall the Matrix Cell Carousel Access Panel.

Close the Processing Center Cover.

Re-install Matrix Cell Hopper.

Turn the power ON.

Select Startup from the Main Menu.

If the power is off for less than 15 minutes, there is a 15-minute warm-up.

If the power is off for more than 15 minutes, there is an hour warm-up.

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11. MEIA Verification:

Select MAINTENANCE from the Main Menu. Select CALS AND CHECKS. Select OPTICS. Select MEIA VERIFICATION. Remove Matrix Cell Hopper. Select CONTINUE. Follow instructions on screen. Place the Standard Hopper into position. Insert the Standard into the Standard Hopper. Select CONTINUE to begin the MEIA Verification. This will take ~ 10 minutes. When finished, select OK to acknowledge completion of the verification. Press PRINT on the keyboard. Retrieve the Standard by pressing the white MEIA Standard Release lever. Open the MEIA Optical Retrieval Door and remove the Standard. Store it upside down in the black box. Reinstall Matrix Cell Hopper. Exit to the MAIN MENU/MAINTENANCE/OPTICS.

12. FPIA Verification:

Select FPIA VERIFICATION.
Follow instruction on the screen, select Continue.
Press down the back of the clip on top of the FPIA Optical Standard.
Load the Standard into the Reaction Vessel Carousel at the Load Station.
Press on the front of the clip to provide a flat surface.
Select Continue to begin the procedure.
This will take ~ 20 minutes.
When finished, select OK to acknowledge completion of the verification.
Press PRINT on the keyboard.
Press down on the back of the clip on top of the FPIA Optical Standard.
Lift and remove the Standard ,store in assigned place in the black box.
Exit to Main Menu.

 Cleaning Segments and Sample Cup Adapters: Use disinfectant wipes to clean segment and Sample Cup Adapters.