

Ward Manual

PHC Diagnostic Virology & Reference Laboratory

I. General Information

The SPH Virology Laboratory is located at St. Paul's Hospital
1081 Burrard Street,
Room 625, Burrard Building,
Vancouver, B.C. V6Z 1Y6

The lab is open from 8am – 5pm, Monday through Friday and 8am to 4pm on Saturdays, Sundays and Statutory holidays.

Specimens are accepted at the St. Paul's Hospital accessioning area.

The Virology division provides direct clinical consultation services through the SPH Microbiologist on call. A 24-hour service is available for processing emergency specimens on evenings, weekends and holidays with the prior approval of the St Paul's Hospital Microbiologist on-call.

Important telephone numbers are:

Dr. Christopher Lowe - Medical Microbiologist	(604) 806-8422
Dr. Nancy Matic - Medical Microbiologist	(604) 806-8423
Virology Lab – Main Lab	(604) 806-8420
Willson Jang - Micro/Virology Team Lead	(604) 806-8369
Matthew Young – Virology Technical Coordinator	(604) 806-8426
Tanya Lawson – Virology Technical Coordinator	(604) 682-2344 x62344
Technologist on-call pager	(604) 258-3520
Call Center for Virology results	1 877 747-2522

The SPH Virology Laboratory performs a full range of diagnostic services including:

- Serological testing for CMV IgG, Hepatitis A,B and C and HIV Ag/Ab Combo
- Molecular diagnostic testing by PCR for Adenovirus, Cytomegalovirus (CMV), Epstein Barr Virus (EBV), Enterovirus, Hepatitis B Virus (HBV), Human Herpes Virus 8 (HHV8), HIV, Herpes Simplex Virus (HSV), Norovirus, Polyomavirus (JC and BK viruses), Varicella Zoster Virus (VZV), SARS-CoV-2 (COVID-19) and Respiratory Virus PCR Panel consisting of Adenovirus, Influenza A and B, Parainfluenza 1,2,3, Respiratory Syncytial Virus (RSV) and human Metapneumovirus (HMPV).
- Monitoring of chronic or recurrent viral diseases by viral load measurement (HIV, HBV, CMV, BK, EBV and HHV8)
- Hepatitis B Antiviral Resistance Testing

I. General Information (cont'd)

Tests performed by Virology lab (listed alphabetically) and SQ test codes

TEST	SQ CODE	TEST	SQ CODE
Adenovirus PCR (eye)	PVPCR	Hepatitis B antiviral resistance	PHBRES
Adenovirus PCR (respiratory)	RESPCR	Hepatitis B confirmation	PHBSC
COVID-19 (SARS-CoV-2)	COVID	Hepatitis C Antibody	PHCV
CMV IgG	PCMVG	Hepatitis C Confirmation	PHCVC
CMV PCR (blood)	PCMVB	HIV Ag/Ab Combo	HIVCA
CMV PCR (non blood)	PVPCR	HHV8 DNA PCR	HHV8P
CSF for Virology	PCSFT	HIV Viral load	VLB
EBV PCR (non blood-CSF)	PVPCR	HIV send out	HIVSO
EBV PCR (blood)	PEVB	HIV Confirmatory Test	PHIVCT
Enterovirus PCR	PVPCR	HSV PCR	PVPCR
Hepatitis A IgM	PHAM	Influenza A&B, RSV (3 viruses)	PFLABR
Hepatitis A IgG	PHAIG	Influenza A and B PCR	RESPCR
Hepatitis B surface Antigen	PHBSAG	Metapneumovirus (Human)	RESPCR
Hepatitis B surface Antibody	PHBSAB	Norovirus PCR	PVNOR
Hepatitis B core IgM	PHBCM	Parainfluenza Virus 1, 2 ,3	RESPCR
Hepatitis B core total	PHBCAB	Polyomavirus PCR	PPOLY
Hepatitis B e Antigen	PHBEAG	Respiratory PCR Panel (8 viruses)	RESPCR
Hepatitis B e Antibody	PHBEAB	RSV PCR	RESPCR
Hepatitis B DNA PCR	HBDNAB	VZV PCR	PVPCR

II. Requisition

For outside labs, the Virology and Reference Laboratory request form must be filled out completely. The following information must be present on each form or delay in testing may occur:

1. Patient's name
2. Patient date of birth
3. Patient PHN if BC resident
4. Patient medical coverage and home address (if non-resident of BC)
5. Physician name and billing number
6. Specimen type
7. Test desired

The specimen vial must be labeled with the patient name, date of collection and the specimen site.

III. Viral Specimen Collection Kits

- Use the COPAN flocked swab and the COPAN Universal Transport Medium (UTM) vial for **all** viral PCR testing including respiratory viruses (red top).
- **Exception:** Approved nasopharyngeal collection kits for COVID-19 viral PCR also include:
 - *Copan Red top 365C*
 - *Copan Red top BD 220531*
 - *VWR Starplex*
 - *Roche cobas ® PCR Media dual swab kit*
 - *Yocon Viral Transport Medium*

Virology collection kits are provided at no charge by the Virology lab. Call the Virology lab at (604) 806-8420 to arrange shipment of collection kits and requisitions, or pick up viral collection kits from the fridge in the Accessioning area of the SPH Lab.

NOTE: DO NOT USE CALCIUM ALGINATE SWABS for any Virology testing.

IV. Specimen Collection and Storage

- Generally samples should be obtained as early as possible after onset of illness.
- DO NOT TRANSPORT LEAKING VIALS.
- Label the specimen vial appropriately with at least two identifiers. **Note: Unlabelled non critical specimens will not be tested.**

Specimen Site	Instructions	Special Notes
Anti-Coagulated Blood	For HIV, HBV, CMV, EBV, HHV8 and Polyomavirus viral load assays, collect min 7 mls of EDTA anticoagulated blood tube. (ACD, Heparin, PPT tubes are not accepted for PCR testing). Separate plasma from whole blood within 4 hours of collection by centrifugation at 1300x for 10 minutes at room temperature. Minimum volume of 3.0ml of plasma is required; store plasma at 2-8°C for 72 hours. For longer storage, store at -20°C or colder.	anti-coagulated blood tubes received in the Virology lab more than 6 hours after collection will not be tested. Refer to Table II for molecular testing blood volume requirements.
Coagulated Blood	For viral serology, collect a coagulated blood sample in gold top SST blood tube using standard venipuncture technique.	Refer to Table I for viral serology blood volume requirements
CSF	Collect in a sterile container. Submit at least 1 ml for viral PCR. DO NOT dilute in viral transport medium. Store at 2-8°C.	Transport to the lab immediately.
Cervical	Clean off excess mucus from the cervix. Swab the endocervix with the COPAN swab. Break off the swab into the UTM viral transport medium vial. Store at 2-8° C until ready to transport.	

Specimen Collection and Storage continued

Specimen Site	Instructions	Special Notes
Eye	Take sample prior to the application of topical anesthetic. Pull the mucosa away from the globe by pulling on the lower eyelid. Rub the mucosal surface of the conjunctiva with the sterile flocked swab. Immediately immerse the swab into the UTM transport media vial. Break off the applicator stick short enough that the swab remains in the medium and cap fits tightly on the vial; store at 2-8° C after collection.	Deep ocular samples like aqueous and vitreous aspirates, biopsies and enucleations should be transported to the lab immediately after collection.
Nasopharyngeal swab	Insert the COPAN flocked swab through the nostril into the posterior nasopharynx. Rotate the swab when removing it. Break off the applicator stick short enough that the swab remains in the medium and cap fits tightly on the vial; store at 2-8° C after collection.	
Nasopharyngeal washings (NPW)	Use suction or syringe drawback method for collecting the specimen. Sterile saline is expelled into the nasopharyngeal cavity using catheter and drawn back out immediately into a sterile leak-proof container (fluid should be cloudy with minimal amount of mucous). Do not use the viral transport media to collect nasal washes; store at 2-8°C until transport. Nasopharyngeal washings are optimal for upper respiratory tract viral infections.	Call the Respiratory Technologist on call for collection of these samples.
Rectal	Gently insert swab into rectum and rotate to collect sufficient stool onto the swab. Break off the swab into UTM viral transport medium. Store swab at 2-8° C until transport.	
Skin lesions	Use a sterile COPAN flocked swab to open the vesicular lesion. Rub the base of the lesion to dislodge the infected cells. Break off the applicator stick short enough that the swab remains in the medium and cap fits tightly on the vial; store at 2-8° C after collection.	
Stool	For Norovirus PCR collect at least 5-10 grams in a sterile specimen collection container. Choose portions with mucous or blood. DO NOT contaminate with urine or water. DO NOT ADD to viral transport medium. Store stool container at 2-8°C for 48 hours or freeze at -20°C if transportation is to be delayed.	

Specimen Collection and Storage (cont'd)

Specimen Site	Instructions	Special Notes
Throat	Rub the COPAN swab over the posterior pharynx. Break off the applicator stick short enough that the swab remains in the medium and cap fits tightly on the vial; store at 2-8° C after collection.	
Tissue	Place the tissue in the virology UTM transport medium vial and store vial at 2-8°C until ready to ship.	
Urethral	Gently insert the COPAN swab into urethra. Break off the swab into UTM transport medium vial; store at 2-8° C until transport.	
Urine	Collect 10 mls of first-void of urine in a sterile container; store at 2-8°C and transport within 24 hours.	

**TABLE I
VIRAL SEROLOGY**

VIRUS	Validated BLOOD TYPE and volume	SPECIMEN STORAGE **	MINIMUM VOLUME	TESTING FREQUENCY	*TURNAROUND TIME
CMV IgG	7 ml SST	2-8° C for <14 days	0.5 ml serum	Monday-Friday, daily 8 am - 5 pm	24 hours
HIV Ag/Ab combo	7 ml SST	2-8° C for 14 days (or 3 days at room temp)	0.5 ml serum	Monday-Friday, daily 8 am - 5 pm	24 hours
HBsAg	7 ml SST	2-8° C for 6 days	0.5 ml serum	Monday-Friday, daily 8 am - 5 pm	24 hours
HBsAg Confirmation	7 ml SST	2-8° C for 6 days	0.5 ml serum	Monday-Friday, twice weekly 8 am - 5 pm	3 days
HbsAb	7 ml SST	2-8° C for 14 days	0.5 ml serum	Monday-Friday, daily 8 am - 5 pm	24 hours
HbcAb Total	7 ml SST	2-8° C for 14 days	0.5 ml serum	Monday-Friday, daily 8 am - 5 pm	24 hours
HbclgM	7 ml SST	2-8° C for 7 days	0.5 ml serum	Monday-Friday, twice weekly 8 am - 5 pm	3 days
HBeAg	7 ml SST	2-8° C for 7 days	0.5 ml serum	Monday-Friday, twice weekly 8 am - 5 pm	3 days
HbeAb	7 ml SST	2-8° C for 7 days	0.5 ml serum	Monday-Friday, twice weekly 8 am - 5 pm	3 days
HAV IgG	7 ml SST	2-8° C for 14 days	0.5 ml serum	Monday-Friday, twice weekly 8 am - 5 pm	3 days
HAV IgM	7 ml SST	2-8° C for 7 days	0.5 ml serum	Monday-Friday daily 8 am - 5 pm	24 hours
HCV Ab	7 ml SST	2-8° C for 7 days	0.5 ml serum	Monday-Friday daily 8 am - 5 pm	24 hours
HCV Ab Confirmation	7 ml SST	2-8° C for 7 days	0.5 ml serum	Monday-Friday once a week 8 am - 5 pm	5 days

** Specimens may be stored on or off the separator gel for the indicated storage temperature and time

TABLE I (cont'd)

VIRAL SEROLOGY PANELS

VIRUS	Validated BLOOD TYPE and volume	SPECIMEN STORAGE **	MINIMUM VOLUME	TESTING FREQUENCY	*TURNAROUND TIME
Blood Body Fluid exposure/ needle stick protocol (PHC EHU) <ul style="list-style-type: none"> • HBsAg • HBsAb • HBcAb • HIV Ag/Ab • HCV 	7 ml SST	2-8° C for 14 days (or 3 days at room temp)	0.5 ml serum	Monday-Friday Daily 8 am - 5 pm	24 hours
Serology panel for PHC heart transplant recipients and donors. <ul style="list-style-type: none"> • HBsAg • HbsAb • HbcAb • HIV Ag/Ab • HCV • CMV IgG 	7 ml SST	2-8° C for 14 days (or 3 days at room temp)	1 ml serum	7 days a week	3 hours
Serology panel for PHC renal transplant recipients and donors. Testing performed at BCCDC					
Serology panel for prenatal screening Testing performed at BCCDC					

*Turnaround time refers to hours/days for analytical phase (ie: interval between receipt of specimen by Virology lab and performance of test to completion and reporting)

**Specimens may be stored on or off the separator gel for the indicated storage temperature and time

TABLE II

MOLECULAR TESTING

VIRUS	SAMPLE TYPE	MINIMUM VOLUME	STORAGE/ SHIPPING	TESTING FREQUENCY	*TURN-AROUND TIME
Adenovirus PCR	Urine, eye/conjunctiva swab	1 ml of urine.	Ship at 4C	Monday-Friday, daily 8:00 a.m. – 4:00 pm	2 days
CMV DNA PCR (blood)	6 ml EDTA only (lavender)	2 ml plasma	Separate plasma within 24 hours of collection. Store plasma @ 2-8C for up to 6 days and -20C for >6 days	Monday-Friday, daily 8:00 a.m. – 4:00 p.m.	2 days
CMV DNA PCR (non blood)	BAL, gastric biopsy, Lung aspirate, CSF, urine Bone marrow aspirate is NOT an acceptable specimen	0.5 ml CSF Minimum 2 ml of BAL or aspirate Biopsy must be submitted in viral UTM	Store in freezer until shipped Ship at 4C Ship at 4C	Monday-Friday, daily 8:00 a.m. – 4:00 pm	2 days
COVID NAT PCR	Nasopharyngeal Wash or NP swab, tracheal aspirate or BAL or Saline Gargle	2 ml viral transport media (see page 3, III. Viral Collection Kits) Minimum 2mL of BAL, aspirate or wash	Store at 4C	Daily	24 hours
EBV DNA PCR (non blood)	CSF, Sterile fluids ie: pleural effusion	0.5 ml CSF	Store in freezer until shipped	Monday-Friday, daily 8:00 a.m. – 4:00 pm.	24 hours
EBV DNA PCR (blood)	6 ml EDTA only (lavender)	2 ml plasma	Separate plasma within 6 hours of collection. Store plasma @ 2-8C for 72 hours and -20C for >72 hours	Monday-Friday, daily 8:00 a.m. – 4:00 p.m.	2 days

Table II continued

Molecular Testing

VIRUS	SAMPLE TYPE	MINIMUM VOLUME	STORAGE/ SHIPPING	TESTING FREQUENCY	*TURN-AROUND TIME
Enterovirus RNA PCR	CSF Stool	0.5 ml CSF Submit in sterile container	Store in freezer until shipped. Ship on ice. Store in fridge until shipped.	Monday-Friday, daily 8:00 a.m. – 4:00 pm.	24 hours
HBV DNA viral load	6 ml EDTA only (lavender)	2 ml plasma	Separate plasma within 24 hours of collection. Store plasma @ 2-8C for up to 6 days and -20C for >6 days.	Monday-Friday daily 8:00 a.m. – 4:00 p.m.	2 days
HBV Antiviral Resistance Testing	6 ml EDTA only (lavender)	2 ml plasma	Separate plasma within 6 hours of collection. Store plasma @ -20C. Send frozen.	Batch Testing	3-4 weeks
HHV8 Viral load (Testing must be approved by PHC Medical Microbiologist)	6 ml EDTA only (lavender)	2 ml plasma	Separate plasma within 6 hours of collection. Store plasma @ 2-8C for 72 hours and -20C for >72 hours	Once/week	5 days

Table II continued
Molecular Testing Continued

VIRUS	SAMPLE TYPE	MINIMUM VOLUME	STORAGE/ SHIPPING	TESTING FREQUENCY	*TURN-AROUND TIME
HIV RNA Viral load	6 ml EDTA only (lavender)	2 ml plasma	Separate plasma within 24 hours of collection. Store plasma @ 2-8C for up to 6 days and -20C for >6 days	Monday-Friday daily 8:00 a.m. – 4:00 p.m.	2 days
HSV DNA PCR	CSF	0.5 ml CSF	Store in freezer until shipped. Ship on ice	Monday-Friday, daily 8:00 a.m. – 4:00 p.m.	24 hours
	Skin swab, genital or oral swab	2 ml viral UTM	Store and ship at 4C	Monday-Friday, daily 8:00 a.m. – 4:00 p.m.	24 hours
Norovirus/Norwalk PCR (Testing must be approved by PHC Medical Microbiologist or Infection Prevention & Control)	Stool, emesis	1 ml in sterile container	Store at 4C	Monday-Friday, daily Sample must be in Virology by noon	24 hours
Polyomavirus DNA PCR (BK Virus and JC Virus)	6 ml EDTA only (lavender)	2 ml plasma	Separate plasma within 6 hours of collection. Store plasma @ 2-8C for 72 hours and -20C for >72 hours	Monday-Friday, daily 8:00 a.m. – 4:00 p.m.	3 days
	CSF	0.5 ml CSF	Store in freezer until shipped. Ship on ice		
Respiratory Virus PCR Panel	Nasopharyngeal Wash or NP swab, tracheal aspirate or BAL	2 ml viral UTM	Store at 4C	Monday-Friday, daily	24 hours

Table II continued

Molecular Testing Continued

VIRUS	SAMPLE TYPE	MINIMUM VOLUME	STORAGE/ SHIPPING	TESTING FREQUENCY	*TURN-AROUND TIME
VZV DNA PCR	CSF	0.5ml CSF	Store in freezer until shipped. Ship on ice	Monday-Friday, daily 8:00 a.m. – 4:00 p.m.	24 hours
	Skin swab, genital or oral swab	2 ml Viral UTM	Store and ship at 4C	Monday-Friday, daily 8:00 a.m. – 4:00 p.m.	24 hours

*Turn around time refers to hours/days for analytical phase (ie: interval between receipt of specimen/test request and performance of test to completion). Add 24 hours for reporting of result to health care provider. **Stat** and **Urgent** requests will be reviewed by the Medical Microbiologist and tests will be run accordingly based upon review.

V. Transport

1. For outside labs, when sending specimens, package the sample, the Virology and Reference Laboratory request form and ice pack in separate plastic bags and put them all in a non-leaking container. For transport within St Paul's Hospital, send the specimen to the main lab as soon as it is collected.
2. Package diagnostic specimens correctly in order to comply with shipping regulations and to avoid breakage and spillage.
3. Generally viral PCR specimens are stored at 2-8°C after collection and shipped on ice within 2 days. Viruses are labile and speed of transport is essential.
4. Anticoagulated bloods being sent for molecular testing must be transported at room temperature. Anticoagulated blood tubes must arrive in the Virology lab within 6 hours of specimen collection. If this is not achievable, the plasma must be removed aseptically from the cells and placed in a sterile polypropylene vial. The plasma must be shipped on ice and in accordance with shipping regulations.
5. Coagulated blood for viral serology does not need to be separated unless transport is delayed. Send coagulated blood at room temp as soon as possible to the laboratory and package as diagnostic specimens.
6. CSF for viral PCR should be transported on ice.

VI. Reporting

Positive or critical results are called daily to the requesting physician/ward or clinic for the following tests:

- Adenovirus PCR
- CMV PCR (blood)
- CMV PCR (non blood)
- EBV PCR (blood)
- EBV PCR (non blood)
- Hepatitis A IgM
- Norovirus PCR
- Polyomavirus PCR
- VZV PCR
- Respiratory Virus PCR
- Any positive PCR from CSF
- COVID-19 PCR (inpatients)

For PHC inpatients, the Infection Prevention and Control practitioners are automatically notified of the above critical results as soon as results are reported in the system. Patient reports are under no circumstances sent by facsimile by Virology lab. To obtain verbal results or faxed copies of patient reports, please call the call Center at **1-877-747-2522**. Results that are called out are documented in the “call-back” section in LIS.

VII. Test Descriptions

A. Molecular Diagnostic Testing

1. *Adenovirus PCR*

This is a Real time qualitative PCR assay that detects viral DNA in eye specimens, urines and respiratory samples including lung biopsies.

2. *Cytomegalovirus (CMV) PCR (blood)*

Real-time quantitative PCR measures CMV, viral load in plasma.
The dynamic range of the assay is 35 IU/mL to 10 million IU/mL

3. *COVID-19 (SARS-CoV-2) NAT PCR*

This is a Real time qualitative PCR assay that detects COVID-19 viral RNA in Respiratory specimens.

4. *Cytomegalovirus (CMV) PCR (non blood)*

Qualitative PCR detects CMV DNA in biopsies, aspirates, CSF, urines and BALs.

5. *EBV PCR (blood)*

Real-time quantitative PCR measures EBV, viral load in plasma.
The dynamic range of the assay is 1000 copies/mL to 14 million copies/mL.

6. *EBV PCR (non blood)*

This is a Real time qualitative PCR assay that detects viral DNA in CSF samples.

7. *Enterovirus PCR*

This is a Real time qualitative PCR assay that detects viral DNA in swabs and CSF samples.

VII. Test Descriptions (cont'd)

8. *Hepatitis B DNA viral load*

This is an in-vitro PCR assay for the quantitation of Hepatitis B Virus in human plasma from HBV-infected individuals.

This assay is not intended for use as a screening test for HBV or as a diagnostic test to confirm the presence of HBV infection.

The assay reportable range is 25 IU/mL to 1.7×10^8 IU/mL.

9. *HBV Antiviral Resistance Testing*

This is an in-vitro PCR and sequencing assay for the detection of Hepatitis B Virus (HBV) anti-viral resistance mutations and HBV genotype in human plasma from HBV-infected individuals. Only patients with a HBV viral load ≥ 1000 IU/mL will be routinely tested. Resistance and genotyping testing is only orderable by certain Gastroenterologists and Infectious Disease physicians. HBV resistance testing is routinely limited to 2 tests, per year, unless approved by Medical Microbiologist.

10. *Herpes Simplex Virus (HSV) PCR*

This is a Real time qualitative PCR assay that detects viral DNA in genital or oral swabs and CSF samples.

11. *HIV-1 RNA Quantitative PCR*

Quantitation of HIV RNA copy number is available to monitor antiviral therapy and to predict disease progression in HIV infected persons. **This test must not be used to diagnose HIV infection.**

The test has a dynamic range of 40 copies/ml to 10 million copies/ml

12. *Human Herpes Virus 8 PCR*

This test can be used to help with the diagnosis of HHV8 related diseases and to monitor response to treatment. Test requests must be approved by the PHC Medical Microbiologist.

13. *Influenza A&B, RSV Virus PCR Panel*

This is a Real time qualitative PCR assay that detects viral DNA/RNA in Respiratory specimens. This panel includes Influenza A, Influenza B, and Respiratory Syncytial Virus.

14. *Norovirus PCR*

This is a Real time qualitative PCR assay that detects viral DNA in stool or emesis samples. Testing must be approved by PHC Medical Microbiologist or Infection Prevention & Control.

15. *Polyomavirus PCR*

Real-time PCR detects polyomaviruses, BK virus and JC virus, in plasma and in CSF samples.

The dynamic range of the assay is 1000 copies/ml to 10 million copies/ml

VII. Test Descriptions (cont'd)

16. Respiratory Virus PCR Panel

This is a Real time qualitative PCR assay that detects viral DNA/RNA in Respiratory specimens. This panel includes Influenza A, Influenza B, Parainfluenza Type 1,2,3, Adenovirus, Respiratory Syncytial Virus and human Metapneumovirus.

17. Varicella Zoster (VZV) PCR

This is a Real time qualitative PCR assay that detects viral DNA in skin swabs and CSF samples.

B. Viral Serology

1) Cytomegalovirus (CMV) Serology

This antibody test is a qualitative assay that detects IgG to CMV.

2) Hepatitis Serology

a) **Hepatitis A**- Hepatitis A IgG antibody testing is performed daily, Monday through Friday, and should be used to determine immune status. Hepatitis A IgM (run daily) indicates acute infection and must be requested when an acute primary infection is suspected. All positive Hepatitis A IgM results are called to the requesting physician or laboratory. The physician must also report acute Hepatitis A infections to the local Communicable Disease Department. HA IgM testing is performed on demand.

b) **Hepatitis B surface antigen**- (HBsAg) is regarded as the cardinal marker of viral activity and infectivity.

c) **Hepatitis B core antibody, total (IgG plus IgM) and IgM**. Anti HBc Total is most useful as a marker of past infection. In some cases it is the only marker of past infection. This antibody does not confer immunity to hepatitis B re-infection. Anti HBc IgM indicates acute infection.

d) **Hepatitis B surface antibody** (HBsAb) is the cardinal marker of immunity to HBV. Occasionally, however, HBsAg and HBsAb may co-exist. This usually indicates an intermediate stage towards disappearance of HBsAg and development of full immunity. This is a quantitative test; a level of 10.0 IU being accepted as the cutoff for protective immunity.

e) **Hepatitis B "e" antigen and antibody**- HBeAg is considered to be a marker of viral replication and infectivity. The presence of HBeAb is indicative of a resolving infection and associated with lower HBV DNA levels. This antibody does not confer immunity to hepatitis B re-infection.

f) **Hepatitis C virus (HCV)** Most HCV infections are sub-clinical and chronic hepatitis is common. The mean time to appearance of anti-HCV in acute hepatitis C is 70 +/- 15 days. A confirmatory assay is run weekly when required.

VII. Test Descriptions (cont'd)

3) HIV Ag/Ab Combo Screen

The HIV Ag/Ab Combo assay is a chemiluminescent microparticle immunoassay (CMIA) for the simultaneous qualitative detection of HIV p24 antigen in HIV 1 and antibodies to human immunodeficiency virus type 1 and/or type 2 (HIV-1/HIV-2) in human serum or plasma. The HIV Ag/Ab Combo assay is intended to be used as an aid in the diagnosis of HIV-1/HIV-2 infection and as a screening test for donated blood and plasma. The HIV Ag/Ab Combo result does not distinguish between the detection of HIV p24 antigen, HIV-1 antibody, or HIV-2 antibody. Preliminary HIV Ag/Ab reactive results are confirmed by HIV Confirmatory Test, carried out at the BC Centre for Disease Control.