

Alberta Prenatal Screening Program for Selected Communicable Diseases

Public Health Guidelines

**Disease Control and Prevention
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Superseded

List of Acronyms and Selected Terms

AHW	Alberta Health and Wellness
Anti-HBs	Antibody to Hepatitis B surface antigen
AZT	Azidothymidine
CBS	Canadian Blood Services
CDRS	Communicable Disease Reporting System
CSF	Cerebral Spinal Fluid
CRS	Congenital Rubella Syndrome
CVS	Congenital Varicella Syndrome
DCP	Disease Control and Prevention
EDD	Estimated Date of Delivery
ER3	Electronic Reports <ul style="list-style-type: none">• Electronic delivery of lab test results from Provincial Laboratory of Public Health• Provides individual test results or lab reports on notifiable diseases
Fetus	An unborn human offspring up to time of birth
FNIHB	First Nations and Inuit Health Branch, Health Canada
FTA-ABS	Fluorescent Treponemal Antibody Absorption test
HBIG	Hepatitis B Immune Globulin
HBsAg	Hepatitis B surface antigen
HBV	Hepatitis B virus
HIV	Human Immunodeficiency virus
Infant	A child under 1 year of age
MAC	<i>Mycobacterium Avium</i> Complex
MMR	Measles, Mumps, Rubella Vaccine

MOH	Medical Officer of Health
Neonate	From birth to 1 month of age
PHO	Provincial Health Office
Postpartum	The first two months after delivery
PPHL	Provincial Public Health Laboratory (ProvLab)
PT	Prenatal Testing
RHA	Regional Health Authority
RPNN	Regional Partner Notification Nurse
RPR	Rapid Plasma Reagin test
SAP	Special Access Program
STI	Sexually Transmitted Infections
TP-PA	<i>Treponema Pallidum</i> Particle Agglutination test

Purpose

- To describe current and *future public health practice* for prenatal screening of selected communicable diseases in Alberta.
- To provide a historical description of past prenatal screening practices in Alberta.
- To describe the roles and responsibilities of Alberta Health and Wellness (AHW), the Provincial Public Health Laboratory (ProvLab), Regional Health Authorities (RHA), the attending physician and the expectant mother in the Alberta Prenatal Screening Program for selected communicable diseases.
- To describe the targets and target measurements of the Alberta Prenatal Screening Program for selected communicable diseases.

Goals of Prenatal Communicable Disease Screening

The broad goal of prenatal screening tests is to identify selected communicable diseases and to provide suitable interventions to protect and enhance the health of pregnant women and their infants.

1. Prenatal screening tests are recommended for five communicable diseases to identify pregnant women who are:
 - Positive for HIV and/or hepatitis B and/or reactive for syphilis.
 - Susceptible to rubella and varicella.
2. The anticipated target for prenatal screening involves approximately 37,723 pregnancies (average annual number of live births plus still births in Alberta, 1998 to 2002) brought to term in Alberta each year.¹ Pregnant women should be screened for these communicable diseases as part of their prenatal care.

Targets of Prenatal Communicable Disease Screening

100% of pregnant woman will be screened prenatally for these five communicable diseases. Screening consists of history taking and/or serological screening.

Program targets for the prenatal screening of each communicable disease are located under the applicable disease section: HIV, hepatitis B, syphilis, rubella or varicella.

Background

A. Historical

AHW has coordinated the prenatal screening program in partnership with the physician (via Alberta Medical Association [AMA]) providing prenatal care, the hospitals providing obstetrical services, the ProvLab, Canadian Blood Services (CBS), regional laboratories, the local Medical Officer of Health (MOH) or designate, and women seeking prenatal care. The screening tests were implemented in stages:

- i. Syphilis - 1950s
- ii. Rubella - 1970s
- iii. Hepatitis B - 1985
- iv. HIV - September 1, 1998
- v. Varicella - August 1, 2002

B. Summary of Prenatal Screening

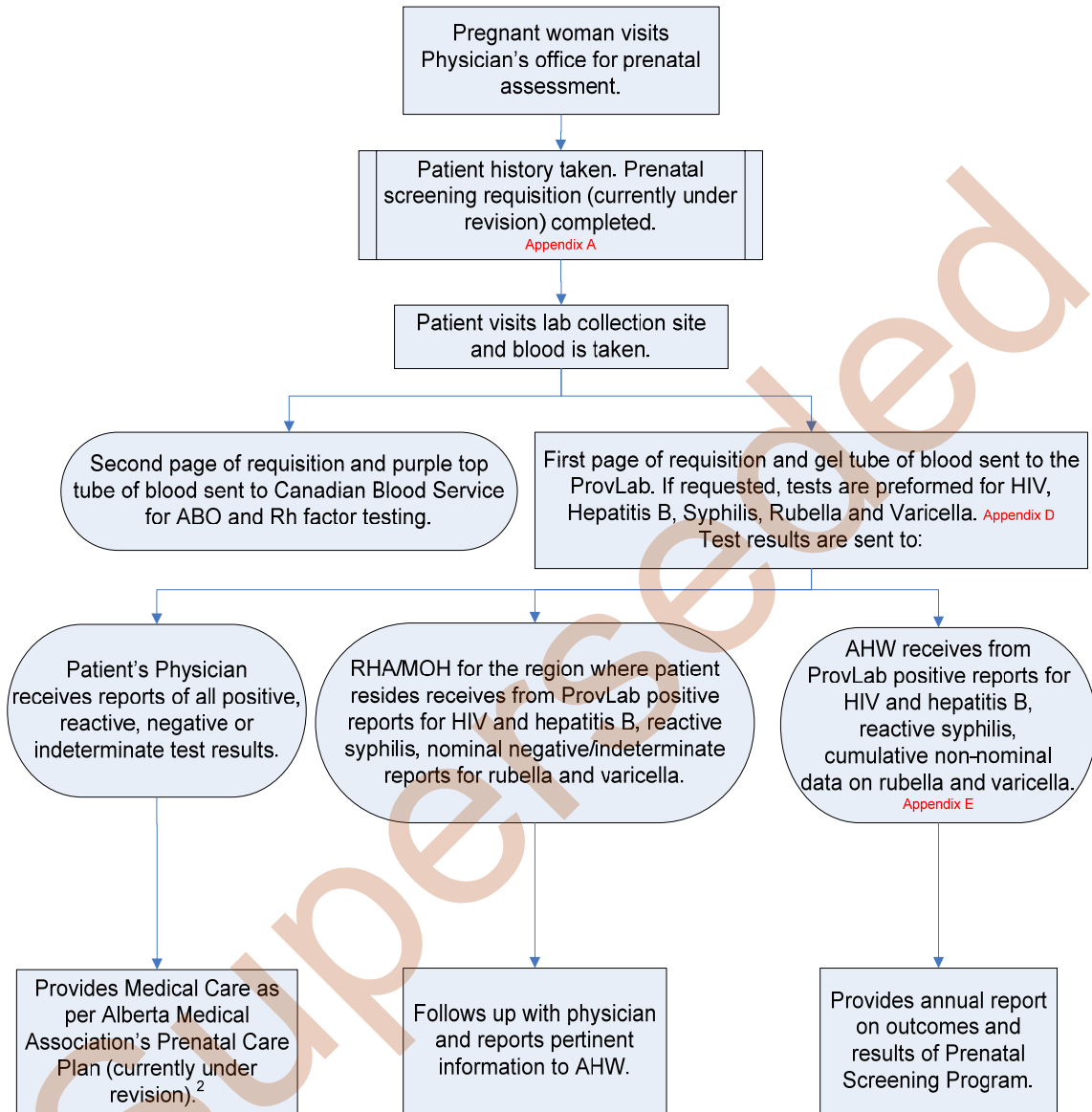
Beginning August 1, 2002:

- i. All prenatal screening tests for these communicable diseases were consolidated at ProvLab if accompanied by a prenatal requisition form (Appendix A).
 - Prior to this date screening tests for hepatitis B and HIV were performed at the CBS, and syphilis and rubella testing at regional laboratories and ProvLab.
- ii. A new requisition (Appendix A) was developed with input from the Alberta Medical Association (AMA), the CBS, ProvLab and public health professionals.
 - Negative/indeterminate screening tests for rubella and varicella were specified for inclusion in prenatal screening by the Provincial Health Office (PHO) (Appendix B).
- iii. All family physicians, obstetricians and midwives received information packages from the PHO announcing the change (Appendix C).

Beginning December 1, 2005:

- i. In addition to reporting negative rubella serology results, ProvLab began reporting all indeterminate (10-15 IU/mL) rubella serology results. Individuals with indeterminate results are to be considered non-immune (Appendix B).

C. Prenatal Screening Flowchart



Summary of Roles* in the Alberta Prenatal Screening Program

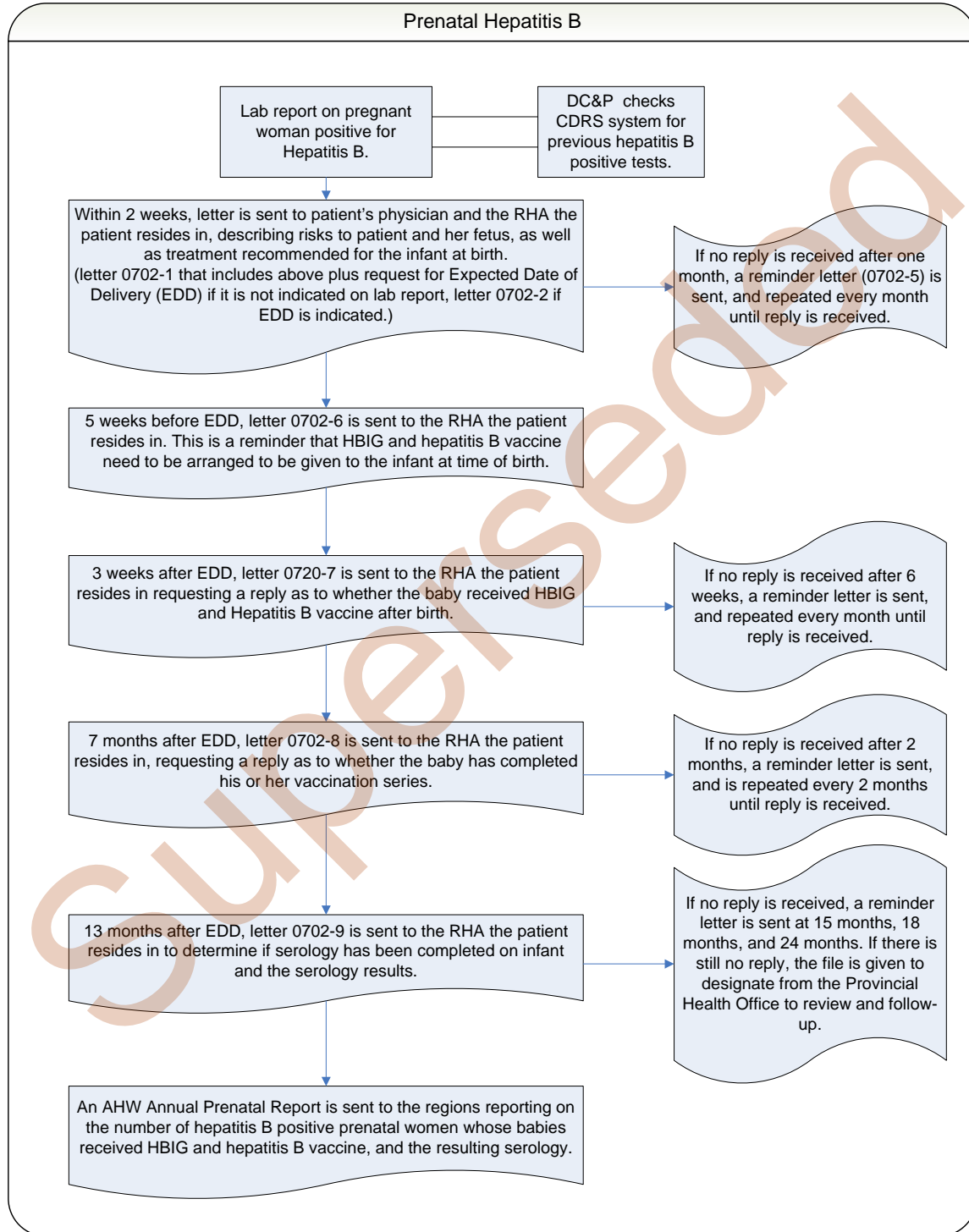
	Mother	Physician/Midwife	RHA/FNIHB	AHW
First Prenatal Visit	<ul style="list-style-type: none"> Provide pertinent history to healthcare provider. 	<ul style="list-style-type: none"> Follow the Alberta Medical Association's (AMA) <i>Prenatal Clinical Guidelines and Information for Health Professionals on HIV in Pregnancy</i>. Complete <i>Prenatal Testing – Initial Screen for Pregnant Women</i> (See Appendix A). Refer to Health Professional Resources available on AHW website at www.health.gov.ab.ca. 	N/A	N/A
After prenatal visit	<ul style="list-style-type: none"> Visit lab collection site for specimen collection. <p>Awareness of prenatal care recommendations for preserving personal health as well as that of the unborn baby.</p>	<ul style="list-style-type: none"> Once prenatal screening results received, provide medical follow-up as recommended. Provide necessary information to RHA (via Alberta Prenatal Record). 	<ul style="list-style-type: none"> For notifiable diseases, follow-up with physician as per guidelines and collect information on expected date of delivery (EDD) of patient. 	<ul style="list-style-type: none"> Communicate with RHAs on timely completion of NDR/Case report form, ensuring expected date of delivery (EDD) of patient is included. See algorithms p. 5 to 7.
At birth	<ul style="list-style-type: none"> Awareness of prenatal care recommendations of the healthcare provider for self. 	<ul style="list-style-type: none"> Follow recommendations for appropriate medical care. Provide necessary information to RHA. 	<ul style="list-style-type: none"> If required, ensure appropriate treatment and/or other follow-up for the mother and treatment or prophylaxis for the infant is provided as per current guidelines. Provide this information to AHW. 	<ul style="list-style-type: none"> Follow-up with RHAs on the appropriate treatment or prophylaxis for the infant. See algorithms p. 5 to 7.
Post-partum	<ul style="list-style-type: none"> Awareness of postpartum care recommendations of the healthcare provider for self and infant. 	<ul style="list-style-type: none"> Follow recommendations as per previous documents. Provide necessary information to RHA. 	<ul style="list-style-type: none"> Continue surveillance of the baby until necessary follow-up has been completed at 12-18 months of age. Offer MMR and/or Varicella vaccine as appropriate. 	<ul style="list-style-type: none"> Communicate with RHAs about the baby until necessary serology, treatment or post-exposure prophylaxis has been completed. See algorithms p. 5 to 7.

* The Role of ProvLab is discussed on page 8.

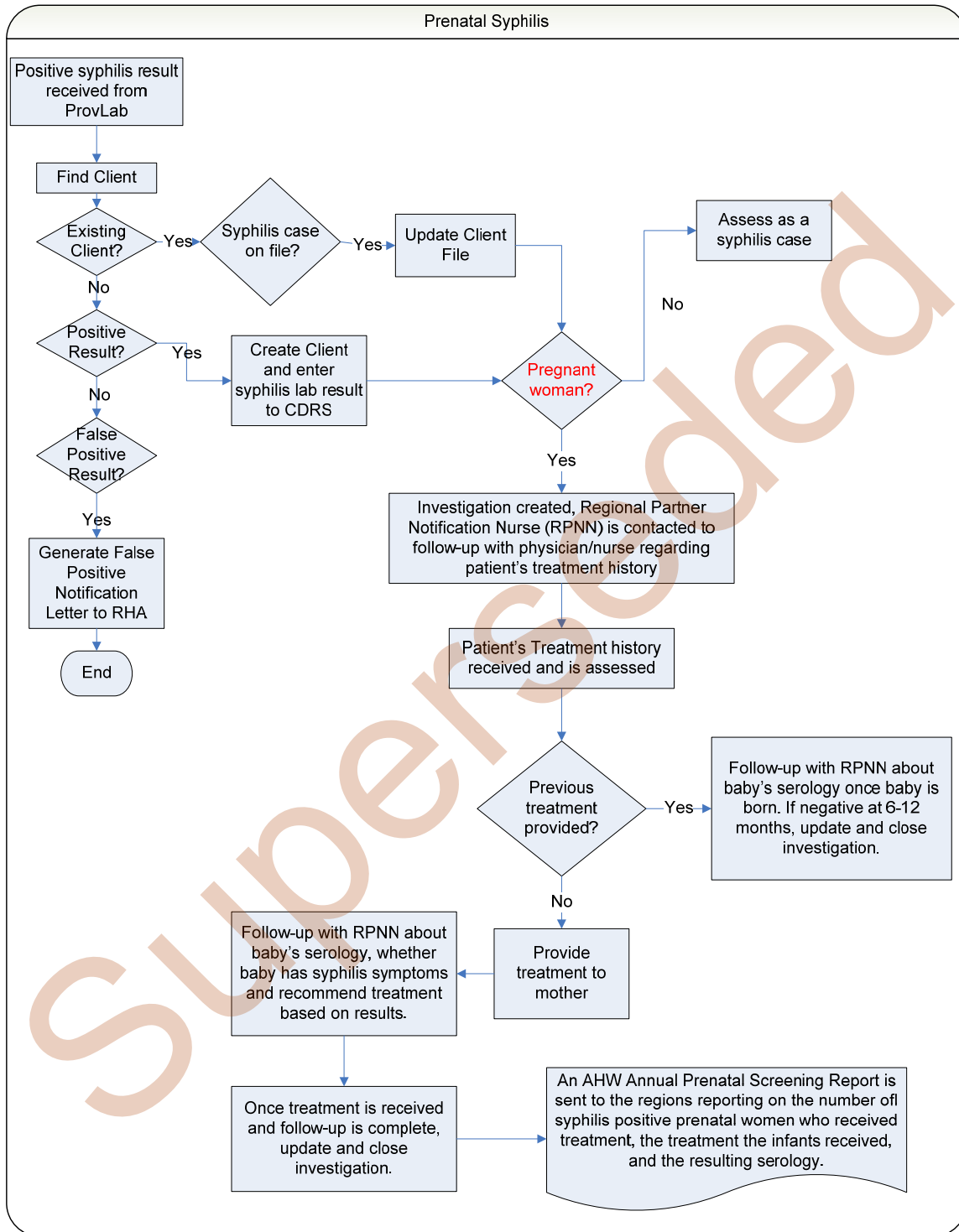
A. Roles of Alberta Health and Wellness

i. Prenatal HIV (under development)

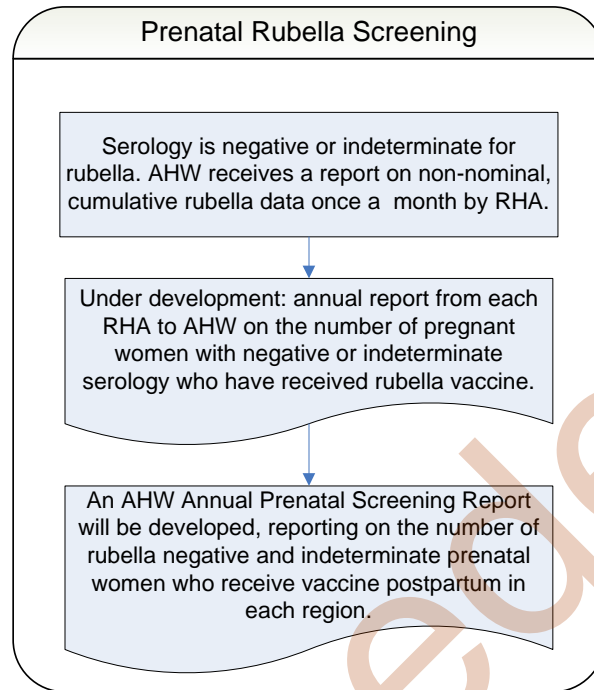
ii. Prenatal Hepatitis B



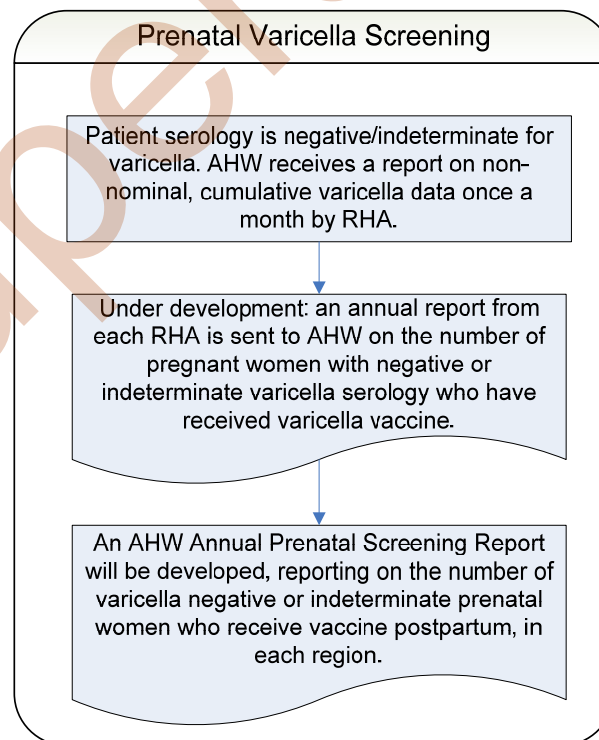
iii. Prenatal Syphilis



iv. Prenatal Rubella



v. Prenatal Varicella



B. Roles of ProVLab

Results Reported from ProVLab

Specimens received with the prenatal requisition at ProVLab are given a special 'PT' (prenatal testing) prefix. The PT prefix is used as criteria for the electronic data pull for test results within the prenatal program.²

Please note: specimens from pregnant women that are not accompanied by a prenatal requisition are not assigned a PT prefix.

The ProVLab initiated new prenatal screening reporting processes to AHW and RHAs on January 1, 2005. Monthly and cumulative line lists for all five disease markers and other selected data elements are forwarded to RHAs and AHW by ProVLab.

The following outlines the five markers tested, who test results are reported to and how they are reported. Details of prenatal test information and reporting algorithms are contained in Appendix D.

i. HIV

- Negative test results are reported to physician.
- Positive HIV antibody test results, both new and previously known, are reported to the physician, RHA and AHW.
- Number of provincial tests (positive and negative) performed and other variables are reported to AHW.
- The ProVLab is able to link previous positives that have been tested at the ProVLab, but not if they have been tested elsewhere or under a different personal identifier.
 - For HIV data from Northern Alberta, the current active database in cohort (name of the ProVLab laboratory information system) that the ProVLab looks up for patients starts from 1997. There is a separate cohort database for HIV from 1993 to 1996 that the technologist looks up separately when a patient tested positive for HIV and has no HIV data in the current active database.
 - For Southern Alberta, the testing information before Feb 2002 (when Southern Alberta Laboratory implemented the use of cohort) is in a separate ProVLab database.

ii. Hepatitis B

- Negative test results are reported to the physician.
- Positive HBsAg, both new and previously known, are reported to physician, RHA and AHW.
- For HBsAg from Northern Alberta, the data on cohort is from 1993 onwards. Again for Southern Alberta, the data is in cohort only from Feb 2002 onwards. HBsAg is further complicated by the fact that other regional labs also perform HBsAg so ProVLab does not have complete history on patients when checking for previous positives.
- Number of tests performed (positive and negative) and other selected variables are reported to AHW.

iii. Syphilis

- Non-reactive test results are reported to physician.
- All reactive rapid plasma reagin test (RPR), reactive *Treponema pallidum* particle agglutination test (TP-PA) and reactive fluorescent treponemal antibody absorption test (FTA-ABS) are reported to the physician and AHW.
- Number of tests performed (reactive and non-reactive) are reported to AHW.

iv. Rubella

- Positive test results are reported to the physician.
- Negative and indeterminate (non-immune) IgG test results are reported to the physician and the RHA (via lab report).
- Cumulative number of tests performed with the number negative, indeterminate and positive results are reported to AHW.

v. Varicella

- Positive test results are reported to the physician.
- Negative and indeterminate (non-immune) IgG test results are reported to the physician and the RHA (via lab report).
- Cumulative number of tests performed with number negative, indeterminate and positive results are reported to AHW.

How Results are Reported by ProvLab

- i. To the Submitting Healthcare Provider
 - Mail, or
 - Fax, or
 - Electronic Reporting (ER2 or ER3), and
 - Phone call to clinic for positive HIV and positive HBsAg.
- ii. To the RHA
 - Mail, or
 - Fax, or
 - Electronic Reporting 3 (ER3) – currently used by some RHAs.
- iii. To AHW
 - ER3 (provides individual test results or lab reports on notifiable diseases).
 - A compilation of the data in line lists is also provided, including the total number of women tested by age and region, an identifier line list of pregnant women positive for HIV, hepatitis B and syphilis, and a total number of negative and indeterminate tests for varicella and rubella IgG.

Prenatal HIV Screening

A. Rationale for Prenatal HIV Screening

HIV transmission can be reduced in infants through HIV screening of pregnant women and appropriate management of the HIV infected pregnant woman and infant after delivery.

- i. Mother-to-child transmission of HIV, which can occur during pregnancy, delivery or breastfeeding, is responsible for more than 90% of HIV infection in children worldwide.³
- ii. The number of Canadian women living with HIV infection and becoming pregnant is increasing.⁴⁻⁶
- iii. The implementation of strategies, including prenatal screening with appropriate interventions, can theoretically prevent >98 per cent of perinatal HIV-1 transmission.⁷

B. Targets of Prenatal HIV Screening

No cases of HIV will occur in infants born to HIV-positive women in any given year.

- i. 100% of pregnant women who do not decline testing will be screened.
- ii. 100% of women who test HIV positive will be informed of the positive test by an appropriate healthcare provider.
- iii. 100% of HIV infected pregnant women will be offered antepartum and intrapartum interventions, including antiretroviral therapy and caesarean section if appropriate.
- iv. 100% of infants born to women who are HIV-positive will be offered HIV prophylaxis.
- v. 100% of infants born to HIV-positive mothers will have HIV serology by 18 months of age.
 - >90% of babies born to HIV-positive women will test negative for HIV by 18 months of age.

C. Recommended Protocol⁷⁻⁹

Care of the Pregnant and Postpartum Woman

- i. Early diagnosis of HIV infection allows the pregnant woman to receive effective antiretroviral therapies to protect her own health.
 - In addition, antiretroviral drugs (e.g., ZDV) greatly improve the chances that her child will be born free of infection.
- ii. All HIV-positive pregnant women should be promptly referred to an Infectious Disease /HIV Specialist.
- iii. Medical care and management of HIV in pregnant women can be complex because of:
 - The need for combination antiretroviral therapy.
 - Management of common side effects of these medication therapies.
 - The need for careful monitoring of HIV RNA level (viral load).
 - Monitoring of immune status (CD4 count).
 - The potential for adverse short- or long-term effects of antiretroviral therapies on the fetus and the infant.
- iv. HIV-positive pregnant woman should be given information on factors that reduce perinatal HIV transmission, which include:
 - Antiretroviral therapy (for the mother's health and/or prevention of vertical transmission),
 - Obstetrical options (e.g., caesarean section),
 - Formula feeding.

For additional information and pamphlets see *Health Information* and *For Health Professionals* links on AHW website at: www.health.gov.ab.ca.

Care of the Neonate

- i. Since HIV can be transmitted through breast milk, breast-feeding is not recommended for HIV-positive woman.
 - Free formula for infants born to HIV-positive mothers is available through provincial programming (access through the Northern and Southern Alberta HIV Clinics).
- ii. Infants born to HIV-positive woman should be referred to a paediatric infectious disease specialist for ongoing assessment and care, including serological testing at 18 months age to determine HIV serostatus, and appropriate HIV prophylaxis and treatment.

D. Measurement of Prenatal HIV Screening Targets

- i. 100% of pregnant women who do not decline testing will be screened.

$$\frac{\text{\# of pregnancies screened for HIV}}{\text{\# of pregnancies* - \# who declined testing}}$$

* Includes spontaneous abortions in women who saw a physician (MD billing), therapeutic abortions, and deliveries (still and live births).

- ii. 100% of women who test HIV positive will be informed of the positive test by an appropriate healthcare provider and referred to Infectious Disease /HIV Specialist for appropriate care.

(Unable to measure this outcome at present)

- iii. 100% of infants born to HIV positive women will be offered HIV prophylaxis.

$$\frac{\text{\# of infants on HIV prophylaxis}}{\text{\# of infants born to HIV-positive women}}$$

- iv. 100% of infants born to HIV positive mothers will have serology by 18 months of age.

$$\frac{\text{\# of infants with completed serology}}{\text{\# of infants born to HIV-positive women}}$$

- v. >90% of babies born to HIV-positive women will test negative for HIV by 18 months of age.

$$\frac{\text{\# of HIV-positive infants}}{\text{\# of infants born to HIV-positive women}}$$

$$\frac{\text{\# of HIV-negative infants}}{\text{\# of infants born to HIV-positive women}}$$

NOTE: All measures of prenatal screening targets are preliminary and will be refined as the *Alberta Prenatal Screening Program for Selected Communicable Diseases* evolves.

Hepatitis B

A. Rationale for Prenatal Hepatitis B (HBV) Screening^{11,12}

Hepatitis B transmission can be reduced in infants through hepatitis B screening of pregnant women and appropriate follow-up of the infant after delivery.

- i. Infants born to women who have acute hepatitis B infection during the third trimester of pregnancy have a risk of up to 90% of acquiring HBV without appropriate prophylaxis.¹⁰
 - Up to 90% of infants infected with HBV in the first few months of life will become chronic carriers.
- ii. One dose each of Hepatitis B immune globulin (HBIG) and Hepatitis B vaccine, administered within 12 hours after birth, are 85 to 95% effective in preventing both Hepatitis B infection and the chronic carrier state.

B. Targets of Prenatal Hepatitis B Screening

No cases of hepatitis B will occur in infants born to HBV-positive women in any given year.

- i. 100% of pregnant women will be screened for HBV.
- ii. 100% of women who test positive for HBV will be informed of the positive test by an appropriate healthcare provider.
- iii. 100% of infants born to women with HBV will receive prophylaxis (HBIG and 3 doses of hepatitis B vaccine) as per recommended protocols.
- iv. 100% of infants born to HBV-positive women will have hepatitis B serology completed. (i.e., the caregiver of the infant will be encouraged to have the infant tested via a blood specimen).
- v. >90% of infants born to HBV-positive women will test negative for Hepatitis B surface antigen (HBsAg) by 18 months of age.

C. Recommended Protocol¹¹⁻¹⁵

- i. All infants born to HBV-positive women should be given an intramuscular dose of 0.5 ml HBIG as soon as possible and within 12 hours of birth.
 - The efficacy of HBIG decreases sharply if given more than 48 hours after birth.
 - HBIG has no proven efficacy if given more than seven days after birth.
- ii. The initial dose of hepatitis B vaccine should be given within 12 hours of birth.
 - Vaccine and HBIG may be given at the same time but at different sites.
 - If exceptional circumstances prevent immediate administration of vaccine and HBIG, they should be given at the first possible opportunity. Their administration, however, should never be delayed unnecessarily.
 - If the first dose of vaccine is delayed beyond the second month of age, a repeat dose of 0.5 mL HBIG should be administered at three months of age.
- iii. The second and third dose of the vaccine series should be given one and six months after the first dose or during the two and six month clinic visits.
- iv. Neonates weighing less than 2000g born to HBV-positive women should have an individualized schedule that includes HBIG, at least four doses of vaccine and assessment of antibody response after the series has been completed.
- v. Testing of the infant for HBsAg and antibodies to hepatitis B surface antigen (anti-HBs) is recommended at 12 months of age to monitor the success of prophylaxis.
 - If HBsAg positive, the infant is likely to become a chronic carrier and should be referred to and followed by a pediatric specialist.
 - If the infant is negative for both HBsAg and anti-HBs, a fourth dose is given and serology for anti-HBs is repeated four weeks later. If still negative, complete the series (two more doses) and repeat serology four weeks later. If still negative, the infant is considered a non-responder.

D. Measurement of Prenatal Hepatitis B Screening Targets

- i. 100% of pregnant women will be screened for hepatitis B.

$$\frac{\text{\# of pregnancies screened for HBV}}{\text{\# of pregnancies}^*}$$

* Includes spontaneous abortions in women who saw a physician (MD billing), therapeutic abortions, and deliveries (still and live births).

- ii. 100% of women who test positive for hepatitis will be informed of the positive test by an appropriate healthcare provider.

(Unable to measure this outcome at present)

- iii. 100% of infants born to HBV-positive women will receive prophylaxis as per recommended protocols.

$$\frac{\text{\# of infants who have received hepatitis B prophylaxis}}{\text{\# of infants born to HBV-positive women}}$$

- iv. 100% of infants born to HBV-positive women will have serology completed.

$$\frac{\text{\# of infants with completed serology}}{\text{\# of infants born to HBV-positive women}}$$

- >90% of infants born to HBV-positive women will test negative for HBsAg by 18 months of age.

$$\frac{\text{\# of HBV-negative infants}}{\text{\# of infants born to HBV-positive women}}$$

$$\frac{\text{\# of HBV-positive infants}}{\text{\# of infants born to HBV-positive women}}$$

NOTE: All measures of prenatal screening targets are preliminary and will be refined as the *Alberta Prenatal Screening Program for Selected Communicable Diseases* evolves.

Syphilis

A. Rationale for Prenatal Syphilis Screening¹⁷

*Congenital syphilis (CS) can be prevented, either by screening pregnant women for syphilis, appropriately treating those who are infected, and/or preventing reinfection.*¹⁶

- i. The majority of infants with congenital syphilis are infected in utero, but they can also be infected by contact with an active genital lesion at the time of delivery.
- ii. The risk of transmission is much greater when the mother has untreated primary, secondary or early latent syphilis in pregnancy than if she has late latent syphilis.

Congenital Syphilis

- 2/3 of cases are asymptomatic.
- Manifestations of early CS include fulminant disseminated infection, mucocutaneous lesions, osteochondritis, anemia, hepatosplenomegaly, neurosyphilis.
- Manifestations of late CS include interstitial keratitis, lymphadenopathy, hepatosplenomegaly, bone involvement, anemia, Hutchinson's teeth, and neurosyphilis.

B. Targets of Prenatal Syphilis Screening

No cases of congenital syphilis will occur in any given year.

- i. 100% of pregnant women will be screened for syphilis.
- ii. 100% of women who test syphilis positive for a new infection will be informed of the positive test and be provided with appropriate counselling and management according to the disease status by an appropriate healthcare provider.
- iii. 100% of women will be offered treatment for infectious or newly diagnosed syphilis as per recommended protocols.
- iv. 100% of infants born to mothers who tested positive for infectious or newly diagnosed latent syphilis be assessed by a Paediatric Infectious Diseases specialist regarding the need for treatment.
- v. 100% of these infants born with reactive results will have the recommended serological testing at six and 12 months.

C. Recommended Protocol¹⁷

Care of the Pregnant Woman

- i. Pregnant women who continue to be at high risk for syphilis during pregnancy should be rescreened in the third trimester of pregnancy.

Risk factors include: sex with men who have sex with men and women, sex trade workers, street involvement, injection drug use, multiple sexual partners, previous history of syphilis, HIV and/or other STIs, those originating from or having sex with an individual from a country with a high prevalence of syphilis and sexual partners of individuals with any of the preceding risk factors.

- ii. All women with infectious or newly diagnosed syphilis during pregnancy should be referred to a medical expert and receive treatment appropriate to their stage of disease.
 - Benzathine penicillin G is the strongly preferred agent during pregnancy and can only be accessed through regional or provincial STD services.
 - If the mother is >20 weeks gestation, an ultrasound should be performed and she should ideally be managed in consultation with an obstetrician/maternal-fetal medicine specialist.
 - If fetal abnormalities are identified, the mother should be hospitalized for treatment and fetal monitoring.
- iii. In women with a history of adequately treated syphilis, retreatment during pregnancy is not necessary unless there is clinical or serologic evidence of new infection (four-fold rise in a non-treponemal test titre) or history of recent sexual contact with an individual who has early syphilis.

Care of the Neonate

- i. Infected infants are frequently asymptomatic at birth and may be seronegative if maternal infection occurred late in gestation.
- ii. All babies should be assessed at delivery by a pediatrician, and if a maternal non-penicillin regimen was used, consideration should be given to treating the baby empirically for congenital syphilis.
- iii. Infants should be treated at birth:
 - If symptomatic.
 - If the infant's non-treponemal titre is four-fold (two tubes) higher than the mother's.

- If maternal treatment was inadequate, did not contain penicillin, is unknown or occurred in the last month of pregnancy, or if maternal serologic response is inadequate.
 - If adequate follow-up of the infant cannot be ensured.
- iv. Infants with reactive serologic tests to syphilis should have repeat serological testing at six and 12-18 months to determine clearance of passively transferred maternal antibodies or the presence of congenital infection.

Superseded

SYPHILIS TREATMENT GUIDELINES (Pregnant Women and Neonates)¹⁷

	Stage	Preferred treatment	Alternative treatment for penicillin allergic patients
Pregnant women	<ul style="list-style-type: none"> • Primary • Secondary² • Early latent (< 1 year duration) 	Benzathine penicillin G 2.4 million units IM as a single dose. ¹	<ul style="list-style-type: none"> • There is no satisfactory alternative to penicillin for the treatment of syphilis in pregnancy; insufficient data exists to recommend ceftriaxone in pregnancy. • Strongly consider penicillin desensitization followed by treatment with penicillin. (<i>Refer to 1998 Canadian STD Guidelines</i>) • Strongly consider penicillin desensitization followed by treatment with penicillin. (<i>Refer to 1998 Canadian STD Guidelines</i>) • Ceftriaxone 2 gm IV/IM QD x 10-14 days.
	<ul style="list-style-type: none"> • Late latent syphilis • Latent syphilis of unknown duration • Cardiovascular syphilis and other tertiary syphilis not involving the central nervous system. 	Benzathine penicillin G 2.4 million units IM weekly for 3 doses.	
	<ul style="list-style-type: none"> ○ Neurosyphilis 	Crystalline Penicillin G 3-4 million U IV every four hours (16-24 million U/day) for 10-14 days.	
Congenital syphilis	<ul style="list-style-type: none"> • Early (< 1 month) 	Crystalline penicillin G 50,000 U/kg IV every 12 hours for the first week of life and every eight hours thereafter for 10 days of total therapy.	<ul style="list-style-type: none"> • If no neurological involvement and normal CSF: Benzathine penicillin G 50,000 U/kg IM (max 2.4 MU) weekly for three successive weeks. • No data is available to recommend penicillin alternatives in the case of penicillin allergy.
	<ul style="list-style-type: none"> • Late (> 1 month) 	Crystalline penicillin G 50,000 U/kg/ IV every six hours for 10-14 days.	
Sexual Contacts	<ul style="list-style-type: none"> • Epidemiological treatment of sexual contacts in the preceding 30 days to primary, secondary and early latent syphilis.³ 	Benzathine penicillin G 2.4 million units IM as a single dose	See comment below on Azithromycin. ⁴

1. Some experts recommend 3 weekly doses (total of 7.2 million units) of benzathine penicillin G in HIV infected individuals.
2. Secondary syphilis in late pregnancy (> 20 weeks gestation) should be treated with two doses of benzathine penicillin G 2.4 mu given one week apart (see note under Pregnancy below).
3. If sexual contact is unreliable or unable to test, then epidemiological treatment should be strongly considered.
4. In light of recent reports of failure of azithromycin for the treatment of early syphilis and rapid development of azithromycin resistance in *T. pallidum*, this agent has not been included in the treatment options for early syphilis.

D. Measurement of Prenatal Syphilis Screening Targets

- i. 100% of pregnant women will be screened for syphilis.

$$\frac{\text{\# of pregnancies screened for syphilis}}{\text{\# of pregnancies}^*}$$

* Includes spontaneous abortions in women who saw a physician (MD billing), therapeutic abortions, and deliveries (still and live births).

- ii. 100% of women who test reactive for a new syphilis infection will be informed of the positive test by an appropriate healthcare provider.

(Unable to measure this outcome at present)

- iii. 100% of women will be offered treatment for infectious or newly diagnosed syphilis as per recommended protocols.

(Unable to measure this outcome at present)

- iv. 100% of infants born to mothers who are syphilis reactive will be tested at birth and receive appropriate follow-up according to the guidelines.

$$\frac{\text{\# of infants being tested}}{\text{\# of infants born to syphilis reactive women}}$$

- v. 100% of reactive infants born will have the recommended serological testing at six and 12-18 months.

$$\frac{\text{Total \# of reactive infants with completed serology at six and 12-18 months}}{\text{\# of infants born to syphilis reactive women}}$$

$$\frac{\text{\# of syphilis reactive infants}}{\text{\# of infants born to syphilis reactive women}}$$

$$\frac{\text{\# of syphilis non-reactive infants}}{\text{\# of infants born to syphilis reactive women}}$$

NOTE: All measures of prenatal screening targets are preliminary and will be refined as the *Alberta Prenatal Screening Program for Selected Communicable Diseases* evolves.

Rubella

A. Rationale for Prenatal Rubella Screening¹²

Congenital rubella syndrome (CRS) can be prevented by providing rubella-containing vaccine to all women of childbearing age who do not have proof of immunity (positive rubella IgG test or record of prior immunization with two doses of rubella-containing vaccine) AND by screening ALL pregnant women for rubella immunity and immunizing those with negative/indeterminate serology, if eligible, to prevent CRS in future pregnancies.

- i. One or two cases of CRS occur every year in Canada.
- ii. Up to one-third of cases of CRS occur in second and subsequent pregnancies.
- iii. Rubella virus continues to circulate in the community, and not all pregnant women are immune. Some segments of the population are not immunized against rubella because they are missed, refuse immunization or come from countries where rubella vaccination is not part of the routine immunization program.
- iv. Increasingly, mothers of CRS infants are foreign born and less likely to have been immunized against rubella before immigration to Canada.¹⁸

Congenital Rubella Syndrome

- Can result in miscarriage, stillbirth and fetal malformations, including congenital heart disease, cataracts, deafness and mental retardation.
- The risk of fetal damage following maternal infection is particularly high in the earliest months after conception (85% in the first trimester) with progressive diminution of risk thereafter, and is very uncommon after the 20th week of pregnancy.
- Infected infants who appear normal at birth may later show eye, ear or brain damage.
- Congenital infection may become chronic and give rise to such problems as diabetes mellitus and panencephalitis later in life.
- A small number of congenitally infected infants may shed the virus in the urine and nasopharyngeal secretions for 1 year or more.

B. Targets of Prenatal Rubella Screening

No cases of congenital rubella syndrome will occur in a given year.

- i. 100% of women who seek prenatal care identified as having no documented immunity to rubella, will be screened for rubella antibody.
- ii. 100% of women with negative or indeterminate serology for rubella will be assessed and, if eligible, be offered a rubella-containing vaccine (e.g., Measles-Mumps-Rubella or MMR).

C. Recommended Protocol^{12,14,15}

- i. A rubella-containing (e.g., MMR) vaccine should be given to all non-pregnant women of childbearing age unless they have documented proof of immunity.
 - Women immunized with live vaccine should avoid pregnancy for at least one month after immunization.
- ii. A rubella-containing vaccine is offered in an effort to prevent congenital rubella syndrome in future pregnancies.
- iii. Pregnant women with negative or indeterminate serology for rubella will be assessed and, if eligible, be offered a rubella-containing vaccine in the immediate post-partum period, preferably while still in hospital, or alternately at the child's first clinic visit.
 - Women who have **two documented doses** of rubella-containing vaccine DO NOT require a third dose regardless of negative or indeterminate serology.
 - These women should be considered falsely negative or a non-responder.
 - However, if exposed to rubella disease during pregnancy, these women should be considered non-immune and appropriate public health follow-up should occur.
 - Women who have **one documented dose** of a rubella-containing vaccine but still have negative rubella serology, should be offered one dose of MMR postnatally and be considered protected with no further serological testing required.
- iv. Rh_o(D) immune globulin (Rh IG) may interfere with the response to rubella vaccine.
 - Women susceptible to rubella, who are given Rh IG in the peripartum period, should receive MMR vaccine as soon as possible following delivery.
 - Serological testing for rubella (IgG) should be done 2 months following vaccine administration to assess immune response.

Immunization History	Serological Status	Action
Two or more documented doses	Negative* or indeterminate**	<ul style="list-style-type: none"> ▪ None. ▪ BUT if exposed to rubella disease during pregnancy, consider non-immune.
One documented dose	Negative* or indeterminate**	<ul style="list-style-type: none"> ▪ Provide one dose of MMR vaccine postnatally. ▪ No further serological testing required.
No documentation	Negative* or indeterminate**	<ul style="list-style-type: none"> ▪ Provide one dose of MMR vaccine postnatally.****
No documentation	Positive***	<ul style="list-style-type: none"> ▪ None.

ProvLab Rubella IgG Results Reported:

*Negative serology (<10 IU/mL) **Indeterminate serology (10-15 IU/mL) ***Positive serology (>15 IU/mL)

****Revised February 12, 2007

Revised July 18, 2007

D. Measurement of Prenatal Rubella Screening Targets

- i. 100% of women who seek prenatal care will be screened for rubella antibody if indicated.
- ii. 100% of women with negative or indeterminate serology for rubella will be assessed and, if eligible, be offered a rubella-containing vaccine (e.g., MMR).

$$\frac{\# \text{ of women who received rubella vaccine postpartum}}{\# \text{ of postpartum women} - \# \text{ of postpartum women with a history of positive serology}}$$

$$\frac{\# \text{ of women who received rubella vaccine postpartum}}{\# \text{ of postpartum women with a history of negative or indeterminate rubella serology}}$$

$$\frac{\# \text{ of women who did not receive or refused vaccine postpartum}}{\# \text{ of postpartum women with a history of negative or indeterminate rubella serology}}$$

NOTE: All measures of prenatal screening targets are preliminary and will be refined as the *Alberta Prenatal Screening Program for Selected Communicable Diseases* evolves.

Varicella

A. Rationale for Prenatal Varicella Screening¹²

Congenital varicella syndrome (CVS) can be prevented by ensuring all women of childbearing age have immunity to varicella and by screening all pregnant women, with no documented history of immunity (disease) or immunization, for varicella antibodies.

- i. If a woman contracts varicella during the first 20 weeks of pregnancy, there is up to a 2% risk that the virus will infect the fetus, causing congenital varicella syndrome.
- ii. Severe neonatal varicella can occur in up to 30% of infants when the onset of maternal varicella was from five days before to two days after birth. The mortality rate of these infected infants can be 20 to 30%.

Congenital Varicella Syndrome (CVS)

- May be mild or severe.
- Manifestations may include low birth weight, cicatricial skin scarring, ophthalmic abnormalities, limb hypoplasia and cortical atrophy as well as a variety of other anomalies.
- Almost one-third of affected infants die by early in the second year of life.

B. Targets of the Prenatal Varicella Screening

No cases of congenital varicella syndrome will occur in any given year.

- i. 100% of women who seek prenatal care identified as having an uncertain or no history of chickenpox disease, and have not received immunization with varicella vaccine, will be screened for varicella antibody.
- ii. 100% of women with negative or indeterminate serology for varicella will, if eligible, be offered varicella vaccine.

C. Recommended Protocol^{12,14,15,19}

Care of the Pregnant and Postpartum Woman

- i. Non-pregnant women of child-bearing age who are susceptible to varicella should be immunized with two doses of varicella vaccine; those who are vaccinated should avoid pregnancy for one month after vaccination.

- ii. Susceptible pregnant women who report exposure to varicella disease should be offered VZIG within 96 hours after the exposure.
- iii. Pregnant women with a history of varicella disease or immunization do not require serological testing for varicella immunity. The tests currently available are not sensitive enough to detect vaccine-induced immunity.
- iv. Women with negative or indeterminate serology for varicella will be assessed and, if eligible, be offered varicella vaccine.
 - Varicella vaccine should be given within a week of giving birth. Some RHAs offer the vaccine in hospital, others through public health centres.
 - A second dose of varicella vaccine needs to be given at least 28 days after the first dose.
- v. Rh_o(D) immune globulin (Rh IG) may interfere with the response to varicella vaccine.
 - Varicella immunization of susceptible post-partum women should be delayed for 2 months after they have received Rh IG.

Care of the Neonate

- i. VZIG is recommended for neonates of mothers who develop varicella the five days before or 48 hours after delivery.

D. Measurement of Prenatal Varicella Screening Targets

- i. 100% of women who seek prenatal care will be screened for varicella antibody if eligible.
- ii. 100% of women with negative or indeterminate serology for varicella will, if eligible, be offered varicella vaccine.

of women who received varicella vaccine postpartum
postpartum women - # of postpartum women with a history of positive serology

of women who received varicella vaccine postpartum
of postpartum women with a history of negative or indeterminate varicella serology

of women who did not receive or refused varicella vaccine postpartum
of postpartum women with a history of negative or indeterminate varicella serology

Revised July 18, 2007

NOTE: All measures of prenatal screening targets are preliminary and will be refined as the *Alberta Prenatal Screening Program for Selected Communicable Diseases* evolves.

Superseded

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Alberta Health and Wellness. (2005). *Public Health Notifiable Disease Management Guidelines* [Electronic version]. Available on-line at: http://www.health.gov.ab.ca/professionals/ND_index.html

Alberta Medical Association Website: www.albertadoctors.org

- Clinical Resources/Child Health/Prenatal Care
- Clinical Resources/Women's Health/HIV Screening

Alberta Perinatal Health Program Website: www.aphp.ca

ProvLab (Provincial Laboratory for Public Health) website: www.provlab.ab.ca

Superseded

APPENDIX A

Prenatal Testing – Initial Screen for Pregnant Women

Requisition

Provincial Laboratory for Public Health (Microbiology)
Calgary site: 3030 Hospital Drive NW, Calgary, T2N 4W4
 Tel: (403) 944-1200 Fax: (403) 270-2216

Edmonton site: 8440-112 Street, Edmonton, T6G 2J2
 Tel: (780) 407-7121 Fax: (780) 407-3864

24-hour phone line for Prenatal screening results (780) 407-8667

Canadian Blood Services (CBS)
Calgary site: 737-13 Ave. S.W. Calgary T2R 1J1
 Phone: (403) 410-2660 Fax: (403) 410-2790

Edmonton site: 8249-114 St. Edmonton T6G 2R8
 Phone: (780) 431-8759 Fax: (780) 431-8779

For lab use only

Prenatal Testing – Initial Screen for Pregnant Woman

Requisition must be completed by Physician/Midwife prior to specimen collection. **NB.** This requisition is for *initial prenatal screen only, not* for follow-up testing.

Patient Information

All information in this area must be completed or testing will not be performed. Please ensure writing is legible or patient label is on both pages of requisition.

Surname		Given Name(s)	
Date of Birth	Day	Month	Year
Personal Health Number (PHN) or unique ID number if no PHN			
Address		City	Postal code
Name of Hospital for Delivery		Expected Date of Delivery	
		Day	Month
		Year	
Last Menstrual Period	Gravida	Para	Rh Immune Globulin given this pregnancy?
Day	G	P	<input type="checkbox"/> Yes <input type="checkbox"/> No
Month			Date RhIG Given
Year			Day
			Month
			Year

Physician/Midwife Information

Physician/Midwife Name			
Address		City	Postal code
PRAC ID		Phone	Fax
Please send copy of results to – Name			
Address		City	Postal code
PRAC ID		Phone	Fax

Physician/Midwife **must** complete history provided by patient. Please ensure writing is legible on both pages.

Provincial Laboratory for Public Health (Microbiology) Routine prenatal screening includes: • Syphilis serology 227 • Hepatitis B (Hepatitis B surface antigen) 443 • Varicella (chickenpox) immunity (varicella IgG) <input type="checkbox"/> There is a history of chickenpox or immunization with chickenpox vaccine 66 <small>197</small> When the above box is marked, varicella IgG testing will NOT be performed. • Rubella immunity (rubella IgG) <input type="checkbox"/> There is previous documentation of rubella immunity, i.e., positive rubella IgG test 55 <small>198</small> When the above box is marked, Rubella IgG testing will NOT be performed. • HIV serology (Mark an X below if patient declines HIV testing.) <input type="checkbox"/> Patient declined HIV Testing 510 <small>192</small> When the above box is marked, HIV testing will NOT be performed. Note: Patient must be informed about HIV testing and given the option to decline.	Canadian Blood Services Routine prenatal screening includes: • ABO/Rh • RBC Antibody Screen <hr/> Follow-up Testing • Submit follow-up blood samples for patients who test negative for HIV/HSV/Syphilis and have ongoing risk factors for acquisition of these infections. Use a Provincial Laboratory Requisition , write "follow-up testing in pregnancy" and mark the required tests on the requisition. • Submit follow-up blood samples for RBC serology to the Canadian Blood Services. Use Canadian Blood Services requisition number LL4527: Perinatal Follow-up Testing for Red Blood Cell Serology.
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Specimen Collection Information

Specimen Collection Collect: <ul style="list-style-type: none"> One - 5ml (13x75mm) or 7ml (13x100mm) Gel separator tube and send the tube with top copy of the requisition to Provincial Lab One - 7ml (13x100mm) EDTA tube and send the tube with bottom copy of the requisition to Canadian Blood Services Please label all tubes with full name, PHN and date of collection 			
Date of collection	Time of collection (24 hour)	Collected by	Collection Facility
Day			
Month			
Year			

HS0001-133 (2002/11)

Provincial Laboratory Copy

Provincial Laboratory for Public Health (Microbiology)

Calgary site: 3030 Hospital Drive NW, Calgary, T2N 4W4
Tel: (403) 944-1200 Fax: (403) 270-2216

Edmonton site: 8440-112 Street, Edmonton, T6G 2J2
Tel: (780) 407-7121 Fax: (780) 407-3864

24-hour phone line for Prenatal screening results (780) 407-8667

Canadian Blood Services (CBS)

Calgary site: 737-13 Ave. S.W. Calgary T2R 1J1
Phone: (403) 410-2660 Fax: (403) 410-2790

Edmonton site: 8249-114 St. Edmonton T6G 2R8
Phone: (780) 431-8759 Fax: (780) 431-8779

For lab use only

Prenatal Testing – Initial Screen for Pregnant Woman

Requisition must be completed by Physician/Midwife prior to specimen collection. **NB.** This requisition is for *initial prenatal screen only, not* for follow-up testing.

Patient Information

All information in this area must be completed or testing will not be performed. Please ensure writing is legible or patient label is on both pages of requisition.

Surname				Given Name(s)			
Date of Birth	Day	Month	Year	Personal Health Number (PHN) or unique ID number if no PHN			
Address				City	Province	Postal code	
Name of Hospital for Delivery					Expected Date of Delivery		
			Day	Month	Year		
Last Menstrual Period	Day	Month	Year	Gravida G	Para P	Rh Immune Globulin given this pregnancy? <input type="checkbox"/> Yes <input type="checkbox"/> No	Date RhIG Given
			Day	Month	Year		

Physician/Midwife Information

Physician/Midwife Name				
Address		City	Province	Postal code
PRAC ID		Phone	Fax	
Please send copy of results to – Name				
Address		City	Province	Postal code
PRAC ID		Phone	Fax	

Physician/Midwife *must* complete history provided by patient. Please ensure writing is legible on both pages.

	<p>Canadian Blood Services Routine prenatal screening includes:</p> <ul style="list-style-type: none"> • ABO/Rh • RBC Antibody Screen <hr/> <p>Follow-up Testing</p> <ul style="list-style-type: none"> • Submit follow-up blood samples for patients who test negative for HIV/HSV/Syphilis and have ongoing risk factors for acquisition of these infections. Use a Provincial Laboratory Requisition, write "follow-up testing in pregnancy" and mark the required tests on the requisition. • Submit follow-up blood samples for RBC serology to the Canadian Blood Services. Use Canadian Blood Services requisition number LL4527: Perinatal Follow-up Testing for Red Blood Cell Serology.
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Specimen Collection Information

Specimen Collection						
<p>Collect:</p> <ul style="list-style-type: none"> • One - 5ml (13x75mm) or 7ml (13x100mm) Gel separator tube and send the tube with top copy of the requisition to Provincial Lab • One - 7ml (13x100mm) EDTA tube and send the tube with bottom copy of the requisition to Canadian Blood Services • Please label all tubes with full name, PHN and date of collection 						
Date of collection	Day	Month	Year	Time of collection (24 hour)	Collected by	Collection Facility

HS0001-133 (2002/11)

Canadian Blood Services Copy

Superseded

APPENDIX B
AHW Communications

10025 Jasper Avenue
Box 1360
Edmonton, Alberta
Canada T5J 2N31

June 25, 2002

To: Dr. J. Preiksaitis, Director, Provincial Laboratory of Public Health-Microbiology
Medical Officers of Health

Re: Reporting negative varicella and rubella serology results following testing of prenatal screening specimens

Beginning August 1, 2002 all communicable disease prenatal screening tests will be performed at the Provincial Laboratory of Public Health. All pregnant women in Alberta, unless they decline, will be tested for HIV, hepatitis B, syphilis, varicella, and rubella. The results of these tests are, as usual, to be sent to the woman's physician.

When a woman tests *positive* for HIV, hepatitis B, syphilis, rubella, and varicella, the Laboratory is also to forward a copy of the result to the appropriate regional Medical Officer of Health (MOH) and a copy to Alberta Health and Wellness (AHW).

Similarly, when a test is *negative* for varicella or rubella, the Laboratory will notify the physician, the local MOH and AHW*. This will facilitate immunization for women with negative serology for varicella and rubella, to which it should be offered in the post-natal period.

If you have any questions or comments, I would be pleased to hear from you.

Sincerely,

Dr. Nicholas Bayliss
Provincial Health Officer

cc Dr. Karen Grimsrud, Deputy PHO

*Please note: AHW requires cumulative data, i.e. number tested and number negative

November 18, 2005

TO: ALL MEDICAL OFFICERS OF HEALTH/CD CONTACTS –
REGIONAL HEALTH AUTHORITIES

Re: Change in Reporting of Rubella Immunity

The Provincial Laboratory for Public Health's rubella serology protocol (see Figure 1) has been revised (see Figure 2). This revision relates to the reporting of rubella IgG titres between 10 and 15 IU/mL. **Starting December 01, 2005**, the Provincial Laboratory for Public Health (PLPH) will report rubella titres between 10 and 15 IU/mL as **indeterminate** and these individuals should be considered **non-immune**.

The precision with which rubella IgG antibodies can be measured depends upon a variety of factors including lot-to-lot variation of the rubella kits, and short-term biological fluctuations of antibody levels of individuals.

This change in reporting is based on a review of cumulative laboratory data which indicated that levels of rubella antibody close to the breakpoint of 10 IU/mL fluctuate above and below this value on repeat testing. For example, individuals with rubella antibody levels close to this breakpoint may test above this level and be reported as immune (≥ 10 IU/mL) or at a later time may test below this level and be reported as negative (<10 IU/mL). Therefore, samples between 10 and 15 IU/mL are better classified as indeterminate and these individuals should be considered non-immune for rubella.

In accordance with the *Canadian Immunization Guide* (sixth edition 2002):

- 1. Women of childbearing age who are found to be non-immune serologically should be advised to receive rubella-containing vaccine in the immediate post partum period.**
2. All adolescents and women who emigrate from countries where rubella vaccine is not routinely administered (Asia, Africa, Caribbean, South and Central America) should be offered immunization.

.../2

3. The immunization history of all women of childbearing age (13 to 45 years of age) should be reviewed and:
 - non-pregnant women of childbearing age who have no documented history of vaccination or serologic evidence of immunity should be offered immunization;
 - the antibody status of all pregnant women should be checked to determine susceptibility and those women who are susceptible (negative or indeterminate serology) in the post partum period should be immunized with a rubella-containing vaccine;
 - susceptible pregnant women should be advised to avoid individuals with rubella and report any contact with cases to their physician immediately.
4. Pregnant women exposed to rubella should have serology done as soon as possible to determine susceptibility.
5. All health care workers (male and female), including students, who have face-to-face contact with patients who may be pregnant must have documented immunity to rubella. If no documentation is available, one dose of rubella-containing vaccine should be administered at the first opportunity.
6. All staff in daycare facilities should be immunized against rubella.

Comments on the prenatal laboratory reports will continue to recommend MMR vaccine for non-immune females and that public health be contacted.

Non-prenatal laboratory reports will now include two comments recommending:

- a rubella-containing vaccine for non-immune clients;
- consultation with public health if history of immunization status is uncertain.

Hopefully these changes in the reporting comments will reduce the number of inquiries regarding indeterminate rubella serology results.

The change in interpretation of rubella serology will likely increase the number of prenatal rubella reports requiring follow-up. The data is being reviewed more closely for an accurate estimate.

Please direct any questions you may have to Susan Smith, Acting Manager, Communicable Disease Control at (780) 644-0004 or email: Susan.E.Smith@gov.ab.ca.

Sincerely,

Original signed by K. Grimsrud

K. Grimsrud, M.D., M.H.Sc., FACPM
Deputy Provincial Health Officer

SS/ac
Enclosure

cc: Dr. Shainoor Virani, Associate Provincial Health Officer
Dr. Bonita Lee, PLPH, North
Dr. Kevin Fonseca, PLPH, South
Dr. Jodi Abbott, Executive Director, Disease Control & Prevention
Agnes Honish, Senior Manager, Communicable Disease/Infection Control & Emergency Preparedness
Elaine Sartison, Senior Manager, Immunization Program
Susan Smith, Acting Manager, Communicable Disease Control
Lisa Lachance, Communicable Disease Nurse Consultant

Attachment
Figure 1 - Previous Rubella Serology Protocol

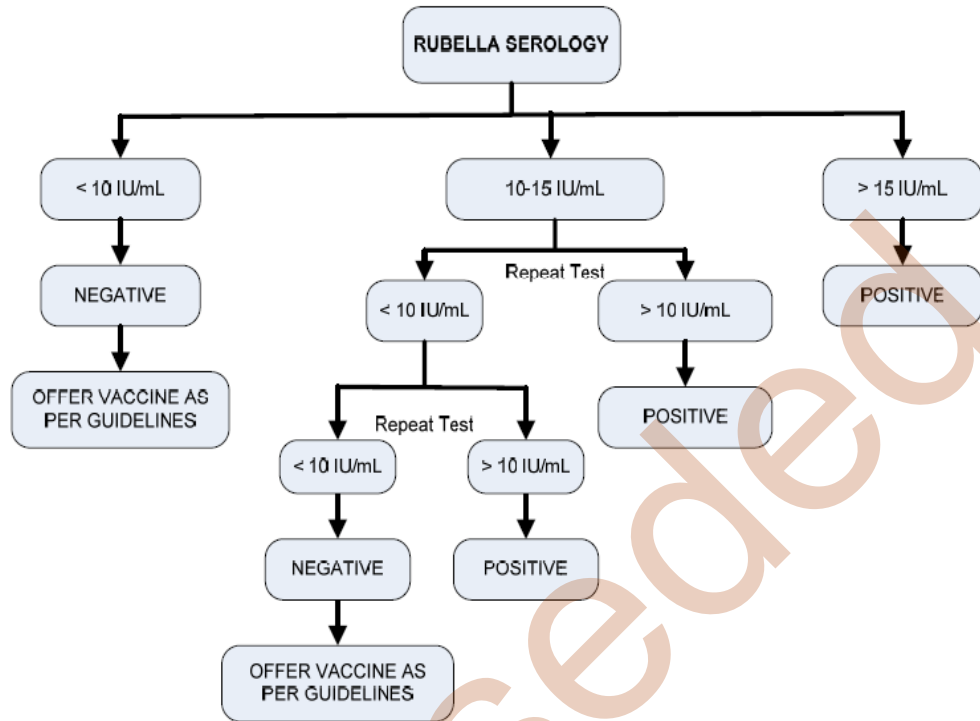
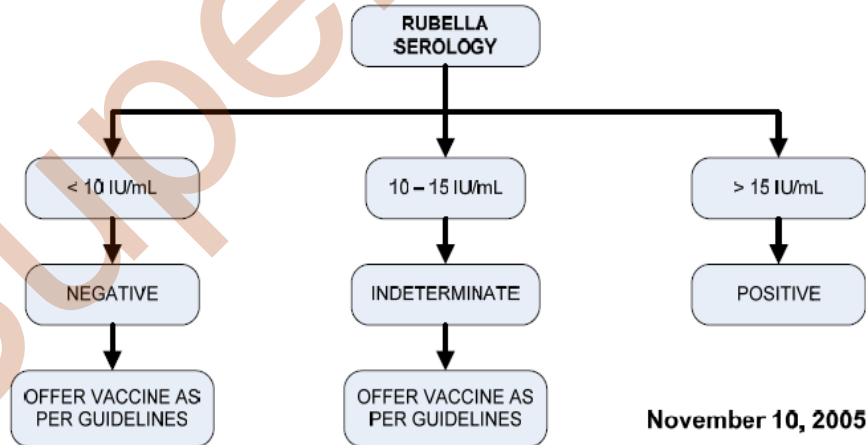


Figure 2 - New Rubella Serology Protocol



November 10, 2005

Superseded

APPENDIX C

Communication to Physicians and Midwives

June 28, 2002

To: Physicians and Midwives Providing Prenatal Care

Re: Prenatal Screening Tests

Dear Colleague:

The information contained in the attached communication package provides details of changes to the prenatal screening test that are to be implemented August 1, 2002. The Canadian Blood Service, the Provincial Laboratory of Public Health (Microbiology), the Alberta Medical Association, and Alberta Health and Wellness, jointly developed the information materials. Contained in this package is:

- *Bulletin: Prenatal Screening Information for Physicians and Midwives.*
- *Prenatal Testing- Initial Screen for Pregnant Women* (sample requisition) and order form
- *Prenatal Follow-up Testing for Red Blood Cell Serology* (sample requisition) and order form.
- *Recommendations for Prenatal Screening Tests – Communicable Disease.*

Thank you for your assistance in implementing the new process for prenatal screening.

Sincerely,

Dr. Nicholas Bayliss
Provincial Health Officer

Recommendations for Prenatal Screening Tests - Communicable Disease

Syphilis

- Screening for infection with syphilis is recommended in pregnancy in the first trimester and again at approximately 36 weeks if the mother is at high risk for acquiring syphilis. If the patient is found to have reactive tests for syphilis, prompt evaluation by an infectious disease expert is recommended.
- Appropriate treatment of syphilis during the early stages of pregnancy can virtually eliminate the risk of transmission.

HIV

- Screening for HIV in pregnant women is now accepted as the standard of care and should be offered to all pregnant women, ideally before the end of the first trimester.
- It is important to inform patients of the importance of screening and their right to decline testing. The use of educational materials can be helpful in minimizing refusals.
- Early treatment of HIV infected pregnant women, in conjunction with an HIV specialist, can reduce the risk of transmission of HIV from approximately 25% to less than 1%.

Hepatitis B

- Screening for hepatitis B carriers in pregnancy identifies infants who require preventive treatment (HBIG and hepatitis B vaccine) shortly after birth. Without this treatment, about 70% - 90% of infants born to hepatitis B positive mothers would become carriers.
- Physicians and midwives should ensure the availability of HBIG and the first dose of vaccine at the delivering hospital for administration to the infant within the first few hours of birth.
- Public health follow-up will continue in the community and the remaining 2 doses of vaccine will be administered to the infant at the time of other routine immunization.

Rubella

- All women with negative rubella IgG, or indeterminate test results, should be offered MMR vaccine post delivery, preferably while in hospital. Alternately, contact your local MOH or public health clinics for MMR administration to the patient at the time of her infant's immunization at 2 months of age.
- Rubella susceptible women who receive anti-Rho (D) immune globulin postpartum should receive MMR vaccine at the same time and be tested for rubella IgG 3 months later **OR** delay immunization for 3 months postpartum.
- Due to interference with antibody response, women who receive other immune globulin products should have MMR immunization delayed for 5 months.

Varicella

- All women with negative varicella IgG, or indeterminate test results, should be immunized with varicella vaccine in the postnatal period.
- Because of the relatively short expiration of the varicella vaccine currently in use, the immunization of susceptible females should be administered at public health clinics. Arrangements for postnatal immunization should be made through your local MOH or public health clinics.

Superseded

APPENDIX D
ProvLab Testing Algorithms

Provincial Laboratory of Public Health (PPHL) – Prenatal Screening Program test information and reporting algorithms (updated April 6, 2006).

Background:

The prenatal requisition is an important first step for appropriate specimen collection, laboratory process for accessioning, testing and reporting of the results in the prenatal program. The five markers screened in the prenatal program include:

- HIV – HIV antibody
- Hepatitis B - hepatitis B surface antigen (HBsAg)
- Syphilis – RPR screen
- Varicella immunity – Varicella IgG
- Rubella immunity – Rubella IgG

Specimens received with the prenatal requisition at PPHL are given a special '**PT**' prefix that is used to trigger some elements that are unique to prenatal testing:

- 1) Special prenatal report comments have been designed to be reported with significant results of the five markers:
 - Positive HIV antibody
 - Positive HBsAg
 - Positive RPR with positive TPPA (99% of FTA would have tested positive in this situation)
 - Positive RPR with negative TPPA and positive FTA
 - Negative/indeterminate rubella IgG (From August 2002 to November 2005, the assay used at PPHL and the reporting algorithm for prenatal rubella IgG did not report indeterminate rubella IgG. A modification of the testing and reporting algorithm took place on December 1 2005 and since then rubella IgG can be reported as negative or indeterminate depending on the testing results).
 - Negative/indeterminate varicella IgG
- 2) Only with prenatal testing that positive HIV antibody of patients with previously confirmed HIV positive results will be reported to both Regional Public Health and Communicable Disease (AHW)
- 3) Only with prenatal testing that positive HBsAg of patients with previously confirmed HBsAg positive results will be reported to both Regional Public Health and Communicable Disease (AHW)
- 4) Only with prenatal testing that negative/indeterminate rubella IgG results of patients get reported to Regional Public Health
- 5) Only with prenatal testing that negative/indeterminate varicella IgG results of patients get reported to Regional Public Health
- 6) The prenatal requisition asks for pregnancy-specific data that is useful in the interpretation and management from the laboratory perspective the results of the test including: gravida para, expected date of delivery, last menstrual period. But unfortunately the compliance in providing the data is not good by the physicians' office
- 7) The PT prefix is used as a criteria for data pull for testing within the prenatal program

On the prenatal requisition, there is a recommendation for pregnant women with high risk factors for HIV, HBV or syphilis to be re-screened during their pregnancy. The suggestion is for the submitter to write on a routine PPHL requisition: 'pregnant – follow-up test'. This is to be used as a trigger for data entry at PPHL and for data pulling on pregnancy-related testing outside of the initial prenatal screening, i.e., testing performed not using the prenatal requisition. Unfortunately the data is not uniformly provided by physicians/healthcare workers and the various phases people used to describe pregnancy make the collection of this data difficult from the laboratory perspective.

For women with no prenatal care and present at delivery, the obstetric units can order the prenatal tests. The marker that is of most urgency is HIV antibody, as there is time-sensitive management issue for the neonate. Whether STAT testing is ordered is at the discretion of the physician looking after the pregnant woman presenting at delivery. The virology laboratories in Calgary and Edmonton currently work from 8:00-23:00 on weekdays and 8:00 to 17:00 on weekends. Virologist-on-call is available to approve call-

back of technologist should there be a high-risk woman where STAT HIV testing is required during after-hours.

Part I The five conditions, test markers and notifiability

Please note that the named tests performed in the laboratory may be subjected to changes when newer and better assays are available.

▪ **Syphilis**

The initial screening assay for syphilis is a non-treponemal-specific assay: **RPR**. If RPR is reactive, two treponemal-specific assays will be performed: TPPA and FTA. Please see figure 1(Part III) for laboratory algorithm.

Notifiable conditions for syphilis are: Any positive RPR +/- TPPA or FTA

▪ **Hepatitis B (HBV)**

The laboratory test to be performed is Hepatitis B surface antigen (**HBsAg**). The current commercial assay used at PPHL is a two-step test (AxSym, Abbott) - an initial screening test for HBsAg and a confirmation test for HBsAg (by neutralization). Please see figure 2 (Part III) for laboratory algorithm. If the screening test is positive for a patient not known within the PPHL database as HBsAg confirmed positive, a supplementary HBV test marker, Total antibody to HBV core antigen (Total HBcAB), will also be performed.

Notifiable conditions are: Newly identified positive HBsAg (confirmed by neutralization) AND previously identified positive HBsAg (laboratory testing will stop at the positive screening assay, i.e., no confirmation will be repeated for previously confirmed HBsAg). NB: previously known HBsAg positive case is notifiable only when the testing is requested with the prenatal requisition, i.e., PT testing.

▪ **HIV (when the patient has not declined testing)**

The laboratory test to be performed is **antibody to HIV**. The current laboratory test algorithm can include up to three different laboratory assays: an initial screening assay (AxSym, Abbott), a second screening assay (ECI, Ortho Diagnostics), and the confirmatory assay - Western Blot. Please see figure 3 (Part III) for laboratory algorithm.

Notifiable conditions are: Newly identified positive HIV antibody case (confirmed by Western Blot) AND previously identified positive HIV case (laboratory testing will stop at the positive screening assay, i.e., no confirmation will be repeated for previously confirmed case). NB: previously known HIV positive case is notifiable only when the testing is requested with the prenatal requisition, i.e., PT testing

▪ **Varicella immunity** (except when there is a history of chicken pox or immunization with chickenpox vaccine)

The laboratory test to be performed is **varicella IgG** (Dade Behring). The results reported by PPHL can be: positive, negative or indeterminate. Please see figure 4 (Part III) for laboratory algorithm.

Notifiable conditions are: negative or indeterminate varicella IgG. (Only prenatal testing is notifiable)

▪ **Rubella immunity** (except when there is previous documentation (IgG) of rubella immunity)

The laboratory test to be performed is **rubella IgG** (Abbott AxSym). The results reported by PPHL were negative or positive IgG from August 2002 to November 2005. Since December 1, 2005, rubella IgG can be reported as: positive, negative, or indeterminate. Please see figure 5 (Part III) for laboratory algorithm.

Notifiable conditions are: negative or indeterminate rubella IgG. (Only prenatal testing is notifiable)

Part II Turn-around-time (TAT) of the results:

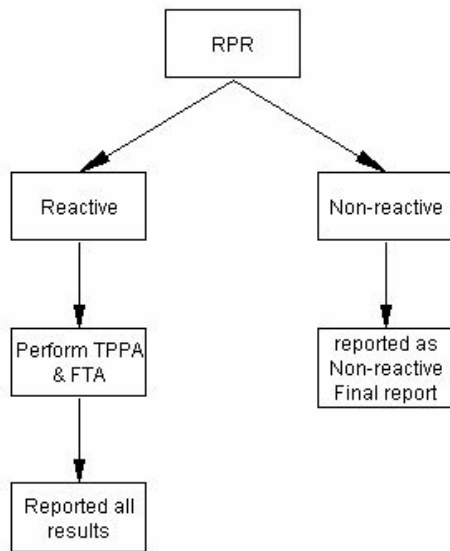
Please note that at the initiation of the prenatal screening program, there was a special request for the all the test results (i.e., up to 5 conditions) from a prenatal specimen to be reported together as a single printout. Special computer programming had to be done at the time so that test results for a specimen would be kept until all the requested tests have been completed and all the results have been validated before the computer will generate an actual report.

Thus the turn-around-time (TAT) of the official laboratory report can be longer than the turn-around-time of the result for an individual test when there is a test for the same specimen that requires a longer TAT. On the other hand, individual test result may be requested by telephone at (780) 407-8667, 24 hours a day and seven days a week. This phone number is for requesting results for prenatal testing only.

TEST	After the specimen has been received by provincial laboratory	
	Negative result is available as a validated result in ProvLab database in	Positive result is available as a validated result in ProvLab database in
Syphilis serology	24 to 72 hours	24 hours to 4 days pending completion of confirmation test
HBsAg	24 hours	24 hours to 4 days pending completion of confirmation test
Antibody to HIV	24 hours	24 hours to 7 days pending completion of confirmation test
Rubella IgG	24 hours	24 hours
Varicella IgG	24 to 72 hours	24 to 72 hours

Part III Laboratory test algorithm and Prenatal test comments:

Figure 1 Syphilis



Notifiable conditions for syphilis are: Any positive RPR, TPPA or FTA

Prenatal specific comments that are in use:
Syphilis - tested positive comment #1 - *RPR positive TPPA positive (FTA most of time is also positive)*
"This patient has tested positive during prenatal screening by RPR and TP.PA tests, suggestive of infection with syphilis. Urgent evaluation by an expert is recommended."
Syphilis - tested positive comment #2 - *RPR positive TPPA negative FTA positive* - in use since Sep 2, 2003:
"Syphilis tests on this prenatal blood sample suggest either a Biological false positive or an acute syphilis infection. Please submit a follow-up blood as soon as possible and indicate on the requisition that it is a 'follow-up prenatal syphilis as requested by the Laboratory'. If the patient has risk factors or clinical symptoms suggestive of acute syphilis infection, urgent evaluation by an expert is also recommended."

Another comment that can appear on prenatal report but is also used in other type of syphilis testing when - *RPR positive TPPA negative FTA negative*
"The reactive reagin antibody test likely represents a false positive result, if clinical situation warrants, please submit another specimen in 4-6 weeks."

Figure 2 HBV

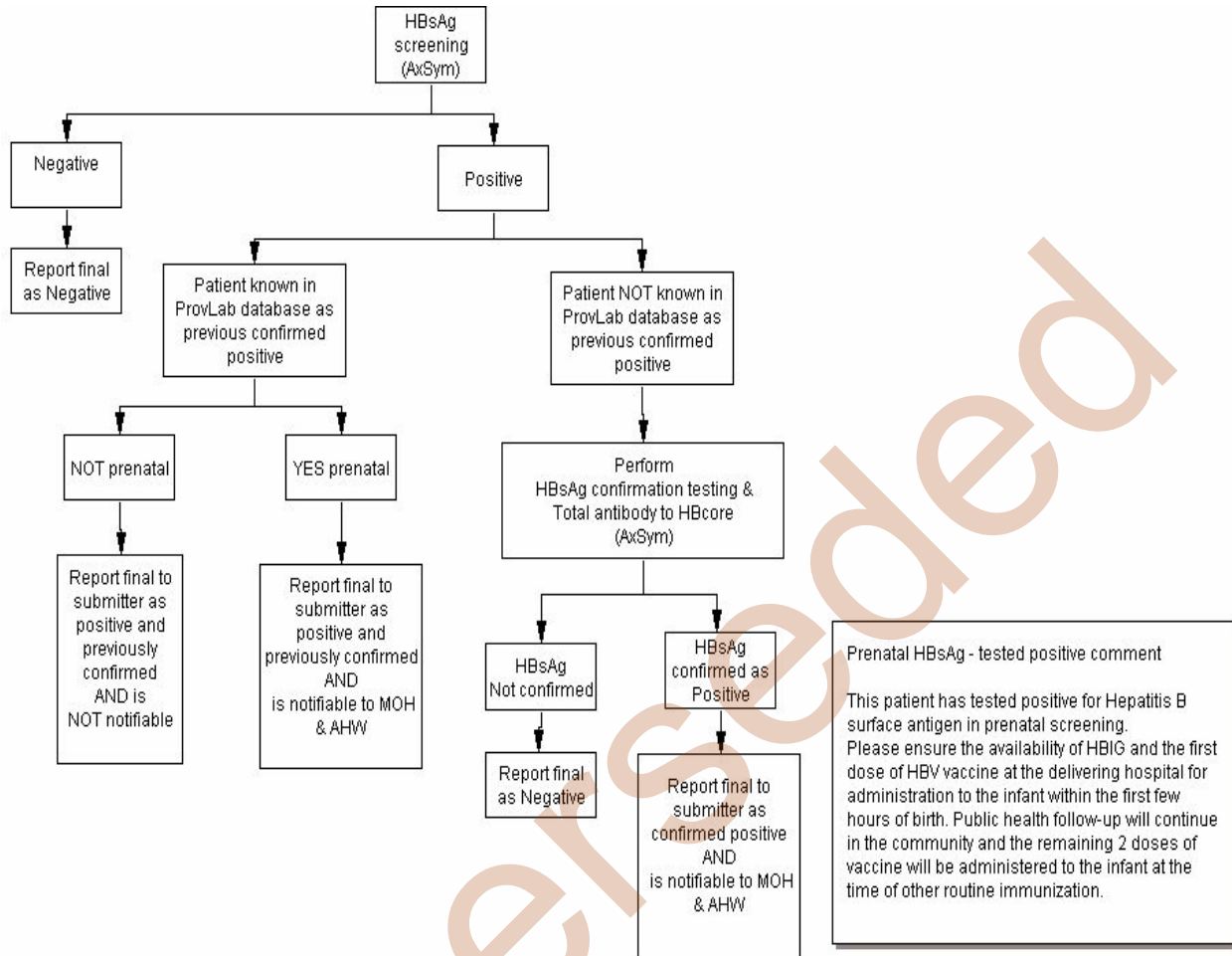
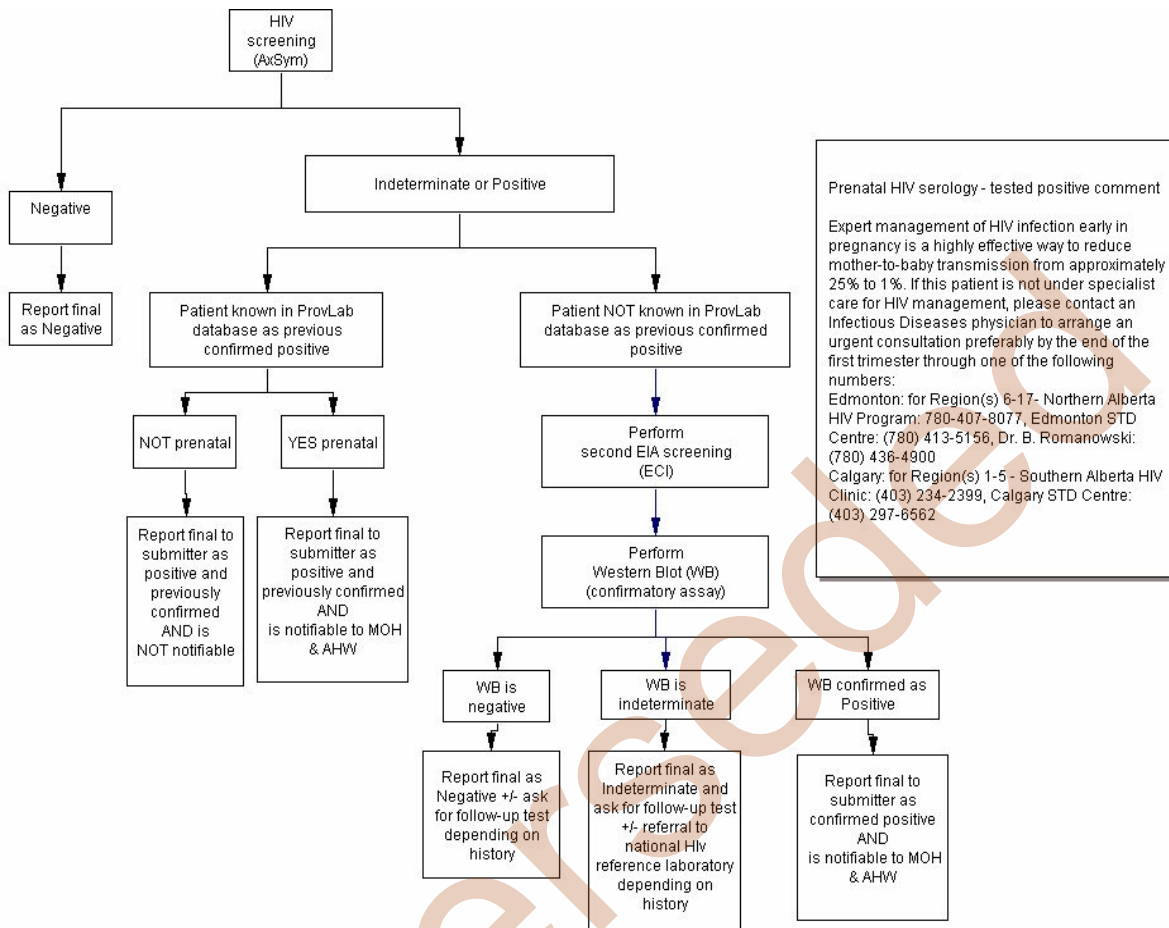


Figure 3 HIV



Prenatal HIV serology - tested positive comment

Expert management of HIV infection early in pregnancy is a highly effective way to reduce mother-to-baby transmission from approximately 25% to 1%. If this patient is not under specialist care for HIV management, please contact an Infectious Diseases physician to arrange an urgent consultation preferably by the end of the first trimester through one of the following numbers:
 Edmonton: for Region(s) 6-17- Northern Alberta HIV Program: 780-407-8077, Edmonton STD Centre: (780) 413-5156, Dr. B. Romanowski: (780) 436-4900
 Calgary: for Region(s) 1-5 - Southern Alberta HIV Clinic: (403) 234-2399, Calgary STD Centre: (403) 297-6562

Virologists review all the HIV Western Blot results and provide clinical consultation to the submitting physicians by phone. Indeterminate HIV antibody results are only reported to the submitting physician(s) with consultation provided to the physicians by the virologist. If there is a patient with suspected acute seroconversion with negative\indeterminate Western Blot, a letter will be written by the virologist to the Regional MOH with c.c. to the submitting physician. A recommendation is always made for a follow-up HIV serology to confirm the seroconversion, i.e., follow-up blood to demonstrate a positive Western Blot.

Figure 4 Varicella

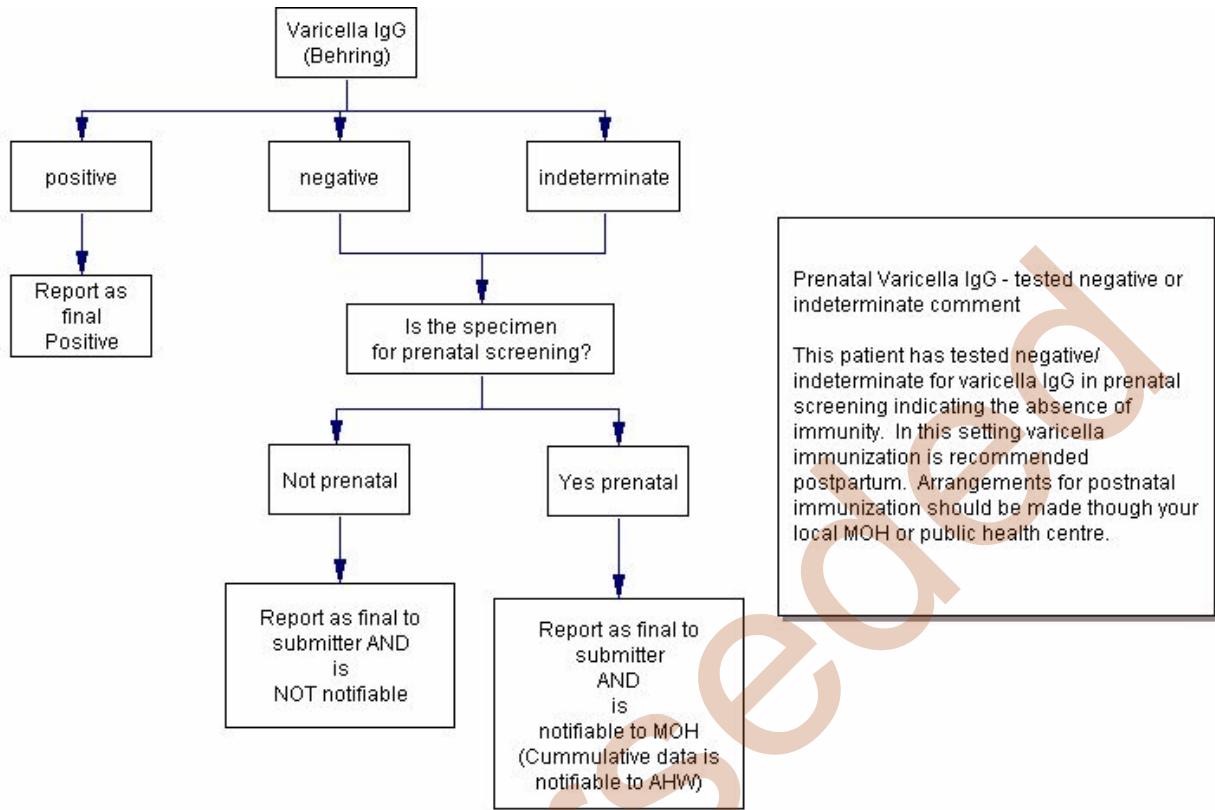
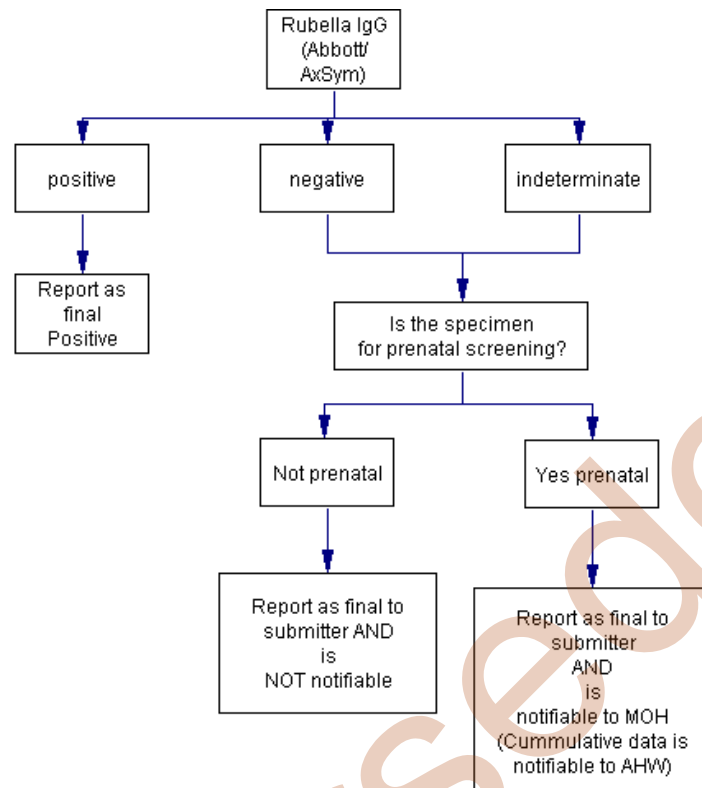


Figure 5 Rubella



Prenatal Rubella test comments #1 - for negative/indeterminate IgG (in use from Aug 1 2002 to Nov 30 2005)

This patient has tested negative/indeterminate for rubella IgG in prenatal screening indicating the absence of immunity. All women with negative/indeterminate rubella IgG, should be offered MMR vaccine post delivery, preferably while in hospital. Alternately, contact your local MOH or Public Health Centre for MMR administration to the patient at the time of her infant's immunization at 2 months of age.

Prenatal Rubella test comment #2 - for patient with low antibody level that is close to the cut-off (10 IU as protective level) and fluctuating between positive and negative and has tested as negative. (in use from Aug 1 2002 to Nov 30 2005)

This patient has low antibody levels to rubella, and on separate occasions may test as either rubella IgG antibody positive or negative. Contact your local MOH or Public Health Clinic for assessment and follow-up of this patient.

New rubella ind/neg IgG comment * (Implementation date December 1, 2005)

This patient tested negative/indeterminate for rubella IgG indicating the probable absence of immunity. All women in the prenatal screening program with negative or indeterminate rubella IgG results, should be offered MMR vaccine after delivery, preferably while in hospital. Alternatively, contact your local MOH or Public Health Centre for MMR administration to the mother at the time of her infant's immunization at 2 months of age.

Other individuals with negative/indeterminate rubella IgG results should also be offered a rubella containing vaccine if their history of immunization is uncertain; consult your local MOH or Public Health Centre.

*This comment appear on all rubella neg/ind reports including non-prenatal testing, but only prenatal neg/ind rubella IgG report is notifiable.