# Hepatitis B Vaccine

Revision Date: April 2, 2024

Rationale for Update: Post-immunization serology recommendations updated.

Please consult the Product Monograph <sup>(1,2)</sup> for further information about the vaccine.				
	ENGERIX®-B	RECOMBIVAX HB®		
Manufacturer	GlaxoSmithKline Inc.	Merck Canada Inc.		
Licensed use	Hepatitis B vaccine can be administered at a	ny age from birth onward.		
Off-license use	None	Vaccine dose for all children from birth up to and including 10 years of age in Alberta is 0.5 mL (5 µg). (3,4)		
Pre-exposure:	Universal			
	Students in Grade 6 Universal program i	n Alberta.		
Indications for use of provincially	Students in Grades 7 through 12 who have not received a series of hepatitis B vaccine.			
funded vaccine	Individuals born March 1, 2018 or later for when immunization with DTaP-IPV-Hib-HB is not needed or contraindicated.			
See Serology Recommendations for those	Individuals born in 1981 or later who would have been eligible for the school universal hepatitis B vaccine program and who have not received a series of hepatitis B vaccine.			
recommended to have pre-	Endemic			
immunization serology.	<ul> <li>Children whose families have immigrated to Canada from areas where there is a high prevalence of hepatitis B (endemic for hepatitis B). See <u>Hepatitis B Virus Infection</u> – <u>High Endemic Geographic Areas</u>.</li> </ul>			
	Non-immune adults who have immigrated to Canada from areas where there is a high prevalence of hepatitis B. <sup>(4)</sup> See <u>Hepatitis B Virus Infection – High Endemic Geographic Areas</u> .			
	Populations or communities in Alberta in which hepatitis B is highly endemic, following consultation with the local Medical Officer of Health.			
	Chronic Health Conditions			
	<ul> <li>Individuals with hemophilia and others receiving repeated infusions of blood or blood products (hepatitis B vaccine is not provided for parents providing home infusion for their children).</li> </ul>			
	Individuals with chronic liver disease from any cause, including hepatitis C infection. <sup>(4)</sup>			
	<ul> <li>Individuals with Inflammatory Bowel disease (IBD) who will be on long term immunosuppressive medications including but not limited to Imuran® or TNF antagonists like Remicade® or Humira®.<sup>(4,5)</sup></li> </ul>			



### Lifestyle Risks

- Individuals with lifestyle risks for infection including:
  - Men who have sex with men (MSM).<sup>(4)</sup>
  - Individuals with more than one sexual partner in the previous six months. (4)
  - o Individuals with a history of a sexually transmitted infection. (4)
  - Individuals seeking evaluation or treatment for a sexually transmitted infection.<sup>(4)</sup>
  - o Individuals who engage in high risk sexual practices. (4)
  - Individuals who have unprotected sex with new partners.<sup>(4)</sup>
  - o Individuals who use illicit drugs<sup>(3,4)</sup> and associated drug-using paraphernalia (e.g., tubes used for snorting), resulting in blood exposure.

# Immunosuppressive Chronic Health Conditions that may be HYPORESPONSIVE to hepatitis B vaccine

- Individuals with chronic health conditions that may be HYPORESPONSIVE to hepatitis B vaccine should receive a higher dose of hepatitis B (see dose section for hyporesponsive individuals). These include:
  - Individuals with chronic renal disease or who are undergoing chronic hemodialysis/peritoneal dialysis, including those who are pre-dialysis (progressive renal insufficiency).
  - o Individuals with congenital immunodeficiencies. (4)
  - o Individuals infected with HIV.(4)
  - Candidates for and recipients of solid organ transplant. See:
    - Immunization for Children Expecting Solid Organ Transplant before 18
       Months of Age (Accelerated),
    - Immunization for Children Expecting Solid Organ Transplant at 18 months of Age or Older (Catch-up Schedule) and
    - Immunization for Adult Solid Organ Candidates and Recipients.
  - Recipients of hematopoietic stem cell transplant (HSCT). See:
    - Immunization for Child Hematopoietic Stem Cell Transplant Recipients and
    - Immunization for Adult Hematopoietic Stem Cell Transplant Recipients.

### **Occupational/Other Settings**

- Individuals who are workers, volunteers or students (accepted into post-secondary educational programs) and who have a reasonable anticipated risk of exposure to blood/bloody body fluids and/or sharps injuries during the course of their work. See Occupational Considerations for Immunization
- Children and workers in child care settings in which there is a hepatitis B infected (acute or chronic) child or worker. (4)
- Residents and staff of institutions or group homes for the developmentally challenged.
- Inmates in provincial correctional facilities who will be incarcerated for a sufficient length of time to complete a hepatitis B vaccine series.
- Inmates in long-term correctional facilities: Immunization is the responsibility of the Federal Correctional Service. However, vaccine will be provided provincially for completion of immunization of discharged inmates who began their hepatitis B series in the correctional facility.



### Post-exposure:

Indications for use of provincially funded vaccine  Newborns born to hepatitis B infected mothers (acute cases or carriers) should receive hepatitis immune globulin (HBIG) and the first dose of hepatitis B vaccine as soon as possible after birth (within 12 hours) but within seven days after birth if HBIG/hepatitis B vaccine is delayed for any reason.<sup>(6)</sup>

#### Notes:

- If prenatal screening has not been done prior to delivery, it should be done as soon as possible after admission for delivery. In addition, repeat testing should be considered in uninfected, susceptible women with continuing high risk factors.
- If results can be obtained within 12 hours, the first dose of hepatitis B vaccine should be administered. HBIG administration should be delayed pending results.<sup>(4)</sup>
  - If results will not be available within 12 hours, administer hepatitis B vaccine and consider administration of HBIG, taking into account maternal risk factors and erring on the side of providing HBIG if there is any question of possible maternal hepatitis B infection. (4)
- Infants (other than newborns) younger than 12 months of age:
  - Hepatitis B vaccine and HBIG if the mother or primary caregiver is an acute case.
  - Hepatitis B vaccine only if the caregiver or significant household contact is a chronic carrier.

Refer to: Public Health Notifiable Disease Management Guidelines – Hepatitis<sup>(7)</sup> and Alberta Prenatal Screening Program for Selected Communicable Diseases Public Health Guidelines – Hepatitis B.<sup>(6)</sup>

- Susceptible household contacts, sexual partners and needle-sharing partners of individuals with acute or chronic hepatitis B infection.
  - Hepatitis B vaccine. HBIG may be recommended for some individuals depending upon the time from exposure and the specifics surrounding the exposure.

Refer to: Public Health Notifiable Disease Management Guidelines – Hepatitis B. (7)

- Percutaneous (needle stick) or mucosal exposure:
  - Post-exposure follow-up and prophylaxis should be based on the immunization history and antibody status of the exposed person and, if known, the infectious nature of the source.

Refer to: Canadian Immunization Guide: Hepatitis B Vaccine (Figures 1 & 2). (4) <a href="https://www.canada.ca/en/public-health/services/publications/healthy-living/canadian-immunization-quide-part-4-active-vaccines/page-7-hepatitis-b-vaccine.html">https://www.canada.ca/en/public-health/services/publications/healthy-living/canadian-immunization-quide-part-4-active-vaccines/page-7-hepatitis-b-vaccine.html</a>.

When a susceptible individual sustains a "community needle stick" injury (needle stick in a non-health care setting), the risk of exposure to hepatitis B is increased. If the individual has no history of a hepatitis B vaccine series and the source is HBsAg positive, high risk, unknown or not available for testing, HBIG should be administered (as soon as possible but within seven days of exposure) with the first dose of the hepatitis B vaccine series.

Refer to: <u>Alberta Guidelines for Post-Exposure Management and Prophylaxis</u>: HIV, Hepatitis B, Hepatitis C and Sexually Transmitted Infections.<sup>(8)</sup>

- Susceptible individuals of sexual assault:
  - HBIG and hepatitis B vaccine should be offered.

Refer to: <u>Alberta Guidelines for Post-Exposure Management and Prophylaxis</u>: HIV, Hepatitis B, Hepatitis C and Sexually Transmitted Infections.<sup>(8)</sup>



Henatitis A and B Combined Vaccine			
Hepatitis A and B Combined Vaccine.  Hepatitis A and B Combined Vaccine may be considered for individuals eligible for both pre-exposure hepatitis A and hepatitis B vaccines. See Biological Products – Hepatitis A and B Combined Vaccine: Twinrix®.			
See Serology Recommendations and Follo	ow-up		
ENGERIX®-B RECOMBIVAX HB®			
ENGERIX®-B ( <u>20 μg/1.0 mL</u> )	RECOMBIVAX HB® (10 μg/1.0 mL)		
<ul> <li>Given as 0.5 mL</li> <li>❖ Dose 1: at birth</li> <li>❖ Dose 2: two months of age</li> <li>❖ Dose 3: six months of age</li> <li>Notes:</li> <li>➤ The response to hepatitis B vaccine may be diminished in infants with a birth weight below 2,000 grams.<sup>(4)</sup></li> <li>➤ Neonates weighing less than 2,000 grams born to infected mothers require four doses of vaccine administered at birth, 1, 2, and 6 months of age, followed by serologic testing one month after completion of the series and the infant should be at least 9 months of age.<sup>(4,6)</sup></li> <li>➤ The final (third/fourth) dose in the series should not be administered to infants before 24 weeks (168 days) of age.<sup>(9)</sup></li> <li>Infanrix hexa® may be considered for infants eligible for both DTaP-IPV-Hib and</li> </ul>			
Other infants younger than 12 months of a Given as 0.5 mL  Dose 1: two months of age  Dose 2: four months of age  Dose 3: twelve months of age  Notes:  Neonates weighing less than 2,000 g hepatitis B vaccine at birth should recadministered at 1, 2, and 6 months of lf the infant is identified as a significat offer hepatitis B vaccine as soon as pure Infanrix hexa® may be considered for infants Hepatitis B vaccines. See Biological Products indications.  Children 12 months of age up to and inclusing Given as 0.5 mL  Dose 1: day 0  Dose 2: one month after dose one	grams who received their first dose of ceive three additional doses of vaccine of age.  In thousehold contact of a hepatitis B carrier cossible.  It is eligible for both DTaP-IPV-Hib and of a DTaP-IPV-Hib-HB: Infanrix hexa® for more ding 10 years of age (3 doses):		
	pre-exposure hepatitis A and hepatitis B vacce and B Combined Vaccine: Twinrix®.  See Serology Recommendations and Follo  ENGERIX®-B  ENGERIX®-B (20 µg/1.0 mL)  Newborns born to hepatitis B infected more Given as 0.5 mL  Dose 1: at birth  Dose 2: two months of age Notes:  The response to hepatitis B vaccine is weight below 2,000 grams. (4)  Neonates weighing less than 2,000 grams doses of vaccine administered at birth serologic testing one month after combe at least 9 months of age. (4.6)  The final (third/fourth) dose in the serbefore 24 weeks (168 days) of age. (9)  Infanrix hexa® may be considered for infants Hepatitis B vaccines. See Biological Products indications.  Other infants younger than 12 months of age  Dose 1: two months of age  Dose 3: twelve months of age  Notes:  Neonates weighing less than 2,000 gradinistered at 1, 2, and 6 months or administered at 1, 2, and 6 months or admin		



### Students 11 to 15 years of age (2 doses):

This includes grade 6 students younger than 11 years of age as eligibility for a two-dose series is determined by grade level.

### 2 dose Schedule

### Given as 1.0 mL

- ❖ Dose 1: day 0
- Dose 2: six months after dose one

Minimal acceptable spacing between the first and second dose is 24 weeks. (1,4)

#### Notes:

- In the event that a 0.5 mL dose is given, a 3 dose schedule must be followed.
  - ❖ Dose 1: day 0
  - Dose 2: one month after dose one
  - Dose 3: six months after dose one
- ➢ If required, minimal acceptable interval is 0, 1, and 4 months, with one month (28 days) between the first and second dose, at least two months (56 days) between the second and third dose and at least four months (112 days) between the first and third dose.<sup>(4)</sup>
- If a student will turn 16 years of age before a 2-dose series can be completed a 3-dose schedule should be initiated.
- For individuals who received a 1.0 mL dose of hepatitis B vaccine as their first dose at 11 to 15 years of age and present at 16 years of age or older for subsequent doses the series reverts to a 3-dose schedule following the appropriate dosing for age.

## Children 16 years of age up to and including 19 years of age (3 doses):

### Given as 0.5 mL

- ❖ Dose 1: day 0
- Dose 2: one month after dose one
- Dose 3: six months after dose one

### Adults 20 years of age and older (3 doses):

### Given as 1.0 mL

- ❖ Dose 1: day 0
- Dose 2: one month after dose one
- Dose 3: six months after dose one

Dose and
Schedule for
<b>Hyporesponsive</b>
Individuals

# (see Indications section above)

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### RECOMBIVAX HB® (10 µg/1.0 mL)

### 0 to 15 years

# Individuals 0-15 years of age inclusive (3 doses):<sup>4</sup>

### Give as 1.0 mL dose (20 µg)

- ❖ Dose 1: day 0
- ❖ Dose 2: one month after dose one
- ❖ Dose 3: six months after dose one

# Individuals 0–15 years of age inclusive (3 doses):

### Give as 1.0 mL (10 µg)

- ❖ Dose 1: day 0
- ❖ Dose 2: one month after dose one
- Dose 3: six months after dose one



Dose and Schedule for Hyporesponsive Individuals (cont.)

### ENGERIX®-B (20 μg/1.0 mL)

RECOMBIVAX HB® (10 µg/1.0 mL)

### 16 to 19 years

Individuals 16 years of age up to and including 19 years of age

(4 doses):(1,4)

Give as 2.0 mL dose (40 µg)

- ❖ Dose 1: day 0
- Dose 2: one month after dose one
- Dose 3: two months after dose one
- ❖ Dose 4: six months after dose one

#### Notes:

- Those initiating a four dose schedule with Engerix®-B should complete the series using the same vaccine whenever possible.
- Minimum interval between dose three and dose four is 4 months and at least 6 months from dose one.<sup>(1)</sup>

Individuals 16 years of age up to and including 19 years of age

### (3 doses):

Give as 1.0 mL dose (10  $\mu$ g)

- Dose 1: day 0
- Dose 2: one month after dose one
- ❖ Dose 3: six months after dose one

If any dose in the series was Engerix®-B, a total of 4 doses of vaccine should be administered for those 16 years of age and older. (9,10)

### ENGERIX®-B (20 μg/1.0 mL)

RECOMBIVAX HB® <u>Adult Dialysis</u> (40µg/1.0 mL)

### 20 years and older

Individuals 20 years of age and older (4 doses):(1,4)

**Give as 2.0 mL dose** (40 μg)

- ❖ Dose 1: day 0
- Dose 2: one month after dose 1
- Dose 3: two months after dose 1
- Dose 4: six months after dose 1

Note: Those initiating a four dose schedule with Engerix®-B should complete the series using the same vaccine whenever possible.

# Individuals 20 years of age and older (3 doses)

**Give as 1.0 mL** (40 μg)

- ❖ Dose 1: day 0
- Dose 2: one month after dose 1
- Dose 3: six months after dose 1

**Note**: Do not use this formulation for individuals younger than 20 years of age. (2)

If any dose in the series was Engerix®-B, a total of 4 doses of vaccine should be administered for those 16 years of age and older. (9,10)

### Note:

Interruption of the hepatitis B vaccines series does not require that any dose be repeated if the minimum intervals between doses are respected.



Route	Intramuscular injection		
Post- immunization Serology	See Serology Recommendations and Follow-up		
Contraindications	<ul> <li>Known severe hypersensitivity to any component of the vaccine.</li> <li>Anaphylactic reactions to a previous dose of vaccine containing hepatitis B antigen.</li> <li>For Recombivax HB® only:</li> <li>Anaphylactic reactions to latex.</li> </ul>		
Precautions	Should not be administered in the gluteal area or intradermally, as this may result in lower immune response. (1,2,4)		
Possible reactions	See Product Monograph		
Pregnancy	Hepatitis B vaccine should be administered to pregnant women when indicated. (4) Data is not available on the effect of hepatitis B vaccine on fetal development; (1,2) however, the risk is expected to be negligible as the vaccine consists of non-infectious subunits.		
Lactation	Hepatitis B vaccine should be administered to breastfeeding women when indicated. It is not known whether hepatitis B vaccine is excreted in human milk. (1,2)		
Program Notes	<ul> <li>1983 January – Hepatitis B introduced for neonatal program for infants at high risk.         <ul> <li>Hepatitis B dialysis strength (Recombivax®) introduced.</li> </ul> </li> <li>1995 September – Hepatitis B introduced into routine school program for students in grade 5 (3 dose schedule).</li> <li>1999 September – Hepatitis B catch-up for Grade 12 students. (available from September 1999 to June 2002)</li> <li>2016 July – Infanrix hexa® introduced for children under 2 years of age eligible for DTaP-IPV-Hib and Hepatitis B.</li> <li>2017 November – Individuals at high risk: recommended documented series for those with only verbal history or who are anti-HBs positive and recommend a complete second series if anti-HBs negative after first series.</li> <li>2018 February – Individuals with inflammatory bowel disease who will be on long term immunosuppressive medications eligible for hepatitis B vaccine.         <ul> <li>Individuals born in 1981 or later who would have been eligible for the school universal hepatitis B program and who have not received a series of hepatitis B vaccine are eligible for hepatitis B vaccine.</li> </ul> </li> <li>2018 September – Routine school immunization schedule for Hepatitis B changed from being offered in grade 5 to grade 6.</li> <li>2019 August – Routine school immunization schedule for Hepatitis B changed from 3 dose to 2 dose.</li> <li>2023 December – Post-immunization serology recommendations updated.</li> <li>2024 – Post-immunization serology recommendations updated.</li> </ul>		



Groups Pre-immunization Post-immunization Follow-up			
Cioups	Serology	Serology	Follow-up
	recommendation	recommendation	Special Considerations
Individuals with <u>chronic renal</u> <u>disease</u> including hemodialysis, peritoneal dialysis, and pre-dialysis	Pre-immunization serology is not routinely recommended	Serology (anti-HBs) should be done 1 – 6 months following the primary series of hepatitis B vaccine.	Individuals who are hyporesponsive due to renal disease (hemodialysis, peritoneal dialysis and predialysis) often respond suboptimally to hepatitis B vaccine and may need additional antigen to mount a response. If protection is achieved and then wanes, subsequent exposure may result in acute disease or carrier state.
			Individuals who are anti-HBs negative after the first series, <b>should receive a second series</b> , followed by serology one month later. <sup>(4,11)</sup>
			Persons with chronic renal disease or on dialysis should be evaluated yearly for anti-HBs. (4,11) Should antibody testing show suboptimal protection, a booster dose of vaccine should be given. (4,12)
			Individuals with lab confirmation of positive anti-HBs but <b>without</b> documentation of any doses of hepatitis B vaccine OR those with incomplete series should be offered a complete series of hepatitis B vaccine to ensure long term immunity. <sup>(4)</sup>
			See <u>Hepatitis B (HBVD) Algorithm for Chronic Renal Disease</u> for additional information.
Individuals with congenital immunodeficiencies     Candidates for and recipients of solid organ transplant	Pre-immunization serology is not routinely recommended	Serology (anti-HBs) should be done 1 – 6 months following the primary series of hepatitis B vaccine.	Individuals who are hyporesponsive due to congenital immunodeficiencies, HSCT, SOT, HIV infection often respond suboptimally to hepatitis B vaccine and may need additional antigen to mount a response. If protection is achieved and then wanes, subsequent exposure may result in acute disease or carrier state.
(SOT)  Recipients of hematopoietic stem			Individuals who are anti-HBs negative after the first series, <b>should receive a second series</b> , followed by serology one month later. <sup>(4,12)</sup>
cell transplant (HSCT)			Periodic monitoring (by attending physician) for the presence of anti-HBs should be considered, taking into account the severity of the compromised state
Individuals infected with HIV	Pre-immunization serology (anti- HBs, HBsAg and anti-HBc) is	Serology (anti-HBs) should be done 1 – 6 months following the primary series	and whether or not the risk for hepatitis B infection is still present. Should anti-HBs testing show suboptimal protection, a booster dose of vaccine and retesting should be undertaken. (4)
	recommended.	of hepatitis B vaccine.	Individuals with lab confirmation of positive anti-HBs (and anti-HBc negative) but <b>without</b> documentation of any doses of hepatitis B vaccine OR those with incomplete series should be offered a complete series of hepatitis B vaccine to ensure long term immunity. <sup>(4)</sup>



Groups	Pre-immunization Serology recommendation	Post-immunization Serology recommendation	Follow-up Special Considerations
Individuals with chronic liver disease	Pre-immunization serology (anti- HBs, HBsAg and anti-HBc) is recommended.	Serology (anti-HBs) should be done 1 – 6 months following the primary series of hepatitis B vaccine.	Individuals who are negative after the first series, should receive a second series using a higher dose vaccine schedule for hyporesponsive individuals followed by serology one month later. (4) Individuals with lab confirmation of positive anti-HBs (and anti-HBc negative) but without documentation of any doses of hepatitis B vaccine OR those with incomplete series should be offered a complete series of hepatitis B vaccine to ensure long term immunity. (4)
Newborns     Born to hepatitis B infected mothers      Infants (other than newborns) younger than 12 months of age with hepatitis B infected caregiver or household contact	Pre-immunization serology is not recommended	Serology (anti-HBs and HBsAg) is recommended 1 – 6 months following the primary series of hepatitis B vaccine and the infant should be at least 9 months of age. <sup>4</sup>	If the individual is anti-HBs negative after the first series, a second hepatitis B vaccine series <sup>(4)</sup> should be administered, with repeat serology testing one month later.  Once a positive antibody result is documented no further serology is recommended.  Refer to: Public Health Notifiable Disease Management Guidelines – Hepatitis B <sup>(7)</sup> and Alberta Prenatal Screening Program for Selected Communicable Diseases Public Health Guidelines – Hepatitis B. <sup>(6)</sup>
HCWs and Post- Secondary Health Care Students	For HCWs refer to Occupational Considerations for Immunization for pre-immunization serology recommendation.	Serology (anti-HBs) should be done 1 – 6 months following the primary series of hepatitis B vaccine	For HCWs:  If the individual is anti-HBs negative after the first series, a second hepatitis B vaccine series <sup>(4)</sup> should be administered, with repeat serology testing one month later.  If immunization was completed more than six months previously and post- immunization serology was not done, testing should be done as part of a routine assessment.  If the individual is anti-HBs negative the individual should be given 1 booster dose of hepatitis B vaccine followed by serology one month later. If the individual is still negative after the 4th dose, the second series of hepatitis B vaccine should be completed followed by serology 1 month later. (4)  Once a positive antibody result is documented no further serology is recommended.  HCWs upon hire or during their WHS 'communicable disease assessment' and Post-secondary HCW students who have lab confirmation of positive anti-HBs but without documentation of any doses of hepatitis B vaccine or incomplete series should be offered a complete series of hepatitis B vaccine to ensure long term immunity. (4,12)  HCWs who have been previously assessed do not require reassessment or updating at this time.



recommendations for the respective eligibility groups.			
Groups	Pre-immunization Serology recommendation	Post-immunization Serology recommendation	Follow-up Special Considerations
Individuals who are workers or volunteers and who have a reasonable anticipated risk of exposure to blood/bloody body fluids	Pre-immunization serology is not routinely recommended.	Serology (anti-HBs) should be done 1 – 6 months following the primary series of hepatitis B vaccine.	If the individual is anti-HBs negative within 6 months of completion of the first series, a second hepatitis B vaccine series <sup>(4)</sup> should be administered, with repeat serology testing one month later.  If immunization was completed more than six months previously and post-immunization serology was not done, testing should be done as part of a routine assessment.  If the individual is negative, one booster dose of hepatitis B vaccine should be administered followed by serology one month later. If the individual is still negative after the 4 <sup>th</sup> dose, the second series of hepatitis B vaccine should be completed followed by serology one month later.  Once a positive antibody result is documented no further serology is recommended.
Susceptible     household contacts,     sexual partners and     needle-sharing     partners of     individuals with     acute or chronic     hepatitis B infection	Refer to: Public Health Notifiable Disease Management Guidelines – Hepatitis B <sup>(7)</sup> for specific serology recommendations and interpretation.	Once a positive antibody result is documented no further serology is recommended.  Individuals with lab confirmation of positive anti-HBs but <b>without</b> documentation of any doses of hepatitis B vaccine OR those with incomplete series should be offered a complete series of hepatitis B vaccine to ensure long term immunity.	

Groups	Pre-immunization Serology	Post-immunization Serology	Follow-up
	recommendation	recommendation	Special Considerations
Lifestyle risks  • Men who have sex with men (MSM)  • Individuals with more than one sexual partner in the previous six months  • Individuals with a history of a sexually transmitted infection (STI)  • Individuals seeking evaluation or treatment for a STI  • Individuals who engage in high risk sexual practices  • Individuals who have unprotected sex with new partners	Pre-immunization serology (anti-HBs, HBsAg and anti-HBc) is recommended.	Post-immunization serology is not routinely recommended.	Reimmunization (i.e. booster dose or reimmunization with a complete series) is not generally recommended. (12,13)  For individuals who were immunized as infants, children or adults, testing for anti-HBs years after immunization might not distinguish vaccine non-responders from responders. (12) Anti-HBs wanes and titres may become non-detectable over time, however immune memory persists. (4)  If post-immunization serology was inadvertently done and found to be anti-HBs negative, one booster dose of hepatitis B vaccine should be administered. Additional serology is not required.
Individuals who use illicit drugs and associated drugusing paraphernalia resulting in blood exposure	Pre-immunization serology (anti-HBs, HBsAg and anti-HBc) is recommended.	Serology (anti-HBs) should be done 1 – 6 months following the primary series of hepatitis B vaccine.	If the individual is negative for antibody after the first series, a second hepatitis B vaccine series <sup>(4)</sup> should be administered, with repeat serology testing one month later.  If immunization was completed more than six months previously and post-immunization serology was not done, testing should be done as part of a routine assessment.  If the individual is negative the individual should be given 1 booster dose of hepatitis B vaccine followed by serology one month later. If the individual is still negative after the 4th dose, the second series of hepatitis B vaccine should be completed followed by serology 1 month later.  Once a positive antibody result is documented no further serology is recommended.



recommendations to		<u> </u>	
Groups	Pre-immunization Serology recommendation	Post-immunization Serology recommendation	Follow-up
			Special Considerations
Non-immune adults who have immigrated to Canada from endemic areas	Pre-immunization serology (anti- HBs, HBsAg and anti-HBc) is recommended	Post-immunization serology is not recommended.	Reimmunization (i.e. booster dose or reimmunization with a complete series) is not generally recommended. (12,13)
			For individuals who were immunized as infants, children or adults, testing for anti-HBs years after immunization might not distinguish vaccine non-responders from responders. (12) Anti-HBs wanes and titres may become non-detectable over time, however immune memory persists. (4)
			If post-immunization serology was inadvertently done and found to be anti-HBs negative these individuals do not qualify for additional doses of provincially funded vaccine.
Individuals with hemophilia and others receiving  reported intuiting of	lia and serology is not routinely recommended blood	Post-immunization serology is not routinely recommended	Reimmunization (i.e. booster dose or reimmunization with a complete series) is not generally recommended. (12,13)
blood or blood products			For individuals who were immunized as infants, children or adults, testing for anti-HBs years after immunization might not distinguish vaccine non-
Individuals with Inflammatory Bowel disease (IBD) who	Pre-immunization serology is not recommended	Post-immunization serology is not recommended	responders from responders. <sup>(12)</sup> Anti-HBs wanes and titres may become non-detectable over time, however immune memory persists. <sup>(4)</sup>
will be on long term immunosuppressive medications	recommended	Tecommended	If post-immunization serology was inadvertently done and found to be anti-HBs negative these individuals do not qualify for additional doses of provincially funded
<u>Children</u> whose families have immigrated to Canada from an endemic area	Pre-immunization serology is not recommended	Post-immunization serology is not recommended	vaccine.
Populations or communities in Alberta in which hepatitis B is highly endemic	Pre-immunization serology is not routinely recommended	Post-immunization serology is not recommended.	



For individuals who are eligible for more than one reason – follow the most comprehensive serology recommendations for the respective eligibility groups.

Groups	Pre-immunization	Post-immunization	Follow-up
	Serology recommendation	Serology recommendation	Special Considerations
Children and workers in child care settings in which	Pre-immunization serology is not recommended	Post-immunization serology is not recommended	Reimmunization (i.e. booster dose or reimmunization with a complete series) is not generally recommended. (12,13)
there is a hepatitis B infected child or worker			For individuals who were immunized as infants, children or adults, testing for anti-HBs years after immunization might not distinguish vaccine non-
Residents and staff of institutions or group homes for the			responders from responders. $^{(12)}$ Anti-HBs wanes and titres may become non-detectable over time, however immune memory persists. $^{(4)}$
<u>developmentally</u> <u>challenged</u> .			If post-immunization serology was inadvertently done and found to be anti-HBs negative these individuals do
Inmates in provincial correctional facilities			not qualify for additional doses of provincially funded vaccine.
Students in Grade 6	Pre-immunization serology is not	Post-immunization serology is not	
<ul><li>Students in Grades</li><li>7 through 12</li></ul>	recommended	recommended	
Individuals born in 1981 or later			
Percutaneous     (needle stick) or	Refer to:	or Post-Exposure Man	agement and Prophylaxis <sup>(8)</sup> : for specific serology
mucosal exposure (blood and body fluid exposures)	recommendations at		. Tot opening colorogy
Susceptible     individuals of sexual	Refer to:		
individuals of <u>sexual</u> <u>assault</u>	Alberta Guidelines for recommendations and		agement and Prophylaxis <sup>(8)</sup> : for specific serology

Any individual who fails to respond to the second series of vaccine are unlikely to benefit from further doses. (4) Therefore, if protective levels are not achieved, the individual should be considered a non-responder and susceptible.



SEROLOGY INTERPRETATION			
Serology Result	Interpretation		
<ul> <li>anti-HBs positive</li> <li>HBsAg negative</li> <li>anti-HBc negative</li> </ul>	Considered immune. Refer to Serology Recommendations and Follow-Up Table for those requiring documented doses of hepatitis B vaccine regardless of positive anti-HBs serology.		
<ul><li>anti-HBs <u>positive</u></li><li>HBsAg negative</li><li>anti-HBc <u>positive</u></li></ul>	Considered immune. No vaccine indicated.		
<ul><li>anti-HBs negative</li><li>HBsAg negative</li><li>anti-HBc negative</li></ul>	Susceptible. Proceed with immunization as per eligibility criteria.		
<ul><li>anti-HBs negative</li><li>HBsAg positive</li><li>anti-HBc negative</li></ul>	Refer to: Alberta Public Health Hepatitis B Notifiable Disease Guidelines for interpretation and follow-up.		
<ul><li>anti-HBs negative</li><li>HBsAg negative</li><li>anti-HBc positive</li></ul>	Refer to: Alberta Public Health Hepatitis B Notifiable Disease Guidelines (Table 4B) for interpretation and follow-up.		
**Anti-HBs positive is ≥10 IU/L; negative is < 10 IU/L			

#### References

- 1. GlaxoSmithKline Inc. Engerix®-B: Hepatitis B vaccine (recombinant). Prod Monogr [Internet]. 2023;1–30. Available from: https://ca.gsk.com/media/6239/engerix-b.pdf.
- 2. Merck Canada Inc. Recombivax HB®: Hepatitis B vaccine (recombinant) [Internet]. Product Monograph. 2012. Available from: https://pdf.hres.ca/dpd\_pm/00016542.PDF.
- 3. Alberta Advisory Committee on Immunization (AACI). May 31, 2011. Record of Decisions. 2011.
- 4. National Advisory Committee on Immunization. Canadian Immunization Guide (Evergreen ed.) [Internet]. Ottawa, ON: Public Health Agency of Canada. 2017. Available from: <a href="https://www.phac-aspc.gc.ca/publicat/cig-gci/index-eng.php">www.phac-aspc.gc.ca/publicat/cig-gci/index-eng.php</a>.
- Wasan S. A Practical Guide to Vaccinating the Inflammatory Bowel Disease Patient. Am Coll Gastroenterol Am J Gastroenterol. 2010;(105):1231–8.
- 6. Alberta Health. Prenatal Screening Guidelines for Select Communicable Disease [Internet]. 2018. Available from: <a href="https://open.alberta.ca/dataset/0ac7acb6-dc90-4133-8f63-5946d4bbf4d1/resource/782751ed-17b9-4116-9aa4-227e55ec0299/download/alberta-prenatal-screening-guidelines-2018-10.pdf">https://open.alberta.ca/dataset/0ac7acb6-dc90-4133-8f63-5946d4bbf4d1/resource/782751ed-17b9-4116-9aa4-227e55ec0299/download/alberta-prenatal-screening-guidelines-2018-10.pdf</a>.
- 7. Alberta Health and Wellness. Hepatitis B (Acute and Chronic) [Internet]. Public Health Notifiable Disease Management Guidelines. Available from: <a href="https://open.alberta.ca/publications/hepatitis-b-acute-and-chronic">https://open.alberta.ca/publications/hepatitis-b-acute-and-chronic</a>.
- 8. Alberta Government. Alberta Guidelines for Post-Exposure Management and Prophylaxis: HIV, Hepatitis B, Hepatitis C and Sexually Transmitted Infections [Internet]. 2019. Available from: <a href="https://open.alberta.ca/dataset/f1e62045-b801-49a8-8549-ddc6b283ae67/resource/bf50d5ab-fe5d-41d0-91ae-c43c2167fea0/download/pep-quidelines-2019-03.pdf">https://open.alberta.ca/dataset/f1e62045-b801-49a8-8549-ddc6b283ae67/resource/bf50d5ab-fe5d-41d0-91ae-c43c2167fea0/download/pep-quidelines-2019-03.pdf</a>.
- 9. Advisory Committee on Immunization Practices (ACIP). General Best Practice Guidelines for Immunization. [Internet]. 2017 [cited 2019 Jan 25]. Available from: <a href="https://www.cdc.gov/vaccines/hcp/acip-recs/general-recs/index.html">https://www.cdc.gov/vaccines/hcp/acip-recs/general-recs/index.html</a>.
- 10. Immunization Action Coalition. Ask the Experts: Hepatitis B [Internet]. 2019 [cited 2019 Jan 25]. Available from: <a href="https://www.immunize.org/ask-experts/topic/hepb/#recommendations">https://www.immunize.org/ask-experts/topic/hepb/#recommendations</a>.
- 11. Advisory Committee on Immunization Practices (ACIP). Guideline for Vaccinating Kidney Dialysis Patients and Patients with Chronic Kidney Disease [Internet]. 2012 [cited 2016 Mar 15]. Available from: <a href="https://www.cdc.gov/vaccines/pubs/downloads/dialysis-guide-2012.pdf">www.cdc.gov/vaccines/pubs/downloads/dialysis-guide-2012.pdf</a>.
- 12. Centers for Disease Control and Prevention. Prevention of Hepatitis B Virus Infection in the United States: Recommendations of the Advisory Committee on Immunization Practices (ACIP) [Internet]. Morbidity and Mortality Weekly Report (MMWR), 67(No.RR-1). 2018. p. 1–31. Available from: http://dx.doi.org/10.15585/mmwr.rr6701a1.
- National Advisory Committee on Immunization. Update on the recommended use of Hepatitis B vaccine. [Internet].
   2017. Available from: <a href="https://www.canada.ca/en/public-health/services/publications/healthy-living/update-recommended-use-hepatitis-b-vaccine.html">https://www.canada.ca/en/public-health/services/publications/healthy-living/update-recommended-use-hepatitis-b-vaccine.html</a>.

