

<b>Section 7:</b>	<b>Biological Product Information</b>	<b>Standard #: 07.234</b>
<b>Created by:</b>	Province-wide Immunization Program Standards and Quality	
<b>Approved by:</b>	Province-wide Immunization Program, Standards and Quality	
<b>Approval Date:</b>	March 1, 2013	<b>Revised:</b> January 1, 2020

	Recombivax HB®	Engerix®-B
<b>Manufacturer</b>	Merck Canada Inc.	GlaxoSmithKline Inc.
<b>Biological Classification</b>	Inactivated: Recombinant	
<b>Indications for Provincially Funded Vaccine</b>	<p><b>Pre-exposure:</b> Refer to Serology Recommendations and Follow-up section at end of document for pre-immunization serology recommendations.</p> <p><b>Universal:</b></p> <ul style="list-style-type: none"> <li>• Students in Grade 6 Universal program in Alberta.</li> <li>• Students in Grades 7 through 12 who have not received a series of hepatitis B vaccine. <ul style="list-style-type: none"> <li>○ For students in ungraded classes, vaccine can be provided on a case by case basis, generally at 10 years up to and including 18 years of age. The guiding principle should be to offer protection to students prior to them leaving the school system.</li> </ul> </li> <li>• Individuals born March 1, 2018 or later for when immunization with DTaP-IPV-Hib-HB is not needed or contraindicated.</li> <li>• 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.</li> </ul> <p><b>Endemic:</b></p> <ul style="list-style-type: none"> <li>• Children from birth up to and including 6 years of age, whose families have immigrated to Canada from areas where there is a high prevalence (8% or higher) of hepatitis B (endemic for hepatitis B). See Hepatitis B Virus Infection – High Endemic Geographic Areas.</li> <li>• Non-immune adults who have immigrated to Canada from areas where there is a high prevalence (8% or higher) of hepatitis B. See Hepatitis B Virus Infection – High Endemic Geographic Areas.</li> <li>• Populations or communities in which hepatitis B is highly endemic, following consultation with the Office of the Chief Medical Officer (OCMOH).</li> </ul> <p><b>Chronic Health Conditions:</b></p> <ul style="list-style-type: none"> <li>• Hemophiliacs 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> <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®.</li> <li>• Individuals with chronic liver disease from any cause, including hepatitis C infection.</li> </ul> <p><b>Notes:</b></p> <ul style="list-style-type: none"> <li>▪ Individuals with chronic liver disease with lab confirmation of positive anti-HBs but without documentation of any doses of hepatitis B vaccine should be offered a series of hepatitis B vaccine to ensure long term immunity.</li> <li>▪ Individuals with chronic liver disease with lab confirmation of positive anti-HBs with any incomplete series should have their series completed.</li> </ul>	

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	<p><b>Lifestyle Risks:</b></p> <ul style="list-style-type: none"> <li>• Individuals with lifestyle risks of infection including: <ul style="list-style-type: none"> <li>○ Men who have sex with men (MSM).</li> <li>○ Individuals with more than one sexual partner in the previous six months.</li> <li>○ Individuals with a history of sexually transmitted infection.</li> <li>○ Individuals seeking evaluation or treatment for a sexually transmitted infection.</li> <li>○ Individuals who engage in high risk sexual practices.</li> <li>○ Individuals who have unprotected sex with new partners.</li> <li>○ Individuals who use illicit drugs and associated drug-using paraphernalia (e.g., needles, tubes used for snorting), resulting in blood exposure.</li> </ul> </li> </ul> <p><b>Immunosuppressive Chronic Health Conditions that may be HYPORESPONSIVE to Hepatitis B Vaccine:</b></p> <ul style="list-style-type: none"> <li>• Individuals with chronic health conditions that may be HYPORESPONSIVE to hepatitis B vaccine should receive a higher dose of hepatitis B (see dose section). These include: <ul style="list-style-type: none"> <li>○ Individuals with chronic renal disease or who are undergoing chronic hemodialysis/peritoneal dialysis, including those who are pre-dialysis (progressive renal insufficiency).</li> <li>○ Individuals with congenital immunodeficiencies.</li> <li>○ Individuals infected with HIV.</li> <li>○ Candidates and recipients of Solid Organ Transplant (SOT) – See <i>Standard for Immunization of Transplant Candidates and Recipients</i>.</li> <li>○ Recipients of Hematopoietic Stem Cell Transplant (HSCT) – See <i>Standard for Immunization of Transplant Candidates and Recipients</i>.</li> </ul> </li> </ul> <p><b>Notes:</b></p> <ul style="list-style-type: none"> <li>▪ Individuals with lab confirmation of positive anti-HBs but without documentation of any doses of hepatitis B vaccine should be offered a series of hepatitis B vaccine to ensure long term immunity.</li> <li>▪ Individuals with lab confirmation of positive anti-HBs with any incomplete series should have their series completed.</li> <li>▪ Periodic serological testing may be done by the attending physician for hyporesponsive individuals. See serology section for more information.</li> </ul> <p><b>Occupational/Other Settings:</b></p> <ul style="list-style-type: none"> <li>• 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. Refer to Hepatitis B Risk Assessment.</li> <li>• Children and workers in child care settings in which there is a hepatitis B infected staff or child. <ul style="list-style-type: none"> <li>○ If exceptional circumstances such as biting behavior or special medical conditions exist and Hepatitis B status is unknown, consult with MOH/designate.</li> </ul> </li> <li>• Residents and staff of institutions or group homes for the developmentally challenged.</li> <li>• Inmates in provincial correctional facilities who will be incarcerated for a sufficient length of time to complete a hepatitis B vaccine series.</li> </ul> <p><b>Note:</b></p> <ul style="list-style-type: none"> <li>▪ Immunization of inmates in long-term correctional facilities 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 federal prisons.</li> </ul> <p><b>Note:</b></p> <ul style="list-style-type: none"> <li>• Combined hepatitis A and B vaccine may be considered for individuals 1 year of age and older eligible for both pre-exposure hepatitis A and B vaccines if they do not require the double strength hepatitis B vaccine (see Twinrix® Vaccine Biological Page).</li> </ul>	

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	<p><b>Post-exposure:</b> Refer to Serology Recommendations and Follow-up section at end of document for post-immunization serology recommendations.</p> <ul style="list-style-type: none"> <li>• <b>Infants:</b> <ul style="list-style-type: none"> <li>○ <b>Newborns</b> born to hepatitis B surface antigen positive (HBsAg) mothers (acute cases or carriers) should receive hepatitis B immune globulin (HBIG) and the first dose of hepatitis B vaccine as soon as possible after birth (within 12 hours) but within 7 days after birth if HBIG/hepatitis B vaccine is delayed for any reason.</li> </ul> </li> </ul> <p><b>Notes:</b></p> <ul style="list-style-type: none"> <li>▪ 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.</li> <li>▪ 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.</li> <li>▪ If results are not 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.</li> </ul> <ul style="list-style-type: none"> <li>○ <b>Infants (other than newborns) younger than 12 months of age:</b> <ul style="list-style-type: none"> <li>▪ Hepatitis B vaccine and HBIG if the mother or primary caregiver is an acute case.</li> <li>▪ Hepatitis B vaccine only if the caregiver or significant household contact is a chronic carrier.</li> </ul> </li> </ul> <p>Refer to: <a href="#">Public Health Notifiable Disease Management Guidelines – Hepatitis B</a> and <a href="#">Alberta Prenatal Screening Program for Selected Communicable Diseases Public Health Guidelines – Hepatitis B</a>.</p> <ul style="list-style-type: none"> <li>• <b>Susceptible household contacts, sexual partners and needle sharing partners of individuals with acute or chronic hepatitis B infection.</b> <ul style="list-style-type: none"> <li>○ Hepatitis B vaccine. HBIG may be recommended for some individuals depending on the time from exposure and the specifics of the exposure. Refer to: <a href="#">Public Health Notifiable Disease Management Guidelines – Hepatitis B</a></li> </ul> </li> </ul> <p><b>Notes:</b></p> <ul style="list-style-type: none"> <li>▪ Susceptible household contacts, sexual partners and needle-sharing partners with lab confirmation of positive anti-HBs but without documentation of any doses of hepatitis B vaccine should be offered a series of hepatitis B vaccine to ensure long term immunity.</li> <li>▪ Susceptible household contacts, sexual partners and needle-sharing partners with lab confirmation of positive anti-HBs with any incomplete series should have their series completed.</li> </ul> <ul style="list-style-type: none"> <li>• <b>Percutaneous (needle stick) or mucosal exposure.</b> <ul style="list-style-type: none"> <li>○ 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.</li> </ul> </li> </ul> <p><b>Notes:</b></p> <ul style="list-style-type: none"> <li>▪ Individuals sustaining percutaneous (needle stick) or mucosal exposure with lab confirmation of positive anti-HBs but without documentation of any doses of hepatitis B vaccine should be offered a series of hepatitis B vaccine to ensure long term immunity.</li> <li>▪ Individuals sustaining percutaneous (needle stick) or mucosal exposure with lab confirmation of positive anti-HBs with any incomplete series should have their series completed.</li> <li>▪ 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</li> </ul>	

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	<p>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.</p> <ul style="list-style-type: none"> <li>• <b>Susceptible individuals of sexual assault.</b> <ul style="list-style-type: none"> <li>○ HBIG and hepatitis B vaccine should be offered.</li> </ul> </li> </ul> <p>For further guidelines related to post-exposure follow-up refer to the following:</p> <ul style="list-style-type: none"> <li>• <a href="#">Public Health Notifiable Disease Management Guidelines – Hepatitis B</a></li> <li>• <a href="#">Alberta Guidelines for Post-Exposure Management and Prophylaxis: HIV, Hepatitis B, Hepatitis C and Sexually Transmitted Infections</a></li> <li>• <a href="#">Canadian Immunization guide: Hepatitis B Vaccine (Figures 1 &amp; 2)</a></li> </ul>	
<b>Serology</b>	<b>See Serology Recommendations and Follow-up at end of document.</b>	
<b>Schedule and Dose For Healthy Individuals</b>	<p>May consider use of Infanrix hexa® in children 2 months up to and including 23 months of age. See <i>Infanrix hexa® Vaccine Biological Page (#07.214)</i> for indications. The schedule and spacing considerations for Infanrix-hexa® vaccine varies slightly from those of the individual HBV and DTaP-IPV-Hib vaccines. Ensure the appropriate schedule is followed for the vaccine(s) that are being used.</p>	
	<p>Individuals being immunized with Recombivax HB® Vaccine (10 mcg/1.0 mL):</p>	<p>Individuals being immunized with Engerix®-B Vaccine (20 mcg/1.0 mL):</p>
<p><b>Newborns born to hepatitis B surface antigen positive (HBsAg) mother (3 doses):</b>  <b>Give as 0.5 mL</b></p> <ul style="list-style-type: none"> <li>○ Dose 1 – at birth, given with HBIG</li> <li>○ Dose 2 – 2 months of age</li> <li>○ Dose 3 – 6 months of age</li> </ul> <p><b>Note:</b></p> <ul style="list-style-type: none"> <li>• Third dose should not be given to infants before 6 months (24 weeks or 168 days) of age.</li> </ul> <p><b>Newborns with birth weight less than 2000 grams born to hepatitis B surface antigen positive (HbsAg) mother (4 doses):</b>  <b>Give as 0.5 mL</b></p> <ul style="list-style-type: none"> <li>○ Dose 1 – at birth, given with HBIG</li> <li>○ Dose 2 – 1 month of age</li> <li>○ Dose 3 – 2 months of age</li> <li>○ Dose 4 – 6 months of age</li> </ul> <p><b>Notes:</b></p> <ul style="list-style-type: none"> <li>• The response to hepatitis B vaccine may be diminished in infants with a birth weight below 2,000 grams. Neonates weighing less than 2,000 grams who receive hepatitis B vaccine at birth require four doses of hepatitis B vaccine; administered at birth, 1, 2 and 6 months of age, followed by serologic testing at minimum 9 months of age and at least one month after completion of series.</li> <li>• Fourth dose should not be given to infants before 6 months (24 weeks or 168 days) of age.</li> </ul>		

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	<p><b>Other infants from birth up to and including 11 months of age (3 doses):</b>  <b>Give as 0.5 mL</b></p> <ul style="list-style-type: none"> <li>○ Dose 1 – 2 months of age</li> <li>○ Dose 2 – 4 months of age</li> <li>○ Dose 3 – 12 months of age</li> </ul> <p><b>Notes:</b></p> <ul style="list-style-type: none"> <li>• Third dose should not be given to infants before 6 months (24 weeks or 168 days) of age.</li> <li>• If the infant is identified as a significant household contact of a hepatitis B carrier, offer hepatitis B vaccine as soon as possible following identification.</li> <li>• For children who begin immunization off schedule, minimum intervals can be used - refer to Spacing Considerations.</li> </ul> <p><b>Infants with birth weight less than 2000 grams who receive hepatitis B vaccine at birth (e.g., father or other primary caregiver is HBsAg positive) (4 doses):</b>  <b>Give as 0.5 mL</b></p> <ul style="list-style-type: none"> <li>○ Dose 1 – at birth</li> <li>○ Dose 2 – 1 month of age</li> <li>○ Dose 3 – 2 months of age</li> <li>○ Dose 4 – 6 months of age</li> </ul> <p><b>Notes:</b></p> <ul style="list-style-type: none"> <li>• The response to hepatitis B vaccine may be diminished in infants with a birth weight below 2,000 grams. Neonates weighing less than 2,000 grams who receive hepatitis B vaccine at birth require four doses of hepatitis B vaccine; administered at birth, 1, 2 and 6 months of age, followed by serologic testing at minimum 9 months of age and at least one month after completion of series.</li> <li>• Fourth dose should not be given to infants before 6 months (24 weeks or 168 days) of age.</li> </ul>	
	<p><b>Children 12 months of age up to and including 10 years of age (3 doses):</b>  <b>Give as 0.5 mL</b></p> <ul style="list-style-type: none"> <li>○ Dose 1 – day 0</li> <li>○ Dose 2 – 1 month after dose 1</li> <li>○ Dose 3 – 6 months after dose 1</li> </ul> <p><b>Note:</b></p> <ul style="list-style-type: none"> <li>• If the child is identified as a significant household contact of a hepatitis B carrier, offer hepatitis B vaccine as soon as possible following identification.</li> </ul>	
	<p><b>Students 11 years of age up to and including 15 years of age (2 doses):</b>  <b>Give as 1.0 mL</b></p> <ul style="list-style-type: none"> <li>• This includes grade 6 students younger than 11 years of age as eligibility for a two-dose series is determined by grade level. <ul style="list-style-type: none"> <li>○ Dose 1 – day 0</li> <li>○ Dose 2 – 6 months after dose 1</li> <li>○ Minimal acceptable spacing between the first and second dose is 24 weeks.</li> </ul> </li> </ul> <p><b>Notes:</b></p> <ul style="list-style-type: none"> <li>• In the event that a 0.5 mL dose is given, a 3 dose schedule must be followed:  <b>Give as 0.5 mL</b> <ul style="list-style-type: none"> <li>○ Dose 1 – day 0</li> <li>○ Dose 2 – 1 month after dose 1</li> <li>○ Dose 3 – 6 months after dose 1</li> <li>○ If required, the minimum 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 4 months (112 days) between the first and third dose.</li> </ul> </li> <li>• If a student will turn 16 years of age before a 2-dose series can be completed, a 3-dose schedule should be initiated.</li> </ul>	

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	<p><b>Children 16 years of age up to and including 19 years of age (3 doses):</b>  <b>Give as 0.5 mL</b></p> <ul style="list-style-type: none"> <li>○ Dose 1 – day 0</li> <li>○ Dose 2 – 1 month after dose 1</li> <li>○ Dose 3 – 6 months after dose 1</li> </ul> <p><b>Notes:</b></p> <ul style="list-style-type: none"> <li>• If required, the minimum 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 4 months (112 days) between the first and third dose.</li> <li>• 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 appropriate dosing for age.</li> </ul>	
	<p><b>Adults 20 years of age and older (3 doses):</b>  <b>Give as 1.0 mL</b></p> <ul style="list-style-type: none"> <li>○ Dose 1 – day 0</li> <li>○ Dose 2 – 1 month after dose 1</li> <li>○ Dose 3 – 6 months after dose 1</li> </ul> <p><b>Notes:</b></p> <ul style="list-style-type: none"> <li>• 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 appropriate dosing for age.</li> <li>• For individuals delayed for second dose of vaccine, third dose should routinely be offered 5 months after second dose. For individuals at high risk of hepatitis B infection, minimal intervals may be considered in consultation with MOH/MOH designate.</li> </ul>	
	<p><b>Spacing Considerations:</b></p> <ul style="list-style-type: none"> <li>• Interruption of the immunization schedule does not require any dose(s) be repeated if the minimum intervals between doses are respected.</li> <li>• For those who may have an alternate immunization history refer to #03.110 Standard for Recommended Immunization Schedules.</li> <li>• If a second hepatitis B immunization series is required this can be started once the need is identified.</li> <li>• Immunization started in another province or territory prior to grade 6 can be completed as they present to public health using the current schedule and dose recommended in Alberta.</li> </ul>	
<b>Schedule and Dose for Hyporesponsive Individuals</b>	<p><b>Hyporesponsive</b> individuals being immunized with Recombivax HB® Vaccine (10 mcg/1.0 mL):</p>	<p><b>Hyporesponsive</b> individuals being immunized with Engerix®-B Vaccine (20 mcg/1.0 mL):</p>
	<b>Birth to 15 years of age</b>	
	<p><b>Individuals from birth up to and including 15 years of age (3 doses):</b>  <b>Give as 1.0 mL</b></p> <ul style="list-style-type: none"> <li>○ Dose 1 – day 0</li> <li>○ Dose 2 – 1 month after dose 1</li> <li>○ Dose 3 – 6 months after dose 1</li> </ul>	<p><b>Individuals from birth up to and including 15 years of age (3 doses):</b>  <b>Give as 1.0 mL</b></p> <ul style="list-style-type: none"> <li>○ Dose 1 – day 0</li> <li>○ Dose 2 – 1 month after dose 1</li> <li>○ Dose 3 – 6 months after dose 1</li> </ul>

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	<p style="text-align: center;"><b>16 years to 19 years of age</b></p> <p><b>Individuals 16 years of age up to and including 19 years of age (3 doses): Give as 1.0 mL</b></p> <ul style="list-style-type: none"> <li>○ Dose 1 – day 0</li> <li>○ Dose 2 – 1 month after dose 1</li> <li>○ Dose 3 – 6 months after dose 1</li> </ul>	
	<p><b>Individuals 16 years of age up to and including 19 years of age (4 doses): Give as 2.0 mL</b></p> <ul style="list-style-type: none"> <li>○ Dose 1 – day 0</li> <li>○ Dose 2 – 1 month after dose 1</li> <li>○ Dose 3 – 2 months after dose 1</li> <li>○ Dose 4 – 6 months after dose 1</li> </ul> <p><b>Notes:</b></p> <ul style="list-style-type: none"> <li>• Those initiating a four dose schedule with Engerix®-B should complete the series using the same vaccine whenever possible.</li> <li>• Minimum interval between dose three and dose four is 4 months and at least 6 months between dose one and dose four.</li> </ul>	
	<p>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.</p>	
	<p><b>Hyporesponsive</b> individuals being immunized with Recombivax HB® Adult Dialysis Strength Vaccine (40 mcg/1.0 mL):</p>	<p><b>Hyporesponsive</b> individuals being immunized with Engerix®-B Vaccine (20 mcg/1.0 mL):</p>
	<p style="text-align: center;"><b>20 years and older</b></p> <p><b>Individuals 20 years of age and older (3 doses) Give as 1.0 mL</b></p> <ul style="list-style-type: none"> <li>○ Dose 1 – day 0</li> <li>○ Dose 2 – 1 month after dose 1</li> <li>○ Dose 3 – 6 months after dose 1</li> </ul> <p><b>Note:</b> Do not use this formulation for individuals younger than 20 years of age.</p>	
	<p><b>Individuals 20 years of age and older (4 doses): Give as 2.0 mL</b></p> <ul style="list-style-type: none"> <li>○ Dose 1 – day 0</li> <li>○ Dose 2 – 1 month after dose 1</li> <li>○ Dose 3 – 2 months after dose 1</li> <li>○ Dose 4 – 6 months after dose 1</li> </ul> <p><b>Notes:</b></p> <ul style="list-style-type: none"> <li>• Those initiating a four dose schedule with Engerix®-B should complete the series using the same vaccine whenever possible.</li> <li>• Minimum interval between dose three and dose four is 4 months and at least 6 months between dose one and dose four.</li> </ul>	
	<ul style="list-style-type: none"> <li>• Hyporesponsive persons 20 years of age and older should receive <b>Recombivax HB® Dialysis Strength</b> Vaccine. If Recombivax HB® Dialysis Strength Vaccine is unavailable; Engerix®-B may be used following the schedule outlined.</li> <li>• 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.</li> </ul>	
	<p><b>Spacing Considerations:</b></p> <ul style="list-style-type: none"> <li>• Interruption of the immunization schedule does not require any dose(s) be repeated if the minimum intervals between doses are respected.</li> <li>• For those who may have an alternate immunization history refer to #03.110 Standard for Recommended Immunization Schedules</li> <li>• If a second hepatitis B immunization series is required this can be started once the need is identified.</li> <li>• Immunization started in another province or territory prior to grade 6 can be completed as they present to public health using the current schedule and dose recommended in Alberta.</li> </ul>	



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<b>Preferred Use</b>	<ul style="list-style-type: none"> <li>There is no preference indicated for the use of Recombivax HB® or Engerix®-B for those eligible for regular strength vaccine. <ul style="list-style-type: none"> <li>Both vaccines are safe and immunogenic for all ages</li> <li>Persons with medical contraindications to one product should be offered the alternate product if supply is available</li> </ul> </li> </ul>	
<b>Route</b>	IM <b>Note:</b> <ul style="list-style-type: none"> <li>Vaccine should not be administered in the gluteal areas as this may result in lower immune response. If vaccine is inadvertently given in the gluteal area the individual should be tested for immunity and re-immunized if antibody concentrations are inadequate.<sup>3</sup></li> </ul>	
<b>Contraindications/ Precautions</b>	<b>Contraindications:</b> <ul style="list-style-type: none"> <li>Known severe hypersensitivity to any component of a hepatitis B containing vaccine.</li> <li>Anaphylactic reactions or other allergic reaction to a previous dose of vaccine containing similar components.</li> <li>For Recombivax HB® only: Anaphylactic reactions to latex.</li> </ul> <b>Precautions:</b> <ul style="list-style-type: none"> <li>None identified.</li> </ul>	
<b>Possible Reactions</b>	<b>Common:</b> <ul style="list-style-type: none"> <li>Injection site pain, soreness, tenderness, pruritus, erythema, ecchymoses, swelling, induration, warmth and nodule formation.</li> <li>Irritability, headache, fatigue/asthenia, malaise, pharyngitis and fever.</li> <li>Loss of appetite, nausea, vomiting, diarrhea and abdominal pain.</li> </ul> <b>Uncommon:</b> <ul style="list-style-type: none"> <li>Dizziness, myalgia</li> </ul> <b>Rare:</b> <ul style="list-style-type: none"> <li>Lymphadenopathy, paresthesia, rash, urticaria and arthralgia.</li> <li>Anaphylaxis, angioedema, allergic reactions.</li> <li>As with any immunization, unexpected or unusual side effects can occur. Refer to the product monograph for more detailed information.</li> </ul> <b>Note:</b> A number of studies have been unable to demonstrate any evidence of a causal association following hepatitis B vaccine and the following chronic illnesses: chronic fatigue syndrome, multiple sclerosis, Guillain-Barré syndrome (GBS) or rheumatoid arthritis.	
<b>Pregnancy</b>	<ul style="list-style-type: none"> <li>Hepatitis B vaccine should be administered to pregnant women when indicated.</li> <li>Data is not available on the effect of hepatitis B vaccine on fetal development; however, the risk is expected to be negligible as the vaccine consists of non-infectious subunits.</li> <li>Eligible pregnant woman should receive provincially funded vaccine.</li> <li>Pregnant women at high risk of hepatitis B infection should be tested for antibody response following receipt of hepatitis B vaccine series. See serology section for more information.</li> </ul>	
<b>Lactation</b>	Can be administered to eligible breastfeeding women. It is not known whether hepatitis B vaccine is excreted in human milk.	
<b>Composition</b>	Each 0.5 mL dose contains: <ul style="list-style-type: none"> <li>5 mcg hepatitis B surface antigen</li> <li>0.25 mg amorphous aluminum hydroxyphosphate</li> <li>4.5 mg sodium chloride</li> <li>35.0 mcg sodium borate</li> <li>Water for injection</li> </ul>	Each 0.5 mL dose contains: <ul style="list-style-type: none"> <li>10 mcg hepatitis B surface antigen</li> <li>0.25 mg aluminum hydroxide</li> </ul> Each 1.0 mL dose contains: <ul style="list-style-type: none"> <li>20 mcg hepatitis B surface antigen</li> <li>0.5 mg aluminum hydroxide</li> </ul>



	Recombivax HB®	Engerix®-B
	<p>Each 1.0 mL dose contains:</p> <ul style="list-style-type: none"> <li>• 10 mcg hepatitis B surface antigen</li> <li>• 0.5 mg amorphous aluminum hydroxyphosphate</li> <li>• 9.0 mg sodium chloride</li> <li>• 70.0 mcg sodium borate</li> <li>• Water for injection</li> </ul> <p>Each 1.0 mL dose of <b>Recombivax HB® Dialysis Strength</b> contains:</p> <ul style="list-style-type: none"> <li>• 40 mcg hepatitis B surface antigen</li> <li>• 0.5 mg amorphous aluminum hydroxyphosphate</li> <li>• 9.0 mg sodium chloride</li> <li>• 70.0 mcg sodium borate</li> <li>• Water for injection</li> </ul> <p>The following manufacturing residuals may be found in the above preparations of Recombivax HB® vaccine:</p> <ul style="list-style-type: none"> <li>• Less than 1% yeast protein</li> <li>• Less than 15 mcg/mL formaldehyde</li> </ul> <p>These presentations are preservative free</p>	<p>Non-medicinal Ingredients:</p> <ul style="list-style-type: none"> <li>• disodium phosphate hydrate</li> <li>• sodium chloride</li> <li>• sodium dihydrogen phosphate dehydrate</li> <li>• water for injection</li> </ul> <p>Single dose presentations are preservative free</p>
	<p>For a detailed list of ingredients see the link below to the Canadian Immunization Guide:  <a href="http://www.phac-aspc.gc.ca/publicat/cig-gci/p01-14-eng.php">http://www.phac-aspc.gc.ca/publicat/cig-gci/p01-14-eng.php</a></p>	
<b>Blood/Blood Products</b>	Contains no human blood/blood products	
<b>Bovine/Porcine Products</b>	Contains no bovine or porcine products	
<b>Latex</b>	Latex in vial stopper	Does not contain latex
<b>Interchangeability</b>	<ul style="list-style-type: none"> <li>• Hepatitis B vaccines produced by different manufacturers can be used interchangeably despite different doses and schedules.</li> <li>• The dose administered should be that recommended by the manufacturer for the specific product being used.</li> <li>• When possible, series should be completed with the same vaccine, especially with hyporesponsive individuals. If this is not possible, hyporesponsive individuals 16 years and older who have received any doses of Engerix®-B vaccine should be completed using the 4 dose schedule. Refer to schedule and dose section for more details.</li> </ul>	
<b>Administration with Other Products</b>	<ul style="list-style-type: none"> <li>• May be given at the same time as other inactivated and live vaccines using a separate needle and syringe for each vaccine.</li> <li>• The same limb may be used if necessary, but different sites must be chosen.</li> </ul>	
<b>Appearance</b>	Slightly opaque, white suspension	
<b>Storage</b>	<ul style="list-style-type: none"> <li>• Store at +2° to +8°C</li> <li>• Do not freeze</li> <li>• Do not use past the expiry date</li> <li>• Store in original packaging when possible to protect from light</li> </ul>	
<b>Vaccine Code</b>	HBV – regular strength product HBVD – dialysis strength vaccine	HBV
<b>Antigen Code</b>	HBV	

	Recombivax HB®	Engerix®-B
<b>Licensed for</b>	<p><b>Recombivax HB® regular strength:</b></p> <ul style="list-style-type: none"> <li>licensed for persons of all ages.</li> <li>A 0.5 mL dose has been approved by Alberta Health for off license use of Recombivax HB® for eligible healthy children from birth up to and including 10 years of age who are not contacts of HBsAg positive mothers.</li> </ul> <p><b>Recombivax HB® Dialysis Strength:</b></p> <ul style="list-style-type: none"> <li>Licensed for individuals 20 years of age and older.</li> </ul>	Individuals of all ages
<p><b>Program Notes:</b></p> <ul style="list-style-type: none"> <li>1983 January 1: Hepatitis B vaccine introduced in Alberta for the neonatal program for infants at high risk; Hepatitis B Dialysis Strength (Recombivax®) introduced.</li> <li>1995 September: Hepatitis B introduced into routine school immunization program for students in grade 5.</li> <li>1999 September: Hepatitis B catch-up school immunization program for grade 12 students was available from September 1999 to June 2002.</li> <li>2016 July 1: 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 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 are eligible for hepatitis B vaccine.</li> <li>2018 February: Individuals with Inflammatory Bowel disease (IBD) who will be on long term immunosuppressive medications became eligible for hepatitis B vaccine</li> <li>2018 September: Routine school immunization schedule for hepatitis B vaccine 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 for grade 6 students.</li> </ul>		
<p><b>Related Resources:</b></p> <ul style="list-style-type: none"> <li>Hepatitis B Vaccine Information Sheet (104505).</li> </ul>		

## SEROLOGY RECOMMENDATIONS AND FOLLOW-UP

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

Groups	Pre-immunization Serology recommendation	Post-immunization Serology recommendation	Follow-up Special Considerations
<ul style="list-style-type: none"> <li>Individuals with <u>chronic renal disease</u> including hemodialysis, peritoneal dialysis, and pre-dialysis</li> </ul>	Pre-immunization serology is not routinely recommended	Serology should be done 1 – 6 months following the primary series of hepatitis B vaccine	<p>Individuals who are hyporesponsive due to renal disease (hemodialysis, peritoneal dialysis and pre-dialysis) 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.</p> <p>Individuals who are negative for antibody after the first series, <b>should receive a second series</b>, followed by serology one month later.</p> <p>Persons with chronic renal disease or on dialysis should be evaluated yearly for anti-HBs. Should antibody testing show suboptimal protection, a booster dose of vaccine should be given.</p> <p>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.</p> <p>See <a href="#">Hepatitis B (HBVD) Algorithm for Chronic Renal Disease</a> for additional information.</p>
<ul style="list-style-type: none"> <li>Individuals with <u>congenital immunodeficiencies</u></li> <li>Candidates for and recipients of <u>solid organ transplant (SOT)</u></li> <li>Recipients of <u>hematopoietic stem cell transplant (HSCT)</u></li> </ul>	Pre-immunization serology is not routinely recommended	Serology should be done 1 – 6 months following the primary series of hepatitis B vaccine	<p>Individuals who are hyporesponsive due to congenital immunodeficiencies, HSCT, SOT and 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.</p> <p>Individuals who are negative for antibody after the first series, <b>should receive a second series</b>, followed by serology one month later.</p> <p>Periodic monitoring (by attending physician) for the presence of anti-HBs should be considered, taking into account the severity of the compromised state and whether or not the risk for hepatitis B infection is still present. Should antibody testing show suboptimal protection, a booster dose of vaccine and retesting should be undertaken.</p>
<ul style="list-style-type: none"> <li>Individuals infected with <u>HIV</u></li> </ul>	Pre-immunization serology (anti-HBs, HBsAg and anti-HBc) is recommended	Serology should be done 1 – 6 months following the primary series of hepatitis B vaccine	<p>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.</p>

<ul style="list-style-type: none"> <li>Individuals with <u>chronic liver disease</u></li> </ul>	<p>Pre-immunization serology (anti-HBs, HBsAg and anti-HBc) is recommended</p>	<p>Serology should be done 1 – 6 months following the primary series of hepatitis B vaccine</p>	<p>Individuals who are negative after the first series, <b>should receive a second series using a higher dose vaccine schedule</b> for hyporesponsive individuals followed by serology one month later.</p> <p>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.</p>
<ul style="list-style-type: none"> <li><u>Newborns born to hepatitis B infected mothers</u></li> <li><u>Infants (other than newborns) younger than 12 months of age with hepatitis B infected caregiver or household contact</u></li> </ul>	<p>Pre-immunization serology is not recommended</p>	<p>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</p>	<p>If the individual is negative for antibody after the first series, a second hepatitis B vaccine series should be administered, with repeat serology testing one month later.</p> <p>Once a positive antibody result is documented no further serology is recommended.</p> <p>Refer to: <a href="#">Public Health Notifiable Disease Management Guidelines – Hepatitis B</a> and <a href="#">Alberta Prenatal Screening Program for Selected Communicable Diseases Public Health Guidelines – Hepatitis B</a>.</p>
<ul style="list-style-type: none"> <li>HCWs and Post-Secondary Health Care Students</li> </ul>	<p>Refer to <a href="#">Occupational Considerations for Immunization</a>. Immunization Recommended for Health Care Workers and Immunization Recommended for Health Care Students for pre-immunization serology recommendation</p>	<p>Serology should be done 1 – 6 months following the primary series of hepatitis B vaccine</p>	<p>If the individual is negative for antibody after the first series, a second hepatitis B vaccine series should be administered, with repeat serology testing one month later.</p> <p>If immunization was completed more than six months previously and post- immunization screening was not done, testing should be done as part of a routine assessment.</p> <ul style="list-style-type: none"> <li>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 4<sup>th</sup> dose, the second series of hepatitis B vaccine should be completed followed by serology 1 month later.</li> </ul> <p>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.</p> <p>HCWs who have been previously assessed do not require reassessment or updating at this time.</p> <p>Once a positive antibody result is documented no further serology is recommended.</p>

<ul style="list-style-type: none"> <li>Individuals who are <u>workers, volunteers</u> or and who have a reasonable anticipated risk of exposure to blood/bloody body fluids</li> </ul>	Pre-immunization serology is not routinely recommended	Serology should be done 1 – 6 months following the primary series of hepatitis B vaccine	<p>If the individual is negative for antibody after the first series, a second hepatitis B vaccine series should be administered, with repeat serology testing one month later.</p> <p>Once a positive antibody result is documented no further serology is recommended.</p>
<ul style="list-style-type: none"> <li>Susceptible <u>household contacts, sexual partners and needle-sharing partners</u> of individuals with acute or chronic hepatitis B infection</li> </ul>	Refer to: <a href="#">Public Health Notifiable Disease Management Guidelines – Hepatitis B</a> (Management of Contacts [Low Risk or High Risk] of Previous Hepatitis B Infection) for specific serology recommendations and interpretation.		<p>Once a positive antibody result is documented no further serology is recommended.</p> <p>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.</p>
<p><u>Lifestyle risks</u></p> <ul style="list-style-type: none"> <li>Men who have sex with men (MSM)</li> <li>Individuals with more than one sexual partner in the previous six months</li> <li>Individuals with a history of a sexually transmitted infection (STI)</li> <li>Individuals seeking evaluation or treatment for a STI</li> <li>Individuals who engage in high risk sexual practices</li> <li>Individuals who have unprotected sex with new partners</li> </ul>	Pre-immunization serology (anti-HBs, HBsAg and anti-HBc) is recommended	Post-immunization serology is not routinely recommended	<p>Reimmunization (i.e. booster dose or reimmunization with a complete series) is not generally recommended.</p> <p>If serology was inadvertently done and found to be antiHBs negative these individuals generally do not qualify for additional doses of provincially funded vaccine, however, may be considered on a case-by-case basis in consultation with MOH.</p>
<ul style="list-style-type: none"> <li>Individuals who use illicit drugs and associated drug-using paraphernalia resulting in blood exposure</li> </ul>	Pre-immunization serology (anti-HBs, HBsAg and anti-HBc) is recommended	Serology should be done 1 – 6 months following the primary series of hepatitis B vaccine	<p>If the individual is negative for antibody after the first series, a second hepatitis B vaccine series should be administered, with repeat serology testing one month later.</p> <p>Once a positive antibody result is documented no further serology is recommended.</p>
<ul style="list-style-type: none"> <li><u>Non-immune adults</u> who have immigrated to Canada from endemic areas</li> </ul>	Pre-immunization serology (anti-HBs, HBsAg and anti-HBc) is recommended	Post-immunization serology is not recommended	<p>Reimmunization (i.e. booster dose or reimmunization with a complete series) is not generally recommended.</p> <p>If serology was inadvertently done and found to be antiHBs negative these individuals do not qualify for additional doses of provincially funded vaccine.</p>

<ul style="list-style-type: none"> <li>• <u>Hemophiliacs</u> and others receiving repeated infusions of blood or blood products</li> </ul>	Pre-immunization serology is not routinely recommended	Post-immunization serology is not routinely recommended	Reimmunization (i.e. booster dose or reimmunization with a complete series) is not generally recommended. If serology was inadvertently done and found to be antiHBs negative these individuals do not qualify for additional doses of provincially funded vaccine.
<ul style="list-style-type: none"> <li>• Individuals with Inflammatory Bowel disease (IBD) who will be on long term immunosuppressive medications</li> </ul>	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. If serology was inadvertently done and found to be antiHBs negative these individuals do not qualify for additional doses of provincially funded vaccine.
<ul style="list-style-type: none"> <li>• <u>Children younger than seven years</u> of age whose families have <i>immigrated</i> to Canada from an endemic area</li> </ul>	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. If serology was inadvertently done and found to be antiHBs negative these individuals do not qualify for additional doses of provincially funded vaccine.
<ul style="list-style-type: none"> <li>• <u>Populations</u> or communities in which hepatitis B is highly endemic</li> </ul>	Pre-immunization serology is not routinely recommended	Post-immunization serology is not recommended	Reimmunization (i.e. booster dose or reimmunization with a complete series) is not generally recommended. If serology was inadvertently done and found to be antiHBs negative these individuals do not qualify for additional doses of provincially funded vaccine.
<ul style="list-style-type: none"> <li>• Children and workers in <u>child care settings</u> in which there is a hepatitis B infected child or worker</li> <li>• Residents and staff of institutions or <u>group homes for the developmentally challenged</u>.</li> <li>• <u>Inmates</u> in provincial correctional facilities</li> </ul>	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. If serology was inadvertently done and found to be antiHBs negative these individuals do not qualify for additional doses of provincially funded vaccine.
<ul style="list-style-type: none"> <li>• Students in Grade 6</li> <li>• Students in Grades 7 through 12.</li> <li>• Individuals born in 1981 or later</li> </ul>	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. <sup>11,12</sup> If serology was inadvertently done and found to be antiHBs negative these individuals do not qualify for additional doses of provincially funded vaccine.
<ul style="list-style-type: none"> <li>• Percutaneous (needle stick) or mucosal exposure (blood and body fluid exposures)</li> </ul>	Refer to: <a href="#">Alberta Guidelines for Post-Exposure Management and Prophylaxis</a> ; for specific serology recommendations and interpretation.		



<ul style="list-style-type: none"> <li>Susceptible individuals of <u>sexual assault</u></li> </ul>	Refer to: <a href="#">Alberta Guidelines for Post-Exposure Management and Prophylaxis</a> : for specific serology recommendations and interpretation.
<b>Any individual who fails to respond to the second series of vaccine are unlikely to benefit from further doses. Therefore, if protective levels are not achieved, the individual should be considered a non-responder and susceptible.</b>	
SEROLOGY INTERPRETATION	
Serology Result	Interpretation
<ul style="list-style-type: none"> <li>anti-HBs <u>positive</u>**</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 style="list-style-type: none"> <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 style="list-style-type: none"> <li>anti-HBs negative</li> <li>HBsAg negative</li> <li>anti-HBc negative</li> </ul>	Susceptible. Proceed with immunization as per eligibility criteria.
<ul style="list-style-type: none"> <li>anti-HBs negative</li> <li>HBsAg <u>positive</u></li> <li>anti-HBc negative</li> </ul>	Refer to: <a href="#">Alberta Public Health Hepatitis B Notifiable Disease Guidelines</a> for interpretation and follow-up.
<ul style="list-style-type: none"> <li>anti-HBs negative</li> <li>HBsAg negative</li> <li>anti-HBc <u>positive</u></li> </ul>	Refer to: <a href="#">Alberta Public Health Hepatitis B Notifiable Disease Guidelines</a> (Table 4B) for interpretation and follow-up.
<b>**Anti-HBs positive is greater than or equal to 10 IU/L; negative is less than 10 IU/L</b>	

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14. National Advisory Committee on Immunization. (2018). *Canadian immunization guide (Evergreen Edition)*. Ottawa, ON: Public Health Agency of Canada. <https://www.canada.ca/en/public-health/services/canadian-immunization-guide.html>