COVID-19 Vaccines

mRNA Moderna Spikevax KP.2

mRNA Pfizer Comirnaty KP.2

October 4, 2023

Reminder:

This videoconference/webinar will be recorded.

Land Acknowledgement

The FNIHB CDC and Nursing Education Teams respectfully acknowledge we are situated on Treaty 6, 7, & 8 territories, the traditional lands of First Nations and Métis people.

We are thankful to play, work, and live along side First Nations and Métis people.

The FNIHB Alberta Region CDC Team has created this training by using Alberta Health and Alberta Health Services documents and information.

Today's Objective

To provide clinical information related to the COVID-19 vaccines available for administration this fall.

Most of us are very familiar with the COVID-19 virus:

- COVID-19 is transmitted though tiny respiratory droplets or aerosols produced by people who have the virus.
- The virus spreads most commonly by breathing in air that contains infected droplets from people coughing, sneezing, talking, laughing, and singing, or when the infected droplets come into direct contact with another person's nose, mouth or eyes.
- The virus may also spread by touching objects or surfaces the virus has landed on and then touching your eyes, nose or mouth with unwashed hands.
- People who have COVID-19 can spread it to others before they start to feel sick.

Summary of COVID-19 in Alberta

Last Year: 2023 – 2024 Season

- 6,080 hospitalizations (378 ICU admissions)
- 751 deaths

So far this year: 2024 – 2025 Season

- 408 hospitalizations (24 ICU admissions)
- 23 deaths

(The seasons typically go from the last week of August of one year, until the third week of August the following year)

COVID-19 Summary for 2023-2024 in Alberta First Nations

- **49** individuals hospitalized due to COVID-19
- **<5** individuals died from COVID-19
- **5,394** individuals received the COVID-19 vaccine

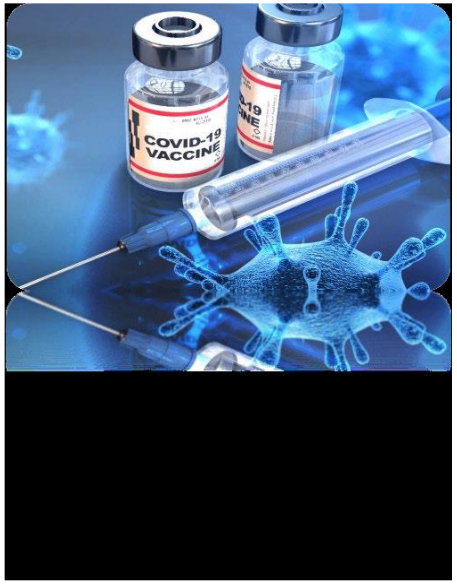
Statistics from AB FNIHB CDC

Before we start:
Reminder about old COVID-19 vaccines

- Currently, there should not be any old COVID-19 vaccine in your vaccine fridge. Old COVID-19 vaccine should have been removed as inventory in AVI and then discarded.
- Please reach out to Melissa Evans for direction if you have COVID-19 vaccine, other than the new COVID-19 KP.2 vaccine, in your vaccine fridge.

COVID-19 Vaccines Available in Alberta

- Only mRNA vaccine is available this fall.
  - Moderna (Spikevax) KP.2 Frozen Vaccine
  - Pfizer (Comirnaty) KP.2 Ultra Frozen Vaccine



COVID-19 Vaccine Program Dates

Program start dates for COVID-19 immunization mirror the influenza immunization program schedule:

- **October 1, 2024**
  - Long term care and congregate care sites
  - Outreach (home care clients)
  - Opportunistic immunizations (health care workers, previously scheduled immunization appointments, individuals visiting the health centre for other reasons)
- **October 15, 2024**
  - Advertised immunization clinics can start

ISC INDIGENOUS SERVICES CANADA

AHS Vaccine Biological Page

New biological pages were posted on the AHS COVID-19 Immunization Information webpage on October 3, 2024.

- COVID-19 Vaccine – **mRNA Pfizer-BioNTech Comirnaty KP.2** – Ultra frozen Vaccine
  - 12 years of age and older
  - Dark grey cap & dark grey label border
- COVID-19 Vaccine – **mRNA Moderna Spikevax KP.2** - Frozen Vaccine
  - 6 months of age and older
  - Royal blue cap & coral blue label

Reminder: For complete and current information, always use the biological pages posted on the AHS website.

mRNA COVID-19 Vaccine Review

- The COVID-19 vaccine protects against COVID-19, which is the disease caused by SARS-CoV-2 coronavirus.
- The Moderna and Pfizer COVID-19 vaccines use the messenger RNA (mRNA) manufacturing platform.
- mRNA (messenger ribonucleic acid) vaccines contain the genetic instructions for making the COVID-19 spike protein. This protein is found on the surface of the virus that causes COVID-19.
- When a person is given the vaccine, their cells will read the genetic instructions like a recipe and produce the spike protein.
- After the protein piece is made, the cell breaks down the instructions and gets rid of them.
- The cell then displays the protein piece on its surface. Our immune system recognizes that the protein doesn’t belong there and begins building an immune response and making antibodies.
- mRNA vaccines do not affect, interact with or alter your DNA in any way.

COVID-19 Vaccine – mRNA Moderna Spikevax KP.2 - Frozen Vaccine 6 months of age and older

Alberta Health Services
Communicable Disease Control

BIOLOGICAL PAGE

Section 7	Biological Product Information	**Standard # 07.226**	
Created and approved by	Provincial Immunization Program Standards and Quality		
Approval date	October 3, 2024	**Revised**	

COVID-19 Vaccine – mRNA Moderna Spikevax KP.2 – Frozen Vaccine

Royal blue cap & coral blue label

	COVID-19 Vaccine – mRNA Moderna Spikevax KP.2 – Frozen Vaccine		Royal blue cap & coral blue label
Manufacturer	Moderna		
Classification	mRNA vaccine		
Indications for Provincially Funded Vaccine	Individuals 6 months of age and older (see scheduling section for specifics).		

Individuals at an increased risk of transmission or severe COVID-19 infection	While all individuals 6 months of age and older are eligible for COVID-19 vaccine, immunization is strongly recommended for the following individuals who may be at an increased risk of COVID-19 infection or severe COVID-19 disease:
	• All adults 65 years of age and older
	• Individuals 6 months of age and older who are:
	  ○ Residents of continuing care homes and senior supportive living accommodations
	  ○ Have certain moderate to severe immunocompromising conditions
	  ○ Pregnant
	  ○ First Nations, Métis, and Inuit individuals, no matter where they live
	  ○ Members of racialized and other equity-deserving communities
	  ○ Individuals who provide essential community services, including healthcare workers.		

Dose	6 months to 11 years of age: • 0.25 mL (25 mcg) 12 years of age and older: • 0.5 mL (50mcg)		
Route	IM in the vastus lateralis or deltoid muscle		

	COVID-19 Vaccine – mRNA Moderna Spikevax KP.2 – Frozen Vaccine		Royal blue cap & coral blue label
Schedule for healthy immunocompetent individuals ***(See below Schedule for individuals with certain immunocompromising conditions)***	Individuals 6 months to 4 years of age: **Previously unimmunized:** • Dose 1: day 0 • Dose 2: at least 8 weeks after dose 1. **Previously immunized with one dose of a non-KP.2 COVID-19 vaccine series, regardless of product type:** • 1 dose, at least 8 weeks from previous dose. **Previously received two or more non-KP.2 COVID-19 vaccine doses, regardless of product type:** • 1 dose, at least 3 months from previous dose. **Note:** Individuals 6 months to 4 years of age should complete a two-dose series of COVID-19 vaccine regardless of the product that was administered for the first dose. The series should not be restarted. Individuals 5 years of age and older: • One dose, at least three months from previous non-KP.2 COVID-19 vaccine dose, regardless of the number of doses received in the past.		

	COVID-19 Vaccine – mRNA Moderna Spikevax KP.2 – Frozen Vaccine		Royal blue cap & coral blue label
Schedule for individuals with certain moderate to severe immunocompromising conditions	Individuals 6 months and older: **Unimmunized/Previously received fewer than 3 doses of non-KP.2 COVID-19 vaccine:** • Immunocompromised individuals should follow the schedule below and receive the appropriate number of doses of Moderna KP.2 COVID-19 vaccine to complete a three-dose COVID-19 vaccine series. Regardless of whether they have received one or two non-KP.2 COVID-19 vaccine doses, the previous dose(s) should be counted, and the series should not be restarted. o Dose 1: day 0 o Dose 2: at least 28 days after dose 1 o Dose 3: 8 weeks after dose 2; however, a minimum interval of 4 weeks may be considered. **Previously received 3 or more doses of non-KP.2 COVID-19 vaccine:** • 1 dose, at least 3 months from previous COVID-19 vaccine dose, regardless of the number of doses received in the past. **Note:** • Specific immunocompromising conditions that make an individual eligible for a three-dose COVID-19 vaccine series: o Solid organ transplant recipients – pre-transplant and post-transplant. o Hematopoietic stem cell transplants recipients – pre-transplant and post-transplant while in immunosuppressed state and individuals receiving Chimeric Antigen Receptor (CAR) T-Cell therapy. See: ▪ Standard for Immunization of Transplant Candidates and Recipients ▪ Child HSCT ▪ Adult HSCT		

	COVID-19 Vaccine – mRNA Moderna Spikevax KP.2 – Frozen Vaccine		Royal blue cap & coral blue label
Schedule for individuals with certain moderate to severe immunocompromising conditions	○ Individuals with malignant hematologic disorders and non-hematologic malignant solid tumors prior to receiving or while receiving active treatment which includes chemotherapy, targeted therapies, and immunotherapy or having received previous COVID-19 vaccines while on active treatment (does not include individuals receiving solely hormonal therapy, radiation therapy or a surgical intervention). ○ Individuals with chronic kidney disease on peritoneal dialysis or hemodialysis. ○ Individuals on: ▪ long term high-dose systemic steroid treatment (prednisone equivalent of ≥ 2 mg/kg/day or 20 mg/day if weight > 10 kg, for ≥ 14 days), or ▪ alkylating agents, or ▪ anti-B-cell therapies – including anti-CD19, anti-CD20, anti-CD22 and anti-CD52 monoclonal antibodies (such as rituximab, ocrelizumab, and ofatumumab), or ▪ antimetabolites (e.g., methotrexate, azathioprine, mycophenolate), or ▪ tumor-necrosis factor (TNF) inhibitors (e.g., adalimumab, certolizumab, etanercept, golimumab, infliximab), or ▪ other agents that are significantly immunosuppressive at clinicians' discretion. • HIV-infected individuals without viral suppression or those with acquired immunodeficiency syndrome (AIDS). • Individuals with moderate to severe primary immunodeficiency (e.g., DiGeorge syndrome, Wiskott-Aldrich syndrome).		

	COVID-19 Vaccine – mRNA Moderna Spikevax KP.2 – Frozen Vaccine		Royal blue cap & coral blue label
Schedule for individuals with certain moderate to severe immunocompromising conditions	**Note:** • Documentation of immunocompromising conditions is not required. Individuals who identify themselves as meeting at least one of the criteria above should be offered a COVID-19 vaccine series. • Immunization of immunocompromised individuals should occur at a time when the individual is most likely to mount an immune response. Physician consultation is recommended regarding the timing of immunization (initiation and interval) based on the individual's treatment and unique circumstances.		

	COVID-19 Vaccine – mRNA Moderna Spikevax KP.2 – Frozen Vaccine		Royal blue cap & coral blue label
Interval between previous COVID-19 infection and COVID-19 immunization	For individuals with a history of COVID-19 infection the following guidance is provided on suggested intervals between infection and COVID-19 immunization. **Note:** • These suggested intervals are based on immunological principles and expert opinion, and may change as evidence on COVID-19, variants of concern (VOCs), and COVID-19 vaccines emerge. When considering whether to administer vaccine doses following the suggested intervals outlined in this table, biological and social risk factors for exposure (e.g., local epidemiology, circulation of VOCs, living settings) and risk of severe disease should also be considered. These intervals are a guide and clinical discretion is advised. Individuals can be immunized at less than the recommended intervals from infection upon request. • For individuals who have not had any previous doses, they may receive their first dose after acute symptoms of COVID-19 have resolved and they are no longer infectious, or they may follow these suggested intervals (with the exception of those with MIS-C who should wait at least 90 days).		

	COVID-19 Vaccine – mRNA Moderna Spikevax KP.2 – Frozen Vaccine		 Royal blue cap & coral blue label
Interval between previous COVID-19 infection and COVID-19 immunization	Infection prior to initiation or completion of a COVID-19 immunization series.	Individuals **without** certain immunocompromising conditions AND no history of multisystem inflammatory syndrome in children (MIS-C).	8 weeks after a positive test.
		Individuals **with** certain immunocompromising conditions (as listed above) AND no history of MIS-C.	4 to 8 weeks after a positive test.
		History of MIS-C (regardless of immunocompromised status).	Receive the vaccine when clinical recovery has been achieved or at least 90 days since the onset of MIS-C, whichever is longer.
	Infection after COVID-19 vaccine series.	All individuals.	3 months after a positive test.

	COVID-19 Vaccine – mRNA Moderna Spikevax KP.2 – Frozen Vaccine		Royal blue cap & coral blue label

Contraindications/ Precautions	**Contraindications:**
	• Known severe hypersensitivity to any component of the vaccine.
	• Two non-medicinal ingredients in the vaccine that have been associated with allergic reactions in other products:
	  ○ Polyethylene glycol (PEG). The potential allergen may be found in bowel preparation products for colonoscopy, laxatives, cough syrup, cosmetics, contact lens care solutions, skin products and some food and drinks.
	  ○ Tromethamine (trometamol or Tris) – component found in contrast media, oral and parenteral medications.
	• Anaphylaxis to a previous dose of COVID-19 mRNA vaccine may not be an absolute contraindication. See COVID-19 Immunization for Individuals with Allergies and Other Health Conditions for recommendations.
	
	Precautions:
	• The safety and effectiveness of Spikevax KP.2 for individuals 6 months of age and older is inferred from several studies of a primary series and booster dose of Spikevax Bivalent (Original/Omicron BA.1) in individuals 6 months to 5 years of age, a booster dose study of Spikevax Bivalent (Original/Omicron BA.1) in individuals 18 years of age and older, a booster dose study of Spikevax XBB.1.5 in individuals 18 years of age and older, as well as data from studies which evaluated the primary series and booster vaccination with Spikevax (Original).
	• There are no known serious warnings or precautions associated with this product.
	• Individuals who have had a serious allergic reaction to another vaccine, drug or food should talk to their health care provider before receiving the vaccine.
	• Individuals receiving anticoagulant therapy or those with a bleeding disorder that would contraindicate intramuscular injection should not be given the vaccine unless the potential benefit clearly outweighs the risk of administration.
	• Administration should be postponed in individuals suffering from acute severe febrile illness.		

	COVID-19 Vaccine – mRNA Moderna Spikevax KP.2 – Frozen Vaccine		Royal blue cap & coral blue label

Myocarditis/Pericarditis	• Very rare cases of myocarditis and/or pericarditis following immunization with Moderna Spikevax vaccines have been reported during post-authorization use.
	  ○ Compared to the original monovalent primary series, the risk of myocarditis and/or pericarditis is now expected to be lower due to the use of a 1-dose schedule in most individuals.
	  ○ Post-market safety surveillance data on previous formulations of mRNA COVID-19 vaccine indicate that the risk of myocarditis following a booster dose is lower compared to that following the second dose in the primary series, and current data do not show a product-specific difference in the risks of myocarditis and/or pericarditis after a booster dose of an mRNA COVID-19 vaccine.
	• Anyone receiving an mRNA COVID-19 vaccine should be informed of the risk of myocarditis and pericarditis and advised to seek medical attention if they develop related symptoms including shortness of breath, chest pain, or the feeling of a rapid or abnormal heart rhythm.		

	COVID-19 Vaccine – mRNA Moderna Spikevax KP.2 – Frozen Vaccine		Royal blue cap & coral blue label

Myocarditis/Pericarditis	• Healthcare professionals are advised to consider the possibility of myocarditis and/or pericarditis in their differential diagnosis if individuals present with chest pain, shortness of breath, palpitations or other signs and symptoms of myocarditis and/or pericarditis following immunization with an mRNA COVID-19 vaccine.
	• Generally, deferral of COVID-19 immunization is not required for those with a prior history of myocarditis or pericarditis that is unrelated to COVID-19 mRNA vaccines.
	  ○ If these individuals have questions or concerns about their prior history of myocarditis or pericarditis and immunization, it is recommended that individuals consult with their clinician. However, consultation with a clinician is not required to receive COVID-19 vaccines.
	• Individuals with a history compatible with pericarditis within 6 weeks of receiving a dose of an mRNA COVID-19 vaccine, who either had no cardiac workup or who had normal cardiac investigations, can be re-immunized when they are symptom free and at least 90 days have passed since previous immunization.
	  ○ If another dose of vaccine is offered, it should be a Pfizer-BioNTech KP.2 COVID-19 vaccine, if 12 years of age and over. This is due to the lower reported rate of myocarditis and/or pericarditis following the Pfizer-BioNTech original (30mcg) vaccine compared to the Moderna Spikevax original (100mcg) vaccine among individuals 12 years of age and older.		

	COVID-19 Vaccine – mRNA Moderna Spikevax KP.2 – Frozen Vaccine		Royal blue cap & coral blue label
Myocarditis/Pericarditis	• In most circumstances, further doses of mRNA COVID-19 vaccines should be deferred among people who experienced myocarditis (with or without pericarditis) within 6 weeks of receiving a previous dose of an mRNA COVID-19 vaccine. ○ However, further doses may be offered if individuals with confirmed myocarditis or pericarditis with abnormal cardiac investigation choose to receive another dose of vaccine after discussing the risks and benefits with their clinician. ○ Informed consent should discuss the unknown risk of recurrence of myocarditis and/or pericarditis following additional doses of COVID-19 vaccine in individuals with a history of confirmed myocarditis and/or pericarditis after a previous dose of mRNA COVID-19 vaccine.		

	COVID-19 Vaccine – mRNA Moderna Spikevax KP.2 – Frozen Vaccine		Royal blue cap & coral blue label
Possible Reactions	**Common:** • Pain, erythema, swelling/ induration at the injection site • Fatigue • Myalgia • Headache • Arthralgia • Axillary swelling or tenderness • Chills • Nausea/vomiting • Fever • Hypoaesthesia (decreased sense of touch or sensation) • Paraesthesia (tingling, itching or pricking sensation) • Dizziness • Irritability in children 5 years of age and younger • Crying in children 5 years of age and younger • Sleepiness in children 5 years of age and younger • Loss of appetite in children 5 years of age and younger • Otitis media in children 5 years of age and younger.		

	COVID-19 Vaccine – mRNA Moderna Spikevax KP.2 – Frozen Vaccine		Royal blue cap & coral blue label
Possible Reactions	**Rare:** • Allergic reaction • Anaphylaxis • Erythema multiforme • Facial paralysis/Bell's palsy. Refer to the product monograph for more detailed information.		

	COVID-19 Vaccine – mRNA Moderna Spikevax KP.2 – Frozen Vaccine		Royal blue cap & coral blue label

Pregnancy	• COVID-19 vaccine should be offered to pregnant individuals regardless of trimester of pregnancy because of the increased risk that infection poses in pregnancy. An mRNA vaccine is preferred due to reassuring published data on the safety of these vaccines in pregnancy.
	• The safety and efficacy of Moderna Spikevax KP.2 in pregnant women have not yet been established.
	• However, data available on the original mRNA vaccines administered in pregnancy did not detect safety signals from post-marketing surveillance. COVID-19 mRNA vaccines can be offered to pregnant individuals as they are more at risk for severe illness from COVID-19 compared with non-pregnant individuals.
	  ○ Evidence to date shows that COVID-19 immunization during pregnancy is safe and does not increase risk for miscarriage, stillbirth, low birth weight, preterm birth, NICU admission, or other adverse pregnancy/birth outcomes.
	  ○ It is recommended that individuals consult their primary health care provider or obstetrician for any vaccine related questions or concerns.
	  ○ However, consultation with a primary health care provider or obstetrician is not required to receive COVID-19 vaccine.
	
	Additional resources:
	Society of Obstetricians and Gynecologists of Canada Statement on COVID-19 Immunization in Pregnancy		

	COVID-19 Vaccine – mRNA Moderna Spikevax KP.2 – Frozen Vaccine		Royal blue cap & coral blue label

Lactation	• It is unknown whether this vaccine is excreted in human milk. A risk to the newborns/infants cannot be excluded.
	• Recent reports have shown that breastfeeding/chestfeeding people who have received mRNA COVID-19 vaccines have antibodies in their breastmilk, which could help protect their babies. More data are needed to determine the level of protection these antibodies might provide to the baby.
	• COVID-19 vaccine is recommended for individuals who are breastfeeding.
	  ○ It is recommended that individuals consult their primary health care provider or medical specialist for any vaccine related questions or concerns.
	  ○ However, consultation with a primary health care provider or medical specialist is not required to receive COVID-19 vaccine.		

	COVID-19 Vaccine – mRNA Moderna Spikevax KP.2 – Frozen Vaccine		Royal blue cap & coral blue label
Composition	• Each 0.5 mL dose of SPIKEVAX contains 50 micrograms of mRNA encoding SARS-CoV-2 spike protein. The mRNA encoding spike protein is derived from the Omicron variant KP.2. (25 mcg for 0.25 mL dose). **Non-medicinal ingredients:** • Acetic acid • Cholesterol • DSPC (1,2-distearoyl-sn-glycero-3-phosphocholine) • SM-102(Heptadecan-9-yl 8-((2-hydroxyethyl) (6-oxo-6-(undecyloxy) hexyl) amino) octanoate) • PEG2000-DMG (1,2-dimyristoyl-rac-glycero-3-methoxypolyethyleneglycol-2000) • Sodium acetate trihydrate • Sucrose • Trometamol • Trometamol hydrochloride • Water for injection. Does not contain any preservatives, antibiotics, adjuvants or human or animal derived materials.		
Blood/Blood Products	Does not contain blood/blood products.		
Bovine/Porcine Products	Does not contain bovine/porcine products.		
Latex	Does not contain latex.		

	COVID-19 Vaccine – mRNA Moderna Spikevax KP.2 – Frozen Vaccine		Royal blue cap & coral blue label

Administration with Other Products	• With the exception of the Respiratory Syncytial Virus (RSV) vaccine, COVID-19 vaccines may be co-administered with, or at any time before or after other vaccines (including, live, inactivated, adjuvanted, or unadjuvanted vaccines), tuberculin skin tests or IGRA (QFT) tests to individuals 6 months of age and older.
	  ○ Limited studies have been conducted on concurrent administration of the RSV vaccine with other vaccines. Until more evidence is available co-administration is not recommended. RSV vaccine should be given with **two-week spacing** before or after influenza and/or COVID-19 vaccines.
	  ○ There is a theoretical risk that COVID-19 vaccines may temporarily affect cell-mediated immunity, resulting in false-negative tuberculin skin testing or IGRA (QFT) test results.
	  ○ In the absence of data and acknowledging the importance of both timely tuberculosis testing and immunization, immunization with COVID-19 vaccines can take place at any time before, after or at the same visit as the TST or IGRA test.
	  ○ However, repeat tuberculin skin testing or IGRA (at least 4 weeks post COVID-19 immunization) of individuals with negative TST or IGRA results for whom there is high suspicion of latent tuberculosis may be considered to avoid missing persons with TB infection.
	• Deferral of COVID-19 immunization is not recommended for individuals who have received anti-SARS-CoV-2 monoclonal antibodies or convalescent plasma provided for treatment or prophylaxis of COVID-19.
	Note:
	• Timing of administration and potential interference between COVID-19 vaccine and monoclonal products not used for treatment or prophylaxis of COVID-19 infection are currently unknown and the primary health care provider or medical specialist should be consulted on a case-by-case basis.
	• mRNA COVID-19 vaccines may be given at any time before or after an immunoglobulin preparation (including RhIg) or blood product has been administered. There is no recommended minimum interval between these products and COVID-19 vaccine.		

	COVID-19 Vaccine – mRNA Moderna Spikevax KP.2 – Frozen Vaccine	 Royal blue cap & coral blue label
Appearance	• White to off-white dispersion. • May contain white or translucent product-related particulates.	

Storage	• Store in freezer between -50˚C to -15˚C.
	• Protect from light.
	• Do not refreeze after thawing.
	• Thawed, unpunctured vials:
	  ○ Thawed, unpunctured vials can be stored at +2˚C to +8˚C for up to 50 days.
	  ○ Thawed, unpunctured vials can be stored at +8˚C to +25˚C for up to 12 hours.
	• Thawed, punctured vials:
	  ○ Thawed, punctured vials (first dose is withdrawn) can be stored at +2°C to +8°C for 24 hours. Discard after 24 hours.
	  ○ Thawed, punctured vials (first dose is withdrawn) can be stored at +8°C to +25°C for 12 hours. Discard after 12 hours.	

Packaging	• 2.5 mL vial (5 x 0.5 mL doses or 10 x 0.25 mL doses) • 10 vials per carton	

	COVID-19 Vaccine – mRNA Moderna Spikevax KP.2 – Frozen Vaccine		Royal blue cap & coral blue label

Preparation	Multidose vials are supplied as a frozen dispersion, does not contain preservative. **Thaw vaccine before use**:
	• Vaccine can be thawed in two ways:
	  ○ From the freezer to room temperature (between +15˚C to +25˚C), thaw for 45 minutes from frozen state.
	  ○ From the freezer to a vaccine fridge (+2˚C to +8˚C), thaw for 6hours from the frozen state.
	• After thawing, let vial stand at room temperature for 15 minutes before administering.
	• Must not be reconstituted, mixed with other medicinal product, or diluted.
	• No dilution is required.
	• Swirl gently after thawing and before each withdrawal.
	• Do **not** shake vial.		

Vaccine Code	COVMODmRNAKP		
Antigen Code	COVID-19		
Licensed for	Individuals 6 months of age and older.		
Off-license use	• An interval of less than 6 months from previous dose for individuals who previously received a COVID-19 vaccine dose series. • Three-dose series for individuals who are moderately to severely immunocompromised.		

	COVID-19 Vaccine – mRNA Moderna Spikevax KP.2 – Frozen Vaccine		Royal blue cap & coral blue label
Notes	• 2024 September 17: Licensed for use in Canada. • 2024 October: Implemented in Alberta.		
Related Resources	• Alberta Health Services Website (2024). COVID-19 mRNA Vaccine Information • COVID-19 mRNA Vaccine Information Sheet (105240)		

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Alberta Vaccine Storage and Handling for COVID-19 Vaccine

Revised: September 2024

This policy is evergreen and will be updated as new evidence becomes available.

Objectives:

- Protect vaccine safety and efficacy and ensure a potent and safe vaccine is administered; and
- Minimize and reduce the cost of vaccine wastage due to cold chain excursions.

See the Alberta Vaccine Storage and Handling for Provincially Funded Vaccines for:

- Accountabilities, roles and responsibilities for staff and immunizers in maintaining vaccine viability for vaccines; and
- Cold chain (storage, transport, and handling) requirements for staff and immunizers.

Alberta Vaccine Storage and Handling Policy for COVID-19 Vaccine

September 2024

Moderna Spikevax KP.2 (Royal Blue Cap, Coral Blue Label)

Thawing/thawed

- If transportation occurs in the thawing/thawed state:
  - The total transportation time should be no longer than 36 hours at +2°C to +8°C.
  - The transported vaccine must be labelled "transported thawing/thawed" and the total time in transportation must be tracked.
- The product should be appropriately packed in a validated container in order to:
  - Prevent contact with ice packs,
  - Prevent movement/vibration of the vials, and
  - Keep the vaccine vials upright.
- As much care as possible should be taken to minimize extra movement in the thawed state
  - The container should be secured in the vehicle so that it does not move around.
- The time in transit in the thawing/thawed state at +2°C to +8°C should be considered part of the 50 days allowed for storage at refrigerator temperatures.

Alberta Vaccine Storage and Handling Policy for COVID-19 Vaccine

September 2024

Moderna Spikevax KP.2 (Royal Blue Cap, Coral Blue Label)

In addition, for frozen and thawing/thawed vaccine:

- Label the container as "Fragile: Handle with Care, Do Not Drop" and "Temperature Sensitive".
- The temperature must be maintained and recorded during transport.
- Record the transportation locations, dates and times, including the duration of time in transit.
- Do not refreeze thawed product
- Do not transport the vaccine at room temperature.
- Transportation of Moderna Spikevax KP.2 punctured vials is permitted.
    - However, transport with caution as there is a risk of microbial contamination during transport of punctured vials.

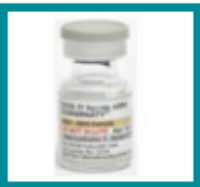
COVID-19 Vaccine – mRNA Pfizer-BioNTech Comirnaty KP.2 – Ultra frozen Vaccine 12 years of age and older

Alberta Health Services
Communicable Disease Control

BIOLOGICAL PAGE

Section 7	Biological Product Information	**Standard # 07.227**	
Created and approved by	Provincial Immunization Program Standards and Quality		
Approval date	October 3, 2024	**Revised**	

COVID-19 Vaccine – mRNA Pfizer Comirnaty KP.2 Ultra frozen Vaccine



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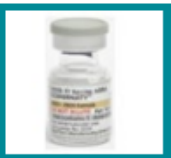
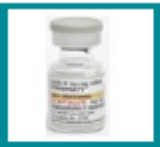
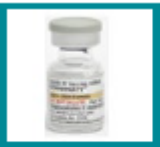
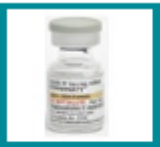
	COVID-19 Vaccine – mRNA Pfizer Comirnaty KP.2 Ultra frozen Vaccine	 Dark gray cap & dark gray label border
Manufacturer	Pfizer-BioNTech	
Classification	mRNA vaccine	
Indications for Provincially Funded Vaccine	• Individuals 12 years of age and older (see scheduling section for specifics)	
Individuals at an increased risk of transmission or severe COVID-19 infection	While all individuals 6 months of age and older are eligible for COVID-19 vaccine, immunization is strongly recommended for the following individuals who may be at an increased risk of COVID-19 infection or severe COVID-19 disease: • All adults 65 years of age and older • Individuals 6 months of age and older who are: o Residents of continuing care homes and senior supportive living accommodations o Have certain moderate to severe immunocompromising conditions o Pregnant o First Nations, Métis, and Inuit individuals, no matter where they live o Members of racialized and other equity-deserving communities o Individuals who provide essential community services, including healthcare workers.	
Dose	0.3 mL (30mcg)	
Route	IM in the vastus lateralis or deltoid muscle	

This section the same as Moderna

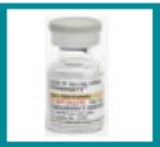
	COVID-19 Vaccine – mRNA Pfizer Comirnaty KP.2 Ultra frozen Vaccine	 Dark gray cap & dark gray label border
Schedule for healthy immunocompetent individuals (See below Schedule for individuals with certain immunocompromising conditions)	**Individuals 12 years of age and older:** • 1 dose, at least three months from previous non-KP.2 COVID-19 vaccine dose, regardless of the number of doses received in the past.	

	COVID-19 Vaccine – mRNA Pfizer Comirnaty KP.2 Ultra frozen Vaccine	 Dark gray cap & dark gray label border
Schedule for individuals with certain moderate to severe immunocompromising conditions	**Individuals 12 years of age and older:** **Unimmunized/previously received fewer than 3 doses of non-KP.2 COVID-19 vaccine:** • Immunocompromised individuals should follow the schedule below and receive the appropriate number of Pfizer KP.2 COVID-19 vaccine doses to complete a three-dose COVID-19 vaccine series. Regardless of whether they have received one or two non-KP.2 COVID-19 vaccine doses, the previous dose(s) should be counted, and the series should not be restarted. ○ Dose 1: day 0 ○ Dose 2: 28 days after dose 1 ○ Dose 3: 8 weeks after dose 2; however, a minimum interval of 4 weeks may be considered.	

This section the same as Moderna, except the individual needs to be 12 years of age to receive Pfizer.

	COVID-19 Vaccine – mRNA Pfizer Comirnaty KP.2 Ultra frozen Vaccine	 Dark gray cap & dark gray label border
Schedule for individuals with certain moderate to severe immunocompromising conditions	**Previously received 3 or more doses of non-KP.2 COVID-19 vaccine:** • 1 dose, at least 3 months from previous COVID-19 vaccine dose, regardless of the number of doses received in the past. • Specific immunocompromising conditions that make an individual eligible for a COVID-19 vaccine series: ○ Solid organ transplant recipients – pre-transplant and post-transplant ○ Hematopoietic stem cell transplants recipients – pre-transplant and post-transplant while in immunosuppressed state and individuals receiving Chimeric Antigen Receptor (CAR) T-Cell therapy. See: ▪ Standard for Immunization of Transplant Candidates and Recipients ▪ Child HSCT ▪ Adult HSCT. ○ Individuals with malignant hematologic disorders and non-hematologic malignant solid tumors prior to receiving or while receiving active treatment which includes chemotherapy, targeted therapies, and immunotherapy or having received previous COVID-19 vaccines while on active treatment (does not include individuals receiving solely hormonal therapy, radiation therapy or a surgical intervention). ○ Individuals with chronic kidney disease on peritoneal dialysis or hemodialysis. ○ Individuals on: ▪ long term high-dose systemic steroid treatment (prednisone equivalent of ≥ 2 mg/kg/day or 20 mg/day if weight > 10 kg, for ≥ 14 days), or ▪ alkylating agents, or ▪ anti-B-cell therapies – including anti-CD19, anti-CD20, anti-CD22 and anti-CD52 monoclonal antibodies (such as rituximab, ocrelizumab, and ofatumumab), or ▪ antimetabolites (e.g., methotrexate, azathioprine, mycophenolate), or ▪ tumor-necrosis factor (TNF) inhibitors (e.g., adalimumab, certolizumab, etanercept, golimumab, infliximab), or ▪ other agents that are significantly immunosuppressive at clinicians' discretion. ○ HIV-infected individuals without viral suppression or those with acquired immunodeficiency syndrome (AIDS). ○ Individuals with moderate to severe primary immunodeficiency (e.g., DiGeorge syndrome, Wiskott-Aldrich syndrome).	

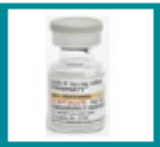
This section the same as Moderna, except the individual needs to be 12 years of age to receive Pfizer.

	COVID-19 Vaccine – mRNA Pfizer Comirnaty KP.2 Ultra frozen Vaccine	 Dark gray cap & dark gray label border
Schedule for individuals with certain moderate to severe immunocompromising conditions	Note: • Documentation of immunocompromising conditions is not required. Individuals who identify themselves as meeting at least one of the criteria above should be offered a COVID-19 vaccine series. • Immunization of immunocompromised individuals should occur at a time when the individual is most likely to mount an immune response. Physician consultation is recommended regarding the timing of immunization (initiation and interval) based on the individual's treatment and unique circumstances.	

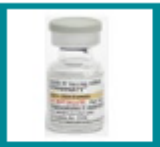
This section the same as Moderna, except the individual needs to be 12 years of age to receive Pfizer.

	COVID-19 Vaccine – mRNA Pfizer Comirnaty KP.2 Ultra frozen Vaccine	 Dark gray cap & dark gray label border
Interval between previous COVID-19 infection and COVID-19 immunization	• For individuals with a history of COVID-19 infection the following guidance is provided on suggested intervals between infection and COVID-19 immunization. **Note:** • These suggested intervals are based on immunological principles and expert opinion, and may change as evidence on COVID-19, variants of concern (VOCs), and COVID-19 vaccines emerge. When considering whether to administer vaccine doses following the suggested intervals outlined in this table, biological and social risk factors for exposure (e.g., local epidemiology, circulation of VOCs, living settings) and risk of severe disease should also be considered. These intervals are a guide and clinical discretion is advised. Individuals can be immunized at less than the recommended intervals from infection upon request. • For individuals who have not had any previous doses, they may receive their first dose after acute symptoms of COVID-19 have resolved and they are no longer infectious, or they may follow these suggested intervals (with the exception of those with MIS-C who should wait at least 90 days).	
Infection prior to initiation or completion of a COVID-19 immunization series.	Individuals **without** certain immunocompromising conditions AND no history of multisystem inflammatory syndrome in children (MIS-C).	8 weeks after a positive test.
	Individuals **with** certain immunocompromising conditions (as listed above) AND no history of MIS-C.	4 to 8 weeks after a positive test.
	History of MIS-C (regardless of immunocompromised status).	Receive the vaccine when clinical recovery has been achieved or at least 90 days since the onset of MIS-C, whichever is longer.
Infection after COVID-19 vaccine series.	All individuals.	3 months after a positive test.

This section the same as Moderna.

	COVID-19 Vaccine – mRNA Pfizer Comirnaty KP.2 Ultra frozen Vaccine	 Dark gray cap & dark gray label border

Contraindications/ Precautions	**Contraindications:**
	• Known severe hypersensitivity to any component of the vaccine.
	• Two non-medicinal ingredients in the vaccine that have been associated with allergic reactions in other products:
	  ○ Polyethylene glycol (PEG). The potential allergen may be found in bowel preparation products for colonoscopy, laxatives, cough syrup, cosmetics, contact lens care solutions, skin products and some food and drinks.
	  ○ Tromethamine (trometamol or Tris) – component found in contrast media, oral and parenteral medications.
	• Anaphylaxis to a previous dose of COVID-19 mRNA vaccine may not be an absolute contraindication. See COVID-19 Immunization for Individuals with Allergies and Other Health Conditions for recommendations.	

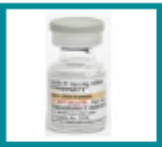
	COVID-19 Vaccine – mRNA Pfizer Comirnaty KP.2 Ultra frozen Vaccine	 Dark gray cap & dark gray label border
	Precautions: • The safety and effectiveness of Pfizer-BioNTech KP.2 is inferred from studies which evaluated the primary series and booster vaccination with Pfizer-BioNTech and supported by studies which evaluated a booster dose of Pfizer-BioNTech Original & Omicron BA.4/BA.5). ○ Safety data accrued with the COMIRNATY (Original) and COMIRNATY Original & Omicron BA.4/BA.5 formulations are relevant to the subsequent variant updated COMIRNATY vaccines because these vaccines are manufactured using the same process. • At the time of authorization, there are no known serious warnings or precautions associated with this product. • Individuals who have had a serious allergic reaction to another vaccine, drug or food should talk to their health care provider before receiving the vaccine. • Individuals receiving anticoagulant therapy or those with a bleeding disorder that would contraindicate intramuscular injection should not be given the vaccine unless the potential benefit clearly outweighs the risk of administration. • Administration should be postponed in individuals suffering from acute severe febrile illness.	

	COVID-19 Vaccine – mRNA Pfizer Comirnaty KP.2 Ultra frozen Vaccine	 Dark gray cap & dark gray label border

Myocarditis/Pericarditis	• Very rare cases of myocarditis and/or pericarditis following immunization with Pfizer-BioNTech vaccines have been reported during post-authorization use.
	  ○ Compared to the original monovalent primary series, the risk of myocarditis and/or pericarditis is now expected to be lower due to the use of a 1-dose schedule in most individuals.
	  ○ Post-market safety surveillance data on previous formulations of mRNA COVID-19 vaccine indicate that the risk of myocarditis following a booster dose is lower compared to that following the second dose in the primary series, and current data do not show a product-specific difference in the risks of myocarditis and/or pericarditis after a booster dose of an mRNA COVID-19 vaccine.
	• Anyone receiving an mRNA COVID-19 vaccine should be informed of the risk of myocarditis and pericarditis and advised to seek medical attention if they develop related symptoms including shortness of breath, chest pain, or the feeling of a rapid or abnormal heart rhythm.
	• Healthcare professionals are advised to consider the possibility of myocarditis and/or pericarditis in their differential diagnosis if individuals present with chest pain, shortness of breath, palpitations or other signs and symptoms of myocarditis and/or pericarditis following immunization with an mRNA COVID-19 vaccine.	

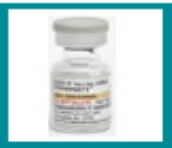
	COVID-19 Vaccine – mRNA Pfizer Comirnaty KP.2 Ultra frozen Vaccine	 Dark gray cap & dark gray label border
Myocarditis/Pericarditis	• Generally, deferral of COVID-19 immunization is not required for those with a prior history of myocarditis or pericarditis that is unrelated to COVID-19 mRNA vaccines. ○ If these individuals have questions or concerns about their prior history of myocarditis or pericarditis and immunization, it is recommended that individuals consult with their clinician. However, consultation with a clinician is not required to receive COVID-19 vaccines. • Individuals with a history compatible with pericarditis within 6 weeks of receiving a dose of an mRNA COVID-19 vaccine, who either had no cardiac workup or who had normal cardiac investigations, can be re-immunized when they are symptom free and at least 90 days have passed since previous immunization. ○ If another dose of vaccine is offered, it should be a Pfizer-BioNTech KP.2 COVID-19 vaccine, if 12 years of age and over. This is due to the lower reported rate of myocarditis and/or pericarditis following the Pfizer-BioNTech original (30 mcg) vaccine compared to the Moderna Spikevax original (100 mcg) vaccine among individuals 12 years of age and older.	
	• In most circumstances, further doses of mRNA COVID-19 vaccines should be deferred among people who experienced myocarditis (with or without pericarditis) within 6 weeks of receiving a previous dose of an mRNA COVID-19 vaccine. ○ However, further doses may be offered if individuals with confirmed myocarditis or pericarditis with abnormal cardiac investigation choose to receive another dose of vaccine after discussing the risks and benefits with their clinician. ○ Informed consent should discuss the unknown risk of recurrence of myocarditis and/or pericarditis following additional doses of COVID-19 vaccine in individuals with a history of confirmed myocarditis and/or pericarditis after a previous dose of mRNA COVID-19 vaccine.	

	COVID-19 Vaccine – mRNA Pfizer Comirnaty KP.2 Ultra frozen Vaccine	 Dark gray cap & dark gray label border
Possible Reactions	**Common:** • Pain, swelling/induration, erythema at the injection site • Fatigue • Headache • Myalgia • Arthralgia • Chills • Fever • Diarrhea • Nausea/vomiting. **Uncommon:** • Lymphadenopathy • Malaise • Asthenia • Decreased appetite • Hyperhidrosis • Lethargy • Night sweats • Hypoaesthesia (decreased sense of touch or sensation) • Paraesthesia (tingling, itching or pricking sensation). **Rare:** • Allergic reaction • Anaphylaxis • Erythema multiforme • Myocarditis/Pericarditis • Facial paralysis/Bell's palsy. Refer to the product monograph for more detailed information.	

	COVID-19 Vaccine – mRNA Pfizer Comirnaty KP.2 Ultra frozen Vaccine	 Dark gray cap & dark gray label border
Pregnancy	• COVID-19 vaccine should be offered to pregnant individuals regardless of trimester of pregnancy because of the increased risk that infection poses in pregnancy. An mRNA vaccine is preferred due to reassuring published data on the safety of these vaccines in pregnancy. • The safety and efficacy of Pfizer-BioNTech KP.2 vaccine in pregnant women has not yet been established. • However, data available on the original mRNA vaccines administered in pregnancy did not detect safety signals from post-marketing surveillance. COVID-19 mRNA vaccines can be offered to pregnant individuals as they are more at risk for severe illness from COVID-19 compared with non-pregnant individuals. ○ Evidence to date shows that COVID-19 immunization during pregnancy is safe and does not increase risk for miscarriage, stillbirth, low birth weight, preterm birth, NICU admission, or other adverse pregnancy/birth outcomes. ○ It is recommended that individuals consult their primary health care provider or obstetrician for any vaccine related questions or concerns. ○ However, consultation with a primary health care provider or obstetrician is not required to receive COVID-19 vaccine. **Additional resources:** Society of Obstetricians and Gynecologists of Canada Statement on COVID-19 Immunization in Pregnancy	

This section the same as Moderna .

	COVID-19 Vaccine – mRNA Pfizer Comirnaty KP.2 Ultra frozen Vaccine	 Dark gray cap & dark gray label border
Lactation This section the same as Moderna .	• It is unknown whether this vaccine is excreted in human milk. A risk to the newborns/infants cannot be excluded. • Recent reports have shown that breastfeeding/chestfeeding people who have received mRNA COVID-19 vaccines have antibodies in their breastmilk, which could help protect their babies. More data are needed to determine the level of protection these antibodies might provide to the baby. • COVID-19 vaccine is recommended for individuals who are breastfeeding. It is recommended that individuals consult their primary health care provider or medical specialist for any vaccine related questions or concerns. However, consultations with a primary health care provider or medical specialist is not required to received COVID-19 vaccine.	

	COVID-19 Vaccine – mRNA Pfizer Comirnaty KP.2 Ultra frozen Vaccine	 Dark gray cap & dark gray label border
Composition	• Each 0.3 ml dose of Comirnaty contains 30 micrograms of mRNA encoding the viral spike (S) glycoprotein of SARS-CoV-2 [Omicron KP.2] • **Non-medicinal ingredients:** o ALC-0315 = ((4-hydroxybutyl)azanediyl)bis(hexane-6,1-diyl)bis(2-hexyldecanoate) o ALC-0159 = 2-[(polyethylene glycol)-2000]-N,N-ditetradecylacetamide o cholesterol o DSPC = 1,2-distearoyl-sn-glycero-3-phosphocholine o sucrose o tromethamine o tromethamine hydrochloride o water for injection. Does not contain any preservatives.	
Blood/Blood Products	Does not contain blood/blood products.	
Bovine/Porcine Products	Does not contain bovine/porcine products.	
Latex	Does not contain latex.	

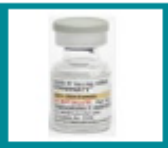
	COVID-19 Vaccine – mRNA Pfizer Comirnaty KP.2 Ultra frozen Vaccine	 Dark gray cap & dark gray label border
Administration with Other Products This section the same as Moderna.	• Except for the Respiratory Syncytial Virus (RSV) vaccine, COVID-19 vaccines may be co-administered with, or at any time before or after other vaccines (including, live, inactivated, adjuvanted, or unadjuvanted vaccines), tuberculin skin tests or IGRA (QFT) tests to individuals 6 months of age and older. (In Alberta, Pfizer KP.2 vaccine is only being used for individuals 12 years of age and older). ○ Limited studies have been conducted on concurrent administration of RSV vaccine with other vaccines. Until more evidence is available, co-administration is not recommended. RSV vaccine should be given with two-week spacing before or after influenza and/or COVID-19 vaccines. ○ There is a theoretical risk that COVID-19 vaccines may temporarily affect cell-mediated immunity, resulting in false-negative tuberculin skin testing or IGRA (QFT) test results. ○ In the absence of data and acknowledging the importance of both timely tuberculosis testing and immunization, immunization with COVID-19 vaccines can take place at any time before, after or at the same visit as the TST or IGRA test. ○ However, repeat tuberculin skin testing or IGRA (at least 4 weeks post COVID-19 immunization) of individuals with negative TST or IGRA results for whom there is high suspicion of latent tuberculosis may be considered to avoid missing persons with TB infection. • Deferral of COVID-19 immunization is not recommended for individuals who have received anti-SARS-CoV-2 monoclonal antibodies or convalescent plasma provided for treatment or prophylaxis of COVID-19.	

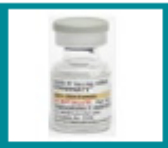
	COVID-19 Vaccine – mRNA Pfizer Comirnaty KP.2 Ultra frozen Vaccine	 Dark gray cap & dark gray label border
Administration with Other Products This section the same as Moderna.	**Note:** • Timing of administration and potential interference between COVID-19 vaccine and monoclonal products not used for treatment or prophylaxis of COVID-19 infection are currently unknown and the primary health care provider or medical specialist should be consulted on a case-by-case basis. • mRNA COVID-19 vaccines may be given at any time before or after an immunoglobulin preparation (including RhIg) or blood product has been administered. There is no recommended minimum interval between these products and COVID-19 vaccine.	

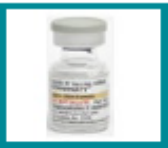
	COVID-19 Vaccine – mRNA Pfizer Comirnaty KP.2 Ultra frozen Vaccine	 Dark gray cap & dark gray label border
Appearance	Clear to slightly opalescent liquid. Thawed suspension may contain white to off-white amorphous particles.	

Storage	• Store in ultra-low temperature freezer between -90˚C to -60˚C .
	• Protect from light until thawed.
	• Do not refreeze after thawing.
	• Thawed, unpunctured vials:
	  ○ Thawed, unpunctured vials can be stored at +2˚C to +8˚C for up to 10 weeks.
	  ○ Thawed, unpunctured vials can be stored at +8˚C to +25˚C for up to 12 hours. Discard after 12 hours.
	• Thawed, punctured vials:
	  ○ Thawed, punctured vials (first dose is withdrawn) can be stored at +2°C to +25°C for 12 hours. Discard after 12 hours.
	• Regardless of storage condition, the vaccine should not be used after the expiration date printed on the vials and cartons.	

Packaging	• 6 doses per vial (Low dead-volume syringes and/or needles can be used to extract 6 doses from a single vial. If standard syringes and needles are used, there may not be sufficient volume to extract a 6th dose from a single vial). • 10 vials per carton.	

	COVID-19 Vaccine – mRNA Pfizer Comirnaty KP.2 Ultra frozen Vaccine	 Dark gray cap & dark gray label border
Preparation	• Multidose vials are supplied as a frozen dispersion, does not contain preservative. Thaw vaccine before use: • Vaccine can be thawed in two ways: ○ From the freezer to room temperature (between +15˚C to +25˚C), thaw for 30 minutes from frozen state. ○ From the freezer to a vaccine fridge (+2˚C to +8˚C), thaw for 6 hours from the frozen state. • Must not be reconstituted, mixed with other medicinal product, or diluted. • No dilution is required. • Before use, mix the thawed vaccine by inverting the vial gently 10 times. • Do **not** shake vial.	

	COVID-19 Vaccine – mRNA Pfizer Comirnaty KP.2 Ultra frozen Vaccine	 Dark gray cap & dark gray label border
Vaccine Code	COVPBmRNAKP	
Antigen Code	COVID-19	
Licensed for	Single dose for individuals 12 years of age and older.	
Off-license use	• Three-dose series for individuals who are moderately to severely immunocompromised.	
Notes	• 2024 September 24: Licensed for use in Canada. • 2024 October: Implemented in Alberta.	
Related Resources	• Alberta Health Services Website (2024). COVID-19 mRNA Vaccine Information • COVID-19 mRNA Vaccine Information Sheet (105240)	

	COVID-19 Vaccine – mRNA Pfizer Comirnaty KP.2 Ultra frozen Vaccine	 Dark gray cap & dark gray label border

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Alberta Vaccine Storage and Handling for COVID-19 Vaccine

Revised: September 2024

This policy is evergreen and will be updated as new evidence becomes available.

Objectives:

- Protect vaccine safety and efficacy and ensure a potent and safe vaccine is administered; and
- Minimize and reduce the cost of vaccine wastage due to cold chain excursions.

See the Alberta Vaccine Storage and Handling for Provincially Funded Vaccines for:

- Accountabilities, roles and responsibilities for staff and immunizers in maintaining vaccine viability for vaccines; and
- Cold chain (storage, transport, and handling) requirements for staff and immunizers.

Alberta Vaccine Storage and Handling Policy for COVID-19 Vaccine

September 2024

Pfizer-BioNTech Comirnaty KP.2 (Grey Cap/Label)

Thawing/Thawed

- If transportation must occur in the thawing/thawed state:
  - The transported vaccine must be labelled "transported thawing/thawed" and the total time in transportation must be tracked.
- The time in transit in the thawing/thawed state at +2°C to +8°C must be considered as part of the 10 weeks allowed for storage at refrigerator temperatures.
- Single vials can be transported in a thawing/thawed state.
- The thawing/thawed product should be appropriately packed in a validated container.
- Do not refreeze thawed product.

Alberta Vaccine Storage and Handling Policy for COVID-19 Vaccine

September 2024

Pfizer-BioNTech Comirnaty KP.2 (Grey Cap/Label)

In addition, for ultra-frozen and thawing/thawed vaccine:

- Label the container as “Fragile: Handle with Care, Do Not Drop” and “Temperature Sensitive”.
- Keep the vaccine vials upright.
- As much care as possible should be taken to minimize movement during onward transportation both within the container and the vehicle.
- The temperature must be maintained and recorded during transport.
- Record the transportation locations, dates and times, including the duration of time in transit.
- Do not transport the vaccine at room temperature.
- Do not transport vials that have been punctured.

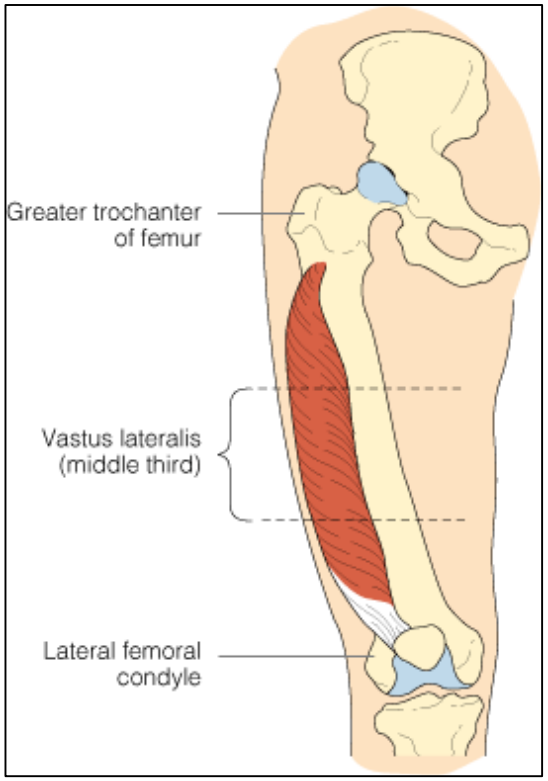
An appropriate temperature monitoring device must be used to transport vaccine.

TEMPERATURE MONITORING

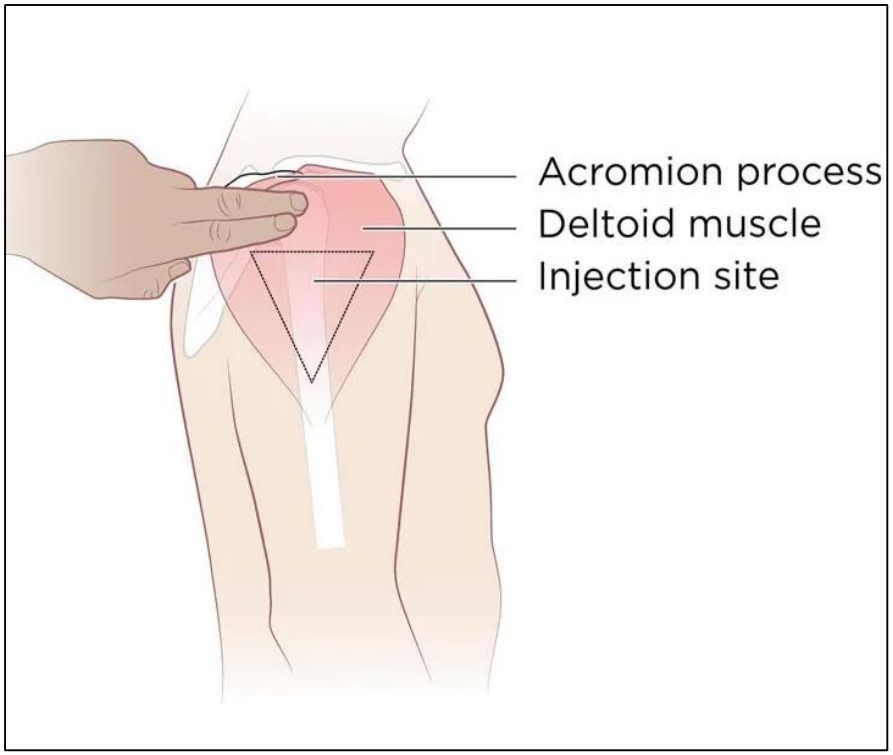
The minimum, maximum, and current temperature of all refrigerators/freezers where vaccine is stored must be monitored and recorded.	
Temperature monitoring devices	The only thermometers and temperature recording devices that are acceptable for monitoring the temperature within vaccine storage units are: • Minimum and Maximum Thermometer. • Data Logger - must function like a min/max device and therefore the minimum, maximum, and current temperatures need to be downloaded twice a day. • Alarmed Temperature Monitoring System - must function like a min/max device and therefore the minimum, maximum, and current temperatures need to be downloaded twice a day. • Chart Recorder in combination with a min/max thermometer Note: Chart recorders can be hard to interpret, inaccurate, and difficult to ascertain minimum and maximum temperatures. In addition, if chart recorders are on the same power supply as the fridge (and do not have back-up power) and the power goes out – there is not enough data to make a decision on vaccine viability. **Fluid-filled bio-safe liquid (bottle) thermometers, bi-metal stem thermometers, and household thermometers are NOT acceptable**.
Continuous temperature recording devices	These include: • Chart Recorders (in combination with a min/max thermometer); OR • Data Loggers (downloaded twice a day); OR • Alarmed Temperature Monitoring System (downloaded twice a day).
Temperature recording	At minimum, the temperature must be recorded and reviewed at the beginning and end of each business day (separated by at least 8 hours) for each refrigerator/freezer storing vaccine.

Vaccine Administration: Dose and Route

Dose and Route: Intramuscular (IM) injection in the deltoid or vastus lateralis muscle.



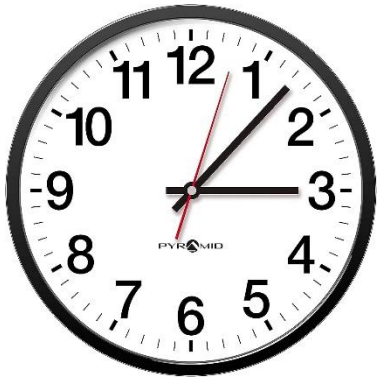
Vastus lateralis (middle third)



Deltoid (injections site noted as the triangle area)

Anaphylaxis

- **All clients are encouraged to wait for 15 minutes after immunization**
- For clients with any known anaphylactic allergies, extend this recommended wait period to **30 minutes**.
- Refer to the FNIHB Anaphylaxis Module on OneHealth.



Vaccine Storage and Handling Principles

Every immunizer must:

- Understand cold chain excursions and the implications of them
- Identify the key staff members at the clinic responsible for vaccine management
- Understand the specific vaccine storage and handling recommendations for this product
- Understand how to monitor and interpret min/max thermometer readings
- Understand the actions required when a cold chain excursion.

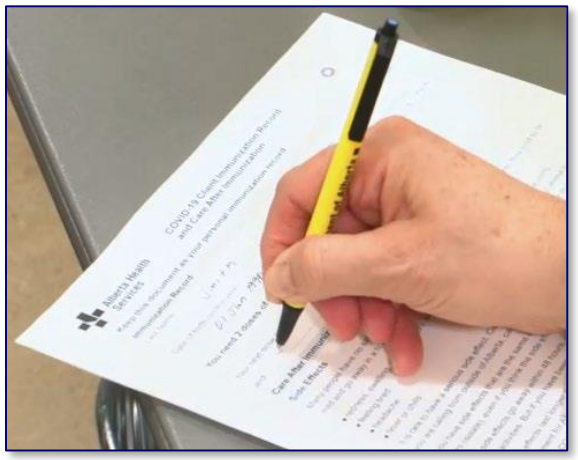
If you have questions about vaccine storage and handling, cold chain breaks, see AB Onehealth (**FNIHB AB Region: Vaccine Management Standards** (February 2023) and/or reach out to a member of the **FNIHB CDC Team**.

mRNA Vaccine Management

- All multi-dose vials to be thawed in the fridge must be marked with the **date and time** of removal from freezer (vaccine depot should indicate on shipment).
- All multi-dose vials must be marked with the **date and time** when stored at room temperature.
- All multi-dose vials must be marked with the **date and time** when **punctured**.
- Communicate use of near expiry vials to other staff members, so the vaccine can be used before it expire; this becomes more important at the end of a clinic.
- Vaccine should be withdrawn from the vial by the immunizer administering the vaccine.

COVID-19 Vaccine Documentation

- Information required to be recorded on all clients includes:
  - Client demographic information
    - full name, personal health number, date of birth, gender, address including postal code
- Reason code for immunization
- Dose number
- Vaccine name & lot number
- Dosage administered
- Site of injection
- Route of administration
- Date of immunization
- Immunizer's first initial and last name, designation & signature



Slide used with permission from AHS.

Pharmacy/Facility Name _____

COVID-19 Client Immunization Record and Care After Immunization

Keep this document as your personal immunization record

Immunization Record		
Last Name	First Name	Middle Initial
Date of Birth *(dd-Mon-yyyy)*	Date of COVID-19 Immunization *(dd-Mon-yyyy)*	
☐ **Your next dose is due** _____	Dose ☐ 1 ☐ 2 (if needed) ☐ 3 (if needed)	
	Vaccine (Manufacturer) ☐ SpikeVax XBB.1.5 (Moderna)	
☐ **You are not due for another dose at this time.** Visit alberta.ca/covid19-vaccine for up-to-date information about additional doses.	**Lot Number** _____	

Care After Immunization

Common Side Effects

Many people have no side effects from COVID-19 vaccines. If you do have side effects, they tend to be mild and go away in a few days. Common side effects may include:

- redness, swelling, a hard spot, or feeling sore where you had the needle
- feeling tired, unwell, or have a headache
- a fever or chills
- body aches, sore joints
- feeling stiff
- feeling sick to your stomach (nausea), vomiting (throwing up)
- swollen lymph nodes
- swelling or feeling sore in your armpit or groin
- feeling dizzy
- a reduced sense of touch or a feeling of numbness
- a rash or hives

Children age 5 years and younger may also get upset easily, be sleepy, cry, or may not want to eat.

Call Health Link at 811 to report any serious or unusual side effects. It is rare to have a serious side effect.

Rare events after getting an mRNA vaccine

There have been very rare reports of myocarditis (inflammation of the heart muscle) and pericarditis (inflammation of the lining around the heart) in the first 7 days after getting an mRNA COVID-19 vaccine. These rare events can cause shortness of breath, chest pain or pressure, or a very fast or abnormal heart rate. Get medical help **right away** if you have any of these symptoms.

For more information about the COVID-19 vaccines, read the COVID-19 vaccine information on **ahs.ca/immunize** or talk to your healthcare provider.

See reverse for more information,

Alberta Health Services

COVID-19 Immunization Record

Site/Clinic Location _____

Last Name	First Name	Initial	Gender
Provincial Health Care Number/ULI	Age	Date of Birth *(dd-Mon-yyyy)*	
Alberta Address	Phone *(Home)*	Phone *(Cell)*	
City	Province: Alberta	Postal Code	Consent to receive appointment reminders or Public Health Notifications ☐ Yes ☐ No
Out of Province Address *(if applicable)*	Province	Status ☐ New to Alberta ☐ Visitor	
☐ Informed Consent	**Date** *(dd-Mon-yyyy)*	**Time** *(hh:mm)*	

Vaccine Given ☐ No - go to **Not Administered** Section ▶
☐ Yes - go to **Administered** Section ▼

(✓)	**Vaccine Administered** *(provide reason code)*	
☐	22	Long-term Care/DSL Resident
☐	50	Routine Recommended Immunization
☐	66	Other Risk

(✓)	**Vaccine NOT Administered** *(provide reason code)*	
☐	NGADVREACT	Previous Adverse Reaction
☐	NGALLERGY	Allergic to Vaccine Ingredient/Component
☐	NGDEFERRED	Deferred
☐	NGIMMUNCOM	Immunocompromised
☐	NGNOCONSNT	No Consent or Unable to Contact
☐	NGNTELIGIB	Not Eligible/Recommended
☐	NGPREGNANT	Pregnancy
☐	NGREFUSE	Refused Vaccine Consent
☐	NGTEMPILL	Temporary Illness

Comment

Vaccine Administration Details

Manufacturer

☐ COVMODmRNAXBB *(Spikevax XBB.1.5)*
☐ 0.25 mL OR
☐ 0.50 mL IM
(Manufacturer: Moderna)
Lot # _____

Site **Arm** ☐ Left ☐ Right
Leg ☐ Left ☐ Right

Immunizer *(First Name, Last Name, Designation)*	Meditech ID	Signature

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Adverse Reaction Reporting

- Use Alberta Health form: “Report of Adverse Reaction following Immunization”
  - speak to FNIHB CDC Team before completing
  - send completed form to FNIHB CDC Team
  - expect written response from FNIHB CDC Team

- Severe reactions are reportable within **24 hours**. All other reactions within one week.

Infection Prevention and Control

- Hand hygiene is critical
  - Must be done between each client
    - ✓*Waterless hand gel*
  - Hand creams to maintain skin integrity
- Gloves are ***not*** recommended during immunizations
- "Respiratory Etiquette" protocol.
  - coughing/sneezing into tissue or upper sleeve
  - providing masks PRN

Infection Prevention and Control

- Vaccine Administration
  - Ensure a clean workspace
    - Clean surface at start and end of day
    - Establish clean work area (blue pad, professional towel, etc.)
      - Avoid placing papers, pens in this area

- Sharps management
  - Use safety syringes and needles
  - Sharps disposal at point of contact

Ordering

Moderna and Pfizer vaccines can be ordered through AVI.
Reach out to your vaccine depot to discuss when shipments will occur.

Informed Consent

- Clients must give informed consent before immunization
- Prior to immunizing, the immunizer must:
  - Determine that the client is eligible (based on current phase and/or eligibility requirements)
  - Review the disease being prevented
  - Review vaccine

  Discuss:

  - Risks and benefits of getting the vaccine and not getting the vaccine
  - Side effects and after care
  - How the vaccine is given
  - Provide the opportunity to ask questions
  - Affirm verbal consent

7 Rights of Immunization

- ✓ Right product (vaccine)
- ✓ Right client
- ✓ Right dose
- ✓ Right time (date/time, interval between doses, usage expiry of vial)
- ✓ Right route, needle length, site/land marking and technique
- ✓ Right reason (meets eligibility criteria)
- ✓ Right documentation (including reason code)

Alberta Health Services

Commitment to Comfort

Needle Fears

- Up to 25% of adults have needle fears
- Up to 10% of those are significant enough to avoid immunizations
  - This translates to **350,000** Albertans

Solution: The AHS Commitment to Comfort (CTC)

- There is strong evidence that these principles improve immunization experience, health outcomes, satisfaction, and repeat attendance to healthcare encounters

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Alberta Health Services

Commitment to Comfort – 5 Core Principles

Make a Comfort Plan

- Establish client preference and offer choice

Use Positive Language

- *Always say:* "you did well", and leave them with a positive memory "by doing this today, you are saving lives"
- *Avoid:* pain descriptors; focus on what the client can do – to make the immunization feel better (see shift attention)

Use Comfort Positions

- When safe, sit client in an upright comfortable position
- Brief muscle tense and release or lie down if client feels faint

Shift Attention

- Shift client attention to a more pleasant activity or thought (e.g., smartphone game, music, small talk)

Use Numbing Cream

- Needs to be obtained and applied by the person being immunized prior to their appointment
- Numbing cream will not be offered at the immunization sites
- Client needs to talk with a pharmacist to select and obtain a product that is right for them

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First of all,…

INDIGENOUS SERVICES CANADA

Questions?

VCHELP@FNTN.CA