Revised: December 19, 2022

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.

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ULTRA-FROZEN VACCINE Pfizer-BioNTech Comirnaty

	Comirnaty for 12 years and older (Grey cap) – NO DILUTION Comirnaty for 12 years and older Original and Omicron BA.4/BA.5 Bivalent Booster (Grey cap and grey label border) – NO DILUTION
Bivalent	Comirnaty for 5 to 11 years (Orange Cap) Comirnaty for 5 to 11 years Original and Omicron BA.4/BA.5 Bivalent Booster (Orange cap) Note: COMIRNATY Original & Omicron BA.4/BA.5 bivalent vaccine has the same ORANGE CAP and ORANGE LABEL BORDER as monovalent COMIRNATY (COVID-19 Vaccine, mRNA). Storage and handling requirements are the same for both of these products, therefore both products are referred to simply as 'orange cap' throughout this document.
旦、	Comirnaty for 6 Months to 4 Years (Maroon Cap)

VACCINE STORAGE REQUIREMENTS

Vaccines that require ultra-low temperature (-75°C) for long term storage

- Vaccine should be stored at -90°C to -60°C in a laboratory grade ultra-low temperature freezer.
- Vaccine can be stored for 12 months from the date of manufacture at -90°C to -60°C.
- Vaccine can be stored at +2°C to +8°C for up to 10 weeks.
- Vaccines should remain in the freezer until ready to immunize.
- Minimize exposure to room light, and avoid exposure to direct sunlight and UV light.
- Vaccine must be thawed prior to use. (See Thawing/Thawed section)

See www.CVDvaccine.ca for additional information.

Must have an alarm setting that provides audible sound in the event that the Storage temperature temperature of the unit deviates beyond the alarm set points or if the door is left monitoring requirements ajar. Must have adjustable alarm set points/range. Should have adjustable temperature set points or temperature controls. Should have a digital temperature display on front that displays current temperature to 1°C resolution. Storage at -90°C to -60°C Ultra-frozen Long term storage for up to 12 months from the date of manufacture. Laboratory grade ultra-low temperature Must continuously keep temperature at -75°C within +/- 15°C in a laboratory freezers grade ultra-low temperature freezer. Thawing and storage between +2°C and +8°C and thawing at room temperature Thawing/Thawed Can be stored at +2°C to +8°C for up to 10 weeks. Storage between 2°C The time in transit in the thawing/thawed state at +2°C to +8°C must be

Thawed vials can be handled in room light conditions.

considered as part of the 10 weeks allowed for storage at refrigerator



temperatures.



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It takes 30 minutes to thaw a vial of vaccine at room temperature from frozen state. Grey cap and grey cap The vaccine can be thawed in a vaccine fridge +2 to +8°C from frozen state. with grey label • A carton of 10 vials can take up to 6 hours to thaw in the refrigerator. Once thawed, do not refreeze. See Alberta Vaccine Storage and Handling Policy for Provincially Funded Vaccine for vaccine storage requirements. Thawing and storage between +2°C and +8°C and thawing at room temperature Undiluted Thawing/Thawed Can be stored at +2°C to +8°C for up to 10 weeks. Storage between 2°C The time in transit in the thawing/thawed state at +2°C to +8°C must be to +8°C considered as part of the 10 weeks allowed for storage at refrigerator temperatures. Thawed vials can be handled in room light conditions. It takes 30 minutes to thaw a vial of vaccine at room temperature from frozen state. The vaccine can be thawed in a vaccine fridge +2 to +8°C from Bivalent frozen state. A carton of 10 vials may take up to 2 hours to thaw Once thawed, do not refreeze. **Maroon Cap** The vaccine can be thawed in a vaccine fridge +2 to +8°C from Maroon cap and orange cap A carton of 10 vials may take up to 4 hours to thaw Once thawed, do not refreeze, **Orange Cap** See Alberta Vaccine Storage and Handling Policy for Provincially Funded Vaccine for vaccine storage requirements. Manufacturer-The vaccine is stable in the manufacturer-provided thermal shipper for up to 30 days provided thermal with appropriate handling and re-icing. shippers Unpacking vaccine Do not discard the original thermal shipper or any of its components. from thermal shipper There are two types of thermal shippers: a **Softbox** thermal shipper and an AeroSafe thermal shipper. Their outer appearance is different, but their components are very similar. The thermal shippers can weigh up to 36.5 kg (81 lbs) when full and should be opened on the floor. Steps for unpacking the thermal shipper 1. Don dry ice PPE. 2. See 'Safe storage and handling of dry ice' below and refer to the dry ice safety data sheet before accessing the contents of the thermal shipper. Break the seal open. When you open the container you will see a temperature monitoring device embedded in the foam lid. **Softbox:** The lid is permanently attached to one flap of the container. Do not pull this flap. When opening the lid, use the three-finger holes in the foam lid, which will allow the lid to swing open.



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	 Aerobox: Gently remove the entire lid, with the temperature-monitoring device, from the inner lid. 5. Press and hold the stop button of the temperature-monitoring device for at least 5 seconds. 6. Remove the dry ice pod. 7. You will now see the box that holds the vial trays. Open the box and you will see the vial trays. Remove the box that holds the vial trays from the container. Do not open the vial trays or remove the vials until you are ready for thawing. 8. Immediately store the vaccine in the ultra-low-temperature freezer. Keep tray at room temperature for less than 5 minutes. 9. Dispose of dry ice (see 'Disposal of dry ice' section below). 10. Return the thermal shipper and temperature-monitoring device to the manufacturer as outlined below.
Returning the thermal shipper	 A preprinted return shipping label will be included inside the thermal shipper or already affixed to the inner flap of the thermal shipper. Softbox - apply the preprinted return shipping label over the existing shipping label. AeroSafe - follow instructions on the inner flap of the thermal shipper to ensure the return label is facing outside. Elements required to be returned (Softbox and AeroSafe): Temperature-monitoring device Foam lid (remains attached to box) Dry ice pod Box that holds the vial trays When the thermal shipper is ready to be returned and all the components are inside, seal it with tape. Note: Ensure the Dry Ice UN1845 markings and diamond-shaped Class 9 hazard label on the thermal shipper are covered by placing a blank label over them in preparation for the return, as the container no longer contains dry ice. Discard empty vial trays as medical waste so they cannot be reused.
Safe storage and handling of dry ice	 Do not store in an airtight container, as it may explode. The dry ice rapidly expands to a gas when exposed to temperatures above -78°C. Work in a well-ventilated space, as asphyxiation is a main hazard of dry ice. Wear insulated (cryogenic) gloves: Wear heavy rubber gloves that insulate against the cold where contact with dry ice may occur. This prevents cold burns and frostbite. Wear safety glasses with side shields, safety goggles or a face shield. Use dry ice tongs or a dry shovel or scoop. Avoid materials incompatible with cryogenic use; some metals such as carbon steel may fracture easily at low temperature. See the product's Material Safety Data Sheet (MSDS) for more information. Pfizer's dry ice MSDS can be found here.
Disposal of dry ice	 Once dry ice is no longer needed, open the container and leave it at room temperature in a well-ventilated area. It will readily turn from a solid to a gas. DO NOT leave dry ice in an unsecured area. DO NOT drain or flush in toilet. DO NOT dispose in the trash. DO NOT place in a closed area, such as an airtight container or walk-in cooler.



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VACCINE TRANSPORT – Ultra-frozen Vaccine

Cold chain must be ma	aintained during transport to another location.
Container	Qualified container that is certified to maintain required temperature and allows for vaccine to be packed securely to prevent movement.
Onward transportation	To reduce the risk of temperature excursions, the manufacturer recommends the vaccine be administered at the point where the vaccine is delivered, and that the product is not transferred to other locations.
	 In order to provide flexibility for the safe re-distribution of vaccine from the point of use/delivery, the manufacturer has indicated that, based on stability data, the product can be transported in an appropriately validated container in either the: Ultra-frozen state at -90°C to -60°C OR Thawed state at +2°C to +8°C.
	First choice. As per manufacturer recommendations, if the vaccine must be transported, transport the vaccine in an ultra-frozen state.
	<u>Ultra-frozen</u>
	Only full trays in their original carton (not individual vials) can be transported in an ultra-frozen state.
	Transfer the vaccine from the ultra-low temperature freezer to the container rapidly. Keep tray at room temperature for less than 5 minutes to prevent thawing.
	The ultra-frozen product should be appropriately packed in a validated container to prevent contact with the dry ice.
	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 undiluted state.
	The thawing/thawed product should be appropriately packed in a validated container.
	Do not refreeze thawed product.
	<u>Diluent</u> (orange cap and maroon cap only)
	 The ideal temperature to transport diluent is between +20 to +25°C, and there are no restrictions or time limits in place while diluent is transported in this range. The diluent can be transported between +2 to +8°C for a maximum of 120 hours.
	It is important to ensure that diluent does not freeze.
	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.



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	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.	
Temperature monitoring	An appropriate temperature monitoring device must be used to transport vaccine. Note: Vaccine shipped from Pharmacy wholesale distributors and Accuristix wholesale distributor utilizing a pre-qualified container with phase-changing technology will not have a temperature monitoring device.	
Receiving vaccine	 When a vaccine shipment is received, it must be examined and stored as specified in the product monograph. Ultra-frozen state – ultra-low temperature freezer at -90°C to -60°C. Thawed state – fridge at +2°C to +8°C. Read and/or stop the recording of the temperature monitoring device upon receipt to determine if it has been activated or alarmed. 	





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COLD CHAIN EXCURSIONS - Ultra-frozen vaccine

All known exposures of vaccine to temperatures outside temperature requirements as specified in the product monograph must be reported. Each cold chain excursion needs to be assessed to determine if it is a cold chain break and vaccine needs to be quarantined.

Ultra-frozen vaccine

Ultra-frozen state (-90°C to -60°C)

- Vaccine is to be stored at -90°C to -60°C in a laboratory grade ultra-low temperature freezer while in a frozen state.
- If the temperature is warmer than -60°C, the vaccine is considered to be in the thawing stage and needs to be stored in a vaccine fridge at +2°C to +8°C. Do not refreeze.
- If the temperature is colder than -90°C, quarantine the vaccine, mark as "DO NOT USE", and store in an ultra-low freezer at -90°C to -60°C until viability has been assessed.

Pre-puncture vaccine



Grey cap and grey cap with grey label

Pre-puncture vaccine can be stored at:

- +2°C to +8°C for 10 weeks
 - If the temperature is colder than +2°C, quarantine vaccine, mark as "DO NOT USE", and store in a vaccine fridge at +2°C to +8°C until viability has been assessed.
- Warmer than +8°C to +25°C for 12 hours
 - o If the temperature is over +25°C (room temperature) within the 12 hour timeframe, quarantine vaccine, mark as "DO NOT USE", and store in a vaccine fridge at +2°C to +8°C until viability has been assessed.
 - Pre-puncture vaccine stored at +8°C to +25°C is to be discarded after 12 hours and counted as wasted doses in the Alberta Vaccine Inventory system (AVI).

Post-puncture vaccine



Grey cap and grey cap with grey label

Post-puncture vaccine can be stored at:

- +2°C to +25°C for 12 hours
 - o If the temperature is colder than +2°C or warmer than +25°C within the 12 hour timeframe, quarantine vaccine, mark as "DO NOT USE", and store in a vaccine fridge at +2°C to +8°C until viability has been assessed.
 - Post-puncture vaccine is to be discarded after 12 hours and counted as wasted doses in the Alberta Vaccine Inventory system (AVI).

Undiluted thawed vaccine



Maroon cap and orange cap

Undiluted thawed vaccine can be stored at:

- +2°C to +8°C for 10 weeks
 - If the temperature is colder than +2°C, quarantine vaccine, mark as "DO NOT USE", and store in a vaccine fridge at +2°C to +8°C until viability has been assessed.
- Warmer than +8°C to +25°C for 12 hours
 - o If the temperature is over +25°C (room temperature) within the 12 hour timeframe, quarantine vaccine, mark as "DO NOT USE", and store in a vaccine fridge at +2°C to +8°C until viability has been assessed.

Undiluted thawed vaccine is to be discarded after 12 hours and counted as wasted doses in the Alberta Vaccine Inventory system (AVI).



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Diluted thawed vaccine



Maroon cap and orange cap

Diluted thawed vaccine can be stored at:

- +2°C to +25°C for 12 hours
 - If the temperature is colder than +2°C or warmer than +25°C within the 12 hour timeframe, quarantine vaccine, mark as "DO NOT USE", and store in a vaccine fridge at +2°C to +8°C until viability has been assessed.
 - Diluted thawed vaccine is to be discarded after 12 hours and counted as wasted doses in the Alberta Vaccine Inventory system (AVI).

Note:

- Temperature excursions to be reported as per process outlined in <u>Alberta Vaccine Storage and Handling Policy for</u> Provincially Funded Vaccine.
- . Timeframe for reporting is within 24 hours.
- Vaccine that is determined not viable, is to be discarded according to the health practitioners' standard of practice and must be entered into AVI as wasted using the correct reason.
- For more information on inventory reconciliation, refer to the <u>Inventory Reconciliation quick reference guide</u>.

Contact Pfizer at 1-833-829-2684 for viability assessment and determination.

See the Pfizer-BioNTech Comirnaty COVID-19 Vaccine Cold Chain Excursion Tool below.

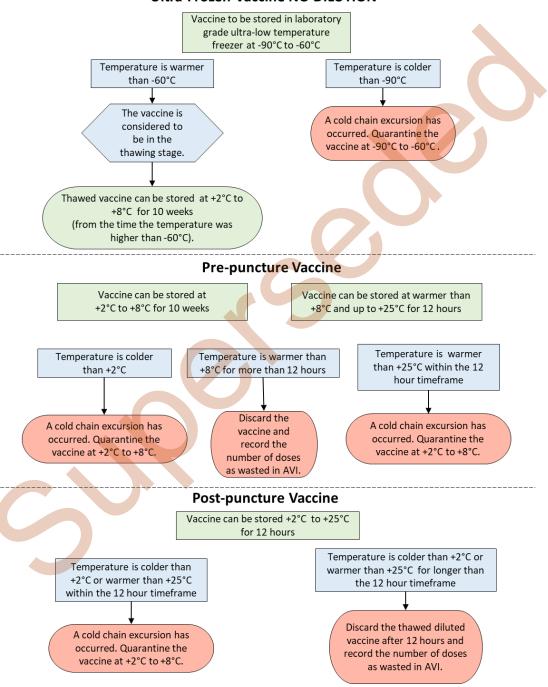


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Pfizer-BioNTech Comirnaty COVID-19 Vaccine Cold Chain Excursion Tool – Comirnaty for 12 years and older (Grey cap) and Comirnaty Original and Omicron BA.4/BA.5 Bivalent Booster for 12 years and older (Grey cap and grey label border) NO DILUTION

Ultra-Frozen Vaccine NO DILUTION



Contact Pfizer at 1-833-829-2684 for viability assessment and determination.



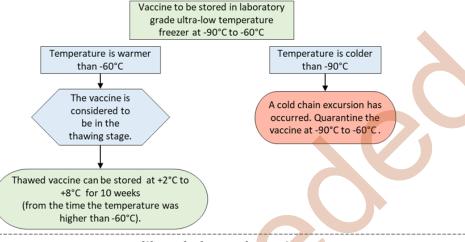
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Pfizer-BioNTech Comirnaty COVID-19 Vaccine Cold Chain Excursion Tool – 6 Months to 4 Years (Maroon Cap) & 5 to 11 years monovalent and bivalent (Orange Cap)

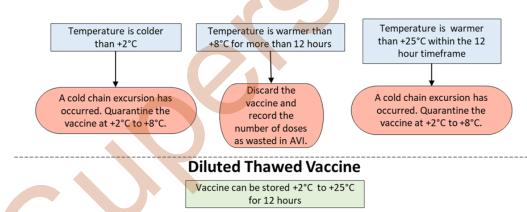


Ultra-Frozen Vaccine - 6 Months to 4 Years & 5 to 11 Years



Undiluted Thawed Vaccine

Vaccine can be stored at +2°C to +8°C for 10 weeks Vaccine can be stored at warmer than +8°C and up to +25°C for 12 hours



+2°C or warmer than +25°C within the 12 hour timeframe

A cold chain excursion has occurred. Quarantine the

Temperature is colder than

Temperature is colder than +2°C or warmer than +25°C for longer than the 12 hour timeframe

Discard the thawed diluted vaccine after 12 hours and record the number of doses as wasted in AVI.

Contact Pfizer at 1-833-829-2684 for viability assessment and determination.

vaccine at +2°C to +8°C.



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FROZEN VACCINE Moderna Spikevax

	Spikevax for 6 years to 11 years (Red cap) Spikevax for 12 years and older (Red cap) (See product monographs for more information)
	Spikevax for 6 months to 5 years (Royal blue Cap)
Spikeryan O 30 m 9 70 m to mysterior Service on termination The Control of the	Spikevax for 18 years and older Original and Omicron BA.1/BA.2 Bivalent Booster (Royal Blue Cap/Green Label)

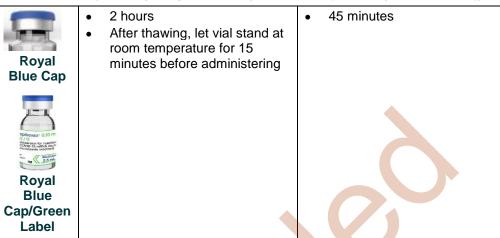
Moderna Spikevax FROZEN VACCINE (Red Cap, Royal Blue Cap & Bivalent [Blue Cap/Green Label])

moderna opinovax i Nobelia (Nobelia), Nobelia odp a Divaloni [Dia odp olicon Labol]/			
	in in the freez	er until ready to immunize. oratory grade freezer until date of	expiration.
Storage temperature monitoring requirements	temperaMust haShould hShould h	we an alarm setting that provides auditure of the unit deviates beyond the averadjustable alarm set points/range. have adjustable temperature set point have a digital temperature display on ture to 1°C degrees resolution.	larm set points or if the door is ajar. s/temperature controls.
Frozen Laboratory grade freezers	 Storage at -25°C to -15°C Long term storage until expiry date. Must continuously keep temperature at -20°C within +/- 5°C. Vaccine can be stored at -25°C to -15°C until date of expiration. 		
Storage between 2°C to +8°C Pre-puncture Thawing/Thawed	Storage at +2°C to +8°C • Can be stored at +2°C to +8°C for 30 days. The time in transit in the thawing/thawed state at +2°C to +8°C must be considered as part of the 30 days allowed for storage at refrigerator temperatures.		
(Do NOT refreeze once thawed)		n be thawed in two ways (refrigerate aries depending on formulation (re Thaw time under refrigeration (+2°C to +8°C)	
	Red Cap	 2 hours and 30 minutes After thawing, let vial stand at room temperature for 15 minutes before administering 	• 1 hour



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Moderna Spikevax FROZEN VACCINE (Red Cap, Royal Blue Cap & Bivalent [Blue Cap/Green Label])





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VACCINE TRANSPORT – Frozen Vaccine

Moderna Spikevax FROZEN VACCINE (Red Cap, Royal Blue Cap & Blue Cap/Green Label [Bivalent])

Cold chain must be maintained during transport to another location.

Container

Qualified container that is certified to maintain temperature at -25°C to -15°C and allows for vaccine to be packed securely to prevent movement.

Onward transportation

- First choice. As per manufacturer recommendations, if the vaccine must be transported, transport the vaccine in the frozen state at -25°C to -15°C but can be as cold as -50°C.
- Do not use dry ice.
- Second choice. In exceptional scenarios, where frozen state transport cannot be accomplished and based on stability data, the manufacturer has indicated that the product can be transported in an appropriately validated container in a thawing/thawed state (at +2°C to +8°C).
- Full cartons or individual vials can be transported in either the frozen or thawed state.

Frozen

- Transfer the vaccine from the freezer to the container rapidly. Keep tray at room temperature for less than 5 minutes to prevent thawing.
- The product should be appropriately packed in a validated container in order to:
 - Prevent contact with ice packs,
 - o Prevent movement of the vials in the container, and
 - Keep the vaccine vials upright.

Thawing/thawed

- If transportation occurs in the thawing/thawed state:
 - The total transportation time should be no longer than 10 hours.
 - The transported vaccine must be labelled "transported thawing/thawed" and the total time in transportation must be tracked.
 - This time can be extended to 12 hours in extenuating circumstances e.g. vehicle breakdown, poor road conditions. This would not be routine practice.
- The product should be appropriately packed in a validated container in order to:
 - Prevent contact with ice packs,
 - Prevent movement 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 30 days allowed for storage at refrigerator temperatures.

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





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Moderna Spikevax FROZEN VACCINE (Red Cap, Royal Blue Cap & Blue Cap/Green Label [Bivalent])

•	
	 Do not transport the vaccine at room temperature. Do not transport vials that have been punctured.
Temperature monitoring	An appropriate temperature monitoring device must be used to transport vaccine. Note: Vaccine shipped from Pharmacy wholesale distributors and Accuristix wholesale distributor utilizing a pre-qualified container with phase-changing technology will not have a temperature monitoring device.
Receiving vaccine	 When a vaccine shipment is received, it must be examined and stored as specified in the product monograph. Frozen state – freezer at -25°C to -15°C Thawed state – fridge at +2°C to +8°C Read and/or stop the recording of the temperature monitoring device upon receipt to determine if it has been activated or alarmed.





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COLD CHAIN EXCURSIONS – Frozen Vaccine

Moderna Spikevax FROZEN VACCINE (Red Cap, Royal Blue Cap & Blue Cap/Green Label [Bivalent])

All known exposures of vaccine to temperatures outside temperature requirements as specified in the product monograph must be reported. Each cold chain excursion needs to be assessed to determine if it is a cold chain break and vaccine needs to be quarantined.

Frozen	 Frozen state Vaccine is to be stored at -25°C to -15°C while in a frozen state. If the temperature is warmer than -15°C, the vaccine is considered to be in the thawing stage and needs to be stored in a vaccine fridge at +2°C to +8°C. Do not refreeze. If the temperature is colder than -50°C, quarantine vaccine, mark as "DO NOT USE", and store in freezer at -25°C to -15°C until viability has been assessed.
Pre-puncture thawed vaccine	Pre-puncture thawed vaccine can be stored at: • +2°C to +8°C for 30 days ○ If the temperature is colder than +2°C, quarantine vaccine and mark as "DO NOT USE", and store in a vaccine fridge at +2°C to +8°C until viability has been assessed. • +8°C to +25°C for 24 hours ○ If the temperature is warmer than +8°C for more than 24 hours, discard vaccine and count as wasted doses in the Alberta Vaccine Inventory system (AVI). ○ If the temperature is over +25°C (room temperature) within the 24 hour timeframe, quarantine vaccine, mark as "DO NOT USE", and store in a vaccine fridge at +2°C to +8°C until viability has been assessed.
Post-puncture thawed vaccine	Post-puncture thawed vaccine can be stored at: • +2°C to +25°C for 24 hours • If the temperature is colder than +2°C or warmer than +25°C within the 24 hour timeframe, quarantine vaccine, mark as "DO NOT USE", and store in a vaccine fridge at +2°C to +8°C until viability has been assessed. • Post-puncture thawed vaccine is to be discarded after 24 hours and count as wasted doses in the Alberta Vaccine Inventory system (AVI).

Note:

- Temperature excursions to be reported as per process outlined in <u>Alberta Vaccine Storage and Handling Policy for Provincially Funded Vaccine</u>.
- Timeframe for reporting is within 24 hours.
- Vaccine that is determined not viable, will be discarded according to the health practitioners' standard of practice and must be entered into AVI as wasted using the correct reason.
- For more information on inventory reconciliation, refer to the <u>Inventory Reconciliation quick reference guide</u>.

Contact Moderna at 1-833-847-4270 for viability assessment and determination. See the Moderna Spikevax COVID-19 Vaccine Cold Chain Excursion Tool below.



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Moderna Spikevax COVID-19 Vaccine Cold Chain Excursion Tool (Red Cap, Royal Blue Cap, Bivalent [Blue Cap/Green Label])

Frozen Vaccine Vaccine to be stored at -25°C to -15°C Temperature is colder Temperature is warmer than -15°C than -50°C The vaccine is A cold chain excursion has considered to occurred. Quarantine the be in the vaccine at -25°C to -15°C. thawing stage. Thawed vaccine can be stored at +2°C to +8°C for 30 days (from the time the temperature was higher than -15°C) **Pre-Puncture Thawed Vaccine** Vaccine can be stored at Vaccine can be stored at greater than +2°C to +8°C for 30 days +8°C and up to +25°C for 24 hours Temperature is warmer than Temperature is colder Temperature is warmer than +25°C within the 24 hour than +2°C +8°C for more than 24 hours timeframe Discard the A cold chain excursion has A cold chain excursion has vaccine and occurred. Quarantine the occurred. Quarantine the record the vaccine at +2°C to +8°C. vaccine at +2°C to +8°C. number of doses as wasted in AVI. Post-Puncture Thawed Vaccine Vaccine can be stored at +2°C to +25°C for 24 hours Temperature is colder than Discard the post-puncture +2°C or warmer than +25°C thawed vaccine after 24 within the 24 hour timeframe hours and record the number of doses as wasted in AVI. A cold chain excursion has occurred. Quarantine the vaccine at +2°C to +8°C.

Contact Moderna at 1-833-847-4270 for viability assessment and determination.



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Novavax Vaccine (+2°C to +8°C)

VACCINE STORAGE REQUIREMENTS

Novavax Vaccine (+2°C to +8°C)

- Vaccine can be stored for 9 months at +2°C to +8°C.
- Protect from light.

See <u>Alberta Vaccine Storage and Handling Policy for Provincially Funded Vaccine</u> for vaccine storage requirements.

VACCINE TRANSPORT

Novavax Vaccine (+2°C to +8°C)

See <u>Alberta Vaccine Storage and Handling Policy for Provincially Funded Vaccine</u> for vaccine transportation requirements.

Container	
Temp. Monitoring	
Receiving	

See <u>Alberta Vaccine Storage and Handling Policy for Provincially Funded Vaccine</u> for vaccine transportation requirements.

Onward transportation

- Vaccine cold chain maintained at +2°C to +8°C during transportation.
- There are no concerns from a stability perspective in transporting the Novavax vaccine
- Vaccine may be transported post-puncture with infection control considerations including: hand hygiene, cleaning vial with alcohol wipe pre-puncture and post puncture before returning to vaccine bags.

COLD CHAIN EXCURSIONS

Novavax Vaccine (+2°C to +8°C)

All known exposures of vaccine to temperatures outside temperature requirements as specified in the product monograph must be reported. Each cold chain excursion needs to be assessed to determine if it is a cold chain break and vaccine needs to be quarantined.

Vaccine that require storage between +2°C and +8°C)

Pre-puncture vaccine can be stored at:

- +2°C to +8°C for 9 months
 - If the temperature is colder than +2°C or warmer than +8°C quarantine vaccine and mark as "DO NOT USE", and store in a vaccine fridge at +2°C to +8°C until viability has been assessed.

Post-puncture vaccine can be stored at:

- +2°C to +25°C for 6 hours
 - If the temperature is colder than +2°C or warmer than +25°C within the 6 hour timeframe, quarantine vaccine, mark as "DO NOT USE", and store in a vaccine fridge at +2°C to +8°C until viability has been assessed.
 - Post-puncture vaccine that has been stored at +2°C to +25°C is to be discarded after 6 hours and counted as wasted doses in the Alberta Vaccine Inventory system (AVI).



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Note:

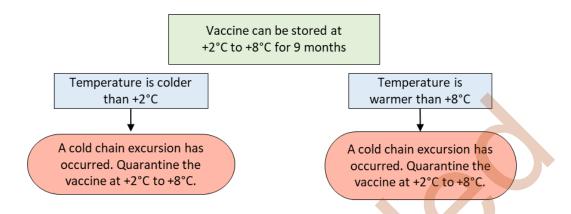
- Temperature excursions are to be reported as per process outlined in <u>Alberta Vaccine Storage and Handling Policy</u> for <u>Provincially Funded Vaccine</u>.
- Timeframe for reporting is within 24 hours.
- Vaccine that is determined not viable, will be discarded according to the health practitioners' standard of practice and must be entered into AVI as wasted using the correct reason.
- For more information on inventory reconciliation, refer to the Inventory Reconciliation quick reference quide.

Contact Innomar QA at 1-833-847-4270 for viability assessment and determination. See the Novavax COVID-19 Vaccine Cold Chain Excursion Tool below.



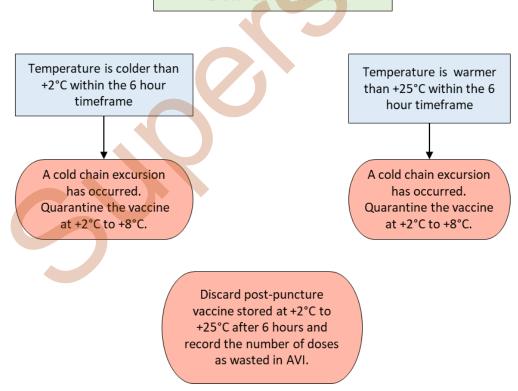
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Novavax Vaccine Cold Chain Excursion Tool



Post-puncture Vaccine

Vaccine can be stored at +2°C to +25°C for 6 hours



Contact Innomar QA at 1-833-847-4270 for viability assessment and determination.



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Janssen (Johnson & Johnson) Vaccine

VACCINE STORAGE REQUIREMENTS

Janssen ((Johnson & Johnson)) Vaccine

Store at -25°C to -15°C or at +2°C to +8°C

See Alberta Vaccine Storage and Handling Policy for Provincially Funded Vaccine for vaccine storage requirements when stored at +2°C to +8°C. Storage temperature Must have an alarm setting that provides audible sound in the event that the temperature of the unit deviates beyond the alarm set points or if the door is ajar. monitoring Must have adjustable alarm set points/range. requirements Should have adjustable temperature set points/temperature controls. Should have a digital temperature display on front that displays current temperature to 1°C degrees resolution. Frozen Storage at -25°C to -15°C Long term storage until expiry date. Laboratory grade Must continuously keep temperature at -20°C within +/- 5°C. freezers Vaccine can be stored at -25°C to -15°C until date of expiration Storage between Can be stored at +2°C to +8°C for a single period of up to 11 months, not +2°C to +8°C exceeding the original expiry date. When moving the product from frozen state to a refrigerator at +2°C to +8°C, the Pre-puncture updated expiry date must be written on the carton and the vial label. The original Thawing/Thawed expiry date should be made unreadable The time in transit in the thawing/thawed state at +2°C to +8°C must be considered as part of the 11 months allowed for storage at refrigerator temperatures. Vaccine can be thawed in two ways: From the freezer to room temperature (+15°C to +25°C). 10 vials will take 4 hours to thaw. 1 vial will take 1 hour to thaw. From the freezer to a vaccine fridge (+2°C to +8°C). 10 vials will take 13 hours to thaw. 1 vial will take 2 hours to thaw.

See Alberta Vaccine Storage and Handling Policy for Provincially Funded Vaccine

for vaccine storage requirements.



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VACCINE TRANSPORT

Janssen (Johnson & Johnson) Vaccine

Cartestan (common a common) racemo		
Cold chain must be maintained during transport to another location.		
Container	Transport at -25°C to -15°C: Qualified container that is certified to maintain temperature at -25°C to -15°C and allows for vaccine to be packed securely to prevent movement. Transport at +2°C to +8°C: See Alberta Vaccine Storage and Handling Policy for Provincially Funded Vaccine for vaccine transportation requirements.	
Onward transportation	 Frozen Vaccine cold chain maintained at -25°C to -15°C during transportation. The product should be appropriately packed in a validated container. Thawing/thawed Vaccine cold chain maintained at +2°C to +8°C during transportation. The time in transport should be considered part of the 11 months allowed for storage at refrigerator temperatures. There are no concerns from a stability perspective in transporting the Janssen (Johnson & Johnson) Vaccine. Vaccine may be transported post-puncture with infection control considerations including: hand hygiene, cleaning vial with alcohol wipe pre-puncture and post puncture before returning to vaccine bags. 	
Temperature monitoring	An appropriate temperature monitoring device must be used to transport vaccine. Note: Vaccine shipped from Pharmacy wholesale distributors and Accuristix wholesale distributor utilizing a pre-qualified container with phase-changing technology will not have a temperature monitoring device.	
Receiving vaccine	 When a vaccine shipment is received, it must be examined and stored as specified in the product monograph. Frozen state – freezer at -25°C to -15°C Thawed state – fridge at +2°C to +8°C Read and/or stop the recording of the temperature monitoring device upon receipt to determine if it has been activated or alarmed. 	



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COLD CHAIN EXCURSIONS

Janssen (Johnson & Johnson) Vaccine

All known exposures of vaccine to temperatures outside temperature requirements as specified in the product monograph must be reported. Each cold chain excursion needs to be assessed to determine if it is a cold chain break and vaccine needs to be quarantined.

it is a cold chain break and vaccine needs to be quarantined.							
Frozen	Frozen state						
	Vaccine is to be stored at -25°C to -15°C while in a frozen state.						
	• If the temperature is warmer than -15°C, the vaccine is considered to be in the thawing stage and needs to be stored in a vaccine fridge at +2°C to +8°C. Do not refreeze.						
	• If the temperature is colder than -25°C, quarantine vaccine, mark as "DO NOT USE", and store in freezer at -25°C to -15°C until viability has been assessed.						
Pre-puncture thawed	Pre-puncture vaccine can be stored at: +2°C to +8°C for a single period of 11 months not exceeding original expiry date						
vaccine	 If the temperature is colder than +2°C or warmer than +8°C, quarantine vaccine, mark as "DO NOT USE", and store in a vaccine fridge at +2°C to +8°C until viability has been assessed. 						
	• +8°C to +25°C for 12 hours						
	 If stored for more than 12 hours, quarantine vaccine, mark as "DO NOT USE", and store in a vaccine fridge at +2°C to +8°C until viability has been assessed. If the temperature is warmer than +25°C (room temperature) within the 12 hour timeframe, quarantine vaccine, mark as "DO NOT USE", and store in a vaccine fridge at +2°C to +8°C until viability has been assessed. 						
Post-puncture thawed vaccine	Post-puncture vaccine can be stored at:						
	• +2°C to +8°C for 6 hours						
tilawed vaccine	 If the temperature is colder than +2°C within the 6 hour timeframe, quarantine vaccine, mark as "DO NOT USE", and store in a vaccine fridge at +2°C to +8°C until viability has been assessed. Post-puncture vaccine that has been stored at +2°C to +8°C is to be discarded after 6 hours and counted as wasted doses in the Alberta Vaccine Inventory system (AVI). 						
	• +8°C to +25°C for 3 hours						
	 If the temperature is warmer than +25°C within the 3 hour timeframe, quarantine vaccine, mark as "DO NOT USE", and store in a vaccine fridge at +2°C to +8°C until viability has been assessed. Post-puncture vaccine that has been stored at +8°C to +25°C is to be discarded after 3 hours and counted as wasted doses in the Alberta Vaccine Inventory system (AVI). Post-puncture vials that have been stored at +8°C to +25°C cannot be rerefrigerated. 						
	Total cumulative storage time post-puncture is 6 hours. This includes any time that the vaccine has been stored at +2°C to +8°C and at room temperature combined. After this time, the vial must be discarded.						



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Janssen (Johnson & Johnson) Vaccine

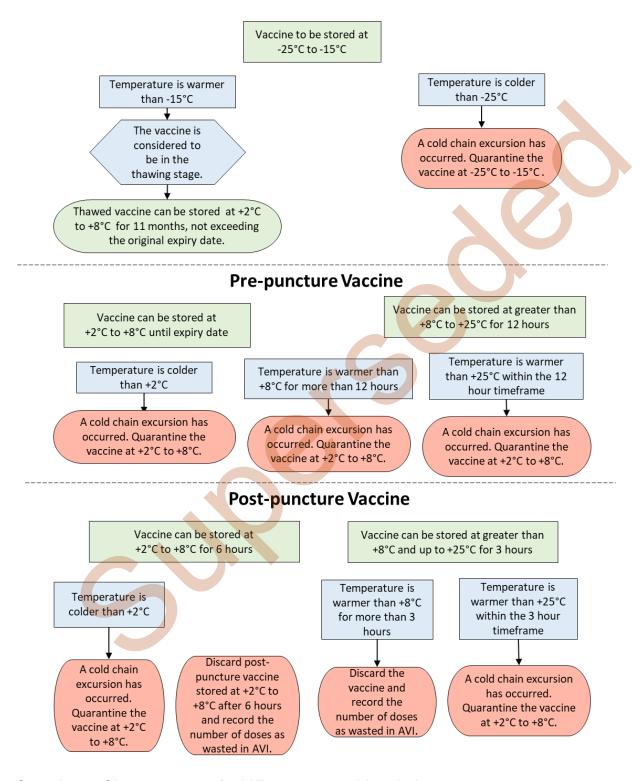
Note:

- Temperature excursions to be reported as per process outlined in <u>Alberta Vaccine Storage and Handling Policy for Provincially Funded Vaccine</u>.
- . Timeframe for reporting is within 24 hours.
- Vaccine that is determined not viable, will be discarded according to the health practitioners' standard of practice
 and must be entered into AVI as wasted using the correct reason. For more information on inventory reconciliation,
 refer to the <u>Inventory Reconciliation quick reference quide</u>.

Contact Innomar QA at 1-833-847-4270 for viability assessment and determination. See the Janssen (Johnson & Johnson) Vaccine Cold Chain Excursion Tool below.



Janssen (Johnson & Johnson) Vaccine Cold Chain Excursion Tool



Contact Innomar QA at 1-833-847-4270 for viability assessment and determination.



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After-hours contact information for temperature excursions

After-hours Reporting Best Practice

- Temperature excursion reporting outside of operation hours should be via email. Email accounts are monitored by more personnel than the phone line.
- If the request is urgent, email subject should include "URGENT:"
- Include the NOC on all after-hours temperature excursion reporting. NOC has the ability to escalate if required.

Organization	Primary Contact	Secondary Contact	Hours of Operation	After-hours Responsiveness
Pfizer Customer Service	CanadaCSVaccine@Pfizer.com	1-833-829- 2684	05:30 - 17:30. MST (M-F)	3 to 4 hours
Innomar QAModernaJanssenNovavax	QA-GMP@innomar- strategies.com	1-833-847- 4270	05:30 - 17:30 MST (M-F)	1 hr if identified as time sensitive. 2 to 4 hrs if not time sensitive.
NOC Mailbox	Vaccine NOC (PHAC/ASPC) vaccinenoc-cnovaccin@phac-aspc.gc.ca	1-613-952- 0865	24 hrs, 7 days a week	Within 1 hour
NOC Liaison	Geordie.Ironside@phac- aspc.gc.ca	1-343-572- 6999	0600 -16:00 MST (M-F)	Immediate if urgent

During regular business hours Pfizer - 1-833-829-2684

Moderna - 1-833-847-4270

Janssen - 1-833-847-4270

Novavax - 1-240-268-2000



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Temperature recording

TEMPERATURE MONITORING

The minimum, maximum, and current temperature of all refrigerators/freezers where vaccine is stored

must be monitored and recorded. The only thermometers and temperature recording devices that are acceptable for **Temperature** monitoring devices 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 These include: temperature Chart Recorders (in combination with a min/max thermometer); OR recording devices Data Loggers (downloaded twice a day); OR Alarmed Temperature Monitoring System (downloaded twice a day). 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.



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Storage and Handling Summary

	Pfizer-BioNTech Comirnaty (Grey cap) and Comirnaty Original and Omicron BA.4/BA.5 Bivalent Booster 12 plus (Grey cap and Grey label)	Pfizer-BioNTech Comirnaty 6 Months to 4 Years & 5 to 11 Years (Maroon and Orange caps [monovalent & bivalent])	Moderna Spikevax (Red Cap, Royal Blue Cap, Bivalent)	Novavax	Janssen
ULT (-90°C to -60°C)	Up to 12 months	Up to 12 months	n/a	n/a	n/a
Freezer Storage (-25°C to -15°C)	Can NOT be stored at -25°C to -15°C	Can NOT be stored at -25°C to -15°C	Until expiry date	n/a	Until expiry date
Refrigerated Storage (+2°C to +8°C)	10 weeks	10 weeks	30 days	9 months	Up to 11 months
Room Temperature Prior to dilution (up to +25°C)	12 hours	12 hours	24 hours	n/a	12 hours
Post-puncture/ After Dilution	12 hours up to +25°C	12 hours up to +25°C	24 hours up to +25°C	6 hours up to +25°C	6 hours +2°C to +8°C 3 hours +8°C to +25°C
Onward Transportation	Ultra-frozen full cartons Refrigerated full cartons or individual unpunctured vials	Ultra-frozen full cartons Refrigerated full cartons or individual unpunctured vials	 Frozen or refrigerated full cartons or individual unpunctured vials 	 Refrigerated punctured or unpunctured vials 	Refrigerated punctured or unpunctured vials

