Alberta Vaccine Storage and Handling for COVID-19 Vaccine

Revised: September 29, 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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Pfizer-BioNTech Comirnaty ULTRA-FROZEN VACCINE – Requires Dilution (Purple Cap)

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 at -90°C to -60°C until the expiry date printed on the vial, or the extended expiry date noted in the Alberta Vaccine Inventory (AVI) system.**
- **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 adding the diluent for reconstitution. (See Undiluted Thawing/Thawed section)**

See www.CVDvaccine.ca for additional information.

Storage temperature monitoring requirements	• 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 left 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.
Ultra-frozen Laboratory grade ultra-low temperature freezers	Storage at -90°C to -60°C • Long term storage until the expiry date printed on the vial, or the extended expiry date noted in AVI. • Must continuously keep temperature at -75°C within +/- 15°C in a laboratory grade ultra-low temperature freezer.
Frozen Laboratory grade freezers	Storage at -25°C to -15°C • Vials can be stored in laboratory grade freezers at -25°C to -15°C for up to 2 weeks and/or transported at -25°C to -15°C. • Vials stored at -25°C to -15°C for up to 2 weeks may be returned one time to the recommended storage temperature of -90°C to -60°C. • Total cumulative time the vials are stored and/or transported at -25°C to -15°C should be tracked and not exceed 2 weeks.

Pfizer-BioNTech Comirnaty ULTRA-FROZEN VACCINE – Requires Dilution (Purple Cap)	

Undiluted Thawing/Thawed
Storage between 2°C to +8°C
	Thawing and storage between +2°C and +8°C and thawing at room temperature
	• Can be stored at +2°C to +8°C for 31 days.
	  ○ The time in transit in the thawing/thawed state at +2°C to +8°C must be considered as part of the 31 days 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 frozen state.
	  ○ A tray can take up to 2-3 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.

Manufacturer-provided thermal shippers	The vaccine is stable in the manufacturer-provided thermal shipper for up to 30 days with appropriate handling and re-icing.

Unpacking vaccine from thermal shipper	• Do not discard the original thermal shipper or any of its components.
	• 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.
	3. Break the seal open.
	4. 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.
	  ○ **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.

Pfizer-BioNTech Comirnaty ULTRA-FROZEN VACCINE – Requires Dilution (Purple Cap)	

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 transparent tape, ensuring tape is not covering the UN label.
	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.

VACCINE TRANSPORT – Ultra-frozen Vaccine

Pfizer-BioNTech Comirnaty ULTRA-FROZEN VACCINE – Requires Dilution (Purple Cap)

Cold chain must be maintained 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
	  ○ Frozen at -25°C to -15°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 or 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.
	<u>Frozen</u>
	• Individual vials or full trays can be transported in a frozen state.
	• The product should be appropriately packed in a validated container.
	<u>Thawing/Thawed</u>
	• In extenuating circumstances only, if transportation must occur in the thawing/thawed state:
	  ○ Undiluted vials can be transported a maximum of three separate occasions in a thawing/thawed state; e.g. vaccine depot to public health office(1), public health office to outreach site(2), and outreach site to public health office(3).
	  ○ The total transportation time for the maximum allowance of three separate shipments 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 time in transit in the thawing/thawed state at +2°C to +8°C must be considered as part of the 31 days 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 to prevent contact with ice packs.
	• Do not refreeze thawed product.

Pfizer-BioNTech Comirnaty ULTRA-FROZEN VACCINE – Requires Dilution (Purple Cap)	
	Diluent • When transporting the diluent, it should be done at room temperature. It is important to ensure that it does not freeze. In addition for ultra-frozen, 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 diluted/reconstituted.
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.

COLD CHAIN EXCURSIONS – Ultra-frozen vaccine

Pfizer-BioNTech Comirnaty ULTRA-FROZEN VACCINE – Requires Dilution (Purple Cap)

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 between -60°C and -15°C (warmer than -60°C and colder than -15°C),
	  ○ the vaccine can be stored in a laboratory grade freezer at -25°C to -15°C for up to 2 weeks OR
	  ○ continue to thawing 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 -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.

Frozen state	**Frozen state** (-25°C to -15°C)
	• 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 AND it is the first time the vaccine has been stored at -25°C to -15°C
	  ○ return to -80°C to -60°C OR
	  ○ return to -25°C to -15°C OR
	  ○ continue to thawing state
	• If the temperature is between -60°C and -25°C AND the vaccine has already been returned once to -80°C to -60°C, quarantine the vaccine, mark as "DO NOT USE", and store in lab grade freezer at -25°C to -15°C until viability has been assessed. If vaccine is considered viable, count the time vaccine was between -60°C and -25°C as part of the two week time limit.
	• If the temperature is colder than -60°C AND the vaccine has already been returned once to -80°C to -60°C, quarantine the vaccine, mark as "DO NOT USE", and store in lab grade freezer at -25°C to -15°C until viability has been assessed. If vaccine is considered viable, count the time vaccine was between -60°C and -25°C as part of the two week time limit.

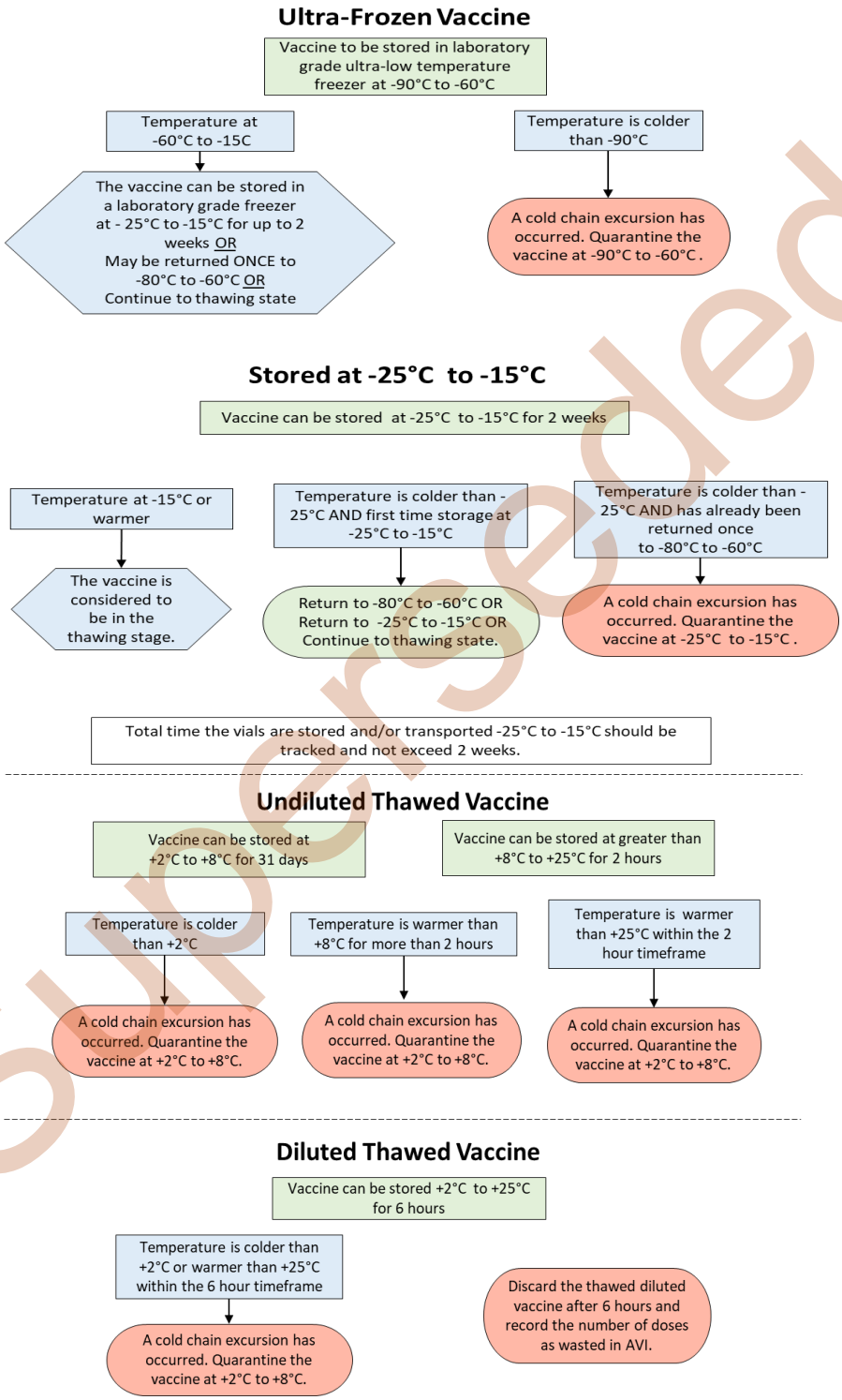
Undiluted thawed vaccine	**Undiluted thawed vaccine** can be stored at:
	• +2°C to +8°C for 31 days
	  ○ If the temperature is colder than +2°C, quarantine vaccine, mark as "DO NOT USE", and store in a vaccine fridge at +2°C to +8°C until viability has been assessed.
	• Warmer than +8°C to +25°C for 2 hours
	  ○ If stored for more than 2 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.

Pfizer-BioNTech Comirnaty ULTRA-FROZEN VACCINE – Requires Dilution (Purple Cap)	
	○ If the temperature is over +25°C (room temperature) within the 2 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	**Diluted thawed 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. ○ Diluted thawed vaccine is to be discarded after 6 hours and counted as wasted doses in the Alberta Vaccine Inventory system (AVI) using "Spoiled" category and "Failure to store" reason.
Note: • Temperature excursions to be reported as per process outlined in Alberta Vaccine Storage and Handling Policy for 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.	

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.

Pfizer-BioNTech Comirnaty COVID-19 Vaccine Cold Chain Excursion Tool (Purple Cap)



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

ULTRA-FROZEN VACCINE Pfizer-BioNTech Comirnaty – NO DILUTION (Gray Cap)

VACCINE STORAGE REQUIREMENTS

Pfizer-BioNTech Comirnaty ULTRA-FROZEN VACCINE – NO DILUTION (Gray Cap)

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.**
- **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.

Storage temperature monitoring requirements	• 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 left 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.
Ultra-frozen Laboratory grade ultra-low temperature freezers	Storage at -90°C to -60°C • Long term storage for up to 12 months from the date of manufacture. • Must continuously keep temperature at -75°C within +/- 15°C in a laboratory grade ultra-low temperature freezer.

Thawing/Thawed
Storage between 2°C to +8°C
	Thawing and storage between +2°C and +8°C and thawing at room temperature
	• Can be stored at +2°C to +8°C for up to 10 weeks.
	  ○ 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.
	• 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 frozen state.
	  ○ 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.

Manufacturer-provided thermal shippers	The vaccine is stable in the manufacturer-provided thermal shipper for up to 30 days with appropriate handling and re-icing.

Pfizer-BioNTech Comirnaty ULTRA-FROZEN VACCINE – NO DILUTION (Gray Cap)	

Unpacking vaccine from thermal shipper	• Do not discard the original thermal shipper or any of its components.
	• 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.
	3. Break the seal open.
	4. 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.
	  ○ **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.

Pfizer-BioNTech Comirnaty ULTRA-FROZEN VACCINE – NO DILUTION (Gray Cap)	
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.

VACCINE TRANSPORT – Ultra-frozen Vaccine

Pfizer-BioNTech Comirnaty ULTRA-FROZEN VACCINE – NO DILUTION (Gray Cap)

Cold chain must be maintained 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.
	<u>Thawing/Thawed</u>
	• 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 to prevent contact with ice packs.
	• Do not refreeze thawed product.
	<u>In addition for ultra-frozen and thawing/thawed vaccine:</u>
	• 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.

Pfizer-BioNTech Comirnaty ULTRA-FROZEN VACCINE – NO DILUTION (Gray Cap)	
	• 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.

COLD CHAIN EXCURSIONS – Ultra-frozen vaccine

Pfizer-BioNTech Comirnaty ULTRA-FROZEN VACCINE – NO DILUTION (Gray Cap)

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.

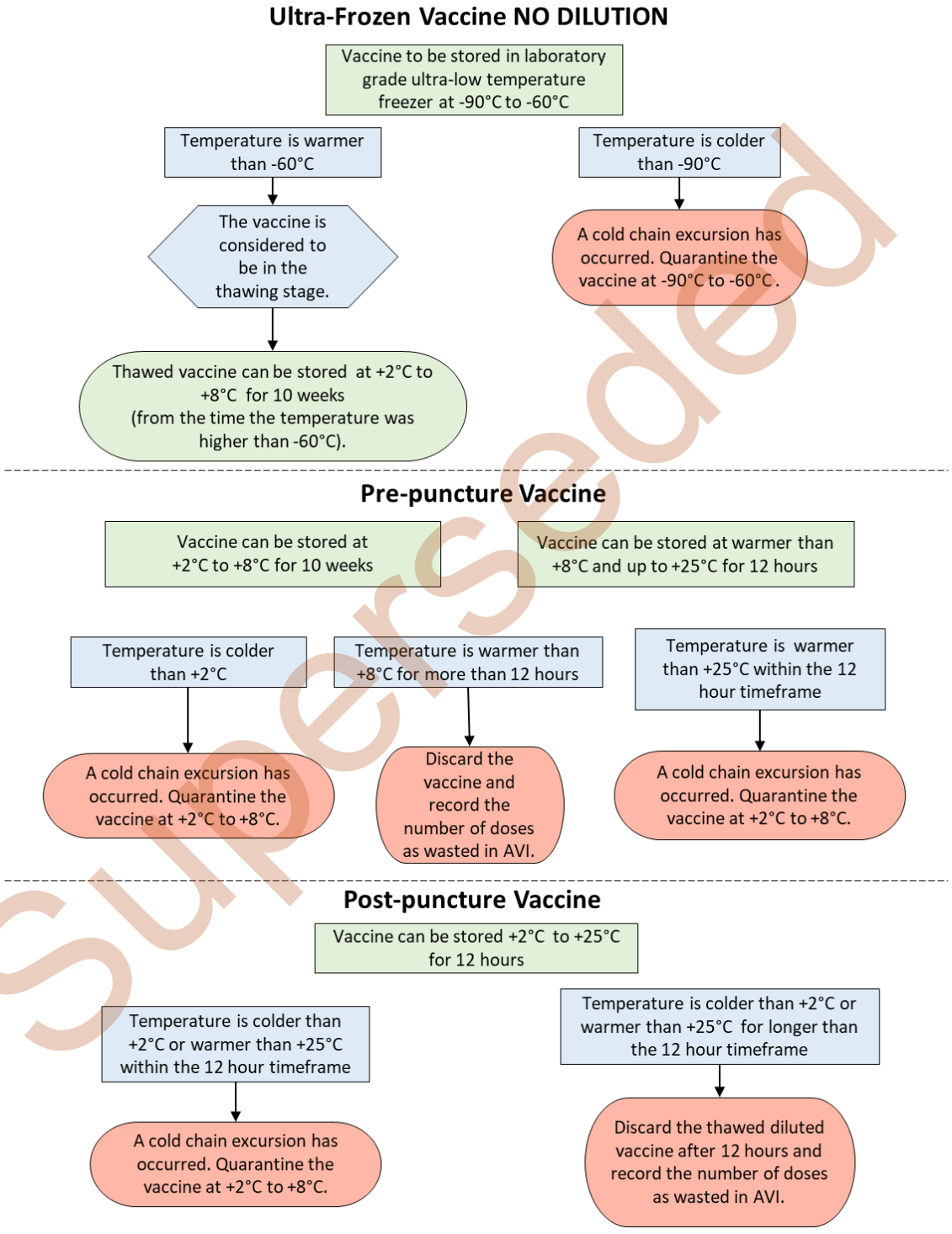
Pre-puncture vaccine	**Pre-puncture vaccine** can be stored at:
	• +2°C to +8°C for 10 weeks
	  ○ If the temperature is colder than +2°C, quarantine vaccine, mark as "DO NOT USE", and store in a vaccine fridge at +2°C to +8°C until viability has been assessed.
	• Warmer than +8°C to +25°C for 12 hours
	  ○ 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) using "Spoiled" category and "Failure to store" reason.

Post-puncture vaccine	**Post-puncture 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.
	  ○ Post-puncture vaccine is to be discarded after 12 hours and counted as wasted doses in the Alberta Vaccine Inventory system (AVI) using "Spoiled" category and "Failure to store" reason.

Note:
- Temperature excursions to be reported as per process outlined in Alberta Vaccine Storage and Handling Policy for 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.

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.

Pfizer-BioNTech Comirnaty COVID-19 Vaccine Cold Chain Excursion Tool – NO DILUTION (Gray Cap)



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

ULTRA-FROZEN VACCINE Pfizer-BioNTech Comirnaty – PEDIATRIC 6 Months to 4 Years (Maroon Cap) & 5 to 11 years (Orange Cap)

VACCINE STORAGE REQUIREMENT

Pfizer BioNTech ULTRA-FROZEN VACCINE – 6 Months to 4 Years (Maroon Cap) & 5 to 11 years (Orange Cap)

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.**
- **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 adding the diluent for reconstitution. (See Undiluted Thawing/Thawed section)**

See www.CVDvaccine.ca for additional information.

Storage temperature monitoring requirements	• 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 left 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.	
Ultra-frozen Laboratory grade ultra-low temperature freezers	Storage at -90°C to -60°C • Long term storage for up to 12 months from the date of manufacture. • Must continuously keep temperature at -75°C within +/- 15°C in a laboratory grade ultra-low temperature freezer.	
Undiluted Thawing/Thawed Storage between 2°C to +8°C	Thawing and storage between +2°C and +8°C and thawing at room temperature • Can be stored at +2°C to +8°C for up to 10 weeks. ○ 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. • 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.	
	 **Maroon Cap**	• The vaccine can be thawed in a vaccine fridge +2 to +8°C from frozen state. • A carton of 10 vials may take up to **2 hours** to thaw Once thawed, do not refreeze.
	 **Orange Cap**	• The vaccine can be thawed in a vaccine fridge +2 to +8°C from frozen state. • A carton of 10 vials may take up to **4 hours** to thaw Once thawed, do not refreeze.
	See Alberta Vaccine Storage and Handling Policy for Provincially Funded Vaccine for vaccine storage requirements.	

Pfizer BioNTech ULTRA-FROZEN VACCINE – 6 Months to 4 Years (Maroon Cap) & 5 to 11 years (Orange Cap)	
Manufacturer-provided thermal shippers	The vaccine is stable in the manufacturer-provided thermal shipper for up to 30 days with appropriate handling and re-icing.
Unpacking vaccine from thermal shipper	• Do not discard the original thermal shipper or any of its components. • 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** 11. Don dry ice PPE. 12. 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. 13. Break the seal open. 14. 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. ○ **Aerobox:** Gently remove the entire lid, with the temperature-monitoring device, from the inner lid. 15. Press and hold the stop button of the temperature-monitoring device for at least **5 seconds.** 16. Remove the dry ice pod. 17. 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.** 18. Immediately store the vaccine in the ultra-low-temperature freezer. Keep tray at room temperature for less than 5 minutes. 19. Dispose of dry ice (see 'Disposal of dry ice' section below). 20. 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.

Pfizer BioNTech ULTRA-FROZEN VACCINE – 6 Months to 4 Years (Maroon Cap) & 5 to 11 years (Orange Cap)	
	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.

VACCINE TRANSPORT – Ultra-frozen Vaccine

Pfizer BioNTech ULTRA-FROZEN VACCINE – 6 Months to 4 Years (Maroon Cap) & 5 to 11 years (Orange Cap)	
Cold chain must be maintained 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.
	<u>Thawing/Thawed</u>
	• 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 to prevent contact with ice packs.
	• Do not refreeze thawed product.
	<u>Diluent</u>
	• When transporting the diluent, it should be done at room temperature. It is important to ensure that it does not freeze.
	<u>In addition for ultra-frozen and thawing/thawed vaccine:</u>
	• 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 diluted/reconstituted.

Pfizer BioNTech ULTRA-FROZEN VACCINE – 6 Months to 4 Years (Maroon Cap) & 5 to 11 years (Orange Cap)	
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.

COLD CHAIN EXCURSIONS – Ultra-frozen vaccine

Pfizer BioNTech ULTRA-FROZEN VACCINE – 6 Months to 4 Years (Maroon Cap) & 5 to 11 years (Orange Cap)

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.

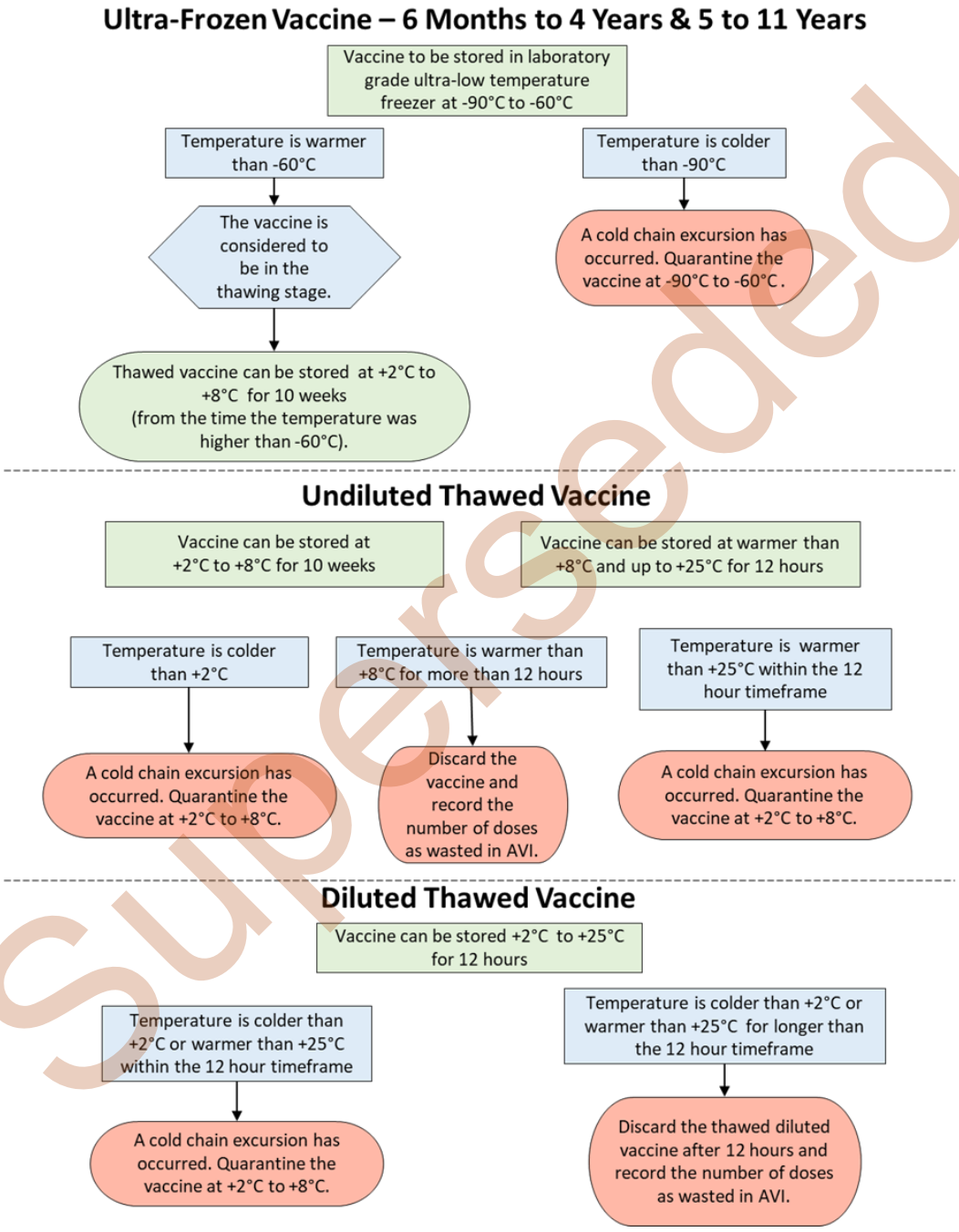
Undiluted thawed vaccine	**Undiluted thawed vaccine** can be stored at:
	• +2°C to +8°C for 10 weeks
	  ○ If the temperature is colder than +2°C, quarantine vaccine, mark as "DO NOT USE", and store in a vaccine fridge at +2°C to +8°C until viability has been assessed.
	• Warmer than +8°C to +25°C for 12 hours
	  ○ 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) using "Spoiled" category and "Failure to store" reason.

Diluted thawed vaccine	**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) using "Spoiled" category and "Failure to store" reason.

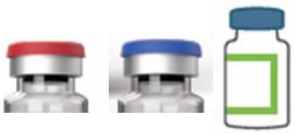
Note:
- Temperature excursions to be reported as per process outlined in Alberta Vaccine Storage and Handling Policy for Provincially Funded Vaccine.
- Timeframe for reporting is within 24 hours.
- Vaccine that is determined not viable, is to be discarded according to the health practitioners' standard of practice and must be entered into AVI as wasted using the correct reason.

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.

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



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



FROZEN VACCINE Moderna Spikevax (Red Cap, Royal Blue Cap, Bivalent)

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

Vaccines that require storage at -20°C
Vaccines should remain in the freezer until ready to immunize.
Store at -25°C to -15°C. Stable in laboratory grade freezer until date of expiration.
Protect from light.

Storage temperature monitoring requirements	• 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. • Must have adjustable alarm set points/range. • 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 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 (Do NOT refreeze once 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.		
	Vaccine can be thawed in two ways (refrigerated or at room temperature) and thaw time varies depending on formulation (red cap or royal blue cap/bivalent).		
		Thaw time under refrigeration (+2°C to +8°C)	**Thaw time at room temperature (+15°C to +25°C)**
	 **Red Cap**	• 2 hours and 30 minutes • After thawing, let vial stand at room temperature for 15 minutes before administering	• 1 hour
	 **Royal Blue Cap**	• 2 hours • After thawing, let vial stand at room temperature for 15 minutes before administering	• 45 minutes
	 **Royal Blue Cap/Green Label**		

VACCINE TRANSPORT – Frozen Vaccine

Moderna Spikevax FROZEN VACCINE (Red Cap, Royal Blue Cap & 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.
	
	<u>Frozen</u>
	• 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,
	  ○ Prevent movement of the vials in the container, and
	  ○ Keep the vaccine vials upright.
	
	<u>Thawing/thawed</u>
	• If transportation occurs in the thawing/thawed state:
	  ○ Unpunctured vials can be transported a maximum of three separate occasions in a thawing/thawed state; e.g. vaccine depot to public health office(1), public health office to outreach site(2), and outreach site to public health office(3).
	  ○ The total transportation time for the maximum allowance of three separate shipments 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.
	
	<u>In addition for frozen and thawing/thawed vaccine</u>:

Moderna Spikevax FROZEN VACCINE (Red Cap, Royal Blue Cap & Bivalent)	
	• 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. • 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.

COLD CHAIN EXCURSIONS – Frozen Vaccine

Moderna Spikevax FROZEN VACCINE (Red Cap, Royal Blue Cap & 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.

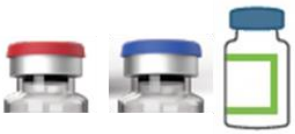
Pre-puncture thawed vaccine	**Pre-puncture thawed vaccine** can be stored at:
	• +2°C to +8°C for 30 days
	  ○ If the temperature is colder than +2°C, quarantine vaccine and mark as "DO NOT USE", and store in a vaccine fridge at +2°C to +8°C until viability has been assessed.
	• +8°C to +25°C for 24 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) using "Spoiled" category and "Failure to store" reason.
	  ○ 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) using "Spoiled" category and "Failure to store" reason.

Note:

- Temperature excursions to be reported as per process outlined in Alberta Vaccine Storage and Handling Policy for Provincially Funded Vaccine.
- 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.

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



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 warmer than -15°C

The vaccine is considered to be in the 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)

Temperature is colder than -50°C

A cold chain excursion has occurred. Quarantine the vaccine at -25°C to -15°C .

Pre-Puncture Thawed Vaccine

Vaccine can be stored at +2°C to +8°C for 30 days

Vaccine can be stored at greater than +8°C and up to +25°C for 24 hours

Temperature is colder than +2°C

A cold chain excursion has occurred. Quarantine the vaccine at +2°C to +8°C.

Temperature is warmer than +8°C for more than 24 hours

Discard the vaccine and record the number of doses as wasted in AVI.

Temperature is warmer than +25°C within the 24 hour timeframe

A cold chain excursion has occurred. Quarantine the vaccine at +2°C to +8°C.

Post-Puncture Thawed Vaccine

Vaccine can be stored at +2°C to +25°C for 24 hours

Temperature is colder than +2°C or warmer than +25°C within the 24 hour timeframe

A cold chain excursion has occurred. Quarantine the vaccine at +2°C to +8°C.

Discard the post-puncture thawed vaccine after 24 hours and record the number of doses as wasted in AVI.

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

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 Alberta Vaccine Storage and Handling Policy for Provincially Funded Vaccine for vaccine storage requirements.

VACCINE TRANSPORT

Novavax Vaccine (+2°C to +8°C)

See Alberta Vaccine Storage and Handling Policy for Provincially Funded Vaccine for vaccine transportation requirements.

Container Temp. Monitoring Receiving	See Alberta Vaccine Storage and Handling Policy for Provincially Funded Vaccine 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.

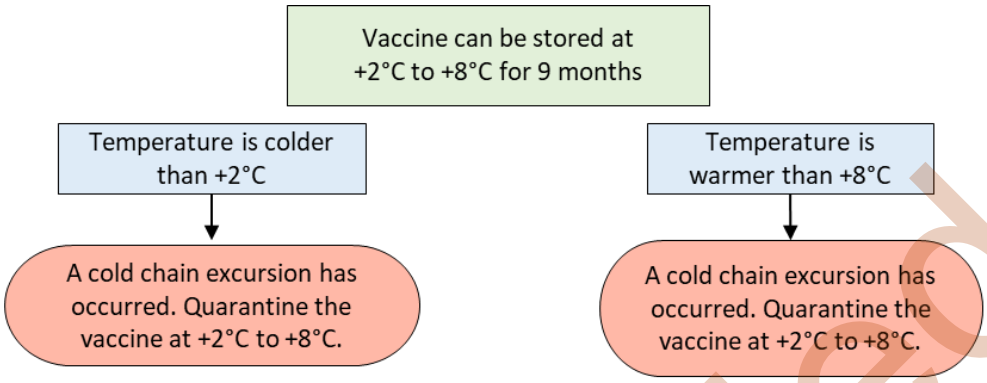
Vaccine that require storage between +2°C and +8°C)	**Pre-puncture vaccine** can be stored at:
	• +2°C to +8°C for 9 months
	  ○ If the temperature is colder than +2°C or warmer than +8°C quarantine vaccine and mark as “DO NOT USE”, and store in a vaccine fridge at +2°C to +8°C until viability has been 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) using “Spoiled” category and “Failure to store” reason.

Note:

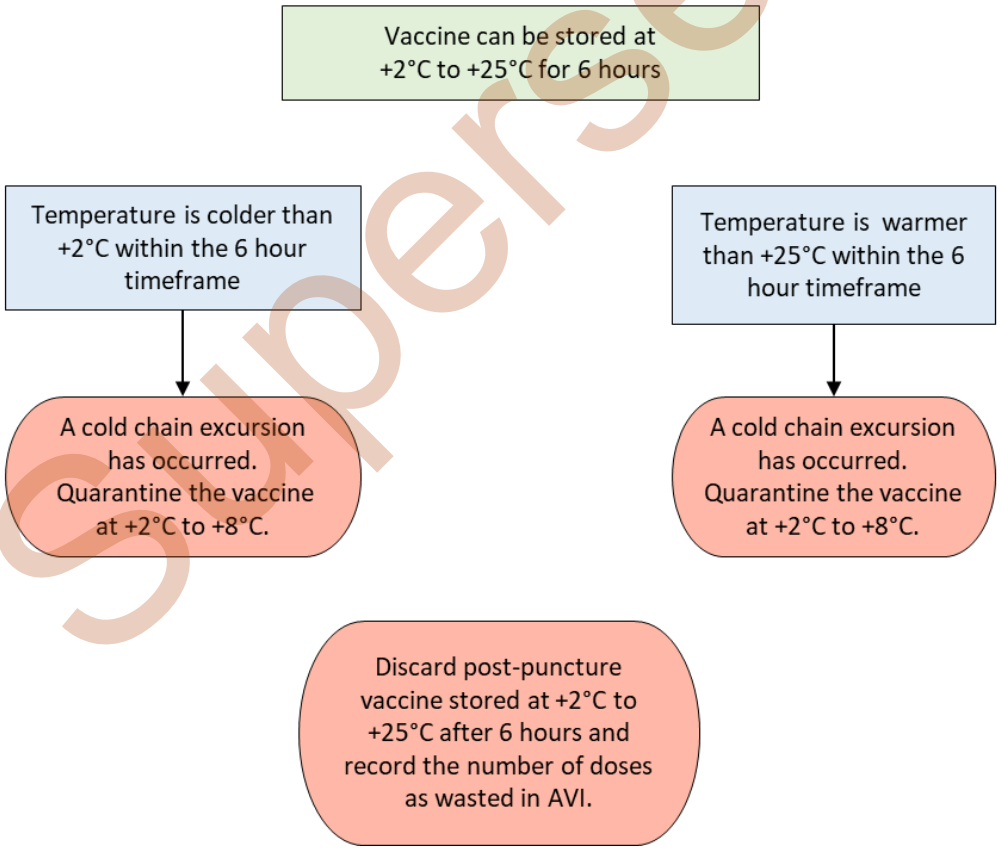
- Temperature excursions are to be reported as per process outlined in Alberta Vaccine Storage and Handling Policy for Provincially Funded Vaccine.
- Timeframe for reporting is within 24 hours**.**
- Vaccine that is determined not viable, will be discarded according to the health practitioners' standard of practice and must be entered into AVI as wasted using the correct reason.

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

Novavax Vaccine Cold Chain Excursion Tool



Post-puncture Vaccine



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

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 monitoring requirements	• 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. • Must have adjustable alarm set points/range. • 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 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
	• Can be stored at +2°C to +8°C for a single period of up to 11 months, not exceeding the original expiry date.
	• When moving the product from frozen state to a refrigerator at +2°C to +8°C, the updated expiry date must be written on the carton and the vial label. The original 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.

VACCINE TRANSPORT

Janssen (Johnson & Johnson) Vaccine

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.

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.

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 vaccine	**Pre-puncture vaccine** can be stored at:
	• +2°C to +8°C until expiry date
	  ○ 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
	  ○ 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) using "Spoiled" category and "Failure to store" reason.
	• +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) using "Spoiled" category and "Failure to store" reason.
	  ○ Post-puncture vials that have been stored at +8°C to +25°C cannot be re-refrigerated.
	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.

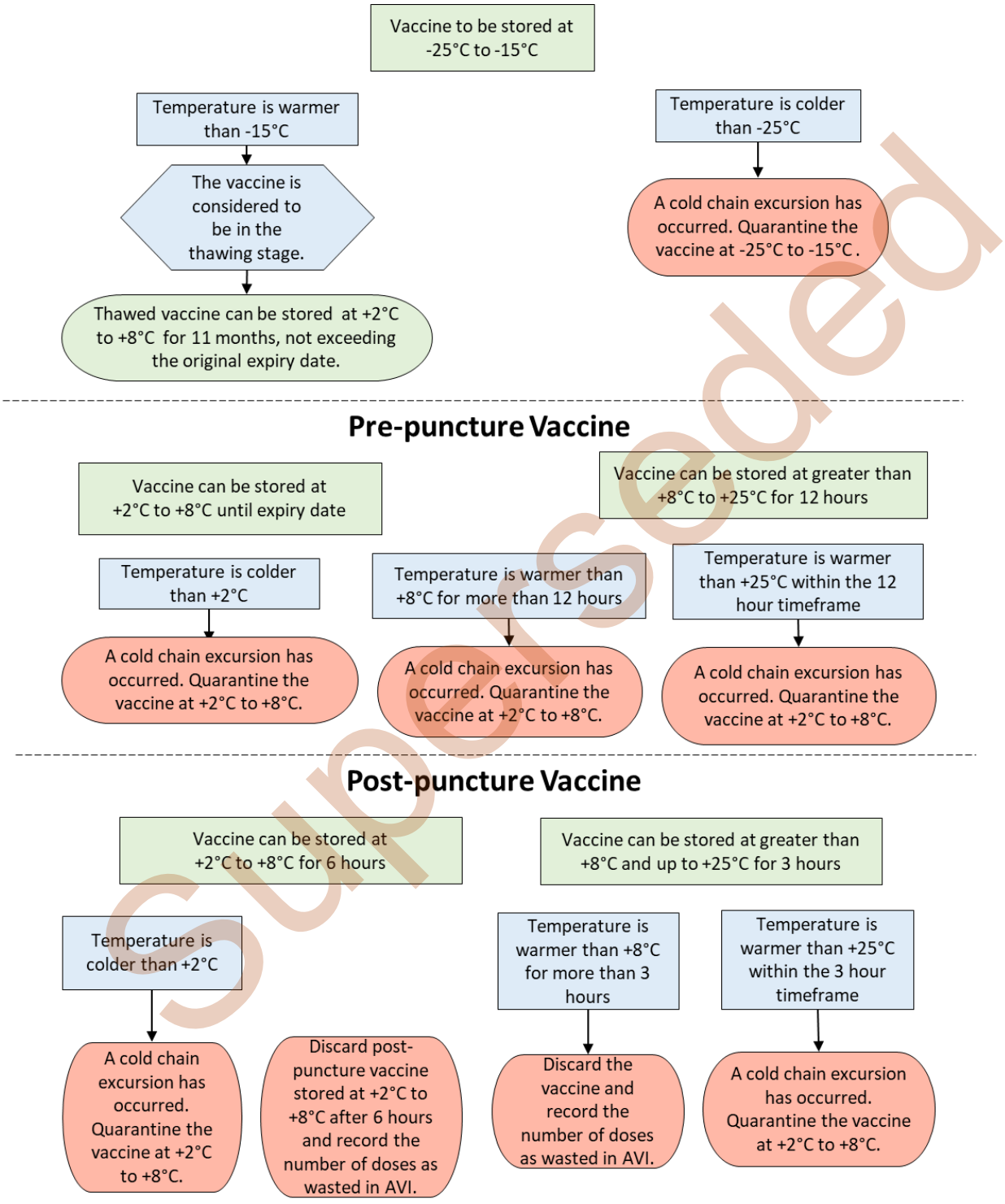
Janssen (Johnson & Johnson) Vaccine

Note:

- Temperature excursions to be reported as per process outlined in Alberta Vaccine Storage and Handling Policy for Provincially Funded Vaccine.
- 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.

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.

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 QA • Moderna • Janssen • Novavax	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	PHAC.vaccine.NOC-CNO.vaccin.ASPC@canada.ca	1-613-952-0865	24 hrs, 7 days a week	Within 1 hour
NOC Liaison	patrick.reid@canada.ca	1-613-295-5491	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

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.

Storage and Handling Summary

	Pfizer-BioNTech Comirnaty 12 plus (Purple cap)	**Pfizer-BioNTech Comirnaty 12 plus** (Gray cap)	**Pfizer-BioNTech Comirnaty 6 Months to 4 Years & 5 to 11 Years** (Maroon and Orange cap)	**Moderna Spikevax** (Red Cap, Royal Blue Cap, Bivalent)	**Novavax**	**Janssen**
ULT (–90°C to – 60°C)	Until the expiry printed on vial, or extended expiry in AVI	Up to 12 months	Up to 12 months	n/a	n/a	n/a
Freezer Storage (-25°C to -15°C)	Two weeks	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)	31 days	10 weeks	10 weeks	30 days	9 months	Up to 11 months
Room Temperature Prior to dilution (up to +25°C)	2 hours	12 hours	12 hours	24 hours	n/a	12 hours
Post-puncture/ After Dilution	6 hours up to +25°C	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 • Frozen vials • Refrigerated full cartons or individual unpunctured vials	• 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