# Alberta Vaccine Storage and Handling for COVID-19 Vaccine

Revised: February 26, 2021

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

**Objectives**:

- Protect vaccine safety and efficacy;
- 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 provincially funded vaccines; and
- Cold chain (storage, transport, and handling) requirements for staff and immunizers in order to maintain the safety and efficacy of provincially funded vaccine.



**Contents**

# Alberta Vaccine Storage and Handling Policy for COVID-19 Vaccine

February 2021

## ULTRA-FROZEN VACCINE Pfizer BioNTech

### VACCINE STORAGE REQUIREMENTS

**Vaccines that require storage at -70°C**

**Minimize exposure to room light, and avoid exposure to direct sunlight and UV light.**

- **Thawed vials can be handled in room light conditions.**

**Vaccines should remain in the freezer until ready to immunize.**

**Vaccine can be stored at -80°C to -60°C for 6 months in a laboratory grade ultra-low temperature freezer.**

**NOTES:**

- **Vaccine must be thawed prior to adding the diluent for reconstitution.**
- **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 www.CVDvaccine.ca for additional information.**

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| **Laboratory grade ultra-low temperature freezers**<br>**(Ultra-frozen)** | • Must continuously keep temperature at -70°C within +/- 10°C.<br>• 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.<br>• Must have adjustable alarm set points/range.<br>• Should have adjustable temperature set points or temperature controls.<br>• Should have a digital temperature display on front that displays current temperature to 1°C resolution. |
| | Undiluted Thawing/Thawed :<br>• See Alberta Vaccine Storage and Handling Policy for Provincially Funded Vaccine for vaccine storage requirements.<br>• Can be stored at +2°C to +8°C for 5 days<br>• The time in transit in the thawing/thawed state at +2°C to +8°C must be considered as part of the 5 days allowed for storage at refrigerator temperatures. |
| **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.<br>• 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.<br>• The thermal shippers can weigh up to 36.5 kg (81 lbs) when full and should be opened on the floor.<br>**Steps for unpacking the thermal shipper**<br>1. Don dry ice PPE.<br>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.<br>3. Break the seal open.<br>4. When you open the container you will see a temperature monitoring device embedded in the foam lid.<br>  ○ **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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| **Unpacking vaccine from thermal shipper (cont.)** | ○ **Aerobox**: Gently remove the entire lid, with the temperature-monitoring device, from the inner lid.<br>5. Press and hold the stop button of the temperature-monitoring device for **5 seconds.**<br>6. Remove the dry ice pod.<br>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.**<br>8. Immediately store the vaccine in the ultra-low-temperature freezer. Keep tray at room temperature for less than 5 minutes.<br>9. Dispose of dry ice (see 'Disposal of dry ice' section below).<br>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.<br>○ **Softbox** - apply the preprinted return shipping label over the existing shipping label.<br>○ **AeroSafe** - follow instructions on the inner flap of the thermal shipper to ensure the return label is facing outside.<br>• Elements required to be returned (**Softbox** and **AeroSafe**):<br>○ Temperature-monitoring device<br>○ Foam lid (remains attached to box)<br>○ Dry ice pod<br>○ Box that holds the vial trays<br>• When the thermal shipper is ready to be returned and all the components are inside, seal it with tape.<br>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.<br>• 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.<br>• Work in a well-ventilated space, as asphyxiation is a main hazard of dry ice.<br>• 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.<br>• Wear safety glasses with side shields, safety goggles or a face shield.<br>• 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.<br>• See the product's Material Safety Data Sheet (MSDS) for more information.<br>• 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.<br>• DO NOT leave dry ice in an unsecured area.<br>• DO NOT drain or flush in toilet.<br>• DO NOT dispose in the trash.<br>• DO NOT place in a closed area, such as an airtight container or walk-in cooler. |

## VACCINE TRANSPORT – Ultra Frozen Vaccine

| Cold chain must be maintained during transport to another location. | |
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| **Container** | Manufacturer-provided thermal shippers or ultra-low portable freezers allow 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.<br>• 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:<br>  ○ Ultra-frozen state at -80°C to -60°C (can be as cold as -90°C) OR<br>  ○ Thawed state at +2°C to +8°C.<br>• First choice. If the vaccine must be transported, the manufacturer strongly recommends transporting the vaccine in the ultra-frozen state.<br><u>Ultra-frozen</u><br>• Only full trays in their original carton (not individual vials) can be transported in an ultra-frozen state.<br>• 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.<br>• The ultra-frozen product should be appropriately packed in a validated container to prevent contact with the dry ice.<br><u>Thawing/Thawed</u><br>• Second choice. If transportation must occur in the thawing/thawed state, the total transportation time should be no longer than 6 hours.<br>  ○ Undiluted thawed vials can be transported from one site to another (e.g. for outreach) as long as the total transportation time does not exceed 6 hours.<br>  ○ This time can be extended to 12 hours in extenuating circumstances e.g. vehicle breakdown, poor road conditions. This would not be routine practice.<br>• The time in transit in the thawing/thawed state at +2°C to +8°C must be considered as part of the 5 days allowed for storage at refrigerator temperatures.<br>• Single vials can be transported in a thawing/thawed undiluted state.<br>• The thawing/thawed product should be appropriately packed in a validated container to prevent contact with ice packs.<br>• Do not refreeze thawed product.<br><u>Diluent</u><br>• When transporting the diluent, it should be done at room temperature. It is important to ensure that it does not freeze.<br><u>In addition for ultra-frozen and thawing/thawed vaccine:</u><br>• Label the container as “Fragile: Handle with Care, Do Not Drop” and “Temperature Sensitive”.<br>• Keep the vaccine vials upright.<br>• As much care as possible should be taken to minimize movement during onward transportation both within the container and the vehicle.<br>• The temperature must be maintained and recorded during transport.<br>• Record the transportation locations, dates and times, including the duration of time in transit.<br>• Do not transport the vaccine at room temperature.<br>• Do not transport vials that have been diluted/reconstituted. |

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| **Temperature monitoring** | An appropriate temperature monitoring device must be used to transport vaccine. |
| **Receiving vaccine** | • When a vaccine shipment is received, it must be examined and stored as specified in the product monograph.<br>  ○ Ultra-frozen state – ultra-low temperature freezer at -80°C to -60°C.<br>  ○ Thawed state – fridge at +2°C to +8°C.<br>• 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

**Cold chain must be maintained during transport to another location.**

Each cold chain excursion needs to be assessed to determine if it is a cold chain break and whether vaccine needs to be quarantined.

**Ultra-frozen vaccine**

**Ultra-frozen state**

- Vaccine is to be stored at -80°C to -60°C in a laboratory grade ultra-low temperature freezer while in a frozen state.
- If the temperature is higher 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 lower than -90°C, quarantine the vaccine, mark as "DO NOT USE", and store in an ultra-low freezer at -80°C to -60°C until viability has been assessed.

**Undiluted thawed vaccine** can be stored at:

- +2°C to +8°C for 5 days
  - If the temperature is lower 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.
- Greater than +8°C to +25°C for 2 hours
  - If stored for more than 2 hours, discard the vaccine and waste out the number of doses using 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 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** can be stored at:

- +2°C to +25°C for 6 hours
  - If the temperature is less than +2°C or more 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.

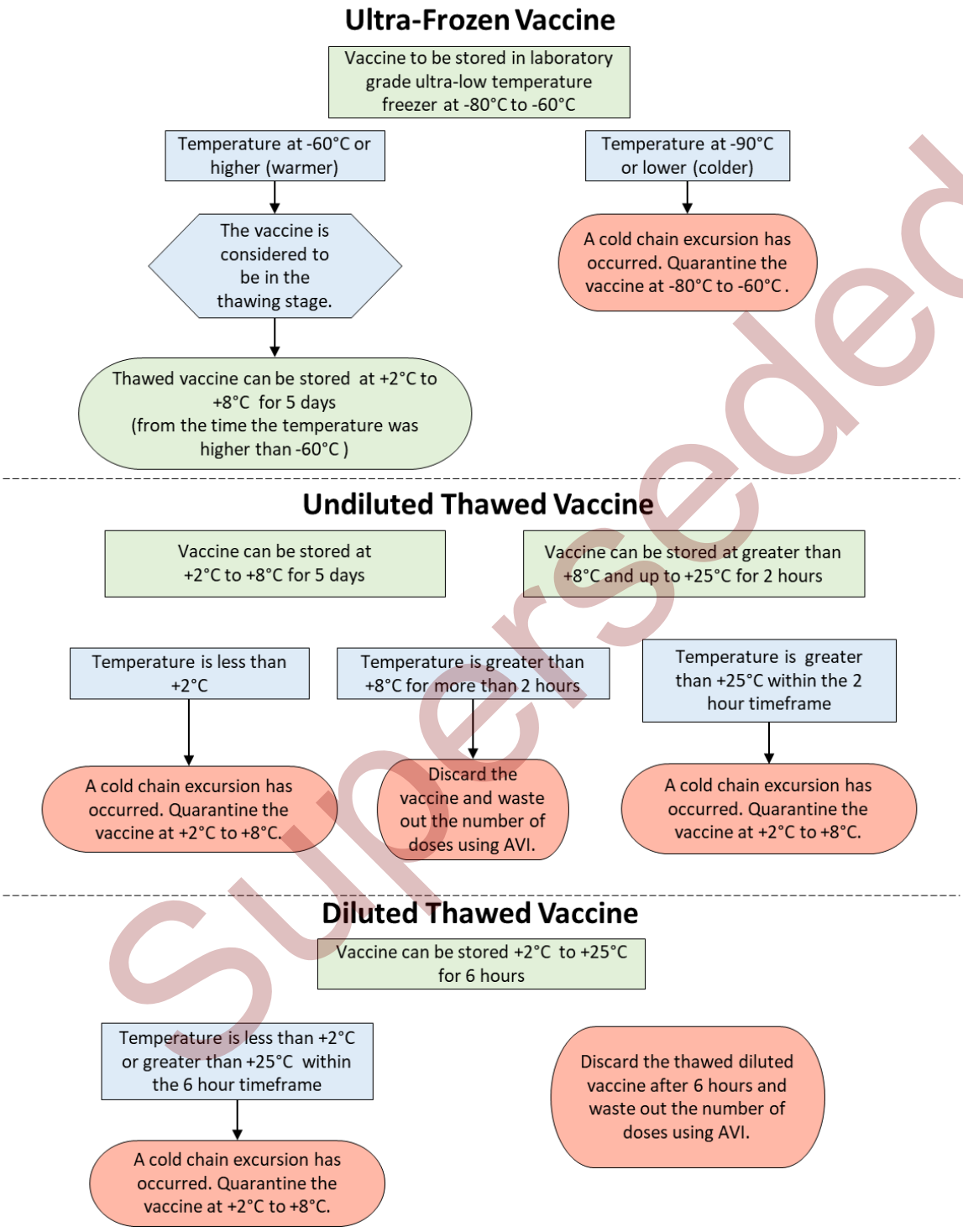
Notes:

- 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, 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 COVID-19 vaccine Cold Chain Excursion Tool below.

## Pfizer-BioNTech COVID-19 Vaccine Cold Chain Excursion Tool




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

# FROZEN VACCINE Moderna

## VACCINE STORAGE REQUIREMENTS

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| **Vaccines that require storage at -20°C**<br>**Vaccines should remain in the freezer until ready to immunize.**<br>**Store at -25°C to -15°C. Stable in laboratory grade freezer until date of expiration.**<br>**Vaccine can be thawed in two ways:**<br>• **From the freezer to room temperature (+15°C to +25°C), thaw for 1 hour from frozen state.**<br>• **From the freezer to a vaccine fridge (+2°C to +8°C); thaw for 2 hours and 30 minutes from frozen state. Let vial stand at room temperature for 15 minutes before administering.** | |
| **Laboratory grade freezers**<br>**(Frozen vaccine)** | • Must continuously keep temperature at -20°C within +/- 5°C.<br>• 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.<br>• Must have adjustable alarm set points/range.<br>• Should have adjustable temperature set points/temperature controls.<br>• Should have a digital temperature display on front that displays current temperature to 1°C degrees resolution. |
| | Pre-Puncture Thawing/Thawed :<br>• See Alberta Vaccine Storage and Handling Policy for Provincially Funded Vaccine.for vaccine storage requirements.<br>• Can be stored at +2°C to +8°C for 30 days<br>• 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 TRANSPORT – Frozen Vaccine

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| **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. The manufacturer recommends transporting the vaccine in the frozen state at -25°C to -15°C and as cold as -40°C.<br>• **Do not use dry ice.**<br>• 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).<br>• Full cartons or individual vials can be transported in either the frozen or thawed state.<br>Frozen<br>• Transfer the vaccine from the freezer to the container rapidly. Keep tray at room temperature for less than 5 minutes to prevent thawing.<br>• The product should be appropriately packed in a validated container in order to:<br>  ○ Prevent contact with ice packs,<br>  ○ Prevent movement of the vials in the container, and<br>  ○ Keep the vaccine vials upright. |

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| **Onward transportation (cont.)** | Thawing/thawed<br>• If transportation must occur in the thawing/thawed state, the total transportation time should be no longer than 6 hours.<br>  ○ Pre-puncture thawed vials can be transported from one site to another (e.g. for outreach) as long as the total time does not exceed 6 hours.<br>  ○ This time can be extended to 12 hours in extenuating circumstances e.g. vehicle breakdown, poor road conditions. This would not be routine practice.<br>• The product should be appropriately packed in a validated container in order to:<br>  ○ Prevent contact with ice packs,<br>  ○ Prevent movement of the vials in the validated container, and<br>  ○ Keep the vaccine vials upright.<br>• As much care as possible should be taken to minimize extra movement in the thawed state<br>  ○ The container should be secured in the vehicle so that it does not move around.<br>• 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.<br>In addition for frozen and thawing/thawed vaccine:<br>• Label the container as “Fragile: Handle with Care, Do Not Drop” and “Temperature Sensitive”.<br>• The temperature must be maintained and recorded during transport.<br>• Record the transportation locations, dates and times, including the duration of time in transit.<br>• Do not refreeze thawed product<br>• Do not transport the vaccine at room temperature.<br>• Do not transport vials that have been punctured. |
| **Temperature monitoring** | An appropriate temperature monitoring device must be used to transport vaccine. |
| **Receiving vaccine** | • When a vaccine shipment is received, it must be examined and stored as specified in the product monograph.<br>  ○ Frozen state – freezer at -25°C to -15°C<br>  ○ Thawed state – fridge at +2°C to +8°C<br>• 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

**Cold chain must be maintained during transport to another location.**

Each cold chain excursion needs to be assessed to determine if it is a cold chain break and vaccine needs to be quarantined.

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| **Frozen vaccine** | **Frozen state**<br>• Vaccine is to be stored at -25°C to -15°C while in a frozen state.<br>• If the temperature is higher 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.<br>• If the temperature is lower than -40°C, quarantine vaccine, mark as "DO NOT USE", and store in freezer at -25°C to -15°C until viability has been assessed.<br>**Pre-puncture thawed vaccine** can be stored at:<br>• +2°C to +8°C for 30 days<br>  ○ If the temperature is lower 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.<br>• +8°C to +25°C for 12 hours<br>  ○ If the temperature is greater than +8°C for more than 12 hours, discard vaccine and count as wasted doses in the Alberta Vaccine Inventory system (AVI) using "Spoiled" category and "Failure to store" reason.<br>  ○ 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.<br>**Post-puncture thawed vaccine** can be stored at:<br>• +2°C to +25°C for 6 hours<br>  ○ If the temperature is less than +2°C or more 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.<br>  ○ Post-punctured thawed vaccine is to be discarded after 6 hours and count as wasted doses in the Alberta Vaccine Inventory system (AVI) using "Spoiled" category and "Failure to store" reason. |

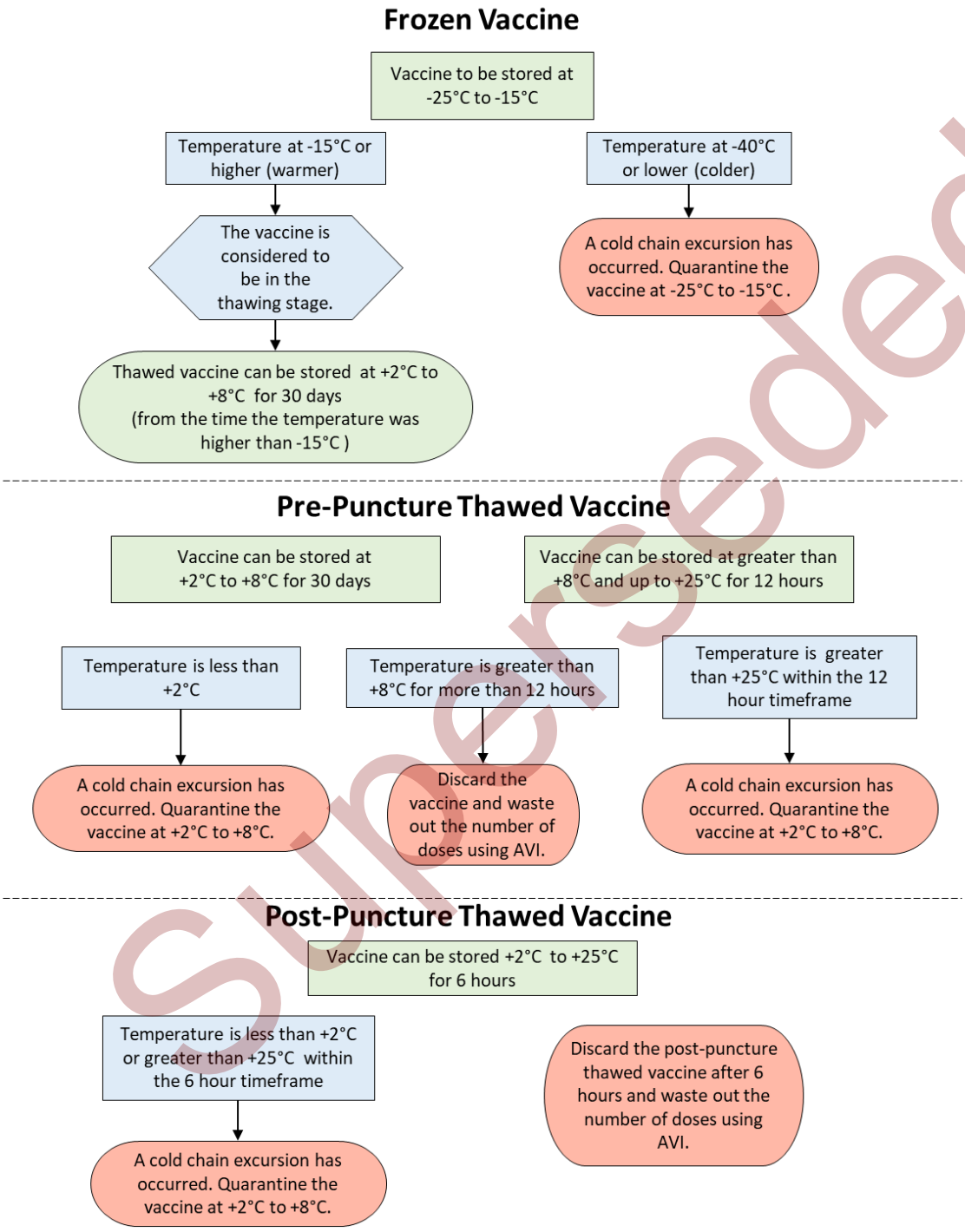
Notes:

- 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 COVID-19 vaccine Cold Chain Excursion Tool below.

## Moderna COVID-19 Vaccine Cold Chain Excursion Tool




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

## After hour 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 (for Moderna vaccine) | 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.

## TEMPERATURE MONITORING

| **The minimum, maximum, and current temperature of all refrigerators/freezers where vaccine is stored must be monitored and recorded.** | |
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| **Temperature monitoring devices** | The only thermometers and temperature recording devices that are acceptable for monitoring the temperature within vaccine storage units are:<br>• Minimum and Maximum Thermometer.<br>• Data Logger - must function like a min/max device and therefore the minimum, maximum, and current temperatures need to be downloaded twice a day.<br>• 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.<br>• Chart **Recorder in combination with a min/max thermometer**<br>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.<br>**Fluid-filled bio-safe liquid (bottle) thermometers, bi-metal stem thermometers, and household thermometers are NOT acceptable**. |
| **Continuous temperature recording devices** | These include:<br>• Chart Recorders (in combination with a min/max thermometer); OR<br>• Data Loggers (downloaded twice a day); OR<br>• 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. |

## Questions

Pfizer COVID-19 Vaccine Storage and Handling

1. Question: Undiluted thawed vaccine has been at room temperature for 1 hour and 45 minutes. Can it be placed back in the fridge and stored at 2°C to 8°C up to 5 days?
   OR once committed to room temperature does it need to be diluted within that 2 hours and administered within 6 hours?
   Answer: It can be put back in the fridge and stored at 2°C to 8°C up to 5 days but it will be important to keep track of **total cumulative time at 2°C to 8°C and at room temperature**.
   This is important to apply as when the vial is removed for use, it will only have 15 minutes remaining at room temperature prior to being diluted for use.
2. Question: Can frozen or thawing/thawed Pfizer vaccine be transported from the point of administration/depot site for use and then stored there?
   Answer: Yes as per Pfizer Redistribution Considerations dated 2020 December 31 as long as the specifications and conditions listed in the ULTRA-FROZEN VACCINE Pfizer BioNTech 'Onward Transportation' section are followed.
3. Question: Can frozen or thawing/thawed Pfizer vaccine be transported from a secondary site to another secondary site?
   Answer: Yes, providing the specifications and conditions listed in the ULTRA-FROZEN VACCINE Pfizer BioNTech 'Onward Transportation' section are followed and the total combined transportation time does not exceed 6 hours.

## References

1. Pfizer-BioNTech COVID-19 Vaccine. http://www.cvdvaccine.ca/
2. Pfizer-BioNTech. (2020 December 9). COVID-19 mRNA Vaccine, Suspension for Intramuscular Injection *Product Monograph*. https://covid-vaccine.canada.ca/info/pdf/pfizer-biontech-covid-19-vaccine-pm1-en.pdf.
3. Pfizer Training Resources. 2020 December 8.
4. Redistribution Considerations for Pfizer-BioNTech COVID-19 Vaccine. 2020 December 31.
5. Moderna COVID-19 Vaccine - Resources for Healthcare Professionals and Patients. https://www.modernacovid19global.com/ca
6. Moderna (2020 December 23) Moderna COVID-19 Vaccine, mRNA-1273 SARS-CoV-2 vaccine, Suspension for intramuscular injection: *Product Monograph*. https://covid-vaccine.canada.ca/info/pdf/moderna-covid-19-vaccine-pm1.pdf
7. Moderna – Memo to Health Canada. Transport of Moderna COVID-19 Vaccine in Exceptional Circumstances. 2020 December 23.