



COVID-19 Vaccine: Storage and Handling Guide for Pfizer COMIRNATY Vaccines

November 25, 2021



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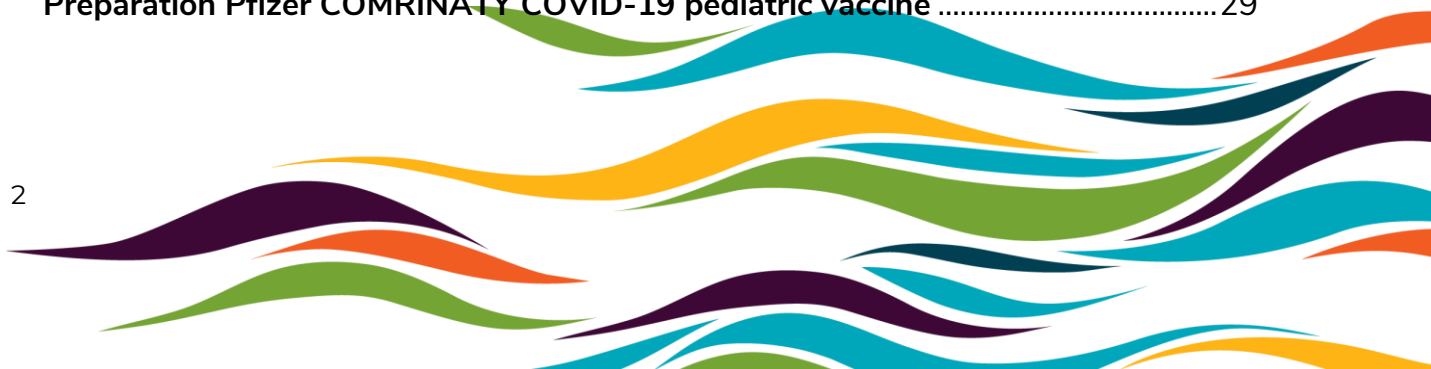
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Introduction

To preserve vaccine safety, quality and efficacy proper storage, handling and transportation conditions must be maintained throughout the vaccine supply chain, from manufacturing to delivery to administration.



General Vaccine Information

- The most up to date information on all vaccines and immunization practices in the Yukon can be found in the [Yukon Immunization Manual](#).
 - Vaccine product information is found in [Section 8 Biological Products](#)
 - It is the responsibility of the immunizer to review and understand the product information page prior to administering vaccines.
- The two Pfizer COMIRNATY COVID-19 vaccines are mRNA vaccines with no adjuvant and no preservatives.
- This document outlines the differences between these two products and the storage and handling requirements for each
 - The colour **purple** will be used for the Pfizer Comirnaty adolescent/adult 30mcg vaccine formula
 - The colour **orange** will be used for the Pfizer Comirnaty pediatric 10mcg vaccine formula

Temperature is one of the most important parameters to control in the transportation, handling, and storage of this vaccine.



Table 1: Important Differences between the two COMIRNATY Formulations/Presentations

Vial Colour	Pfizer COMIRNATY COVID-19 adolescent/adult vaccine product 	Pfizer COMIRNATY COVID-19 pediatric vaccine product 
Age Range	12 years of age and older	5 to <12 years of age
Dilution Required	Yes	Yes
Amount of diluent required per vial (0.9% Sodium Chloride Injection, USP)	1.8mL per vial	1.3mL per vial
Number of doses per vial (after dilution)	6 doses per vial	10 doses per vial
Dose amount	30 micrograms per dose	10 micrograms per dose
Dose volume	0.3mL per dose	0.2mL per dose
Storage Conditions		
ULT freezer storage time (-90 to -60°C)	Until expiry date printed on vial label	6 months after manufacturing date printed on vial label
Freezer storage time (-25 to -15°C)	2 weeks	DO NOT STORE AT (-25 to -15°C)
Refrigerated storage time (2 to 8°C)	1 month	10 weeks
Room temperature storage time (8 to 25°C)	2 hours prior to dilution (including thaw time)	12 hours prior to first puncture
After first puncture (2 to 25°C)	Discard after 6 hours	Discard after 12 hours ¹
Expiry date	Date printed on vial label ²	

¹ Vial labels and cartons may state that a vial should be discarded 6 hours after dilution. The information in the Product Monograph, Yukon Immunization Manual and this guidance document supersede the number of hours printed on vial labels and cartons

² As a reminder, vials of Pfizer COVID-19 vaccine with an expiry date of August 2021 to February 2022 printed on the label may remain in use for 3 months beyond printed date as long as all approved storage conditions have been maintained.

Vaccine Storage Requirements

The vaccine is stored in the ultra-low temperature state at a temperature between -60°C and -90°C , and away from UV rays and direct sunlight.

Ultra-Low Temperature Freezer Storage

- Freezers must ensure that vaccine temperatures are stabilized at -90°C to -60°C .
- The internal temperature should be stabilized before stocking the vaccine.
- The freezer temperature must be set to -80°C manually.
- Monitor the internal temperature of the freezer for 72 consecutive hours before storing the vaccine in the unit.
 - Record the maximum, minimum and current temperatures twice a day.
- Freezers storing the vaccine must have alarms to notify of temperature excursions and the door being left open.
- Freezers storing the vaccines should be up to date on annual inspections and regular maintenance.

Central WGH Warehouse: Receiving the Vaccine from the Manufacturer

- Trays of Pfizer vaccine will arrive in thermal shipping containers (Softbox or AeroSafe) with dry ice. **Do not stack or place anything on top of the thermal shipping container.**
- When you receive the shipping container, inspect to confirm that all ordered vial trays were received.
- The shipping container can weigh up to 36.5 kg and should be opened on the floor.
- Review the [Dry Ice Safety Data Sheet](#) before opening the shipping container.
- When you open the container, you will see a temperature monitoring device embedded in a foam lid.
 - Press and hold the stop button upon receipt.
 - **Do not remove the temperature monitoring device from the lid.** It must be returned with the shipping container after use.
- The dry ice pod is beneath the foam lid. There will also be dry ice in compartments in the container that surround the box. Remove the dry ice pod
- Open the box that contains the vial trays and carefully remove the vial trays. **Do not open vial trays or remove vials until ready for thawing.**
- **Immediately** store vaccine product in ULT freezer.



Use of Dry Ice

- Use of dry ice in confined spaces (small rooms, walk-in coolers) and poorly ventilated rooms can result in a depletion of oxygen causing asphyxiation.
- Only use dry ice in open or well-ventilated areas.
- Use safety glasses with side shields or safety goggles, and waterproof insulated gloves when opening the shipping container.
- Refer to the [Dry Ice Safety Data Sheet](#) and the [Safe Handling Guidelines for Dry Ice](#) for other dry ice protection.



Discarding Dry Ice

- After the thermal shipping container is no longer needed, discard the dry ice using necessary safety precautions outline in the [Dry Ice Safety Data Sheet](#).
- Open the shipping container and leave it at room temperature in a well-ventilated area.
- The dry ice will sublime from a solid or gas.
- **Do not** leave the shipping container in an unsecured area.
- **Do not** drain or flush the dry ice down a toilet.
- **Do not** dispose the dry ice in the trash.
- **Do not** place the shipping container in a closed area, such as an airtight container or walk-in cooler.



Returning the Thermal Shipping Container

- Do not discard the original thermal shipping container or any of its components.
- Discard empty vial trays as medical waste so they can not be reused.
- The shipping container and the included temperature monitoring device must be returned **within 30 days of delivery**.
- When the thermal shipping container is ready to be returned, place all the components inside and seal it with tape.
- Components to be returned:
 - Dry ice pod
 - Included temperature monitoring device
 - Foam lid
 - Box that holds the vial trays
- A preprinted return shipping label will be included inside the shipping container.
- For Softbox containers:
 - Apply the preprinted return shipping label over the existing shipping label.
- For Aerosafe containers:
 - Follow instructions on the inner flap of the shipping container to ensure the return label is facing outside.
- Ensure the “Dry Ice UN 1845” and the diamond shape class 9 hazard label on container are covered by placing a blank sticker label over them as the container should no longer contain dry ice.
- Contact the carrier identified on the return label to arrange the return.
- Place the thermal shipping container at designated pick-up location.



Storage Options for Ultra-Low Temperature State

Ultra-Low Temperature (ULT) Freezer

- The vaccine can be held between -90°C and -60°C until the expiry date.
- **Closed-lid vial trays** or **cartons** removed from ULT storage may be at room temperature for up to **5 minutes**.
- **Open-lid vial trays, or vial trays with less than 195 vials**, removed from ULT storage may be at room temperature for up to **3 minutes**.
 - If at room temperature for close to, but not over 3 minutes, place back in ULT freezer for at least **2 hours** before packing or removing again.
- Individual vials removed from the tray and left at room temperature should not be returned to ULT storage and must be placed at fridge temperature

Portable Ultra-Low Temperature (ULT) Freezer

- A portable ULT freezer and ULT chest freezer should always be plugged in to be used as a backup in case of power outage

Storage Options for Frozen State (only Pfizer adolescent/adult product)

Freezer

- The Pfizer COMIRNATY COVID-19 adolescent/adult vaccine product can be held at -15 to 25°C for 2 weeks.
 - Do not store the vaccine outside the -15°C to -25°C range or on dry ice when in the frozen state
 - Once stored at frozen state, full trays should not be at room temperature for more than **3 minutes** and opened trays should not be at room temperature for more than **1 minute**.
- Once a vial is removed from the tray at room temperature, it should not be returned to frozen storage and should be thawed for use. **DO NOT REFREEZE**



Storage Options for Frozen State (continued) -only Pfizer adolescent/adult product

Transportation Container (Credo Cube or Pelican CoolGuard)

- Transport containers are only used to transport vaccine and are not to be used for long-term storage.
- Transport containers can hold -15°C to -25°C range for 5-6 days (depending on transport container).
- Temp Tale must be used to verify temperature of product upon receipt.



Portable Freezer

- The vaccine can be held at -15°C to -25°C range for a maximum of 2 weeks.
- AC and DC power connections will plug into any outlet (110V or 220V), or a 12V DC mobile power supply.



Counter Top Freezer

- The vaccine can be held at at -15°C to -25°C range for 2 weeks.



Storage Options for Refrigerated State

- The Pfizer COMIRNATY COVID-19 adolescent/adult vaccine product can be held at 2°C to 8°C for 31 days if the vial is not yet punctured and diluted.
 - After first puncture, the vaccine can be held in **refrigerated state for 6 hours.**
- The Pfizer COMIRNATY COVID-19 pediatric vaccine product can held at 2°C to 8°C for 10 weeks if the vial is not yet punctured and diluted.
 - After first puncture, the vaccine can be held in **refrigerated state for 12 hours.**
- Affix a sticker onto each box and vial indicating the date and time it was put into refrigerated state and the date and time it is to be discarded.



Storage Options for Room Temperature

- The Pfizer COMIRNATY COVID-19 adolescent/adult vaccine product can be held at room temperature 8°C to 25°C **for 2 hours if the vial is not yet punctured and diluted.**
 - Label the time it enters room temperature on each vial.
 - After dilution, the vaccine must be used within 6 hours.
 - Label the time of dilution on each vial or syringe.
 - Vaccine does not need to be protected from light when at the room temperature state.
 - Do not expose to UV lights or direct sunlight.
- The Pfizer COMIRNATY COVID-19 pediatric vaccine product can be held at room temperature 8°C to 25°C **for 12 hours prior to first puncture**
 - Label the time it enters room temperature on each vial.
 - After dilution, the vaccine must be used within 12 hours.
 - Label the time of dilution on each vial or syringe.
 - Vaccine does not need to be protected from light when at the room temperature state.
 - Do not expose to UV lights or direct sunlight.

The vaccines cannot be refrozen after thawing.



Temperature Monitoring

To ensure the vaccine is kept at the ideal conditions, temperature should be monitored and recorded on a regular basis.

- The maximum, minimum and current temperatures should be recorded twice a day.
- Check the temperature every time the transport unit, refrigerator or freezer is accessed.
- To prevent temperature change and light exposure, check the storage unit doors throughout the day and always at the end of the day to make sure they are tightly closed.
- See below section on Cold Chain Breaks for what to do in case of temperature excursion.

Contingency Plan for Power Outage

- Back-up generators are used where available to ensure continued power supply to storage units.

Routine monitoring of storage units allows the timely identification of temperature excursions and immediate action to correct them.



Vaccine Transport

Key Guidelines

Pfizer COMIRNATY COVID-19 adolescent/adult vaccine product

- The Pfizer COMIRNATY COVID-19 adolescent/adult vaccine product may be transported in the frozen state (-25°C to -15°C).
 - Any hours used for transport at this state count against the 2-week limit for storage at -25°C to -15°C.
- The Pfizer COMIRNATY COVID-19 adolescent/adult vaccine product can also be transported in the refrigerated state (+2°C to +8°C).
 - Any hours used for transport at this state count against the 120-hour limit for storage at +2°C to +8°C.
- Minimize shaking or agitation during transport.

Pfizer COMIRNATY COVID-19 pediatric vaccine product

- The Pfizer COMIRNATY COVID-19 pediatric vaccine product may be **NOT** be transported in the frozen state (-25°C to -15°C).
- The Pfizer COMIRNATY COVID-19 pediatric vaccine product is to be transported in the refrigerated state (+2°C to +8°C).
- Minimize shaking or agitation during transport.



Transporting in the Frozen (-25°C to -15°C) State - **only Pfizer adolescent/adult product**

- A validated container must be used to transport vaccine.
- The transport container should be properly and prominently labelled with “Vaccine”, “Fragile”, “Handle with Care”, or “Do Not Drop” stickers.
- The vaccine should be handled with care and protected from any agitation.
- Do not place transport container near sources of heat (i.e. heater, engine heat).
- Secure (strap down) transport containers during transport to prevent any unnecessary movement.
- Do not open transport container during transport unless absolutely necessary.
 - If opened, check temperature of TempTale.
- Vials that are transported in the frozen state should not be subjected to repeat instances of transport, unless under exceptional circumstances and under the direction of the Vaccine Program Manager.
 - If necessary to transport a vial for a second time, transportation time must be closely monitored to ensure the cumulative time in frozen state does not exceed 2 week maximum.
- Once thawed and transported in the frozen state, the vaccine can be returned **one time** to the recommended storage condition of -90°C to -60°C.
- Transfers should be limited to decrease likelihood of temperature excursions and disruption to physical stability of vaccine.
- Place a TempTale in the cooler with vaccine. This will monitor and document temperature during transportation.
- Provide a protective barrier of insulating material, such as a flexible insulating blanket, between the vaccines and the gel packs.
- Do not place coolers in the trunk of a car where temperatures cannot be monitored and may be significantly different from interior vehicle temperatures.
- **Diluent must be transported at room temperature**



Packaging process for Frozen (-25°C to -15°C) State (only Pfizer adolescent/adult product):

- Ensure data logger is calibrated for shipment and turn it on.
- Ensure you are wearing dry ice PPE for moving the vaccine from ULT storage to the transport containers.
- The Pfizer vaccine is not supplied in a vaccine box from the manufacturer, therefore, single vials should be carefully wrapped in bubble wrap or foam and placed in a padded envelope or small box. This protects the vaccine from breakage and light, prevents direct contact with gel packs, and reduces the variability of the temperature close to the vaccine.
 - **The envelope or box should be labeled with the name of the vaccine, lot number and expiry date.**
- **The following steps must take place in under 3 minutes.** If the steps take close to, but not over, 3 minutes – the tray must go back into the ULT freezer for 2 hours before being repacked.
 - 1. Start timer for 3 minutes**
 1. Remove tray from ULT freezer.
 2. Place vials needed in small box then in temperature conditioned transport container and ensure they are secured.
 3. Place data logger in transport container. Close lid.



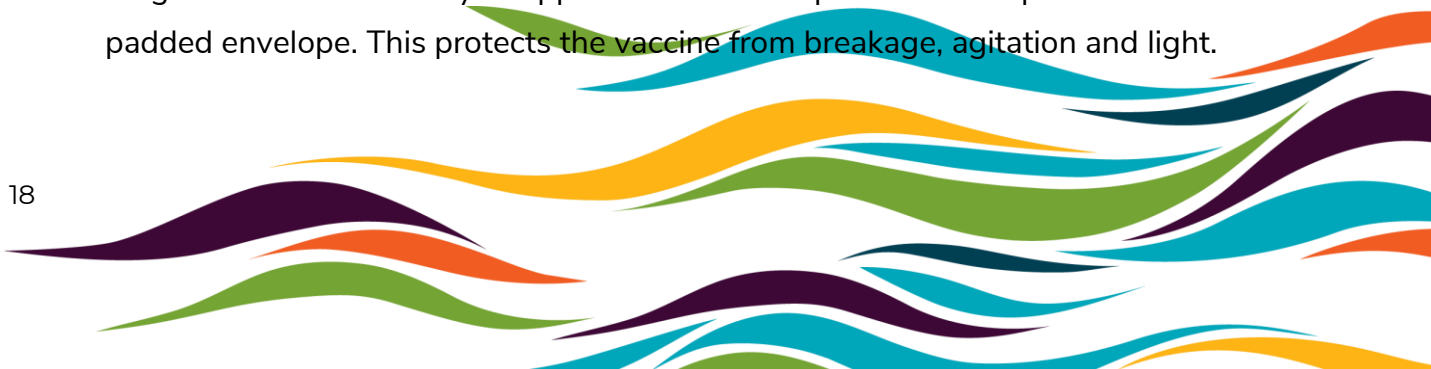
Transporting in the Thawed Refrigerated (+2°C to +8°C) State (both Pfizer adolescent/adult vaccine product and Pfizer COMIRNATY COVID-19 pediatric vaccine)

Transport of vaccine in the thawed state includes: thawed undiluted vials, thawed diluted vials, pre-drawn syringes.

- The transport container should be properly and prominently labelled with “Vaccine”, “Fragile”, “Handle with Care”, or “Do Not Drop” stickers.
- Vaccine to be handled with care and protected as from any agitation.
- Do not place transport container near sources of heat (i.e. heater, engine heat).
- Secure transport containers during transport to prevent any movement.
- Do not open transport container during transport unless absolutely necessary.
 - If opened, check temperature of TempTale
- Vials that are transported in the thawed refrigerated state **should not** be subjected to repeat instances of transport.
- Once thawed to refrigerated state or room temperature (+8°C to +25°C), **DO NOT REFREEZE.**
- Keep vaccines in original packaging wherever possible
- Place a TempTale in the cooler with vaccine.
- Provide a protective barrier of insulating material such as a flexible insulating blanket, between the vaccines and transport container.
- When weather temperatures are below +2°C, transport in a vehicle where the temperature can be kept higher than +8°C to avoid freezing.
- Do not place coolers in the trunk of a car where temperatures cannot be monitored and may be significantly different from interior vehicle temperatures.

Transporting at Room Temperature State (+2°C to +25°C)

- Single vials to be carefully wrapped in bubble wrap or foam and placed in a padded envelope. This protects the vaccine from breakage, agitation and light.



- The envelope or box should be labeled with the name of the vaccine, lot number and expiry date.

Transport Container Requirements

We will be using a combination of Pelican CoolGuard containers, Credo Cube containers and Styrofoam vaccine coolers to transport the vaccine in the recommended temperature range.

- Inspect the transport container for integrity prior to each use.
- A temperature monitoring device must be used during the transport.

About the Credo/Pelican Transport Containers

- The transport containers allow the vaccine to be transported in the frozen or room temperature state.
- The Pfizer COMIRNATY COVID-19 adolescent/adult vaccine can be stored in the containers for a maximum of 5 days.
 - The container weighs 15.6 kg when empty.
 - The containers do not require any electrical power, making them the preferred method of frozen transport.
 - The containers need to be activated and conditioned for 48 hours before use.
 - Refer to the product manual for instructions on activation.
 - Freezer packs are to be spaced 1” apart in the freezer during activation.

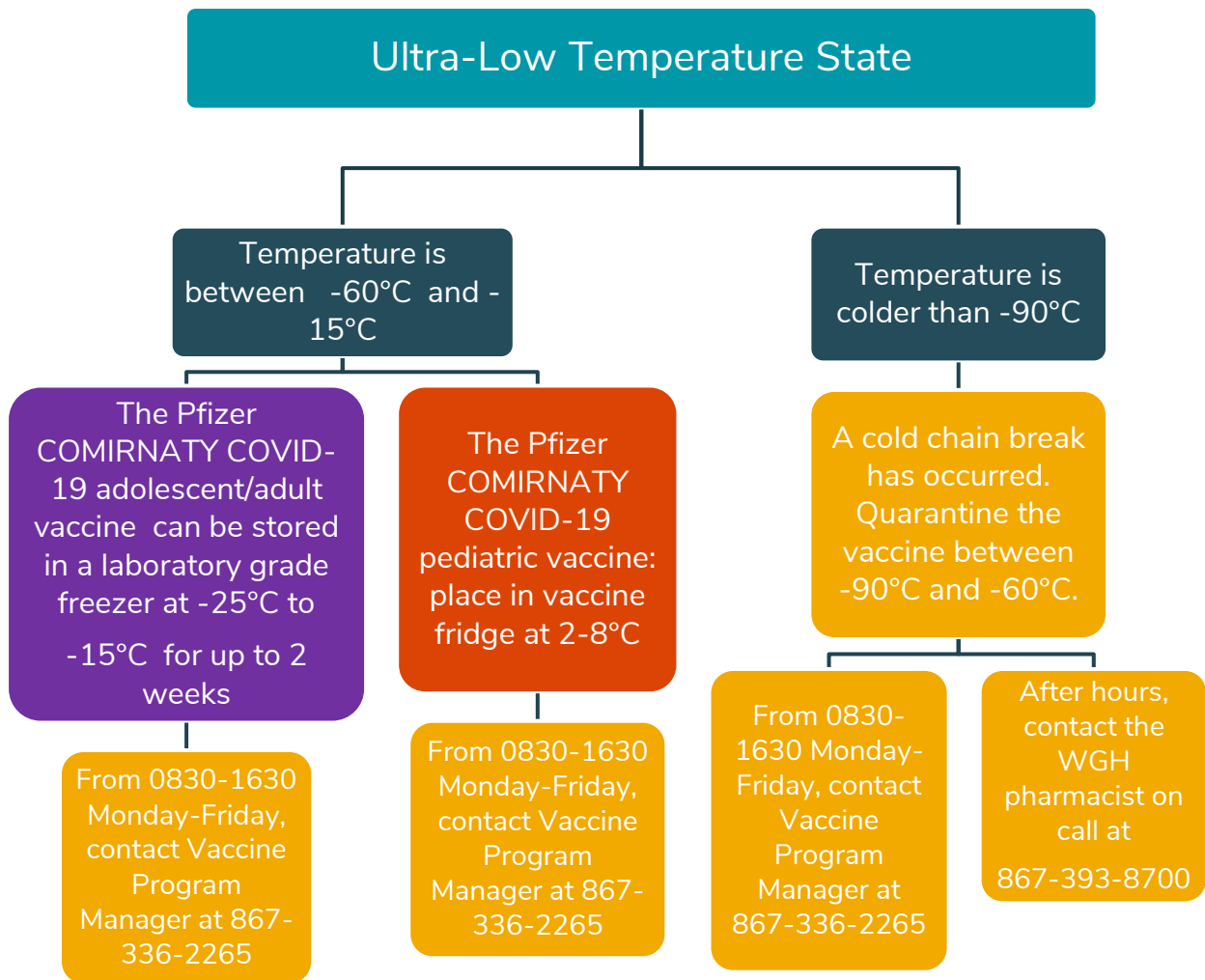
Unexpected Delay During Frozen Transit - only Pfizer adolescent/adult product

In the event of an unexpected delay during transit, the transportation containers can be placed in a -20°C freezer. This will stop the “countdown” to the 5 day maximum length of transportation time in the container. The countdown to the 2 week maximum length of total time in the frozen state continues.



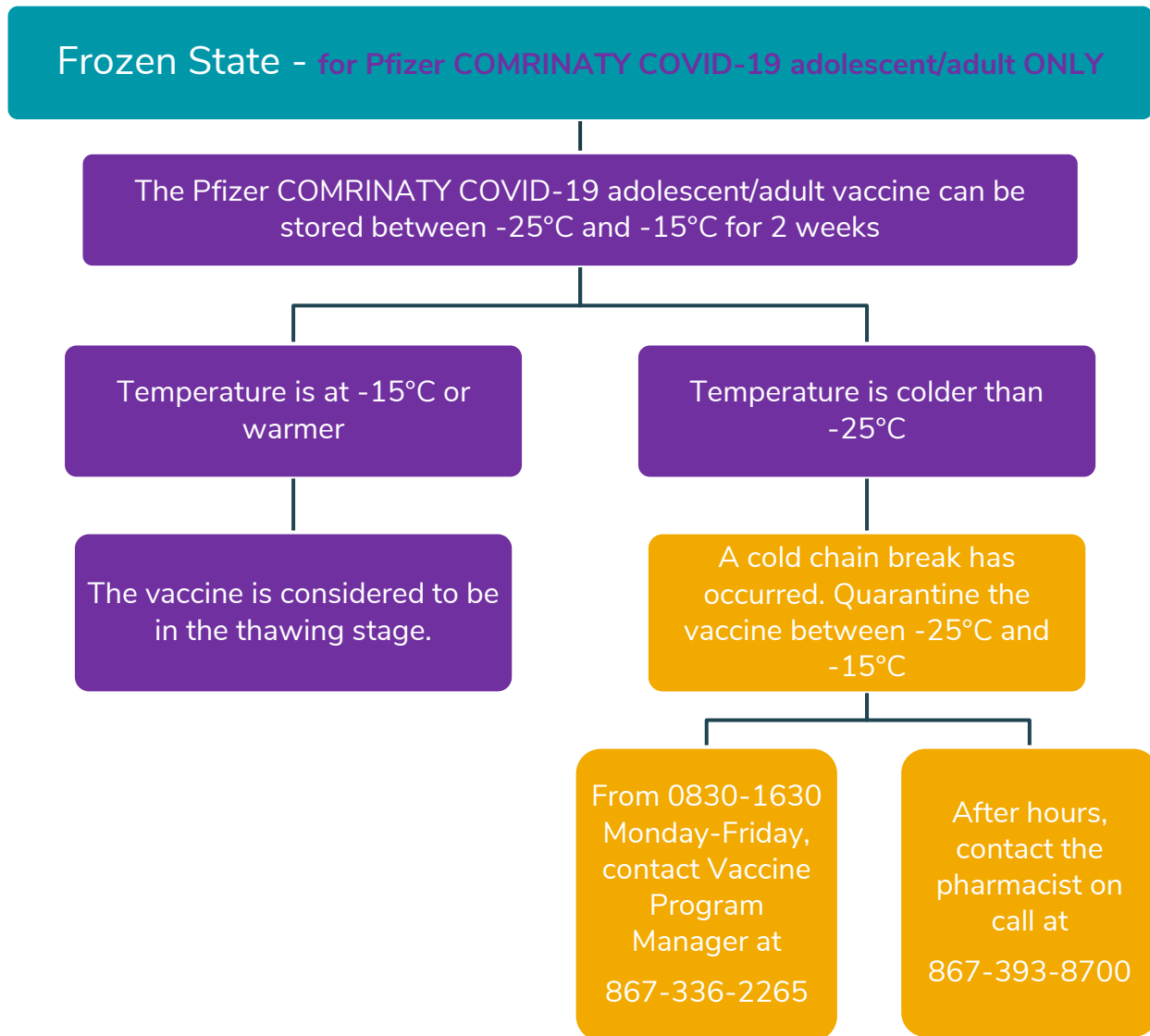
Cold Chain Breaks

Pfizer COMIRNATY COVID-19 Vaccine Cold Chain Break Flow Chart



The vaccine cannot be refrozen after thawing.

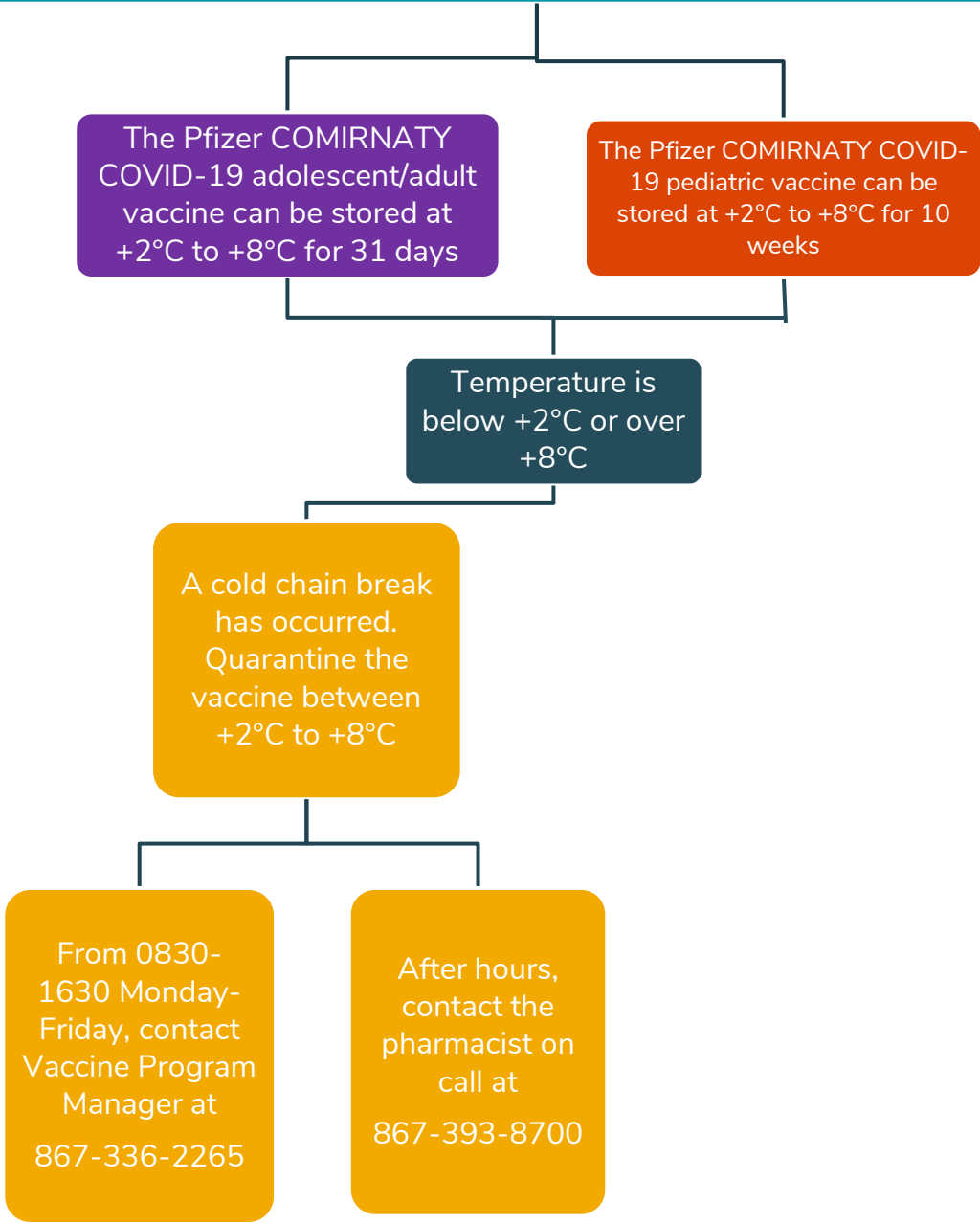




Total time the vials are stored and/or transported at -25°C to -15°C should not exceed 2 weeks.

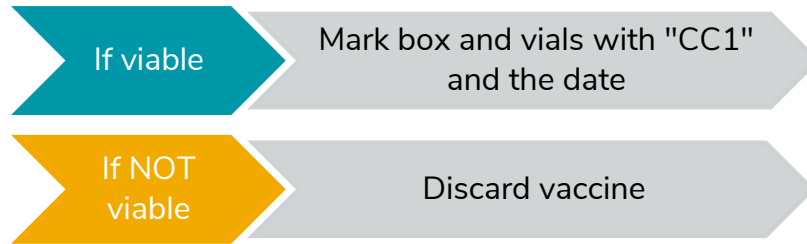


Undiluted Fridge Thawed State



After a Cold Chain Break

- In the event that the vaccine is outside of the designated temperature, contact the Vaccine Program Manager to determine if vaccine is still viable.



Cold Chain Breaks Off-Site

Transportation Container

- If temperature is out of range during check, call the Vaccine Program Manager at 867-336-2265 (M-F 0830-1630).
- If unavailable, call pharmacist on call at WGH at 867-393-8700.

Portable Freezer

- Alarm will sound.
- Call the Vaccine Program Manager at 867-336-2265 (M-F 0830-1630).
- If unavailable, call pharmacist on call at WGH at 867-393-8700.

Counter Top Freezer

- Alarm will sound.
- Call the Vaccine Program Manager at 867-336-2265 (M-F 0830-1630).
- If unavailable, call pharmacist on call at WGH at 867-393-8700.



Immunization Clinics

Preparation for Immunization Clinics

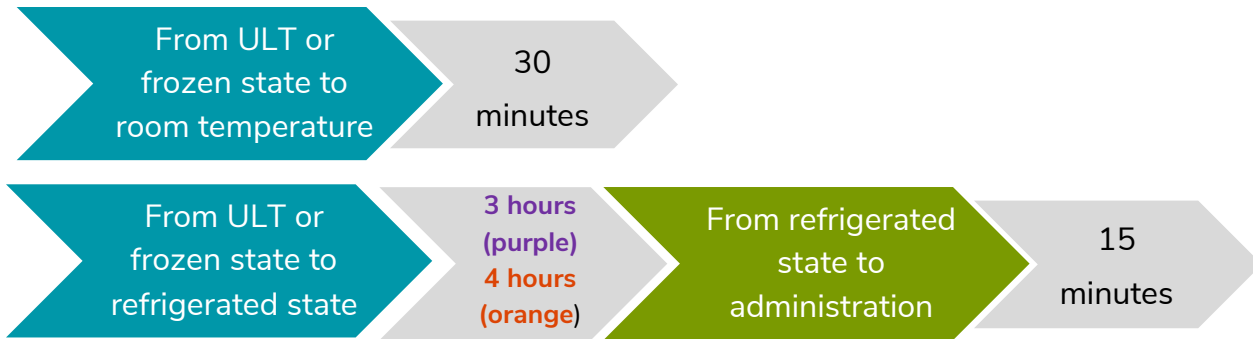
- To prevent waste, only remove the exact number of doses from storage that are needed for the clinic.
- Vials should be transported according to guidelines in this document and Pfizer product pages of the [Yukon Immunization Manual - Section 8 Biologic Products](#) and thawed at the clinic location or placed in the vaccine fridge.
- Undiluted fridge temperature vials can then be stored between +2°C and +8°C for a maximum number of days or weeks (refer to guidance in document above)

At the Immunization Clinic

- Minimize the number of times the storage unit or fridge is opened.
- Record information below to keep track of vaccine viability:
 - Start time of thawing to refrigerator temperature +2°C to +8°C.
 - Start time of thawing to room temperature +8°C to +25°C.
 - Time of vial dilution.
 - Time of pre-draw into syringe.
 - Time and temperature of transport container opening.






Thawing

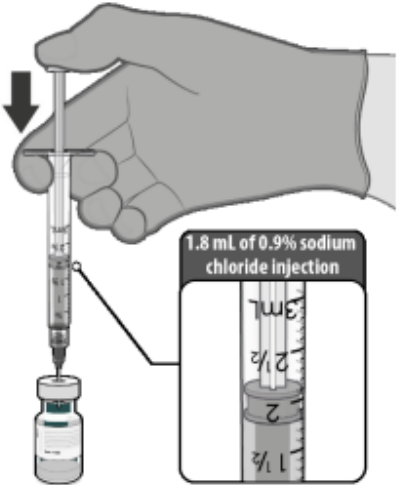
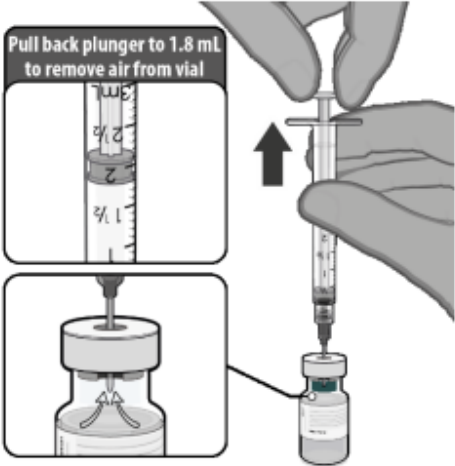
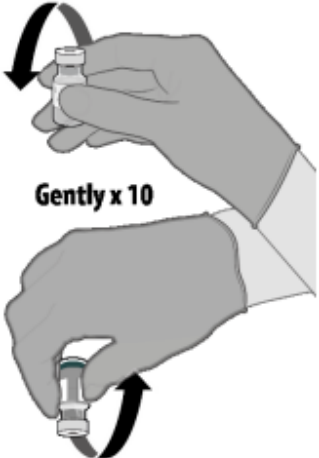


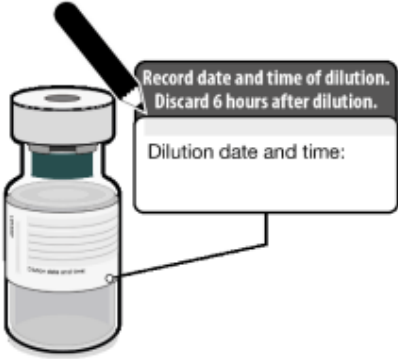
- Refer to the number of booked appointments for the specific location of the clinic to determine how much product to thaw.
 - Assess hourly flow at the clinic.
- Discard any punctured diluted vials after **6 hours (Pfizer COMIRNATY COVID-19 adolescent/adult)** and **12 hours (Pfizer COMIRNATY COVID-19 pediatric)**

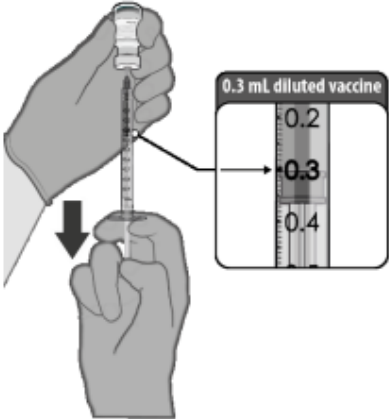
Preparation Pfizer COMIRNATY COVID-19 adolescent/adult

VIAL AND DOSE VERIFICATION (Individuals 12 Years of Age and Older)	
 <div data-bbox="505 1329 704 1392" style="border: 1px solid black; padding: 5px; display: inline-block;">Purple cap</div>	<ul style="list-style-type: none"> • Verify that the vial has a purple plastic cap. If the vial has an orange plastic cap and orange label border, do not use to prepare doses for individuals 12 years of age and older. product.

THAWING PRIOR TO DILUTION (Individuals 12 Years of Age and Older)	
 <p>Prior to dilution No more than 2 hours at room temperature (up to 25°C/77°F)</p>	<ul style="list-style-type: none"> • Thaw vial(s) of COMIRNATY before use either by: <ul style="list-style-type: none"> ○ Allowing vial(s) to thaw in the refrigerator (2°C to 8°C [35°F to 46°F]). A carton of vials may take up to 3 hours to thaw, and thawed vials can be stored in the refrigerator for up to 1 month. ○ Allowing vial(s) to sit at room temperature (up to 25°C [77°F]) for 30 minutes. • Using either thawing method, vials must reach room temperature before dilution and must be diluted within 2 hours of exposure to room temperature.
 <p>Gently x 10</p>	<ul style="list-style-type: none"> • Before dilution, invert vaccine vial gently 10 times. • <u>Do not shake.</u> • Inspect the liquid in the vial prior to dilution. The liquid is a white to off-white suspension and may contain <u>white to off-white opaque amorphous particles.</u> • Do not use if liquid is discoloured or if other particles are observed.


DILUTION (Individuals 12 Years of Age and Older)	
	<ul style="list-style-type: none"> • Obtain sterile 0.9% Sodium Chloride Injection, USP. Use only this as the diluent. • Using aseptic technique, withdraw 1.8 mL of 0.9% Sodium Chloride Injection, USP into a transfer syringe (using 21-gauge or narrower needle). • Cleanse the vaccine vial stopper with a single-use antiseptic swab. • Add 1.8 mL of 0.9% Sodium Chloride Injection, USP into the vaccine vial.
	<ul style="list-style-type: none"> • Equalize vial pressure before removing the needle from the vial by withdrawing 1.8 mL air into the empty diluent syringe.
	<ul style="list-style-type: none"> • Gently invert the vial containing COMIRNATY 10 times to mix. • <u>Do not shake.</u> • Inspect the vaccine in the vial. • The vaccine will be an off-white suspension. Do not use if vaccine is discoloured or contains particulate matter.

	<ul style="list-style-type: none">• Record the date and time of dilution on the COMIRNATY vial label.• Store between 2°C to 25°C (35°F to 77°F).• Discard any unused vaccine 6 hours after dilution.
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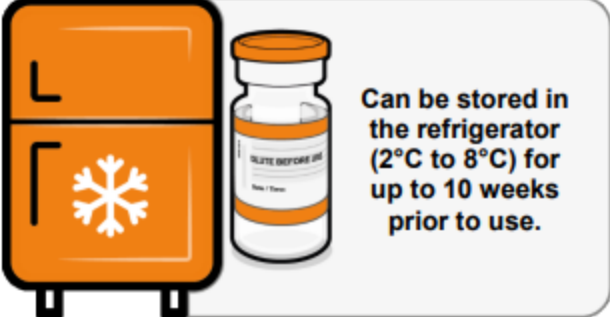
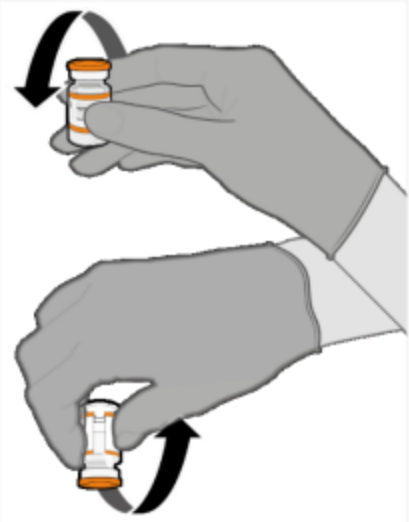
PREPARATION OF INDIVIDUAL 0.3 mL DOSES OF COMIRNATY (Individuals 12 Years of Age and Older)	
	<ul style="list-style-type: none">• Using aseptic technique, cleanse the vial stopper with a single-use antiseptic swab, and withdraw <u>0.3 mL</u> of COMIRNATY, preferentially using low dead-volume syringes and/or needles.• Each dose must contain 0.3 mL of vaccine.• If the amount of vaccine remaining in the vial cannot provide a full dose of 0.3 mL, discard the vial and any excess volume.• Administer immediately, and no later than 6 hours after dilution.• Low dead-volume syringes and/or needles can be used to extract 6 doses from a single vial. In order to ensure consistent withdrawal of 6 doses of 0.3 mL, it is important to adhere to minimizing volume loss during dose extraction.

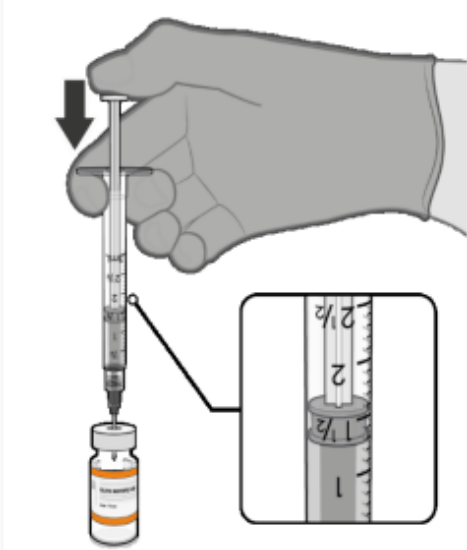
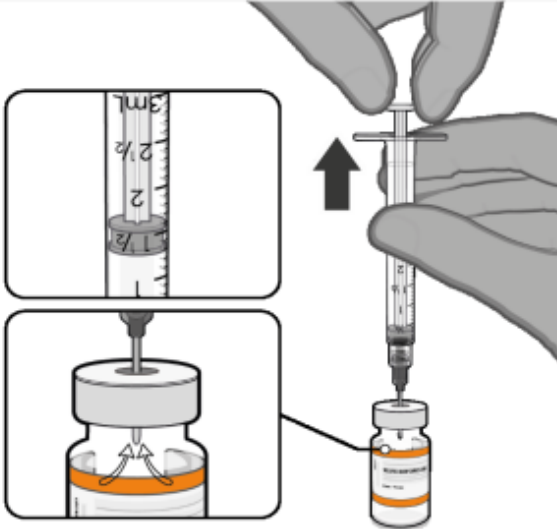


Preparation Pfizer COMIRNATY COVID-19 pediatric vaccine

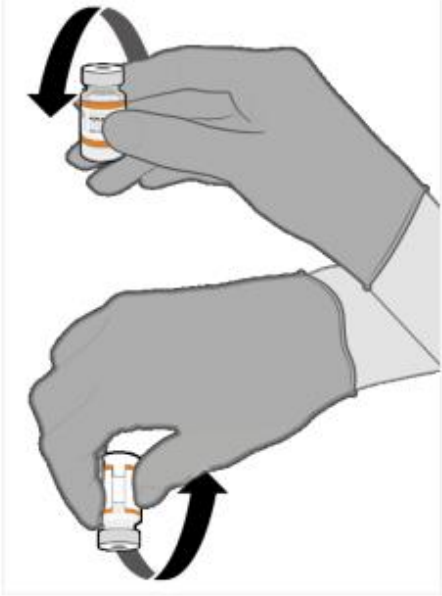

VIAL AND DOSE VERIFICATION (Individuals aged 5 years to <12 years)	
 <p>✓ Orange plastic cap and orange label border.</p>	<ul style="list-style-type: none">• Verify that the vial has an orange plastic cap and an orange label border. Do not use COMIRNATY vials with purple caps to prepare doses for individuals aged 5 years to <12 years.• The date printed on the vial and carton reflects the date of manufacture. The vaccine should not be used after 6 months from the date of manufacture printed on the vial and carton.



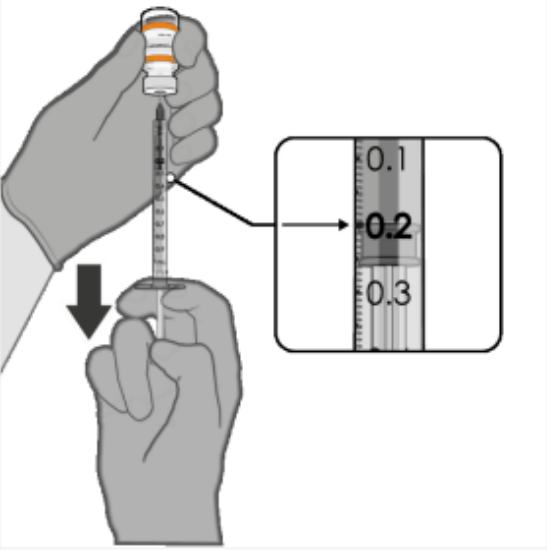
THAWING PRIOR TO DILUTION (Individuals aged 5 years to <12 years)	
 <p>Can be stored in the refrigerator (2°C to 8°C) for up to 10 weeks prior to use.</p>	<ul style="list-style-type: none"> • Thaw vial(s) of COMIRNATY before use either by: <ul style="list-style-type: none"> ○ Allowing vial(s) to thaw in the refrigerator [2°C to 8°C (35°F to 46°F)]. A carton of 10 vials may take up to 4 hours to thaw, and thawed vials can be stored in the refrigerator for up to 10 weeks. ○ Allowing vial(s) to sit at room temperature [up to 25°C (77°F)] for 30 minutes. ○ Vials may be stored at room temperature [up to 25°C (77°F)] for up to 12 hours prior to dilution.
 <p>Gently x 10</p>	<ul style="list-style-type: none"> • Before dilution, mix by inverting vaccine vial gently 10 times. • <u>Do not shake.</u> • Inspect the liquid in the vial prior to dilution. The liquid is a white to off-white suspension and may contain white to off-white opaque amorphous particles. • Do not use if liquid is discoloured or if other particles are observed.

DILUTION (Individuals aged 5 years to <12 years)	
 <p data-bbox="397 890 773 953">1.3 mL of 0.9% sodium chloride injection</p>	<ul data-bbox="943 447 1377 863" style="list-style-type: none"> • Obtain sterile 0.9% Sodium Chloride Injection, USP. Use only this as the diluent. • Using aseptic technique, withdraw 1.3 mL of diluent into a transfer syringe (using 21-gauge or narrower needle). • Cleanse the vaccine vial stopper with a single-use antiseptic swab. • Add 1.3 mL of 0.9% Sodium Chloride Injection, USP into the vaccine vial.
 <p data-bbox="277 1549 889 1581">Pull back plunger to 1.3 mL to remove air from vial.</p>	<ul data-bbox="943 1262 1349 1394" style="list-style-type: none"> • Equalize vial pressure before removing the needle from the vial by withdrawing 1.3 mL air into the empty diluent syringe.



 <p>Gently × 10</p>	<ul style="list-style-type: none">• Gently invert the vial containing COMIRNATY 10 times to mix.• <u>Do not shake.</u>• Inspect the vaccine in the vial.• The vaccine will be a white to off-white suspension. Do not use if vaccine is discoloured or contains particulate matter.
 <p>Use within 12 hours after dilution.</p>	<ul style="list-style-type: none">• Record the date and time of first vial puncture on the COMIRNATY (for age 5 years to <12 years) vial label.• Store between 2°C to 25°C (35°F to 77°F).• Discard any unused vaccine 12 hours after dilution.



PREPARATION OF INDIVIDUAL 0.2 mL DOSES (Individuals aged 5 years to <12 years)	
 <p>0.2 mL diluted vaccine</p>	<ul style="list-style-type: none"> • Using aseptic technique, cleanse the vial stopper with a single-use antiseptic swab, and withdraw <u>0.2 mL</u> of COMIRNATY (for age 5 years to <12 years) preferentially using a low dead-volume syringe and/or needle. • Each dose must contain 0.2 mL of vaccine. • If the amount of vaccine remaining in the vial cannot provide a full dose of 0.2 mL, discard the vial and any excess volume. • Administer immediately, and no later than 12^h hours after dilution. • Low dead-volume syringes and/or needles can be used to extract 10 doses from a single vial. In order to ensure consistent withdrawal of 10 doses of 0.2 mL, it is important to adhere to minimizing volume loss during dose extraction.

When to Record Temperature

- Before leaving the main storage facility with transportation container.
- Upon arrival at the clinic.
- Each time the container is opened.
- At the end of the clinic.

Pre-drawing

- Pre-drawing is not a routinely recommended technique.
- It is acceptable in mass clinic settings to help with clinic flow.
 - 1-2 nurses should be responsible for pre-drawing syringes.
 - This prevents multiple punctured vials and waste of product.
 - Each syringe and vial should be labelled with the date and time of vial dilution.
 - Place pre-drawn syringes in an easily accessible basket, clearly labelled and colour coded where nurses can pick up for next client.

