



Job Aid: (12+) Pfizer-BioNTech COVID-19 Vaccine

Purpose: This job aid will provide instruction on how to store, prepare, reconstitute, and administer the Pfizer-BioNTech COVID-19 vaccine **for 12 years of age and older**. This job aid is consistent with the Canadian product monograph for Pfizer-BioNTech (Comirnaty) COVID-19 vaccine.

For any concern about vaccine suitability or stability please contact the following for consultation and support:

- Contact for Primary Care Clinics/Community Physicians: pharmacists@halton.ca
- Contact for Long-Term Care Homes/Retirement Homes: CovidVaccine@halton.ca

Vaccine Storage Requirements







- Vaccine vials will be delivered in a thawed state. Do not refreeze thawed vials.
- Vials will be packaged in foam and must be remain in the foam to protect from light during storage.
- The vaccine should be stored in a designated area in the vaccine fridge (i.e. shelf or tray).
- During storage, minimize exposure to room light and avoid exposure to direct sunlight and ultraviolet light. Thawed vaccine vials can be handled in room light conditions.
- Vaccine vials must be individually labelled to decrease the risk of vaccine administration errors, and vaccine wastage.

Thawed Unopened Vials (Prior to Dilution)

- Can be stored in refrigeration (+2°C to +8°C) for up to 31 days.
- Can be stored at room temperature (up to 25°C) for up to 2 hours.

Labelling Note: the Date and Time that the vaccine must be used by will be indicated on the vaccine vial label. This is different from the manufacture expiry date. Discard any 12+ Pfizer vaccine that is past the 'use by date & time'.

Thawed Vials (After Dilution):

 Must be stored between +2°C to +25°C and must be used within 6 hours from the time of reconstitution.

Labelling Note: the date and time that the vaccine is reconstituted must be marked on the vial label. **Discard any 12+ Pfizer vaccine that is not used within 6 hours.**

Sample Vaccine Vial Label:

Information on the Right Side of the label will be completed by Halton Region Public Health.

Date & Time of Reconstitution: (must use within 6 hours) July 23, 2021 @ 1300 Pfizer COVID-19 Vaccine
Use by Date & Time: 2021-08-30
@0900

LOT #: FD7206

Manufacturer Expiry: 2021-11-30



Information on the <u>Left Side</u> of the label must be **completed when vaccine is used**.









Step 1: Prepare Vaccine

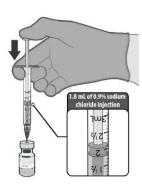


Prior to dilution No more than 2 hours at room temperature (up to 25 °C/77 °F)



- The vial must reach room temperature before dilution and must be diluted within 2 hours of exposure to room temperature (up to 25°C).
- Remove vaccine vial from refrigeration and document the time placed at room temperature on the vial label. Only remove vials from refrigeration as they are needed.
- Vials must sit at room temperature for 15 minutes prior to dilution.
- Check vaccine expiry date.
- Invert vaccine vial gentle 10 times. DO NOT SHAKE.
- 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 the liquid is discoloured or if other particles are observed.

Step 2: Dilution

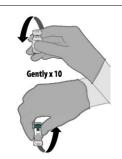


- Check diluent expiry date. Only use 0.9% Sodium Chloride Injection, USP as the diluent. Note: diluent will be sent with the vaccine.
- Using aseptic technique, withdraw 1.8 mL of 0.9% NaCl into a transfer syringe with 21-gauge or narrower needle.
- Using aspetic technique add 1.8 mL of 0.9% NaCl diluent into the vaccine vial.
- Note: there will be remaining volume in the diluent vial. Do not reuse diluent vials, discard after single use.

- Equalize vial pressure before removing the needle from the vial by withdrawing 1.8 mL of air into the empty syringe. (Note: trace amounts of vaccine will be visible in syringe).
- Gently invert the vial containing the Pfizer-BioNTech COVID-19 vaccine 10 times to mix. DO NOT SHAKE.
- Inspect the vaccine, vaccine should be an off-white suspension. Do not use if the vaccine if liquid is discoloured or if other particles are observed.



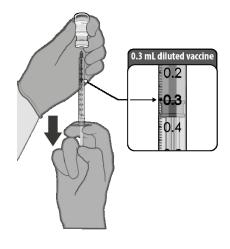






• Record the date and time of reconstitution on the vaccine vial label. Store between (+2°C to 25°C). Discard any vaccine that is not used within 6 hours.

Step 3: Prepare Individual Doses of Vaccine

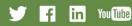


- Using aseptic technique, cleanse the vial stopper with a single-use antiseptic swab.
- Carefully withdraw 0.3 mL of the vaccine into the syringe.
- Once a dose is withdrawn from the vial it should be administered immediately.

Note: pre-loading syringes is strongly discouraged because it increases risk of contamination, vaccine administration errors, and vaccine wastage.

- Each dose must contain 0.3 mL of vaccine. If the amount of vaccine remaining in the vial cannot provide a full dose of 0.3ml, discard the vial. Do not pool excess vaccine from multiple vials.
- After dilution, each vial contains 6 doses. 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. Low dead-volume syringes and/or needles can be used to extract 6 doses from a single vial. If standard syringes and needles are used, there may not be sufficient volume to extract a 6th dose from a single vial.
- If more than 6 doses are withdrawn from the vial, this must be entered in COVax as an extra dose (if training and access to inventory section has been provided) and documented on the EOD Inventory Report.
- If less than 6 doses are withdrawn from the vial, this must be entered in COVax as a wasted dose (if training and access to inventory section has been provided) and documented on the EOD Inventory Report.
- Note: it is recommended to mark down how many doses were yielded from the vial on the side the vaccine vial i.e. If 6 doses were yielded, write down the number 6 on the side of the vial. This will help with reconciliation.





Step 4: ADMINISTER VACCINE	 Pfizer vaccine must be administered within 6 hours of dilution. Visually inspect each dose in the syringe prior to administration to verify the correct dose (0.3ml) and confirm there are no particulates and no discoloration. The diluted vaccine will be an off-white suspension. Administer 0.3 mL intramuscularly, preferably in the deltoid.
Passing more	 Empty vials should be stored securely and properly disposed of per regulation and guidelines by the Ministry of the Environment and Climate Change. Before disposing of empty vials, the labels must be destroyed by removing the label, tearing the label, or marking the label. All packaging associated with the vaccine must be discarded.

Additional Resources:

Training Video from Wellington-Dufferin-Guelph PHU: <u>How to consistently get 6 doses of Pfizer COVID-19 vaccine without using LDV equipment</u>

<u>Product Monograph – Pfizer-BioNTech COVID-19 Vaccine</u>

Pfizer-BioNTech COVID-19 Vaccine Resources & Videos

Ministry of Health- COVID-19 Vaccine Administration

Ministry of Health - Vaccine Storage and Handling Guidance

Registration Guidance Manual for Generators of Liquid Industrial and Hazardous Waste