

COVID-19 Vaccine Provider Training

2022



Part 3: COVID-19 Vaccine Products

Storage, Handling, Preparation



Modules

- Moderna
- Pfizer BioNTech
- Janssen (Johnson & Johnson)



Moderna



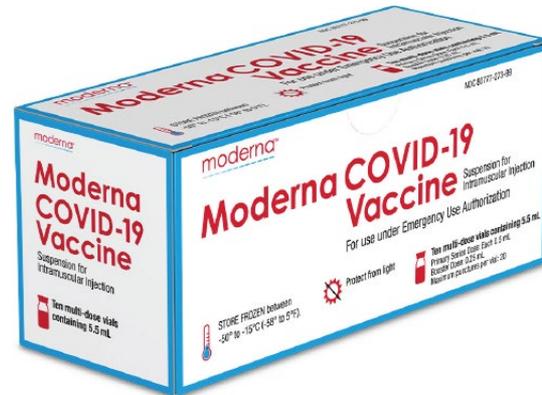
Moderna “Spikevax”

- Messenger ribonucleic acid (mRNA) vaccine
- Approved by the Federal Drug Administration (FDA) for people 18 years and older
- 2 dose primary series: 0.5mL
 - Administered 28 days apart
- Multi-dose vials have a **red cap** and **label with a light blue border**



Moderna “Spikevax” Additional and Booster Dose

- Additional (3rd) dose for immunocompromised individuals: 0.5mL
 - Administered 28 days after 2nd dose
- Booster dose: 0.25mL (half dose)
- Multi-dose vial contains:
 - 10 primary doses (0.5mL)
 - 20 booster doses (0.25mL)

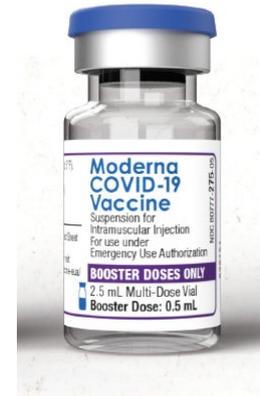


5.5 mL vials for primary series doses or booster doses



Moderna 5 (Blue Cap)

- mRNA vaccine
- Intended for booster dose administration ONLY - available late 2022.
- FDA Emergency Use Authorized (EUA) for people 18 years and older
- Booster dose: 0.5mL
- Multi-dose vials have a dark blue cap and a label with a purple border, containing 5 doses each



2.5 mL vials for booster doses only



Moderna Storage and Handling

Vaccine will arrive *frozen* between -50°C and -15°C (-58°F to 5°F).

Unpunctured Vials:

- May be stored in the freezer between -50°C and -15°C (-58°F to 5°F) through the expiration date.
- May be stored in the refrigerator between 2°C and 8°C (36°F to 46°F) for up to 30 days.
 - If storing in the refrigerator, use beyond-use date labels.

Moderna COVID-19 Vaccine

Store vaccine between 2°C and 8°C (36°F and 46°F) for up to 30 days.

Lot number(s): 123456A

Today's date: 4/01/2021 **USE BY*** Date: 5/01/2021

*After this date/time, do NOT use. Contact the manufacturer for guidance. If directed to discard the vaccine, follow the manufacturer's and your jurisdiction's guidance on proper disposal.

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Vaccine may be transported for 12 cumulative hours.

Transport date	4/5/21		
Time in transport:	2 hrs		
Time remaining:	10 hrs		

Name: Amy Nurse RN



Moderna Storage and Handling

- During storage, minimize exposure to room light and avoid exposure to direct sunlight and ultraviolet light.
- **Frozen vaccine must be thawed before using.**
- The amount of time needed to thaw vaccine varies based on the temperature and number of vials.
 - *In the refrigerator.* Up to 3 hours
 - *At room temperature.* Up to 1 hour and 30 minutes
- Thawed vaccine storage in the refrigerator or at room temperature:
 - *Refrigerator.* Between 2°C and 8°C (36°F to 46°F) for up to 30 days.
 - *Room Temperature.* Between 8°C and 25°C (46°F and 77°F) for up to 24 hours
- Use vials in the refrigerator before removing vials from the freezer.
- **Do NOT refreeze thawed vaccine.**



Moderna Preparation

- If removing the vial from the refrigerator, let stand at room temperature for 15 minutes.
- Check the expiration and beyond-use date/time.
 - Never use vaccine past the expiry date or beyond-use time.
- With the vial upright, gently swirl the vaccine. Do **NOT** shake.
 - If the vial is shaken, contact the manufacturer.
 - **Note:** Gently swirl the vaccine before withdrawing subsequent doses.
- Examine the vaccine. It should be white to off-white in color and may contain white particles.
 - Do **NOT** use if liquid contains other particulate matter or is discolored.
- Using a new, sterile alcohol prep pad, cleanse the stopper of the multidose vaccine vial.



Moderna Preparation

- Withdraw the correct dosage of the vaccine into the syringe.
 - Moderna **red cap**:
 - 0.5mL for the primary *and* additional doses
 - 0.25mL for booster doses
 - Moderna **blue cap**:
 - 0.5mL for booster doses
- Ensure the syringe is not cold to the touch.
- Discard vial when there is not enough vaccine to obtain a complete dose.
 - Do **NOT** combine residual vaccine from multiple vials to obtain a dose.
 - Dispose the vial and residual vaccine as medical waste.



Moderna Preparation

- Note the date *and* time the vial was first punctured.
- Keep the vaccine between 2 °C and 25 °C (36 °F and 77 °F) for up to 12 hours.
 - *Discard any unused vaccine after 12 hours.*
 - *Do NOT refreeze.*
- **DO NOT puncture Moderna red cap vial stopper more than 20 times.**
- Label the syringe with the vaccine name.



Pfizer BioNTech (Gray Cap)

“Comirnaty”



Pfizer 12+ (Gray Cap)

- mRNA vaccine
- FDA approved for people 16 years and older
- FDA authorized for people 12 through 15 years old
- 2 dose primary series: 0.3mL
 - Administered 21 days apart
- **Does NOT require diluent**



Pfizer 12+ (Gray Cap) Additional and Booster Dose

- Additional (3rd) dose for immunocompromised individuals: 0.3mL
 - Administered 28 days after 2nd dose
- Booster dose: 0.3mL
- Multi-dose vials have a gray cap and labels with a gray border, each contain 6 doses



Pfizer 12+ (Gray Cap) Storage

Vaccine will arrive at a temperature between -90°C and -60°C (-130°F and -76°F) in a thermal shipping container with dry ice.

- Frozen vials may be stored in an **ultra-low temperature (ULT) freezer** at -90°C to -60°C (-130°F to -76°F) for up to 12 months from the date of manufacture.
 - Do not store vials at -25°C to -15°C (-13°F to 5°F). Once vials are thawed, they should not be refrozen
- Once received, frozen vials may be immediately transferred to the **refrigerator** [2°C to 8°C (36°F to 46°F)], thawed and stored for up to 10 weeks.
 - Record the 10-week refrigerated expiry date on the carton at the time of transfer.
 - If received at 2°C to 8°C , they should be stored at 2°C to 8°C .
- Doses that are expired must be disposed as medical waste.
 - **NOTE:** Contact the manufacturer to verify whether the expiration date has been extended.



Pfizer 12+ (Gray Cap) Storage

Use **beyond use date labels** to track how long the vaccine has been in the refrigerator (up to 10 weeks).

12 Years of Age and Older (Gray Cap)
Pfizer-BioNTech COVID-19 Vaccine

Store vaccine between 2°C and 8°C (36°F and 46°F) for up to 10 weeks.

Lot number(s): 123456A

Today's date: 06 / 01 / 2021 Time: 2:30 PM

USE BY*

Date: 08 / 10 / 2021 Time: 2:30 PM

*As the 10 week deadline approaches, contact the manufacturer for guidance if you will not be able to use the vaccine.

Name: Amy Nurse RN



Pfizer 12+ (Gray Cap) Storage

- Store vaccine in the original tray or box and protect from light.
- Vaccine stored in ULTs **must** be thawed before use.
- Thaw vaccine in the refrigerator or at room temperature before use.
 - Unpunctured vials may be stored in the refrigerator for up to 10 weeks.
 - Unpunctured vials may be stored between 8°C and 25°C (46°F and 77°F) for a total of 12 hours prior to first puncture.
- The amount of time needed to thaw vaccine varies based on the temperature and number of vials.
- Use vials stored in the refrigerator before removing vials from ULT storage.
- **Do NOT** refreeze thawed vaccine.



Pfizer 12+ (Gray Cap)

Preparation

- Check the vial label to ensure it is the correct formulation based on the age of the recipient.
- Check expiration date and beyond-use date/time.
 - Never use vaccine past the expiry date or beyond-use time.
 - Contact the manufacturer for extended expiration dates.
- Allow vaccine to reach room temperature.
- Gently invert the vial 10 times. **Do NOT shake** the vial.
 - If the vial is shaken, contact the manufacturer.
- The vaccine is white to off-white in color with *no* visible particles.
 - Do **not** use if the liquid is discolored or if particulate matter is observed after inverting.
- Use a new, sterile alcohol prep pad for each vial to wipe the stoppers of the vaccine vials.



Pfizer 12+ (Gray Cap)

Preparation

- Withdraw 0.3mL of vaccine into a new sterile syringe.
- Remove any significant air bubbles with the needle still in the vial to prevent loss of vaccine.
- Ensure the prepared syringe is not cold to the touch.
- Note the date and time the vaccine was first punctured on the vial.
- Keep punctured vials of vaccine between 2°C and 25°C (36° and 77°F) for up to 12 hours.
- *Discard any unused vaccine after 12 hours.*
 - Do **NOT** combine residual vaccine from multiple vials to obtain a dose.
 - Dispose the vial and residual vaccine as medical waste.
- Label syringe with vaccine **and** age indication.



Pfizer BioNTech (Purple Cap) “Comirnaty”



Pfizer 12+ (Purple Cap)

- mRNA vaccine
- FDA approved for people 16 years and older
- FDA authorized for people 12 through 15 years old
- 2 dose primary series: 0.3 mL
 - Administered 21 days apart
- **Diluent required**



Pfizer 12+ (Purple Cap) Additional and Booster Dose

- Additional dose (3rd dose) for immunocompromised: 0.3 mL
 - 28 days after 2nd dose
- Booster dose: 0.3 mL
- Multi-dose vials have a purple cap and a label with a purple border, each containing 6 doses



Pfizer (Purple Cap) Storage

Vaccine will arrive at a temperature between -90°C and -60°C (-130°F to -76°F) in a thermal shipping container with dry ice.

- Once received, remove the vial cartons immediately from the thermal container and preferably store in an **ULT freezer** between -90°C to -60°C (-130°F to -76°F) for up to 12 months from the date of manufacture.
- Unpunctured vials may be stored in a **freezer** between -25°C and -15°C (-13°F and 5°F) for up to 2 weeks.
- Unpunctured vials may be stored in the **refrigerator** between 2°C and 8°C (36°F and 46°F) for up to 1 month (31 days).
 - If received at 2°C to 8°C , they should be stored at 2°C to 8°C .
- Doses that are expired must be disposed as medical waste.
 - **NOTE:** Check the manufacturer webpage to verify whether the expiration date has been extended.



Pfizer (Purple Cap) Storage

Use **beyond-use date labels** to track how long the vaccine has been in the storage unit.

- **Freezer.** Up to **2 weeks** between -25°C and -15°C (-13°F to 5°F).
- **Refrigerator.** Up to **1 month (31 days)** between 2°C and 8°C (36°F and 46°F)

12 Years of Age and Older (Purple Cap)
Pfizer-BioNTech COVID-19 Vaccine

Store vaccine in the FREEZER between -25°C and -15°C (-13°F to 5°F) for up to 2 weeks.

Lot number(s): 123456A

Today's date: 05/18/2021 Time: 2:30 PM

USE BY*

Date: 06/01/2021 Time: 2:30 PM

*If the 2-week deadline is met, move any remaining vials to refrigerated storage for an additional 31 days. Use a refrigerator beyond-use date (BUD) label to reflect the new BUD time frame. Use a refrigerator beyond-use date (BUD) label to reflect the new BUD time frame.

Name: Amy Nurse RN



12 Years of Age and Older (Purple Cap)
Pfizer-BioNTech COVID-19 Vaccine

Store vaccine between 2°C and 8°C (36°F and 46°F) for up to 31 days.

Lot number(s): 123456A

Today's date: 06/01/2021 **USE BY*** Date: 07/01/2021

*As the 31 day deadline approaches, contact the manufacturer for guidance if you will not be able to use the vaccine.

Vaccine may be transported for 12 cumulative hours.

Transport date	<u>06/07</u>		
Time in transport:	<u>2 hrs</u>		
Time remaining:	<u>10 hrs</u>		

Name: Amy Nurse RN



Pfizer (Purple Cap) Storage

- Store vaccine in the original tray or box and protect from light.
- Frozen vaccine **must** be thawed before using.
- Thaw vaccine in the refrigerator or at room temperature:
 - **Refrigerator.** Between 2° C and 8° C (36° F and 46° F) Unpunctured vials may be stored in the refrigerator for up to 1 month (31 days).
 - **Room temperature.** Up to 25° C (77° F) Unpunctured vials cannot be kept at room temperature for more than 2 hours (including thaw time).
- The amount of time to thaw vaccine varies based on on temperature and number of vials.
- Use vials in the refrigerator before removing vials from ULT or freezer storage.
- ***Do NOT refreeze thawed vaccine.***



Pfizer (Purple Cap) Preparation

- Check the vial label to ensure it is the correct formulation based on the age of the recipient.
- Check expiration date and beyond-use date/time.
 - Never use vaccine past the expiry date or beyond-use time.
 - Contact the manufacturer for extended expiration dates.
- Allow vaccine to reach room temperature (vials can be held at room temperature up to 2 hours).
- Gently invert vial 10 times. **Do NOT shake** the vial.
 - If the vial is shaken, contact the manufacturer.
- The vaccine is white to off white in color and may contain opaque particles.
 - Do **NOT** use if liquid is discolored.
- Use a new, sterile alcohol prep pad for each vial to wipe the stoppers of the diluent and vaccine vials.



Pfizer (Purple Cap) Preparation

- Using a 21-gauge (or narrower) needle, **withdraw 1.8 mL of 0.9% sodium chloride** (normal saline, preservative-free) diluent provided with the ancillary kit into a mixing syringe.
 - Discard diluent vial and any remaining diluent.
 - Do **NOT** use bacteriostatic normal saline or other diluents to mix.
- Inject 1.8 mL 0.9% sodium chloride diluent into the vaccine vial.
- Using the mixing syringe, remove 1.8 mL of air from the vaccine vial to equalize the pressure in the vaccine vial.



Pfizer (Purple Cap) Preparation

- Gently invert the vial containing vaccine and diluent 10 times.
 - **Do NOT shake.** If the vial is shaken, contact the manufacturer.
- The vaccine will be off-white in color.
 - Do **NOT** use if the vaccine is discolored or contains particulate matter.
- Note the date and time the vaccine was mixed on the vial.
- Keep mixed vaccine between 2 °C and 25 °C (36 °F and 77 °F) for up to 6 hours.
 - **Discard any unsaved vaccine after 6 hours.**



Pfizer (Purple Cap) Preparation

- Cleanse the stopper on the vial of mixed vaccine with a new, sterile alcohol prep pad.
- **Withdraw 0.3 mL** of mixed vaccine into a new sterile syringe.
- Remove any significant air bubbles with the needle still in the vial to avoid loss of vaccine.
- Ensure the prepared syringe is not cold to the touch.
- Keep mixed vaccine between 2 °C and 25 °C (36 °F and 77 °F) for up to 6 hours.
- ***Discard any unused vaccine after 6 hours.***
 - Do **NOT** combine residual vaccine from multiple vials to obtain a dose.
 - Dispose the vial and residual vaccine as medical waste.
- Label syringe with vaccine name ***and*** age indication.



Pfizer BioNTech (Orange Cap)



Pfizer 5-11 (Orange Cap)

- mRNA vaccine
- FDA authorized for ages 5-11 years
- 2 dose primary series: 0.2mL
 - Administered 21 days apart
- Additional dose (3rd dose) for immunocompromised: 0.2mL
 - Administered 28 days after 2nd dose
- A booster dose is *not* recommended at this time
- Multi-dose vials have an **orange cap** and **label with an orange border**, each containing 10 doses
- **Diluent required**



Pfizer (Orange Cap) Storage

Vaccine will arrive at a temperature between -90°C and -60°C (-130°F to -76°F) in a thermal shipping container with dry ice.

- Frozen vials may be stored in an **ULT freezer** at -90°C to -60°C (-130°F to -76°F) for up to 12 months from the date of manufacture.
 - Do not store vials at -25°C to -15°C (-13°F to 5°F).
 - Once vials are thawed, they should not be refrozen
- Once received, frozen vials may be immediately transferred to the **refrigerator** (2°C to 8°C [36°F to 46°F]), thawed and stored for up to 10 weeks.
 - Record the 10-week refrigerated expiry date on the carton at the time of transfer.
 - If received at 2°C to 8°C , they should be stored at 2°C to 8°C .
- Doses that are expired must be disposed as medical waste.
 - **NOTE:** Contact the manufacturer to verify whether the expiration date has been extended.



Pfizer (Orange Cap) Storage

Use beyond-use date labels to track how long the vaccine has been in the refrigerator (up to 10 weeks).

FORMULATION: 5 Through 11 Years of Age
Pfizer-BioNTech COVID-19 Vaccine

Store vaccine between 2°C and 8°C (36°F and 46°F) for up to 10 weeks.

Lot number(s): 123456A

Today's date: 06 / 01 / 2021 Time: 2:30 PM

USE BY*

Date: 08 / 10 / 2021 Time: 2:30 PM

*As the 10 week deadline approaches, contact the manufacturer for guidance if you will not be able to use the vaccine.

Name: Amy Nurse RN



Pfizer (Orange Cap) Storage

- Store vaccine in the original tray or box and protect from light.
- Vaccine stored in ULTs must be thawed before use.
- Thaw vaccine in the refrigerator or at room temperature before use.
 - Unpunctured vials may be stored in the refrigerator for up to 10 weeks.
 - Unpunctured vials may be stored between 8°C and 25°C (46°F and 77°F) for a total of 12 hours prior to first puncture.
- The amount of time needed to thaw vaccine varies based on the temperature and number of vials.
- Use vials stored in the refrigerator before removing vials from ULT storage.
- *Do NOT refreeze thawed vaccine.*



Pfizer (Orange Cap) Preparation

- Check the vial label to ensure it is the correct formulation based on the age of the recipient.
- Check expiration date and beyond-use date/time.
 - Never use vaccine past the expiry date or beyond-use time.
 - Contact the manufacturer for extended expiration dates.
- Allow vaccine to reach room temperature.
- Gently invert vial 10 times. **Do NOT shake** the vial.
 - If the vial is shaken, contact the manufacturer.
- The vaccine is white to off white in color and may contain opaque particles.
 - Do **NOT** use if liquid is discolored.
- Use a new, sterile alcohol prep pad for each vial to wipe the stoppers of the diluent and vaccine vials.



Pfizer (Orange Cap) Preparation

- Using a 21-gauge (or narrower) needle, **withdraw 1.3 mL of 0.9% sodium chloride** (normal saline, preservative-free) diluent provided with the ancillary kit into a mixing syringe.
 - Discard diluent vial and any remaining diluent.
 - Do **NOT** use bacteriostatic normal saline or other diluents to mix.
- Inject 1.3 mL 0.9% sodium chloride diluent into the vaccine vial.
- Using the mixing syringe, remove 1.3 mL of air from the vaccine vial to equalize the pressure in the vaccine vial.



Pfizer (Orange Cap) Preparation

- Once the diluent is added, gently invert the vial containing vaccine and diluent 10 times.
 - **Do NOT shake.** If the vial is shaken, contact the manufacturer.
- The vaccine will be off-white in color.
 - Do **NOT** use if discolored or contains particulate matter.
- Note the date and time the vaccine was mixed on the vial.
- Keep mixed vaccine between 2 °C and 25 °C (36 °F and 77 °F) for up to 12 hours.
- **Discard any unsaved vaccine after 12 hours.**



Pfizer (Orange Cap) Preparation

- Cleanse the stopper on the vial of mixed vaccine with a new, sterile alcohol prep pad.
- **Withdraw 0.2 mL** of mixed vaccine into the syringe.
- Remove any significant air bubbles with the needle still in the vial to avoid loss of vaccine.
- Ensure the prepared syringe is not cold to the touch.
- Keep mixed vaccine between 2° C and 25° C (36° F and 77° F) for up to 12 hours.
- **Discard any unused vaccine after 12 hours.**
 - Do **NOT** combine residual vaccine from multiple vials to obtain a dose.
 - Dispose the vial and residual vaccine as medical waste.
- Label syringe with vaccine name *and* age indication.



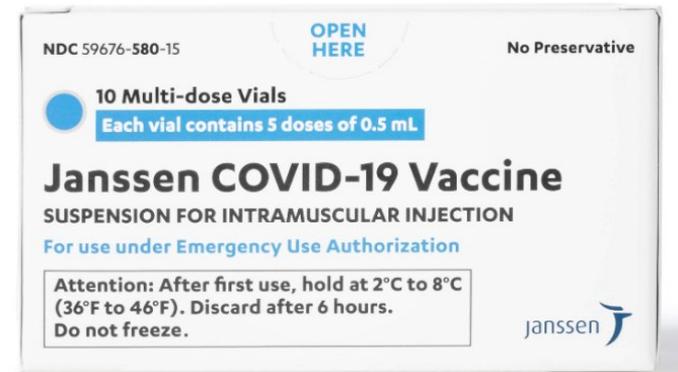
Janssen

(Johnson & Johnson)



Janssen (Johnson & Johnson)

- Viral vector vaccine
- FDA authorized for people 18 years and older
- 1 dose primary series: 0.5mL
- Additional dose (2nd dose) for immunocompromised: **mRNA vaccine** (i.e., Moderna, Pfizer purple cap or gray cap)
- Booster dose: 0.5mL
- Multi-dose vials each contain 5 doses



Janssen Storage

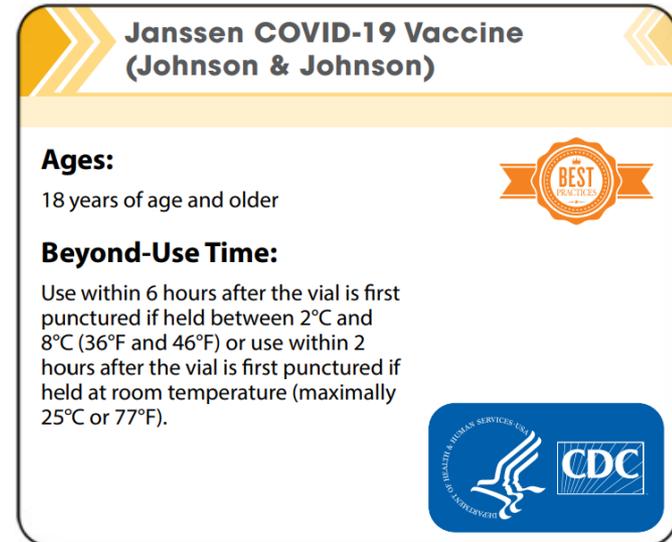
Vaccine will arrive refrigerated at a temperature between 2 °C to 8 °C (36 °F and 46 °F) in a qualified shipping container.

- Unpunctured vials may be stored in a **refrigerator** at temperatures between 2 ° to 8 °C (36 °F and 46 °F) until the expiration date.
 - Do not freeze.
- Doses that are expired must be disposed as medical waste.
 - Use the Janssen online Expiry Checker to verify the expiration date before disposing. (<https://vaxcheck.jnj/>)



Janssen Storage

- Punctured vials may be stored in the refrigerator at 2°C and 8°C (36°F and 46°F) for up to **6 hours**.
- Punctured vials may also be stored at room temperature (9°C to 25°C [47°F to 77°F]) for up to **2 hours**.
- Note the date and time the vial was first punctured (beyond-use date) for best practices.



**Janssen COVID-19 Vaccine
(Johnson & Johnson)**

Ages:
18 years of age and older

Beyond-Use Time:
Use within 6 hours after the vial is first punctured if held between 2°C and 8°C (36°F and 46°F) or use within 2 hours after the vial is first punctured if held at room temperature (maximally 25°C or 77°F).

BEST PRACTICES

CDC



Janssen Preparation

- Check expiration date and beyond-use date/time.
 - Never use vaccine past the expiry date or beyond-use time.
 - Use the online Janssen Expiry Checker or scan the carton's QR code to verify expiration dates.
- Gently swirl the vial upright for 10 seconds. **Do NOT shake** the vial.
 - If the vial is shaken, contact the manufacturer.
- The vaccine should be colorless to slightly yellow and may contain opaque particles.
 - Do **NOT** use if liquid is discolored or contains particulate matter.
- Use a new, sterile alcohol prep pad for each vial to wipe the stoppers of the vaccine vial.



Janssen Preparation

- Choose the correct needle gauge, length and syringe for the recipient.
- Using a new, sterile needle and syringe, **withdraw 0.5mL** of vaccine into the syringe.
- Note the date and time the vial was first punctured.
- Keep the vaccine at 2°C and 8°C (36°F and 46°F) for up to **6 hours** or at room temperature (maximally 25°C or 77°F) for up to **2 hours**.
- *Discard any unused vaccine after 2 hours at room temperature or 6 hours at refrigerated temperature.*
 - Do **NOT** combine residual vaccine from multiple vials to obtain a dose.
 - Dispose of the vial and residual vaccine as medical waste.



Contact

- NMSIIS Help Desk (833) 882-6454

CONTACT INFO	DESCRIPTION
COVID.Vaccines@state.nm.us	COVID-19 Vaccine Record requests; Provider COVID-19 Vaccine Order status; NMSIIS assistance.
COVID.Therapeutics@state.nm.us	Provider questions regarding COVID oral therapeutics (Molnupiravir and Paxlovid); COVID PrEP (Evusheld); mAB; or Remdesivir
COVIDData.compliant@state.nm.us	COVID-19 vaccine storage and handling questions, temperature log and onboarding Vaccine Plan submissions.
COVID.testing-doh@state.nm.us	For Provider questions on testing and test supplies

