

COVID-19 Vaccine Storage and Handling UpdateSeptember 9, 2021

Housekeeping

How to Ask Questions

- Click on the icon found at the bottom part of your screen
- A box will open where you can type in questions, comments, indicate sound problems, etc.
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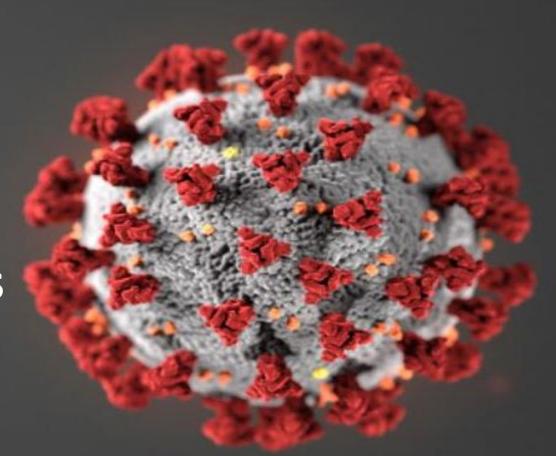
Slides & Recording

 This webinar is being recorded and a link as well as slides will be emailed out through our listserv as well as posted on our website at: www.michigan.gov/COVIDvaccineprovider

Topics Covered

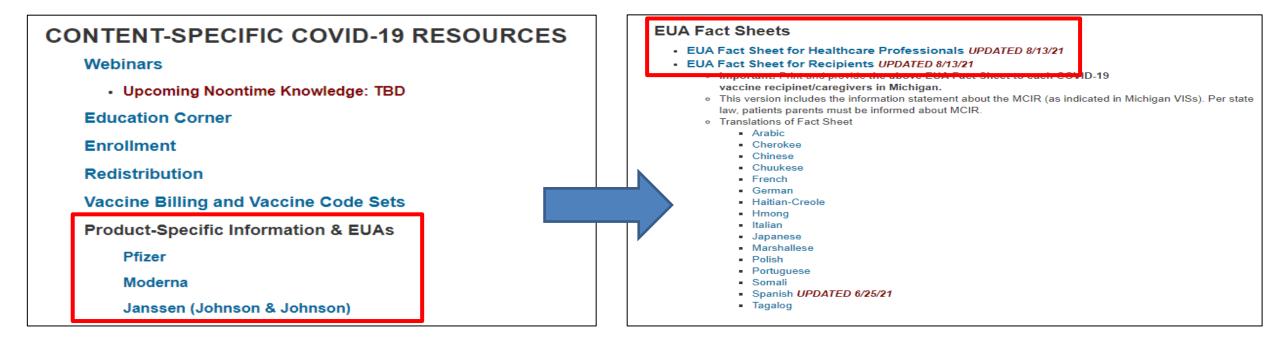
- Storage and Handling Resources
- Janssen (J & J) COVID-19 Vaccine Storage and Handling
- Moderna COVID-19 Vaccine Storage and Handling
- Pfizer COVID-19 Vaccine Storage and Handling
- Temperature Monitoring and Excursions
- Expiration Date Tracking
- Disposal of COVID-19 Vaccine
- CDC Interim Clinical Considerations

COVID-19 Vaccine Storage & Handling Resources



EUA Fact Sheets for Healthcare Providers

• www.michigan.gov/covidvaccineprovider



EUA Fact Sheet for Healthcare Providers Cont.

ENGLISH

FACT SHEET FOR HEALTHCARE PROVIDERS ADMINISTERING VACCINE (VACCINATION PROVIDERS)

EMERGENCY USE AUTHORIZATION (EUA) OF THE PFIZER-BIONTECH COVID-19 VACCINE TO PREVENT CORONAVIRUS DISEASE 2019 (COVID-19)

The U.S. Food and Drug Administration (FDA) has issued an Emergency Use Authorization (EUA) to permit the emergency use of the unapproved product, Pfizer-BioNTech COVID-19 Vaccine, for active immunization to prevent COVID-19 in individuals 12 years of age and older and to provide a third dose to individuals 12 years of age and older who have been determined to have certain kinds of immunocompromise.

COMIRNATY (COVID-19 Vaccine, mRNA) is an FDA-approved COVID-19 vaccine made by Pfizer for BioNTech. It is approved as a 2-dose series for the prevention of COVID-19 in individuals 16 years of age and older and is also authorized for emergency use in individuals 12 through 15 years and to provide a third dose to individuals 12 years of age and older who have been determined to have certain kinds of immunocompromise.

The FDA-approved COMIRNATY (COVID-19 Vaccine, mRNA) and the EUA-authorized Pfizer-BioNTech COVID-19 Vaccine have the same formulation and can be used interchangeably to provide the COVID-19 vaccination series.1

SUMMARY OF INSTRUCTIONS FOR COVID-19 VACCINATION PROVIDERS

Vaccination providers enrolled in the federal COVID-19 Vaccination Program must report all vaccine administration errors, all serious adverse events, cases of Multisystem Inflammatory Syndrome (MIS) in adults and children, and cases of COVID-19 that result in hospitalization or death following administration of Pfizer-BioNTech COVID-19 Vaccine. See "MANDATORY REQUIREMENTS FOR PFIZER-BIONTECH COVID-19 VACCINE ADMINISTRATION UNDER EMERGENCY USE AUTHORIZATION" for reporting requirements.

The Pfizer-BioNTech COVID-19 Vaccine is a suspension for intramuscular injection administered as a series of two doses (0.3 mL each) 3 weeks apart.

A third dose of the Pfizer-BioNTech COVID-19 Vaccine (0.3 mL) administered at least 28 days following the second dose of this vaccine is authorized for administration to individuals at least 12 years of age who have undergone solid

Revised: 23 August 2021

FACT SHEET FOR HEALTHCARE PROVIDERS ADMINISTERING VACCINE (VACCINATION PROVIDERS) EMERGENCY USE AUTHORIZATION (EUA) OF

THE MODERNA COVID-19 VACCINE TO PREVENT CORONAVIRUS DISEASE 2019 (COVID-19)

The U.S. Food and Drug Administration (FDA) has issued an Emergency Use Authorization (EUA) to permit the emergency use of the unapproved product, MODERNA COVID-19 VACCINE, for active immunization to prevent COVID-19 in individuals 18 years of age and

SUMMARY OF INSTRUCTIONS FOR COVID-19 VACCINATION PROVIDERS

Vaccination providers enrolled in the federal COVID-19 Vaccination Program must report all vaccine administration errors, all serious adverse events, cases of Multisystem Inflammatory Syndrome (MIS) in adults, and cases of COVID-19 that result in hospitalization or death following administration of the Moderna COVID-19 Vaccine. See "MANDATORY REQUIREMENTS FOR MODERNA COVID-19 VACCINE ADMINISTRATION UNDER EMERGENCY USE AUTHORIZATION" for reporting requirements.

The Moderna COVID-19 Vaccine is a suspension for intramuscular injection administered as a series of two doses (0.5 mL each) 1 month apart.

See this Fact Sheet for instructions for preparation and administration. This Fact Sheet may have been updated. For the most recent Fact Sheet, please see www.modernatx.com/covid19vaccine-

For information on clinical trials that are testing the use of the Moderna COVID-19 Vaccine for active immunization against COVID-19, please see www.clinicaltrials.gov.

DESCRIPTION OF COVID-19

Coronavirus disease 2019 (COVID-19) is an infectious disease caused by the novel coronavirus, SARS-CoV-2, that appeared in late 2019. It is predominantly a respiratory illness that can affect other organs. People with COVID-19 have reported a wide range of symptoms, ranging from mild symptoms to severe illness. Symptoms may appear 2 to 14 days after exposure to the virus. Symptoms may include: fever or chills; cough; shortness of breath; fatigue; muscle and body aches; headache; new loss of taste or smell; sore throat; congestion or runny nose; nausea or vomiting; diarrhea.

DOSAGE AND ADMINISTRATION

Storage and Handling

The information in this Fact Sheet supersedes the information on the vial and carton labels.

During storage, minimize exposure to room light.

Revised: Aug/12/2021

Moderna revised: August 27, 2021

FACT SHEET FOR HEALTHCARE PROVIDERS ADMINISTERING VACCINE (VACCINATION PROVIDERS)

EMERGENCY USE AUTHORIZATION (EUA) OF THE JANSSEN COVID-19 VACCINE TO PREVENT CORONAVIRUS DISEASE 2019 (COVID-19)

The U.S. Food and Drug Administration (FDA) has issued an Emergency Use Authorization (EUA) to permit the emergency use of the unapproved product, Janssen COVID-19 Vaccine, for active immunization to prevent COVID-19 in individuals 18 years of age and older.

SUMMARY OF INSTRUCTIONS FOR COVID-19 VACCINATION PROVIDERS

Vaccination providers enrolled in the federal COVID-19 Vaccination Program must report all vaccine administration errors, all serious adverse events, cases of Multisystem Inflammatory Syndrome (MIS) in adults, and cases of COVID-19 that result in hospitalization or death following administration of the Janssen COVID-19 Vaccine. See "MANDATORY REOUIREMENTS FOR THE JANSSEN COVID-19 VACCINE ADMINISTRATION UNDER EMERGENCY USE AUTHORIZATION" for reporting requirements.

The Janssen COVID-19 Vaccine is a suspension for intramuscular injection administered as a single dose (0.5 mL).

See this Fact Sheet for instructions for preparation and administration. This Fact Sheet may have been updated. For the most recent Fact Sheet, please see www.janssencovid19vaccine.com.

For information on clinical trials that are testing the use of the Janssen COVID-19 Vaccine for active immunization against COVID-19, please see www.clinicaltrials.gov.

DESCRIPTION OF COVID-19

Coronavirus disease 2019 (COVID-19) is an infectious disease caused by the novel coronavirus, SARS-CoV-2, that appeared in late 2019. It is predominantly a respiratory illness that can affect other organs. People with COVID-19 have reported a wide range of symptoms, ranging from mild symptoms to severe illness. Symptoms may appear 2 to 14 days after exposure to the virus. Symptoms may include: fever or chills; cough; shortness of breath; fatigue; muscle or body aches; headache; new loss of taste or smell; sore throat; congestion or runny nose; nausea or vomiting; diarrhea.

DOSAGE AND ADMINISTRATION

The storage and handling information in this Fact Sheet supersedes the storage and handling information on the carton and vial labels.

Storage and Handling

Storage Prior to First Puncture of the Vaccine Vial

Store unpunctured multi-dose vials of the Janssen COVID-19 Vaccine at 2°C to 8°C (36°F to 46°F) and protect from light. Do not store frozen.

Revised: Aug/27/2021

Janssen (J & J) revised: August 27, 2021

Pfizer revised: August 23, 2021

¹ The licensed vaccine has the same formulation as the EUA-authorized vaccine and the products can be used interchangeably to provide the vaccination series without presenting any safety or effectiveness concerns. The products are legally distinct with certain differences that do not impact safety or effectiveness.



U.S. COVID-19 Vaccine Product Information

<u>Español</u>

Find a suite of information and materials that are needed for each specific COVID-19 vaccine that cover administration, storage and handling, safety, and reporting.

Pfizer-BioNTech

Moderna

Janssen/J&J



Prevaccination Screening Form

Download a prevaccination checklist in multiple languages.

Arabic 🔼 | English 🚨 | French 🔼 | Haitian Creole 🚨 | Korean 🔼 | Portuguese 🚨 | Simplified Chinese 🚨

Spanish 🚨 | Vietnamese 💆

Requirements, Trainings, and Resources

Identification, Disposal, and Reporting of COVID-19

FAQs for Healthcare Professionals

Vaccine Wastage 🔼

COVID-19 Vaccine Quick Reference Guide for Healthcare

Vaccine Storage and Handling Toolkit

Professionals 🔉

https://www.cdc.gov/vaccines/covid-19/info-by-product/index.html

Training and Education

COVID-19 vaccine Ouick кетегепсе Guide for Healthcare

CDC COVID-19 Vaccine Storage and Handling Summaries





Basics

- Store vaccine in a refrigerator. See guidance below for further details.
- Check and record storage unit temperatures each workday. See guidance below for each type of temperature monitoring device. Save storage records for 3 years, unless your jurisdiction requires a longer time period.

Deliveries

Vaccine

- 1. The vaccine will arrive in a 2° to 8°C (36°F and 46°F) qualified shipping container.
- 2. Examine the shipment for signs of damage.
- 3. As a backup to the qualified shipping container, temperature monitors are placed in each shipment. Janssen vaccines may include thawed and frozen/partially frozen vaccines and due to this, only warm monitors will be included in Janssen shipments.
- 4. Remove the instruction card for the temperature monitor immediately. Follow the guide on the back of the card to read
- 5. The expiration date is NOT printed on the vaccine vial or carton. To determine the expiration date:
- Scan the OR code on the outer carton, or
- Call 1-800-565-4008, or
- Visit www.vaxcheck.jnj

Write the expiration date on the carton.

Ancillary Supply Kit

08/24/2021 CS3221394

- An ancillary supply kit will be provided and includes enough supplies to administer 100 doses of vaccine.
- Administration supplies include needles, syringes, sterile alcohol prep pads, vaccination record cards (shot cards), and some PPF.
- The kit is delivered separately from the vaccine. Unpack the kit and check for receipt of the correct administration supplies and quantities.



Pfizer-BioNTech COVID-19 Vaccine

Storage and Handling Summary



- Store vaccine in an ultra-cold freezer, thermal shipping container, freezer, or refrigerator. See guidance below for each storage unit.
- Follow the manufacturer's instructions for returning the thermal shipping container.

Check and record storage unit temperatures each workday. See guidance below for each type of storage unit. Save storage records for 3 years, unless your jurisdiction requires a longer time period.

Deliveries

- 1. The vaccine will arrive in a thermal shipping container at ultra-cold temperatures between -90°C and -60°C (-130°F and -76°F) with dry ice.
- 2. Follow the Pfizer-BioNTech COVID-19 Vaccine Delivery Checklist for detailed steps to ensure the vaccine is received, stored, and handled appropriately (https:// www.cdc.gov/vaccines/covid-19/info-by-product/pfizer/ downloads/delivery-checklist.pdf).
- 3. Review practices for working with dry ice in the Dry Ice Safety for Healthcare Professionals before handling any dry ice (https://www.cdc.gov/vaccines/covid-19/info-byproduct/pfizer/downloads/dry-ice-safety-hcp.pdf)

Ancillary Supply Kit

An ancillary supply kit will be delivered separately from the

- Mixing supplies: Diluent, needles, syringes, and sterile alcohol prep pads
- Mixing supplies are packaged separately with a green identification label.
- Do NOT use mixing supplies to administer vaccine.
- Administration supplies: Needles, syringes, sterile alcohol prep pads, vaccination record cards, and some
- Ancillary supply kits have been reconfigured to support the number of doses ordered.

Thermal Shipping Container

CDC recommends providers consider using the thermal shipping container for temporary storage only. The container requires significant support to store vaccine at proper temperatures, including trained staff, a regular supply of dry ice, and standard operating procedures for regular maintenance.

Use the Controlant temperature monitoring device (TMD) included with the thermal shipping container to monitor the temperature.

- Review contact information.
- If the contact for your order (inVTrckS) is not valid, you will NOT be notified in the event of a temperature excursion. Contact your jurisdiction's immunization program for assistance.
- If your contact is valid and you are not receiving e-mails or cannot load email hyperlinks, refer to Controlant for troubleshooting (https://in.controlant.com/
- Identify up to 4 contacts to receive e-mails and text alerts on Removing vaccine vials/doses for use: the container's temperature status.
- Review DAILY e-mails on the status of the container.
- Click the link in daily e-mails to access and download all temperature data. Save the Excel file summarizing all temperature data for at least 3 years.
- Save the return shipping label provided in your shipping container at delivery. Use the shipping label to return the thermal

- Limit temporary storage in the thermal shipping container to 10 days when possible.
- Arrange for dry ice to maintain the appropriate temperature in the thermal shipping container, Replenish dry ice pellets (10 mm to 16 mm) within 24 hours of delivery and every 5 days thereafter. Follow manufacturer's guidance for adding dry ice.
- Dry ice will NOT be provided to replenish the container.
- Transfer any vaccine remaining in the thermal shipping container after 10 days to a:
- · Freezer for up to 2 weeks, then
- Refrigerator for up to 1 month (31 days)
- Determine the number of vials needed before opening the thermal shipping container.
- Open the thermal shipping container no more than 2 times per day for up to 3 minutes each time. Use packaging tape to reseal the outer carton after each entry.
- Store vaccine vials upright in the tray and protect from light.





- Store vaccine in a freezer or refrigerator. See guidance below for each storage unit.
- Use vaccine vials stored in the refrigerator before removing vials from frozen storage.
- Check and record storage unit temperature each workday. See guidance below for each type of temperature monitoring device. Save storage records for 3 years, unless your jurisdiction requires a longer time period.

Deliveries

- 1. The vaccine will arrive frozen between -50°C and -15°C (-58°F and 5°F).
- 2. Examine the shipment for signs of damage.
- 3. Open the box and remove TagAlert Temperature Monitor from box (placed in the inner box next to vaccine).
- 4. Check the TagAlert temperature monitoring device by pressing the blue "start and stop" button.
- Left arrow points to a green checkmark: The vaccine is ready to use. Store the vaccine at proper temperatures immediately.
- * Right arrow points to a red X: The numbers 1 and/or 2 will appear in the display. Store the vaccine at proper temperatures and label DO NOT USE! Call the phone number indicated in the instructions or your jurisdiction's immunization program IMMEDIATELY!
- 5. The expiration date is NOT printed on the vaccine vial or carton. To determine the expiration date:
- . Scan the QR code located on the outer carton, or
- Go to www.modernatx.com/covid19vaccine-eua/

Ancillary Supply Kit

An ancillary kit with supplies will be provided for administering the vaccine. Administration supplies include needles, syringes, sterile alcohol prep pads, vaccination record cards (shot cards), and some PPE.

The kit is delivered separately from the vaccine. Unpack the kit and check for receipt of the correct administration supplies and quantities.



Unpunctured vials may be stored in the freezer between -50°C and -15°C (-58°F and 5°F).

- Store in the original carton.
- Protect from light.
- Do not store with dry ice or below -50°C (-58°F).

https://www.cdc.gov/vaccines/covid-19/info-by-product/index.html

CDC COVID-19 Vaccine Prep and Admin Summaries





General Information

Vaccine: Janssen COVID-19 Vaccine (Johnson & Johnson) Multidose vial: 5 doses per vial Dosage: 0.5 mL

Do NOT mix with a diluent, 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.

Expiration Date

The expiration date is NOT printed on the vaccine vial or carton. To determine the expiration date

- Scan the QR code located on the outer carton, or
- Call 1-800-565-4008, or
- Go to www.vaxcheck.ini.

Prepare and Administer the Vaccine



Write date on carton. As the expiration date approaches, check the expiration date again. Do not discard vaccine until ensuring the expiration date has passed. Use CDC's expiration date tracking tool to document expiration date changes.

- Assess recipient status:
- Screen for contraindications and precautions.
- Review vaccination history

- Review medical considerations



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Follow aseptic technique. Perform hand hygiene before vaccine preparation, between patients, when changing gloves (if worn), and any time hands become soiled.[†]



With the vial unright, gently swirl the vaccine for 10 seconds 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 a colorless to slightly yellow, clear to very opalescent suspension. Do not use if liquid contains particulate matter or if it is discolored.

Using a new, sterile alcohol prep pad, cleanse the stopper of the multidose vaccine vial.

Choose the correct equipment, including the correct needle size. Use a new, sterile needle and syringe for each injection.

Ensure the needle and syringe are secured tightly together to prevent the vaccine from inadvertently leaking during



- Regardless of the type of syringe used. ensure the amount of vaccine in the syringe equals 0.5 mL.
- If the amount of vaccine remaining in the vial cannot provide a full 0.5 mL dose, discard the vial and contents.
- from multiple vials to obtain



* COVID-19 vaccines and other vaccines may be administered at the same visit, as well as within 14 days of each other. When deciding whether to administer COVID-19 vaccines and other vaccines, providers should consider whether the patient is behind or at risk of becoming behind on recommended vaccines. They should also consider the patient's risk of vaccine-preventable diseases (e.g., during an outbreak) and the reactogenicity profile of the vaccines.

*Gloves are not required unless the person administering the vaccine is likely to come in contact with potentially infectious body fluids or has open lesions on the hands. If worn, perform hand

§ It is not necessary to change needles between drawing vaccine from a vial and injecting it into a recipient unless the needle has been damaged or contaminated.

07/19/2021 CS322139-8



Vaccine Preparation and Administration Summary **General Information**

Pfizer-BioNTech COVID-19 Vaccine

Vaccine: Pfizer-BioNTech COVID-19 Vaccine

Diluent: 0.9% sodium chloride (normal saline, preservative-free) Use a new vial every time.

Multidose vial: 6 doses per vial

Dosage: 0.3 mL

Vaccine MUST be mixed with diluent before administration.

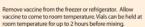
Age Indications

12 years of age and older

- 2-dose series separated by 21 days*
- Moderately to severely immunocompromised people: Consider an additional dose at least 28 days after the initial 2-dose primary series.*
- A series started with Pfizer-BioNTech COVID-19 Vaccine should be completed with this product.

Prepare the Vaccine

Follow aseptic technique. Perform hand hygiene before vaccine preparation, between patients, when changing gloves (if worn), and any time hands become soiled.1



Before mixing, check the expiration dates of the vaccine and diluent. NEVER use expired vaccine or diluent. The expiration dates for the diluent and the vaccine are

located on the respective vials.

With the vaccine at room temperature, gently invertival 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.

Using a new, sterile alcohol prep pad for each vial, wipe off the stoppers of the diluent and vaccine vials. Using a 21-gauge (or narrower) needle, withdraw 1.8 mL of 0.9% sodium chloride (normal saline, preservative-free) into a mixing syringe. Discard diluent vial and any remaining

diluent every time. Do NOT use bacteriostatic normal

saline or other diluents to mix the vaccine.



Inject 1.8 mL 0.9% sodjum chloride into the vaccine vial.

pressure in the vaccine vial.

Gently invert the vial containing vaccine and diluent 10 times. The vaccine will be off-white in color. Do not use if discolored or contains particulate matter Do not shake. If the vial is shaken, contact the manufacturer

Note the date and time the vaccine was

Keep mixed vaccine between 2°C and 25°C (36°F to 77°F), minimize exposure to room light, and avoid exposure to direct sunlight and ultraviolet light. Administer within 6 hours. Discard any unused vaccine after 6 hours. Do not return to freezer storage.



For more information, please see Interim Clinical Considerations for Use of COVID-19 Vaccines Currently Authorized in the United States at https://www.cdc.gov vaccines/covid-19/clinical-considerations/covid-19-vaccines-us.html.

Gloves are not required unless the person administering the vaccine is likely to come in contact with potentially infectious body fluids or has open lesions on the hands. If worn, perform hand hygiene and change gloves between patients.



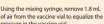
Administration

Intramuscular (IM) injection in the deltoid muscle

Thawing Frozen Vaccine

- Frozen vaccine must be thawed before using.
- Thaw vaccine in the refrigerator or at room temperature:
- Refrigerator: Between 2°C and 8°C (36°E and 46°E) Unpunctured vials may be stored in the refrigerator for up to 1 month (31 days).
- Room temperature (for immediate use): Up to 25°C (77°F). Unpunctured vials cannot be kept at room temperature for more than 2 hours (including thaw time)
- Amount of time needed to thaw vaccine varies based on temperature and number of vials.
- Do NOT refreeze thawed vaccine.
- Use vials in the refrigerator before removing vials from ultracold temperature or freezer storage
- Use CDC's beyond-use date labels for this vaccine to track storage time at refrigerated and frozen temperatures.

(normal saline, preservative-free) diluent









Moderna COVID-19 Vaccine Vaccine Preparation and Administration Summary



General Information

Vaccine: Moderna COVID-19 Vaccine

Multidose vial

 Maximum of 15 doses per vial Dosage: 0.5 mL

Do NOT mix with a diluent.

Age Indications

18 years of age and older

Schedule

- 2-dose series separated by 1 month (28 days)". Moderately to severely immunocompromised people Consider an additional dose at least 28 days after the initial
- 2-dose primary series. A series started with Moderna COVID-19 Vaccine should be completed with this product.

Administration **Expiration Date**

Intramuscular (IM) injection in the deltoid muscle

Thawing Frozen Vaccine

- 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 30 days.
- Room temperature: Between 8°C and 25°C (46°F and 77°F). Unpunctured vials may be held at room temperature for up to
- Amount of time needed to thaw vaccine varies based on temperature and number of vials
- » In the refrigerator: Up to 3 hours
- » Room temperature: Up to 1 hour and 30 minutes
- Do NOT refreeze thawed vaccine.
- Use vials in the refrigerator before removing vials from the freezer
- Use CDC's beyond-use date labels for this vaccine to track storage time at refrigerated temperatures

lookup option, enter the lot number, and the expiration date will be displayed. Another option is to access the website directly: http:// www.modernatx.com/covid19vaccine-eua. CDC's expiration date tracking tool (https://www.cdc.gov/vaccines/covid-19/info-by-product/ Prepare and Administer the Vaccine

Assess recipient status: Screen for contraindications and precautions.

Review vaccination

pfizer/downloads/expiration-tracker.pdf) can facilitate documenting expiration dates.

Follow aseptic technique. Perform hand hygiene before vaccine preparation, between patients, when changing gloves (if worn), and any time hands become soiled.†

To determine the expiration date, scan the QR code located on the vial or carton. The QR code will bring up a website; then choose the

Vaccine must be thawed before using. If removing the vial from the refrigerator, let it stand at room temperature

Unpunctured vials: Check the expiration date. Never use expired vaccine. Punctured vials: Check the beyond-use time. Never use vaccine after the 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 or translucent 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.

*For more information, please see Interim Clinical Considerations for Use of COVID-19 Vaccines Currently Authorized in the United States at https://www.cdc.gov/

vaccines/covid-19/clinical-considerations/covid-19-vaccines-us.html. †Gloves are not required unless the person administering the vaccine is likely to come in contact with potentially infectious body fluids or has open lesions or

Choose the correct equipment, including the correct needle size. Use a new, sterile needle and syringe for each injection

the hands. If worn, perform hand hygiene and change gloves between patients.

https://www.cdc.gov/vaccines/covid-19/info-by-product/index.html

CDC COVID-19 Vaccine Transport Summaries





Procedure

Follow storage and handling best practices outlined in CDC's Vaccine Storage and Handling Toolkit to maintain the cold chain when packing and transporting vaccine. Transport Janssen COVID-19 Vaccine in a portable refrigerator unit or a container/ packout qualified to maintain temperature between 2°C and 8°C (36°F and 46°F). To monitor vaccine temperatures, use a digital data logger with a buffered temperature probe that displays current, minimum, and maximum temperatures. A DDL with an external temperature display is preferred to minimize opening the

Upon arrival at clinic place vaccine in an on-site storage unit that maintains recommended temperatures, if available. If there is no storage unit available, keep the vaccine in the transport container, maintaining recommended temperatures.

Temperature monitoring

Record time and min/max temperatures:

- At the start of transport
- Whenever the transport container is opened
- When transport concludes



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- Vaccine vials may be transported more than once.
- Both punctured and unpunctured vials may be transported.

Refrigerated transport: Between 2°C and 8°C (36°F and 46°F)

- Unpunctured vials: Vaccine may be transported at refrigerated temperatures until the expiration date.
- CDC recommends the total time for transport alone or transport plus clinic workday should be a maximum of 8 hours (e.g., if transport to an off-site clinic is 1 hour each way, the clinic may run for up to 6 hours).
- Punctured vials: Punctured vials may be transported at refrigerated temperatures
- Once punctured, store the vaccine at refrigerated temperatures. Vaccine must be used within 6 hours
- Time used for transport counts as part of the 6-hour
- CDC recommends transporting vaccine in vials. However, there may be instances when the only ontion is to transport predrawn vaccine in a syringe, U.S. Pharmacopeia includes guidance for Vaccine Toolkit: Operational Considerations for Healthcare

Do NOT use dry ice when transporting vaccine.

Detailed information and additional

transport guidelines can be found in

CDC's Vaccine Storage and Handling Toolkit.

CDC's Transport Temperature Log https://www.cdc.gov/vaccines/covid-19/downloads/transport-temperature-log.pdf

transporting predrawn vaccine in syringes in the USP COVID-19 Practitioners

USP COVID-19 Vaccine Toolkit: Operational Considerations for Healthcare Practitioners https://www.usp.org/covid-19/vaccine-handling-toolkit

Pfizer-BioNTech COVID-19 Vaccine

Transporting Vaccine for Vaccination Clinics Held at Satellite, Temporary, or Off-Site Locations



Follow storage and handling best practices outlined in CDC's Vaccine Storage and Handling Toolkit, COVID-19 Vaccine Addendum (https://www.cdc.gov/vaccines/hcp/admin/storage/toolkit/storagehandling-toolkit.pdf), to maintain the cold chain when packing and transporting vaccine.

Transport Pfizer-BioNTech COVID-19 Vaccine with a temperature monitoring device in a:

- Thermal shipping container
- · Portable ultra-cold freezer unit
- Portable freezer unit
- Portable refrigerator unit

Temperature monitoring:

At the start of transport

When transport concludes

personal protective equipment).

General Information

08/24/2021 CS321570-R

· Container/packout qualified to maintain the recommended

Upon arrival at the clinic, place vaccine in an on-site storage unit that maintains recommended temperatures, if available. If there is no storage unit available, keep the vaccine in the transport container. maintaining recommended temperatures.

Record time and minimum/maximum temperatures:

Whenever the transport container is opened

Vaccine vials may be transported more than once.

usp.org/covid-19/vaccine-handling-toolkit)

Transport thawed vaccine at refrigerated temperatures.

o Vaccine stored at refrigerated temperatures should not be refrozen.

Best Practices for Transporting mRNA Vaccines

- Protect vaccines as much as possible from drops, shocks, and vibration.
- To minimize movement, transport vials in the carton whenever possible.
- If individual vials must be transported:
- Place vials with padding materials like bubble wrap or similar materials to prevent breaking.
- Secure storage containers during
- Keep vaccine vials upright whenever possible.
- Protect from light.

Moderna COVID-19 Vaccine

Transporting Vaccine for Vaccination Clinics Held at Satellite, Temporary, or Off-Site Locations



Procedure

Follow storage and handling best practices outlined in CDC's Vaccine Storage and Handling Toolkit to maintain the cold chain when packing, transporting and storing vaccine for satellite, temporary off-site clinics. CDC recommends transporting Moderna COVID-19 vaccine at frozen or refrigerated temperature using a portable freezer or refrigerator unit or a container/packout qualified to maintain the recommended temperatures.

- Both punctured and unpunctured vials may be transported. Vaccine vials may be transported more than once.
- Transport thawed vaccine at refrigerated temperatures. Once thawed, vaccine cannot be refrozen.
- Do NOT use dry ice when transporting vaccine.
- Time used for transport counts as part of any beyond-use timeframes.



Best Practices for Transporting mRNA Vaccines

- Protect vaccines as much as possible from drops, shocks, and vibration
- vials in the carton whenever possible.
- If individual vials must be transported
- · Place vials with padding material like bubble
- · Secure storage containers during transport.
- Keep vaccine vials upright whenever possible.



Upon arrival at clinic, place vaccine in an on-site storage unit that maintains recommended temperatures, if available. If there is no storage unit available, keep the vaccine in the transport container, maintaining recommended temperatures.

Ensure vaccine, including predrawn syringes, is always stored at the appropriate temperatures and conditions.

General Information

Store unnunctured vials between

- -50°C and -15°C (-58°E and 5°E)
- 2°C and 8°C (36°F and 46°F) for up to 30 days
- 8° to 25°C (46° to 77°F) for a total of 24 hours.

Protect from light.

- Only prepare the amount of vaccine needed and ensure vaccine that is prepared first is administered first.
- preparation area and vaccine administration stations. To monitor vaccine temperatures, use a digital data logger with a buffered temperature probe that displays current.

minimum, and maximum temperatures.

Store punctured vials and predrawn syringes between 2° to 25°C (36° to 77°F).

Use vaccine within 12 hours after the first puncture.

Discard any remaining vaccine in vials or predrawn syringes after 12 hours.

Temperature monitoring

Record time and min/max temperatures: Ensure there is an adequate number of storage containers At the start of transport to maintain proper storage temperature for vaccine in the Whenever the storage container is opened

When transport concludes

CDC's Transport Temperature Log https://www.cdc.gov/vaccines/ covid-19/downloads/transport-temperature-log.pdf CDC's beyond-use date (BUD) labels https://www.cdc.gov/

vaccines/covid-19/info-by-product/moderna/downloads/bud tracking-labels.pdf

for Healthcare Practitioners https://www.usp.org/covid-19/

08/24/2021 CS3215714

https://www.cdc.gov/vaccines/covid-19/info-by-product/index.html

Transport equal amounts of vaccines, diluents, and ancillary supplies (including vaccination record cards and

Both punctured and unpunctured vials may be transported. Transport punctured vials at refrigerated temperatures.

syringes in the USP COVID-19 Vaccine Toolkit: Operational Considerations for Healthcare Practitioners (https://www.

. CDC recommends transporting vaccine in vials. However, there may be instances when the only option is to transport predrawn vaccine in a syringe. U.S. Pharmacopeia includes guidance for transporting predrawn vaccine in

Individual vials or partially filled trays must be transported at refrigerated temperatures.

USP COVID-19 Vaccine Toolkit: Operational Considerations



Temperature Log when Transporting Vaccine at Refrigerated Temperatures



When transporting refrigerated vaccines, use:

- A portable refrigerator or vaccine storage container qualified to maintain temperatures between 2°C and 8°C (36°F and 46°F).
- A digital data logger (DDL) with a thermal buffer and external temperature display (preferred). Place the probe as close as possible to the vaccine.
- This temperature log to document temperatures and how long the vaccine is in the portable storage container.

Temperature monitoring and transport time frames

- Most DDLs display minimum/maximum (min/max) temperatures.
- Record the time and min/max temperatures:
- At the start of transport
- . Every time the portable storage container is opened
- When transport is completed
- The total time for transport alone or transport plus clinic workday should be a maximum of 8 hours.*
- Beyond-use date/time (BUD), if applicable, are included in transport time. For example, if the vaccine may be stored at refrigerated temperature for 120 hours, transport is included in this time frame.

If the temperature is out of range, TAKE ACTION!
--

- Do NOT discard the vaccine.
- 2. Label the vaccine "Do Not Use."
- 3. Complete the Vaccine Troubleshooting Record.
- 4. Contact the manufacturer to determine under what conditions (refrigerated) to store the vaccine as quickly as possible.

Today's date: Provider name: Temperatures n										Transport end time: PIN number:						
Time																
Staff initials																
Min/max temperatures																
Temperatures lower than 2°C (36°F) and higher than 8°C (46°F) are out of range.± Complete a Vaccine Troubleshooting Record. Contact the manufacturer and your immunization program.																

- After packing the vaccine, open the portable storage container only when necessary.
- If using a company or personal vehicle, transport vaccines inside the passenger compartment (not in the trunk or bed of a truck, which may be too hot or too cold).
- Avoid leaving the portable storage container in direct sunlight or unattended.
- If needed, transport diluents with their corresponding vaccines to ensure there are equal amounts of vaccines and diluents. Follow the manufacturer's guidance for specific temperature requiremants for dilumnts
- Save this record for 3 years, unless your state/local jurisdiction requires a longer time period. See CDC's Vaccine Storage and Handling Toolkit for additional guidance.
- Refer to CDC's Vaccine Storage and Handling Toolkit for additional guidance when transporting vaccines.

Temperature Log when **Transporting** Vaccine at Refrigerated Temperatures

https://www.cdc.gov/vaccines/covid-19/info-by-product/index.html

If the DDL does not measure min/max temperatures, check and record temperatures hourly.

^{*} Follow the manufacturer's quidance if it differs from this time frame



COVID-19 Vaccine

Temperature Log for Refrigerator Vaccine Storage (Fahrenheit) Days 1-15



Store COVID-19 vaccines between 36°F and 46°F. Using a digital data logger (DDL), check and record the temperature daily using one of the options below. Save this record for 3 years, unless your state/local jurisdiction requires a longer time period. See CDC's Vaccine Storage and Handling Toolkit, COVID-19 Addendum, for additional information.

Option 1: Minimum/Maximum (Min/Max) Temperatures (preferred)

- Most DDLs display minimum and maximum temperatures. Check and record the min/max temperatures at the start of each workday.
- Document these temperatures in the min/max temperature row under the appropriate date.

Option 2: Current Temperature

- If the DDL does not display min/max temperatures, check and record the current temperature at the start and end of the workday.
- Document these temperatures by writing an "X" in the row that corresponds to the refrigerator temperature under the appropriate day of the month.
- 3. Review the continuous DDL temperature data daily.

If the temperature is out of range, TAKE ACTION!

- 1. Do NOT discard the vaccine.
- Label the vaccine "Do Not Use."
- Complete the Vaccine Troubleshooting Record.
- Contact the manufacturer to determine under what conditions (refrigerated) to store the vaccine as quickly as possible.

PIN Number Month **Facility Name** Day of the month 11 12 13 14 15 Time Staff initials Min/max temperatures Temperatures lower than 36°F and higher than 46°F are out of range. Complete a Vaccine Troubleshooting Record. Contact the manufacturer and your immunization program. AM PM Time Staff initials 36°F 37°F 38°F 39°F 40°F 41°F 42°F 43°F 44°F 45°F 46°F

Temperature
Log when
Storing at
Refrigerated
Temperatures

For additional information, see the vaccine manu

12/22/2020 CS3216294

https://www.cdc.gov/vaccines/covid-19/info-by-product/index.html

Freezer Temperature Logs



Moderna COVID-19 Vaccine

Temperature Log for Frozen Vaccine Storage (Fahrenheit) Days 1-15



Store Moderna COVID-19 vaccine between -58°F and 5°F. Using a digital data logger (DDL), check and record the temperature daily using one of the options below. Save this record for 3 years, unless your state/local jurisdiction requires a longer time period. See CDC's Vaccine Storage and Handling Toolkit, COVID-19 Addendum, for additional information.

Option 1: Minimum/Maximum (Min/ Max) Temperatures (preferred)

- Most DDLs display minimum and maximum temperatures. Check and record the min/max temperatures at the start of each workday.
- Document these temperatures in the min/max temperature row under the appropriate date.

Option 2: Current Temperature

- If the DDL does not display min/max temperatures, check and record the current temperature at the start and end of the workday.
- Document these temperatures by writing an "X" in the row that corresponds to the freezer temperature under the appropriate day of the month.
- 3. Review the continuous DDL temperature data daily.

If the temperature is out of range, TAKE ACTION!

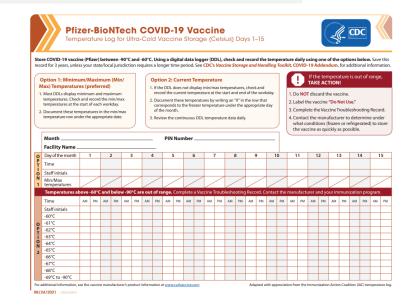
- 1. Do NOT discard the vaccine.
- 2. Label the vaccine "Do Not Use."
- 3. Complete the Vaccine Troubleshooting Record.
- Contact the manufacturer to determine under what conditions (frozen or refrigerated) to store the vaccine as quickly as possible.

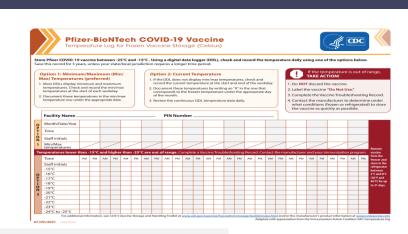
		Month									PIN	Nun	nber																			
	O P	Day of the month Time		ı	:	2	:	3	4	4	:	5	(6	7	7	8	8	9	9	1	0	1	1	1	2	1	3	1	4	1	5
	i O N	Staff initials Min/max		_		<u> </u>		_		<u> </u>		_		<u> </u>		_		<u> </u>		<u> </u>		_				_		_				
•	_	temperatures Temperatures lov	ver th	an -5	8°F a	nd hi	gher	than	5°F aı	re ou	of ra	nge.	Comp	olete a	Vacc	ine Tr	ouble	shoo	ting R	ecord	. Cont	act th	ne ma	nufac	turer	and y	our in	nmun	izatio	n prog	gram	
п		Time	AM	PM	AM	PM	AM	PM	AM	PM	AM	PM	AM	PM	AM	PM	AM	PM	AM	PM	AM	PM	AM	PM	AM	PM	AM	PM	AM	PM	AM	PM
ı		Staff initials																														
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ľ	2	0°F																														
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п		-3°F																														
		-4°F to -58°F																														

 $For additional information, see the vaccine manufacturer's product information at {\verb|https://www.modernatx.com/covid19vaccine-eua/buttoner's product} at {\verb|https://www.modernatx.com/covid19vaccine-eua/buttone-eua/buttone-eua/buttone-eua/buttone-eua/buttone-eua/buttone-$

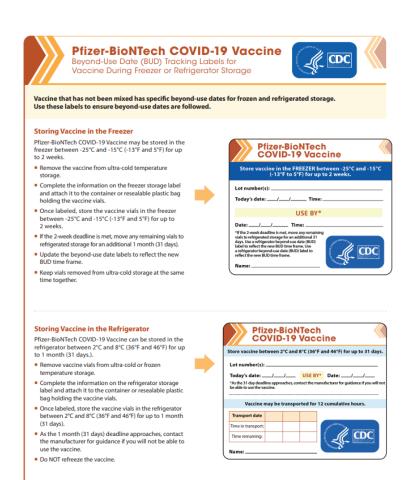
Adapted with appreciation from the Immunization Action Coalition (IAC) temperature log

07/15/2021 CS321571-B

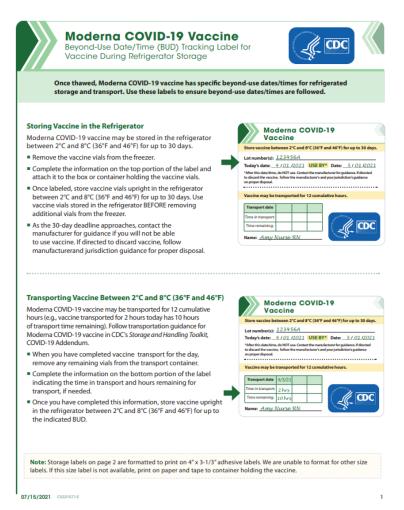




CDC COVID-19 Vaccine BUD Guidance and Labels



07/09/2021 CS321570-E



https://www.cdc.gov/vaccines/covid-19/info-by-product/index.html

CDC COVID-19 Vaccine Storage and Handling Labels







CDC

CDC

CDC

https://www.cdc.gov/vaccines/covid-19/info-by-product/index.html

COVID-19 Vaccine

Quick Reference Guide for



Healthcare Prof

		Pfizer
	Route	Intramu
	Site	Deltoid
	Thawing Frozen Vaccine	Betwee 2°C and Room te Do NOT
	Mixing Vaccine	Mix vaco sodium normal
		Contrai
N		• Severe COVID-
TIC		• Immed compo
TR/		Note: Pe be able
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		States w
	Post-Vaccination Observation	30 minu therapy,
	S D S EI Valloii	15 minu
	Most common	Injectio redness
	adverse events	Systemi

For the purpose of this guidance, an immedial distress (e.g., wheezing, stridor), or anaphylax 'Consider consultation with an allergist-immun a consultation from the Clinical Immunization S these individuals should only be done in an app.

- People with a contraindication to mRNA CI previously received an mRNA COVID-19 with a contraindication to mRNA COVID-19 with a contraindication to mRNA COVID-19 which coviders are considered and many contraindication to mRNA COVID-19 which coviders are considered and many contraindication to mRNA COVID-19 which covidered and mRNA COVID-19 which covidered and many contraindication to mRNA COVID-19 which covidered and many covidered a

People with a contraindication to Jansse

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COVID-19 Vaccine

Quick Reference Guide for Healthcare Professionals



The table below provides basic information on the proper storage, preparation, and administration of the currently authorized COVID-19 vaccine products in the United States. For additional information and detailed clinical guidance go to the manufacturer's and CDC's webpages listed.

		Pfizer	Moderna	Janssen			
AL	EUA	www.fda.gov/emergency- preparedness-and-response/ coronavirus-disease-2019-covid-19/ pfizer-biontech-covid-19-vaccine	www.fda.gov/emergency- preparedness-and-response/ coronavirus-disease-2019-covid-19/ moderna-covid-19-vaccine	www.fda.gov/emergency- preparedness-and-response/ coronavirus-disease-2019- covid-19/janssen-covid-19-vaccine			
NER	CDC Vaccine Information	www.cdc.gov/vaccines/covid-19/ info-by-product/pfizer/index.html	www.cdc.gov/vaccines/covid-19/nfo- by-product/moderna/index.html	www.cdc.gov/vaccines/ covid-19/info-by-product/ janssen/index.html			
GE	Manufacturer Contact information	Website: www.cvdvaccine.com Medical information: 800-438-1985 Customer service: 800-879-3477	Website: www.modernatx.com Medical Information: 866-663-3762	Website: www.vaxcheck.jnj. Medical information: 1-800-565-4008			
	How supplied	Multidose vial: 6 doses	Multidose vial: Maximum of 15 doses	Multidose vial: 5 doses			
	Diluent	0.9% sodium chloride (preservative- free, normal saline) provided in the ancillary kit. Do NOT use other diluent.	None	None			
HANDLING	Storage Temperatures: Before Puncture	Between: -80°C and -60°C (-112°F and -76°F) until the expiration date -25°C and -15°C (-13°F and 5°F) for up to 2 weeks 2°C and 8°C (36°F and 46°F) for up to 1 month (31 days).	Between: -50°C and -15°C (-58°F and 5°F) until the expiration date 2°C and 8°C (36°F and 46°F) for up to 30 days 8°C and 25°C (46° and 77°F) for a total of 24 hours	Between: 2°C and 8°C (36°F and 46°F) until the expiration date.			
TORAGE & I	Storage Temperatures: After puncture	Between: 2°C to 25°C (36°F to 77°F) for up to 6 hours. Discard any unused vaccine after 6 hours.	Between: 2°C and 25°C (36°F and 77°F) for up to 12 hours. Discard any unused vaccine after 12 hours.	Between: 2°C and 8°C (36°F and 46°F) for up to 6 hours. 9°C and 25°C (47°F and 77°F) for up to 2 hours. Discard any unused vaccine after these time frames.			
ST	Transport Temperatures: Before Puncture	Between: -80°C and -60°C (-112°F and -76°F) -25°C and -15°C (-13°F and 5°F) 2°C and 8°C (36°F and 46°F)	Between: -50°C and -15°C (-58°F and 5°F) 2°C and 8°C (36°F and 46°F) for up to 12 cumulative hours.	Between: 2°C and 8°C (36°F and 46°F)			
	Transport Temperatures': After Puncture	Between: 2°C to 25°C (36°F to 77°F) for up to 6 hours.	Between: 2°C and 25°C (36°F and 77°F) for up to to 12 hours.				
	Type of Vaccine	mRNA	mRNA	Viral vector			
	Age Indications	12 years of age and older	18 years of age and older	18 years of age and older			
	Schedule [†]	2-doses, separated by 21 days. Both doses must be Pfizer-BioNTech vaccine	2 doses, separated by 28 days. Both doses should be Moderna vaccine	1 dose only			
	Dos						

COVID-19 Quick Reference Guide

- How supplied
- Diluent
- Storage temperatures
 - Before/after puncture
- Transport temperatures
 - Before/after puncture

https://www.cdc.gov/vaccines/covid-19/downloads/covid19-

vaccine-quick-reference-guide-2pages.pdf



Vaccine Storage and Handling Toolkit

Updated with COVID-19 Vaccine Storage and Handling Information Addendum added March 4, 2021



March 2021

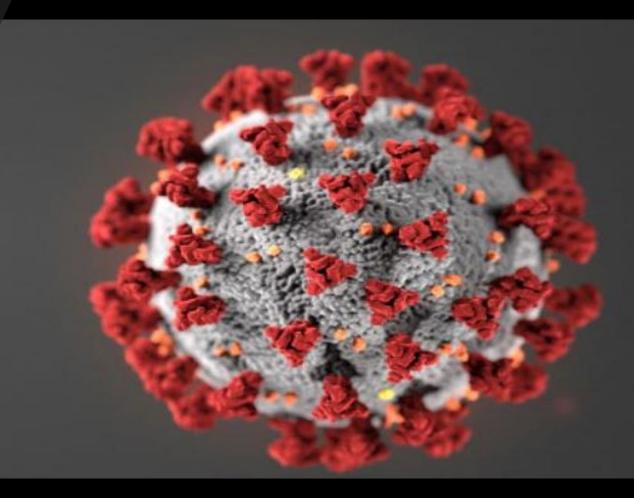
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CDC Vaccine Storage and Handling Toolkit

The Vaccine Storage and Handling Toolkit has been updated with an addendum to address proper storage, handling, transport, and emergency handling of COVID-19 vaccines.



https://www.cdc.gov/vaccines/hcp/admin/storage/ toolkit/storage-handling-toolkit.pdf Janssen (J & J) Vaccine Storage & Handling



Janssen (J & J) COVID-19 Vaccine Refrigerator Storage

- Store vaccine between 2°C and 8°C (36°F and 46°F):
 - Unpunctured vials until the expiration date
 - Punctured vials for up to 6 hours (note the date and time the vial was first punctured, and discard vaccine not used within this time)
 - A punctured vial may be stored at room temperature 9°C to 25°C (47°F to 77°F) for up to 2 hours
- Do not freeze
- Protect from light

Janssen (J & J) COVID-19 Vaccine Transport

- Transport in a portable refrigerator unit or a container/ packout qualified to maintain temperature between 2°C and 8°C (36°F and 46°F)
- Use a digital data logger with a buffered temperature probe that displays current, minimum, and maximum temperatures
- Upon arrival, place vaccine in an on-site storage unit that maintains recommended temperatures, if available. If there is no storage unit available, keep the vaccine in the transport container, maintaining recommended temperatures
- Vaccine vials may be transported more than once
- Do NOT use dry ice when transporting vaccine

Janssen (J & J) COVID-19 Vaccine Transport Cont.

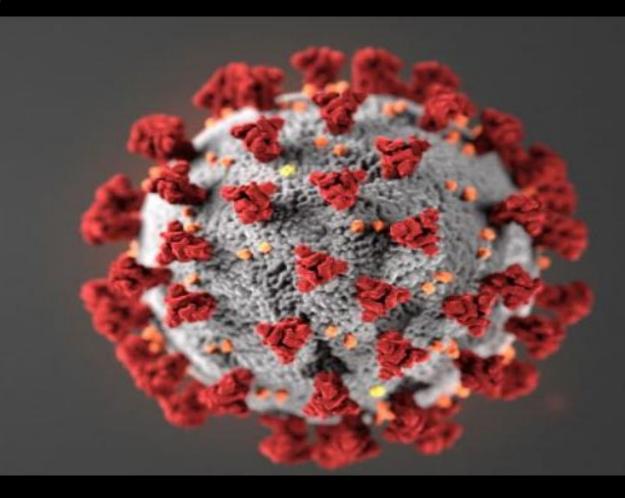
Refrigerated transport: Between 2°C and 8°C (36°F and 46°F)

- **Unpunctured Vials:** may be transported at refrigerated temperatures until the expiration date
 - The total time for transport alone or transport + clinic workday should be a maximum of 8
 hours (e.g., if transport to an off-site clinic is 1 hour each way, the clinic may run for up to 6
 hours)
- Punctured Vials: may be transported at refrigerated temperatures
 - Once punctured, store the vaccine at refrigerated temperatures (must be used within 6 hours)
 - Time used for transport counts as part of the 6-hour time limit

The allowed storage time after first vial puncture or dose withdrawal is either a maximum of 6 hours refrigerated or 2 hours at room temperature. These maximum hold times and temperatures are not cumulative. If stored in the refrigerator after the first puncture, the vaccine can be moved to room temperature for brief periods of time for administration. This does not affect the maximum 6-hour hold period for vaccine stored in the refrigerator.

Can punctured vials be moved between refrigerator and room temperature storage?

Moderna Vaccine Storage & Handling



Moderna COVID-19 Vaccine Freezer Storage

- Vaccine will arrive frozen
- Store unpunctured vaccine in freezer between -50°C and -15°C (-58°F and 5°F)
- Store in original carton
- Protect from light
- Do not store with dry ice or below -50°C (-58°F)

Moderna COVID-19 Vaccine Refrigerator Storage

- Unpunctured Vials: may be stored in the refrigerator between 2°C and 8°C (36°F and 46°F) for up to 30 days
 - After 30 days, remove any remaining vials from the refrigerator and discard
- Punctured Vials: may be stored between 2°C and 25°C (36°F and 77°F) for up to 12 hours
 - After 12 hours, vaccine vials should be discarded
- Use beyond-use date labels to track how long the vaccine has been in the refrigerator
- Do not refreeze thawed vaccine
- Thawed vaccine can be handled in room light

Moderna COVID-19 Vaccine Transport

- Transport vaccine at frozen or refrigerated temperature using a portable freezer or refrigerator unit or a container/packout qualified to maintain the recommended temperatures
- Use a digital data logger with a buffered temperature probe that displays current, minimum, and maximum temperatures
- Upon arrival, place vaccine in an on-site storage unit that maintains recommended temperatures, if available. If there is no storage unit available, keep the vaccine in the transport container, maintaining recommended temperatures
- Transport thawed vaccine at refrigerated temperatures. Once thawed, vaccine cannot be refrozen
- Vaccine vials may be transported more than once
- Do NOT use dry ice when transporting vaccine

Moderna COVID-19 Vaccine Transport Cont.

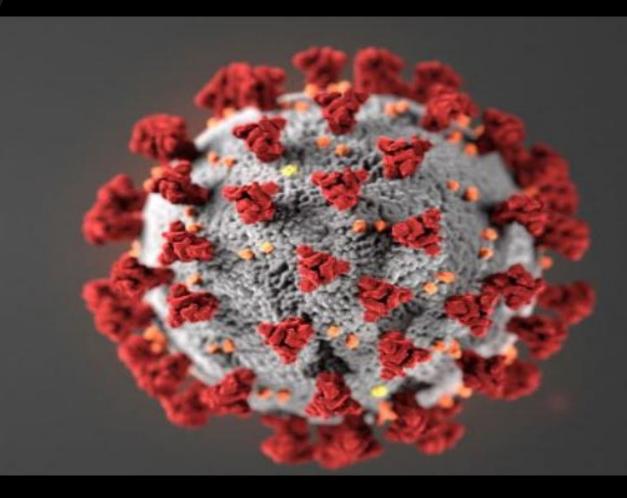
Store Unpunctured Vials Between:

- -50°C and -15°C (-58°F and 5°F)
- 2°C and 8°C (36°F and 46°F) for up to 30 days
- 8°C to 25°C (46°F to 77°F) for a total of 24 hours
- Protect from light
- Store Punctured Vials and Predrawn Syringes: between 2°C to 25°C (36° to 77°F)
 - Use vaccine within 12 hours after the first puncture
 - Discard any remaining vaccine in vials or predrawn syringes after 12 hours
 - * Time used for transport counts as part of any beyond-use timeframes

NO! After the first dose has been withdrawn, vials must be stored between 2°C and 25°C (36°F and 77°F) and used within 12 hours. Any vaccine remaining after 12 hours must be discarded.

If I puncture a multidose vial but do not administer all doses in the multidose vial today, can I store it in the refrigerator for use the following day?

Pfizer Vaccine Storage & Handling



Pfizer COVID-19 Vaccine Ultra-Cold Freezer Storage

- Vaccine will arrive in a thermal shipping container at ultra-cold temperatures between -90°C and -60°C (-130°F and -76°F) with dry ice
- Before mixing, the vaccine may be stored in an ultra-cold freezer between -90°C and -60°C (-130°F and -76°F)
- Store vaccine vials upright in the tray or box
- Protect from light
- Vaccine may be stored until the expiration date

Pfizer COVID-19 Vaccine Freezer Storage

- Before mixing, vaccine may be stored in the freezer between -25°C and -15°C (-13°F to 5°F) for up to 2 weeks
 - Temperatures are within the appropriate range for routinely recommended vaccines, BUT the temperature range for this vaccine is tighter
- Store in the tray or box
- Protect from light
- Do not use dry ice for freezer storage
- Vials stored in the freezer may be returned one time to ultracold temperature storage
 -90°C to -60°C (-130°F to -76°F)
 - Once returned to ultra-cold storage, the 2-week time frame is suspended
- Vaccine stored in the freezer can be transferred to refrigerator storage where it can be stored for up to 1 month (31 days)

https://www.cdc.gov/vaccines/covid-19/info-by-product/pfizer/downloads/storage-summary.pdf

Pfizer COVID-19 Vaccine Refrigerator Storage

- Before mixing, the vaccine may be stored in the refrigerator between 2°C and 8°C (36°F and 46°F) for up to 1 month (31 days)
 - After 31 days, contact the manufacturer for guidance. If directed to discard any remaining vials, follow the manufacturer's and your jurisdiction's guidance for proper disposal
- Monitor how long the vaccine has been in the refrigerator using CDC's beyond-use date labels for Pfizer-BioNTech COVID-19 vaccine
- Store the vaccine in the tray or box
- Protect from light
- Do NOT refreeze thawed vaccine

Pfizer COVID-19 Vaccine Storage Once Mixed

- Once mixed, vaccine can be left at room temperature 2°C to 25°C (35°F to 77°F) for up to 6 hours
 - Discard any remaining vaccine after 6 hours
- Mixed vaccine should NOT be returned to freezer storage
- Minimize exposure to room light, and avoid exposure to direct sunlight and ultraviolet light

Pfizer COVID-19 Vaccine Transport

- Transport Pfizer-BioNTech COVID-19 Vaccine with a temperature monitoring device in a:
 - Thermal shipping container
 - Portable ultra-cold freezer unit
 - Portable freezer unit
 - Portable refrigerator unit
 - Container/packout qualified to maintain the recommended temperatures
- Upon arrival, place vaccine in an on-site storage unit that maintains recommended temperatures, if available. If there is no storage unit available, keep the vaccine in the transport container, maintaining recommended temperatures
- Both punctured and unpunctured vials may be transported. Transport punctured vials at refrigerated temperatures
- Transport thawed vaccine at refrigerated temperatures (do not refreeze)
- Time used for transport counts as part of any beyond-use timeframes
- Vaccine vials may be transported more than once

Temperatures and Transport Container	Temperature Monitoring Device	Beyond-Use Time/Date	Additional Considerations			
Ultra-cold transport: Between -90°C and -60°C (-130°F and -76°F) in the	Thermal shipping container: Controlant temperature monitoring device	Unpunctured vials only: Vaccine may be stored in the thermal shipping	Any time used for transpor counts against the 30-day limit for storage in the			
thermal shipping container, portable ultra-cold freezer, or qualified container/ packout	Portable ultra-cold freezer or qualified container: Digital data logger (DDL) with a probe designed to measure ultra-cold temperatures	container for up to 30 days. Vaccine may be stored in an ultra-cold freezer until the expiration date.	thermal shipping containe Only full trays of vaccine may be transported at ultr cold temperatures.			
Frozen transport: Between 25°C and -15°C (-13°F to 5°F) in a portable freezer or qualified container/packout	DDL with a buffered temperature probe that displays current, minimum, and maximum temperatures	Unpunctured vials only: Vaccine may be stored at frozen temperatures for up to 2 weeks.	Any time used for transport counts against the 2-week limit for storage at these temperatures. Frozen vials may be returned one time to ultracold storage conditions between -90°C and -60°C (-130°F and -76°F).			
Refrigerated transport: Between 2°C and 8°C (36°F and 46°F) for up to 12 total hours in a portable	DDL with a buffered temperature probe that displays current,	Unpunctured vials: Vaccine may be stored at refrigerated temperatures for up to 1 month (31 days).	Any time used for transport counts against the 31-day time limit for storage at these temperatures.			
refrigerator or qualified container/packout	minimum, and maximum temperatures	Punctured vials: Once punctured, the vaccine must be mixed with diluent and used within 6 hours.	Any time used for transport counts against the 6-hour beyond-use time limit.			

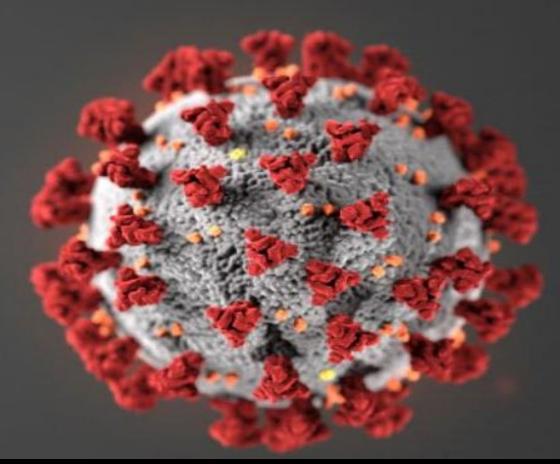
Pfizer COVID-19 Vaccine Transport Cont.

https://www.cdc.gov/vaccines/covid-19/info-by-product/pfizer/downloads/pfizertransporting-vaccine.pdf YES. At the 2-week time frame, you have two options:

- You may transfer vaccine to refrigerated storage between 2°C and 8°C (36°F and 46°F) for up to 31 days. After 31 days, contact the manufacturer for guidance
- You may return vaccine one time to ultra-cold temperature storage between -90°C to -60°C (-130°F to -76°F)

After vaccine has been stored at frozen temperatures for 2 weeks, can it be stored at refrigerated temperatures for an additional 5 days?

Temperature Monitoring and Excursions



Temperature Monitoring

- Use a digital data logger (DDL) with a detachable probe that best reflects vaccine temperatures (e.g., probe buffered with glycol, glass beads, sand, or Teflon®)
 - Ultra-cold temperatures: use a probe designed specifically to measure ultra-cold temperatures
 - Thermal Shipping Container: use the Controlant temperature monitoring device (TMD) included with the thermal shipping container to monitor the temperature
- Check and record the temperature daily
 - Min/Max & Current Temp in the AM
 - Current Temp in the PM
 - Document on temperature log (maintain records for 3 years)

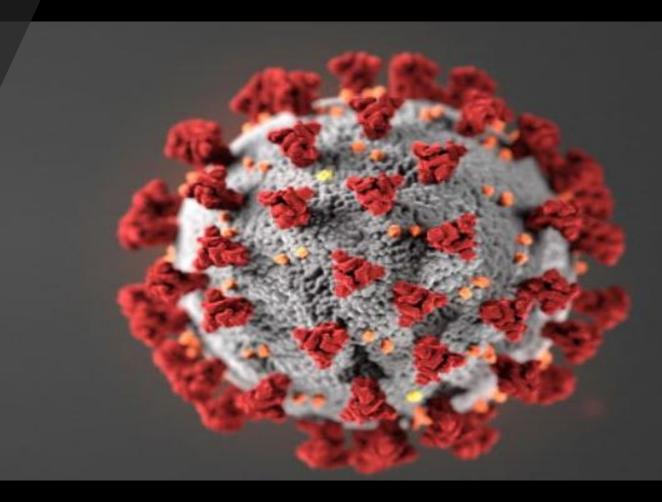
Temperature Monitoring During Transport

- Record time and min/max temperatures:
 - At the start of transport
 - Whenever the storage container is opened
 - When transport concludes
- Document on temperature log (maintain records for 3 years)

Temperature Excursions

- Temperature readings outside recommended range requires immediate action
- Label the vaccine "Do Not Use" and store at the recommended temperature range until you receive manufacturer guidance. If it is a frozen vaccine that has been thawed, store in the refrigerator between 2° C and 8° C (36° F and 46° F) until you receive manufacturer guidance, as refreezing the vaccine may damage it
- Document the date and length of time of the excursion, the storage unit temperature (minimum/maximum, if available), and inventory affected
- Record any other relevant information
- Contact the manufacturer and/or immunization program for guidance
- Document the event and actions taken (maintain records for three years)

Expiration Date Tracking Tool







Use this tracking tool to record updated expiration dates for COVID-19 vaccine as additional stability data are available from the manufacturer. When the current expiration date gets close, contact the manufacturer before discarding vaccine. Document the current date, the vaccine lot number, and the updated expiration date in the appropriate columns, including the information source and the name of the person completing this form. Keep this document for 3 years or longer if required by your jurisdiction..

Product name:	Manufacturer:	Original Expiration Date:			
Expiration date info is available at (include all available information from manufacturer; website, app, phone number.)					

Date	Lot Number	Updated Expiration Date	Info S	ource	Name	
Example: 09/01/2020	ABC123DEF456	06/30/2021		☐ Barcode	Susie Smith RN	
When current expiration date gets close, contact						
the manufacturer before discarding vaccine!						
https://www.cdc.gov/vaccines/covid-19/downloads/expiration-tracker.pdf						

How to Check the Expiration Date

- Moderna: expiration date is NOT printed on the vaccine vial or carton.
 To determine the expiration date: Scan the QR code located on the outer carton, or go to www.modernatx.com/covid19vaccine-eua/
- Janssen (J & J): expiration date is NOT printed on the vaccine vial or carton. To determine the expiration date: Scan the QR code on the outer carton, or call 1-800-565-4008, or visit www.vaxcheck.jnj
- Pfizer: expiration date is located on the vaccine vial. The actual
 expiration date is uploaded to the MCIR Outbreak Inventory, rather than
 a previous "placeholder" expiration date

Pfizer Expiration Extension

Printed Expiry Date	Updated Expiry Date
May 2021	August 2021
June 2021	September 2021
July 2021	October 2021
August 2021	November 2021
September 2021	December 2021
October 2021	January 2022
November 2021	February 2022
December 2021	March 2022
January 2022	April 2022
February 2022	May 2022

- Cartons and vials of Pfizer-BioNTech COVID-19 Vaccine may remain in use for 3 months beyond the expiry date printed on the label as long as authorized storage conditions between -90°C to - 60°C (-130°F to -76°F) have been maintained. Please note: the ultra-cold temperature range has been broadened to include -90° C (-130°F).
- For vials with expiration dates in the future, updated expiry dates for vaccine maintained in ultracold storage are shown here

How Does This Affect Beyond Use Date

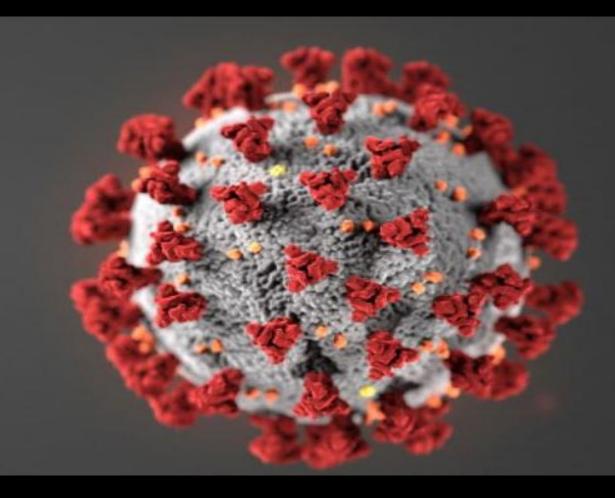
The Beyond Use Date (BUD) for the Pfizer COVID-19 vaccine will be honored. To prevent vaccine from inadvertently being discarded, providers should ensure the new expiration date is indicated, for example label the tray or post on the unit. Below is a BUD example you might encounter

Case scenario #1: You move a vial of Pfizer vaccine from freezer storage to the refrigerator on August 15. It is marked with the expiration date of August 2021 (August 31, 2021). Can you store this vaccine for the full 31 days allowed for refrigeration storage, or do you need to administer it by August 31, 2021?

• Yes, you can store this vaccine vial for the full 31 days (i.e., through September 15, 2021). The recent expiration date extension changes the expiration date to November 2021. The BUD replaces the manufacturer's expiration date (now November/2021) and should be noted on the label along with the initials of the person making the calculation

https://www.michigan.gov/documents/coronavirus/Pfizer Expiration Extension 090221 734479 7.pdf

Disposal of COVID-19 Vaccine



Proper Disposal of Expired Vaccine

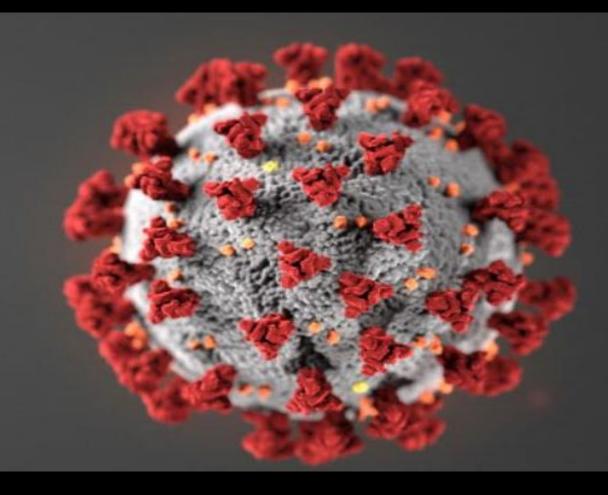
Disposal must be done in accordance with local regulations with appropriate steps taken to ensure proper disposal

- Therefore, dispose of expired vaccine vials (with remaining liquid) by placing them into the Sharps container and treated as medical/biohazard waste
- Do not draw up remaining liquid and dispose of it down the sink drain

How to record non-viable COVID-19 doses in MCIR:

https://www.mcir.org/wp-content/uploads/2021/04/HowToRecordNoLongerViableCOVID-19MDV4302021.pdf

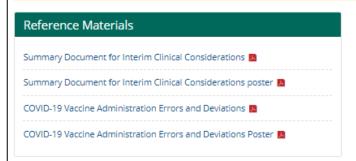
CDC's Interim Clinical Considerations

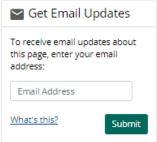


Interim Clinical Considerations for Use of COVID-19 Vaccines Currently Authorized in the United States

NOTICE: FDA has granted full approval of prizer-BioNTech (COMIRNATY) COVID-19 Vaccine. CDC's Advisory.

Committee on Immunization Practices is meeting on Monday, August 30, 2021, to discuss its updated recommendation for this vaccine.





Summary of recent changes (last updated August 25, 2021):

- . New section on people vaccinated for COVID-19 as part of a clinical trial in the United States
- Update considerations for use of an additional mRNA COVID-19 vaccine dose after an initial 2-dose COVID-19 mRNA vaccine series for immunocompromised people

Key points

- COVID-19 vaccination is recommended for everyone aged 12 years and older for the prevention of coronavirus disease 2019 (COVID-19) in the United States.
- COVID-19 vaccines currently authorized by the U.S. Food and Drug Administration are effective against SARS-CoV-2
 infections, including asymptomatic and symptomatic infection, severe disease, and death.
- Available evidence suggests that these vaccines offer protection against known variants, including the Delta variant, particularly against hospitalization and death. The Delta variant, currently the predominant SARS-CoV-2 variant in the United States, is associated with increased transmissibility.
- Efforts to maximize the proportion of people in the United States who are fully vaccinated against COVID-19 remain critical to ending the COVID-19 pandemic.
- . The Advisory Committee on Immunization Practices has issued interim recommendations for the use of:
 - Pfizer-BioNTech COVID-19 vaccine (in persons aged 12–15 years and aged ≥16 years)
 - Moderna COVID-19 vaccine (in persons aged ≥18 years)
 - o Janssen (Johnson & Johnson) COVID-19 vaccine (in persons aged ≥18 years)
- These clinical considerations provide additional information to healthcare professionals and public health officials on use of COVID-19 vaccines.

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Background	Considerations for use of the Janssen COVID-19 vaccine in certain populations			
Authorized age groups for COVID-19 vaccination	Considerations involving pregnancy, lactation, and			
COVID-19 vaccine administration	fertility			
Interchangeability of COVID-19 vaccine products	Vaccination of children and adolescents			
People vaccinated for COVID-19 outside the United States	Patient counseling			
People vaccinated for COVID-19 as part of a clinical trial	Contraindications and precautions			
in the United States	Reporting of vaccine adverse events			
Coadministration of COVID-19 vaccines with other vaccines	Laboratory testing			
COVID-19 vaccination and SARS-CoV-2 infection	Appendix A. Vaccine administration errors and deviations			
Antiviral therapy and COVID-19 vaccination	Appendix B: Triage of people presenting for COVID-19 vaccination			
Vaccinating people with a known COVID-19 exposure or during COVID-19 outbreaks	Appendix C: Ingredients included in COVID-19 vaccines			
Considerations for use of an additional dose of COVID- 19 vaccine following a primary vaccine series	Appendix D: Potential characteristics of allergic reactions, vasovagal reactions, and vaccine side effects following COVID-19 vaccination			
Considerations for use of an additional mRNA COVID- 19 vaccine dose after an initial 2-dose COVID-19 mRNA vaccine series for immunocompromised people	References			
Considerations for uncertain of months with contain	Previous Updates			

CDC Interim Clinical Considerations for Use of COVID-19 Vaccines

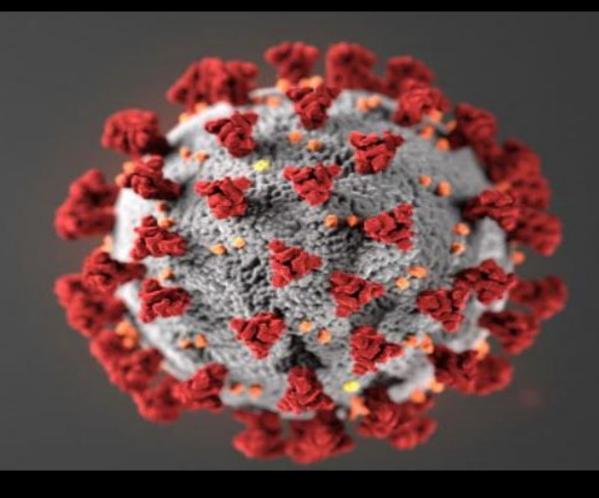
https://www.cdc.gov/vaccines/covid-19/clinical-considerations/covid-19-vaccines-us.html

Thank You!

Next "Noontime Knowledge" Update: September 23, 2021

Please watch your email for a zoom link, and topic!

Questions Email: checcimms@michigan.gov



www.michigan.gov/COVIDvaccineprovider