



Vaccine Storage and Handling Guide 2022

*This document is an adaptation of CDC's Vaccine Toolkit.
Complete information on vaccine storage and handling can be found at:*

www.cdc.gov/vaccines/hcp/admin/storage/toolkit/storage-handling-toolkit.pdf

Rhode Island Department of Health Immunization Resource Manual:
www.health.ri.gov/immunization/for/providers

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Cold Chain

The vaccine cold chain is a temperature-controlled environment used to maintain and distribute vaccines in optimal conditions. The cold chain relies on three main elements:

- Well-trained personnel.
- Reliable transportation and storage equipment.
- Efficient management procedures.

Vaccine Storage and Handling Guidelines

Practices are required to have an assigned primary coordinator and a back-up coordinator to manage storage and handling responsibilities.

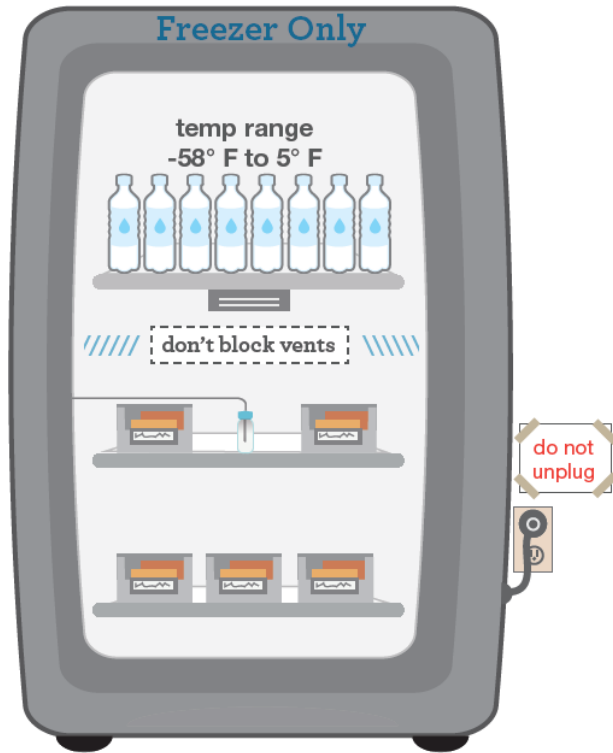
- All staff assigned to vaccine storage and handling responsibilities must complete the *You Call the Shots Vaccine Storage and Handling* training modules found at: <https://www2a.cdc.gov/nip/isd/ycts/mod1/courses/sh/ce.asp>

Vaccine Storage Requirements

Important: purpose-built storage units may have different storage and handling requirements. A purpose-built unit is designed specifically for storage of biologics, including vaccines. If you have a purpose-built unit, **save any user's guides or manufacturer's information insert for guidance on unit-specific storage requirements.**

- Stand-alone refrigerator and freezer units are required for all vaccines.
- The vaccine storage unit must be large enough to store the year's largest vaccine inventory (usually flu season).
- Vaccine storage units must be dedicated to vaccines only. No food, beverages, or bodily fluids for laboratory testing can be stored with vaccines.
- Dorm-style refrigerators* are **not** acceptable for vaccine storage.
- Avoid storing other medications and medical supplies with vaccines. If you do not have a separate refrigerator for other medicines and supplies, store these items **below** vaccines on a different shelf. Storing items on different shelves helps to prevent medical errors.

*A dorm style refrigerator is classified as any size refrigerator with one external door and a freezer within the refrigerator compartment. Per the Centers for Disease Control and Prevention (CDC), all vaccines stored in a dorm-style unit will be deemed non-viable and will need to be returned.



Combination/ Household Style



DO

- ✓ Do make sure the refrigerator door is closed!
- ✓ Do replace crisper bins with water bottles to help maintain consistent temperature.
- ✓ Do label water bottles "Do Not Drink."
- ✓ Do leave 2 to 3 inches between vaccine containers and refrigerator walls.
- ✓ Do post "Do Not Unplug" signs on refrigerator and near electrical outlet.

DON'T

- ✗ Don't use dormitory-style refrigerator.
- ✗ Don't use top shelf for vaccine storage.
- ✗ Don't put food or beverages in refrigerator.
- ✗ Don't put vaccines on door shelves or on floor of refrigerator.
- ✗ Don't drink from or remove water bottles.

Temperature:

- Store refrigerated vaccines between 36°F and 46°F (optimal storage temperature is 40°F/41°F).
- Store frozen vaccines between -58°F and +5°F.

- ✓ Clearly label the designated space for each vaccine.
- ✓ ALL vaccines should be kept in original boxes and NOT loose in bins.
- ✓ Keep vaccines two to three inches away from walls and other boxes.
- ✓ Do not store vaccines in the door, at the bottom, or in drawers of refrigerators or freezers.
- ✓ Water bottles/blocks should be stored in each of the vaccine units.
- ✓ Post **Do Not Unplug** stickers above/near/next to electrical outlets.
- ✓ Place thermometer probe in the center of the unit.

Vaccine Inventory Control

- Conduct a vaccine inventory at least once per week and when vaccine is delivered.
- Avoid stocking excessive vaccine supplies. Limit inventory to a 60-90 day supply for monthly vaccines and two to four weeks for flu vaccines.
- Monitor expiration dates and rotate stock. Use vaccines that expire sooner first.
- If vaccines will expire before they will be used:
 - ✓ Locate another SSV-enrolled provider who is willing to accept vaccines transferred for use. Opened, multi-dose vials cannot be transferred to another practice.
 - ✓ Record transfer information in OSMOSSIS **BEFORE** vaccines are removed from the practice. Vaccines cannot be transferred to any practice not listed in OSMOSSIS.
 - ✓ Use vaccine transport protocols when transferring vaccines.
- Never use expired vaccine or diluent.
- Report expired or wasted vaccines via OSMOSSIS (please read instructions in OSMOSSIS to help choose correct option) immediately. **Return labels will be emailed directly from McKesson** – please check your junk, spam, or clutter folders if you do not see an email from McKesson in your inbox.

Certified Calibrated Thermometers

The CDC requires that vaccine providers use continuous temperature monitoring devices (data loggers) to monitor vaccine temperatures onsite, during transport, and at mass/community clinics.



All SSV providers are eligible to receive a **LASCAR** state-supplied continuous temperature monitoring system from RIDOH.

- LASCAR temperature monitoring devices are cloud-based and require Wifi internet service.
- Although the LASCAR unit records temperatures on a continuous basis, storage unit checks **MUST** be completed twice daily.

When checking the storage unit, please note the following:

- ✓ Are unit doors securely closed?
- ✓ Has the unit been accidentally unplugged?
- ✓ Check the display reading on the LASCAR unit for alarms and Wifi connection.
- ✓ Is the glycol bottle in the center of the unit?

Providers are responsible to have the temperature units calibrated every two years.

Note: Practices are not required to use the state-supplied temperature monitoring device. However, any practice who purchases their own device must purchase a **24/7 continuous monitoring device** that meets CDC guidelines for certified thermometers.

Temperature Monitoring

For RIDOH issued data loggers, practices are responsible for completing the following temperature monitoring steps during each day of business operations:

- Twice daily audit checks are to be completed once at the opening business and once at the closing (2X per day).
- Log into the EasyLog Cloud temperature monitoring system to assess temperature records. After review of temperatures, enter initials into the *Comment* section under the *Table View* once per day (1X per day).
- If approved to temporarily use a paper temperature monitoring log, record the minimum and maximum temperature on the paper log.

If the temperature is outside of the recommended range:

1. **Do not use** vaccines in the affected unit.
2. Contact your Immunization Team Representative (ITR) immediately.
3. If needed, your ITR will email you with the *Temperature Excursion Response Worksheet*. Complete and return the worksheet to your ITR within 48 hours of the temperature excursion.
4. Your ITR will review manufacturer guidance to determine viability of the vaccines. Upon review, your ITR will contact you with further instructions on addressing the excursion and affected vaccines.

If vaccines are determined to be viable, a mark or sticker should be placed on each box. In the event of additional excursions, vaccines with a previous history of an excursion will need to be identified.

Extended Practice Closures (i.e. holiday, vacation) Temperature Monitoring

If your practice is planning to be closed for an extended period, whereby staff does not have physical access to the unit to complete the twice daily audit checks on the data logger where your state-supplied vaccines are stored, your practice must:

1. Contact your Immunization Team Representative (ITR) immediately to inform them about this extended closure with exact dates.
2. All state-supplied vaccines must remain monitored and not go longer than 4 days without an audit being performed. Log into the [EasyLog Cloud](#) temperature monitoring system to assess temperature records every 4 days during your extended closure. After review of temperatures, enter initials into the *Comment* section under the *Table View*) once every 4 days during the extended closure.

The *Extended Practice Closure Temperature Monitoring* policy does not replace the daily monitoring requirements. This exception will only be granted upon notification to an Immunization Representative, if deemed appropriate. Practices that do not notify their Immunization Representative and have an extended lapse in their temperature monitoring will have their vaccine orders placed on hold. Additionally, if a temperature excursion occurs during a lapse of monitoring, a practice may be held liable for the cost of the impacted vaccine due to negligence per the [Vaccine Replacement Policy](#).

Temperature Reviews for Processing Orders

DECLINED Orders:

A vaccine order will be declined if all the information needed to approve the order (e.g. temperature logs, required twice daily audit checks not being done, not logging into EasyLog Cloud once daily and entering initials in *Table View* section during hours of business operations for the practice) is not received within five business days of when the order is placed. The Immunization Team Representative (ITR) will contact the practice in a timely manner to get the needed information.

No Temperature Log:

If there is no temperature data (e.g. if the logger is offline) for the practice, the person reviewing the order will email the practice, cc'ing the ITR, to let the practice know that it needs to submit the temperatures. If the practice does not submit the temperatures within five business days, the order will be **DECLINED**. The ITR is encouraged to promptly contact the practice and ask for the temperature logs to prevent a **DECLINE**. Note: Faxed temperature logs will no longer be accepted starting January 2018; data logger uploads into OSMOSSIS during the ordering process will be required.

HOLD Orders:

An order will be placed on **HOLD** due to either a temperature excursion or a lack of consistent temperature monitoring being completed by the practice. For temperature excursions, this **HOLD** is done due to any changes in vaccine viability stemming from an excursion will affect the inventory and ordering needs of the practice. Upon discovering temperature outside of the appropriate range, the person reviewing the order will email the practice, cc'ing the ITR, to let the practice know of the excursion (as it appears), include the **Temperature Excursion Response Worksheet** link and request that the practice submit the worksheet back to the designated IT within 48 hours. For practices that are not consistently conducting twice daily audit checks or logging into EasyLog Cloud to enter their initials into the *Table View* during days of business operations, orders will also be placed on **HOLD** until these temperature monitoring requirements are maintained per the SSV Terms and Conditions. When an order is placed on **HOLD**, the order status in OSMOSSIS is changed from **SUBMITTED** to **HOLD**. All data entered for the order is retained.

It is the responsibility of the provider to reach out to their Immunization Team Representative (ITR) to follow-up on and resolve the reason for an On Hold or Declined order in a timely manner.

Temperature Reviews for Processing Orders

Multiple On Hold Orders and Temperature Excursions

Practices that have multiple temperature excursions or consistently do not complete the required temperature monitoring steps (auditing 2X a day, initialing 1x a day in *Table View* during business hours), may have their future vaccines orders placed on **HOLD** by the Immunization Team.

If these issues persist for a practice, vaccine orders will remain on **HOLD** until the designated ITR can intervene with additional training and potential site visits to ensure that these matters are addressed by the practice.

If these issues persist after ITR intervention, the ITR will escalate the issue within RIDOH for further review of practice enrollment and negligence of SSV Terms and Condition.

Emergency Vaccine Packing and Transport

- Develop and keep a current **Vaccine Storage Emergency Preparedness Plan**. The written plan must be accessible to all staff and presented to the Immunization Program Representative at each routine site assessment visit.
- The plan should include identification of a back-up site, with a generator, where the practice will store its vaccines should it experience equipment failure or a power outage.

Emergency procedures may be necessary for:

- Equipment failure
- Impending emergency
- Power outages

If power loss is short-term (usually two hours or less), storage temperatures can usually be maintained by water bottles in the refrigerator and by frozen coolant packs in the freezer, depending on the room temperature) during the time of outage. To help ensure safe temperatures during an outage:

- **Do not open storage unit** until power is restored.
- Continue to monitor temperatures of each unit.
- When power is restored, if temperatures are outside of recommended ranges, document duration of inappropriate temperature exposure and follow procedures for reporting any loss to the Office of Immunization.

Do not allow vaccines to remain in a non-functioning unit for an extended period. If you are unsure of how long the power interruption will last, activate your practice's Vaccine Storage Emergency Preparedness Plan.

Vaccine Deliveries

It is important to establish routine, systematic procedures for handling vaccine deliveries. Arrange for vaccine deliveries to be made only when the vaccine coordinator or alternate coordinator is in the office. Consider holidays, vacations, staff schedules, and changes in hours of operation.

All staff members (including non-medical staff) must be aware of the importance of maintaining the vaccine cold chain, and need to immediately notify the vaccine coordinator when vaccines arrive so that the vaccines can be handled and stored properly.

Checking the Condition of the Deliveries

- Examine the shipping container and its contents for any signs of physical damage.
- Cross-check the contents with the packing slip to make sure they match.
- Check the vaccine lot numbers and expiration dates to be sure that you have not received any vaccines or diluents that have already expired or will expire within four months.
- Check that the correct amount and type of diluents have been shipped.
- Check the hot/cold temperature strips to determine if vaccines or diluents have been exposed to temperatures outside the recommended range.
- Check that the vaccines were stacked properly. There should be an insulating barrier (bubble wrap or Styrofoam pellets) between the vaccines and the refrigerated or frozen coolant packs.
- Vaccines that require diluents will arrive in the same shipping container as the diluents. For varicella-containing vaccines, the diluents should arrive in a separate compartment of the same container.
- Immediately store vaccines in the proper vaccine storage unit and do the following:
 1. Rotate vaccines. Use vaccines that will expire sooner first.
 2. Label vaccines (e.g. Pedi/State, Adult/State, or Adult/Private).
 3. Be sure there is appropriate space between boxes of vaccines for adequate airflow.

If there are any discrepancies with the packing slip or concerns about the shipment:

- Mark or label the vaccines in question. Separate from the other vaccines.
- Store the vaccines under appropriate conditions.
- **Do not use** the vaccines.
- Call the RIDOH Office of Immunization for guidance within four hours of delivery.

Transferring Vaccines

Storage issue or impending storm

1. Notify the transfer site when and how much vaccine you will need to store.
2. Provide a list of all vaccine quantities, lot numbers, and expiration dates. Be sure to keep a copy for yourself.
3. When packing vaccine, follow guidelines as specified in this guide.
4. If your practice has lost power or if your unit is unstable, do not retrieve vaccines until your storage unit is operating under proper temperatures.

Lending or borrowing

Lending or borrowing vaccines must begin in the OSMOSSIS system by the lender.

1. Log in to OSMOSSIS using your SSV login or KIDSNET username and password.
2. Select the **TRANSFER VACCINE TO ANOTHER PRACTICE** option.
3. Enter information as required. If a practice is not listed in the dropdown box, **DO NOT** transfer vaccine to them.
4. Pack vaccines for transport using the guidelines provided.
5. Once received, the **borrower** must log in to OSMOSSIS to receive the transfer. Receiving the transfer should be completed within 48 hours upon receipt.

Vaccine shipments received from McKesson or Merck (DK) should be received within OSMOSSIS within 4 hours. All transferred vaccines should be received within OSMOSSIS within 48 hours. Any delays with the OSMOSSIS receipt process may lead to future vaccine orders being placed on hold until these delays are addressed with the practice's ITR.

COVID-19 Vaccine

The COVID-19 vaccines have special storage and handling considerations. This guide will be updated as new vaccines are approved.

Pfizer Adult Formulation (ages 12+)

Purple Cap (dilute)

The Pfizer COVID-19 vaccine authorized for use in individuals ages 12 and up is a different formulation than the vaccine for individuals ages 5-11. The Pfizer COVID-19 vaccine ages 12 and up formulation comes in 6 dose vials with a purple cap.

The complete CDC Pfizer COVID-19 vaccine training module can be found at <https://www2.cdc.gov/vaccines/ed/covid19/pfizer/index.asp>

Staff should review the manufacturer’s guidance located here <https://www.cvdvaccine-us.com/>

The Pfizer vaccine can be stored in:

- An **ultra-low temperature (ULT) freezer** between -80°C and -16°C (-112°F and -76°F) until the expiration date
- A **freezer** between -25°C and -15°C (-13°F to 5°F) for up to 2 weeks.
- A **refrigerator** between 2°C and 8°C (36°F and 46°F) for up to one month (31 days)

The Pfizer COVID-19 vaccine is shipped in a thermal shipping container with dry ice pellets. Each thermal shipping container contains:

- Up to 5 trays of vaccine. Each tray contains 195 multidose vials.
- A Controlant GPS-enabled temperature monitoring device (TMD) to monitor temperatures in the container. TMD will continue to monitor temperatures on site if storing vaccine in the thermal shipping container.





Staff should review the dry ice safety information found here

<https://www.cdc.gov/vaccines/covid-19/info-by-product/pfizer/downloads/dry-ice-safety-hcp.pdf>

The Pfizer thermal shipping container must be unpacked in a specific manner:

1. Press the “Stop Shipment” button on the Controlant TMD for 5 seconds.
2. If light turns green, continue to unpack the vaccine and continue to step 3.
3. **Do not open the trays!**
 - a. Inspect trays
 - b. Count the number of trays
4. If storing vaccine in an ultra-low temperature (ULT) freezer, return **unopened** trays to storage within **5 minutes**.
5. Do not open the vial trays or remove vials until ready to thaw/use the vaccine.
6. If light turns red, wait for the e-mailed status report on the vaccine. Contact the manufacturer immediately if the vaccine cannot be used.

The Pfizer COVID-19 vaccine can be stored in a ULT freezer or in the thermal shipping container.

 <p style="text-align: center; font-weight: bold; color: white;">Ultra-cold freezer</p> <ul style="list-style-type: none"> • Temperature range: -80°C and -60°C (-112°F and -76°F) • Length of storage: Until the expiration date • Vial storage: Store vials upright in the tray. 	 <p style="text-align: center; font-weight: bold; color: white;">Thermal shipping container</p> <ul style="list-style-type: none"> • Temperature range: -80°C and -60°C* (-112°F and -76°F) • Maintenance: Dry ice is required to keep the proper temperature. • Vial storage: Store vials upright in the tray. • Opening: Limit opening the container to twice a day for 3 minutes at a time.
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If storing in a ULT freezer, you must use a DDL with a probe designed specifically to measure ultra-cold temperatures.

If stored in the thermal shipping container:



*Dry ice will be sent to replenish the container for the first time.

The thermal shipping container must be returned to Pfizer within 30 days! After 30 days, the vaccine can be transferred to and stored in the refrigerator.

The vaccine may be stored in the freezer between -25°C and -15°C (-13°F to 5°F) for **up to 2 weeks**.

The vaccine may also be stored in the refrigerator between 2°C and 8°C (36°F and 46°F) for up to **one month**.

If storing in the freezer or refrigerator, you must use an approved DDL. Please see the section titled **Certified Calibrated Thermometers** for more information on appropriate DDLs.

Thawing

Once a vial of the Pfizer COVID-19 vaccine is touched, it starts to thaw and must be either thawed in the refrigerator or at room temperature.

- Refrigerator: Between 2°C and 8°C (36°F and 46°F)
 - ✓ 25 to 195 vials may take 2 to 3 hours to thaw in the refrigerator.
 - ✓ Fewer number of vials will take less time.
- Room temperature: Up to 25°C (77°F) between 30 minutes and 2 hours
 - ✓ Vials at room temperature must be mixed within 2 hours or returned to the refrigerator.
- Do NOT refreeze thawed vaccine.

Gray Cap (do NOT dilute)

The Pfizer COVID-19 vaccine authorized for use in individuals ages 12 years of age and older is a different formulation than the vaccine for individuals 5-11. The Pfizer COVID-19 vaccine (gray cap) comes in 6 dose vials with a gray cap.

Do NOT refreeze any thawed Pfizer 12 years of age and older (gray cap) formulation! Vaccine stored at ultra-cold temperatures must be thawed before use.

Storage Recommendations:

- Thaw vaccine in the refrigerator or at room temperature:
 - 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.
- Amount of time needed to thaw vaccine varies based on temperature and number of vials.

Use CDC's beyond-use date labels for this vaccine to track storage time at refrigerated temperatures.

Pfizer Pediatric Formulations

Orange Cap (ages 5-11)

The Pfizer COVID-19 vaccine authorized for use in individuals ages 5-11 is a different formulation than the vaccine for individuals ages 12 and up. The Pfizer COVID-19 vaccine pediatric formulation comes in 10 dose vials with an orange cap.

Do not store the pediatric formulation (orange cap) in the freezer at -25°C to -15°C (-13°F to 5°F)!

The Pfizer vaccine can be stored in:

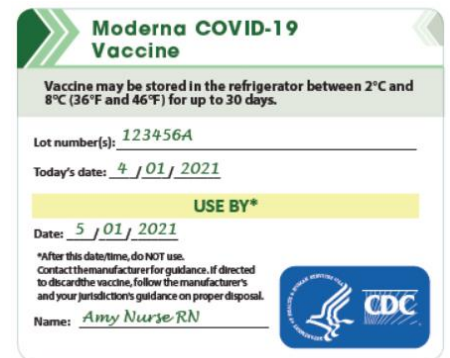
- An **ultra-low temperature (ULT) freezer** between -80°C and -16°C (-112°F and -76°F) until the expiration date
- A **refrigerator** between 2°C and 8°C (36°F and 46°F) for up to 10 weeks

Moderna

The complete CDC Moderna COVID-19 vaccine training module can be found at <https://www2.cdc.gov/vaccines/ed/covid19/moderna/index.asp>

The Moderna COVID-19 vaccine will arrive frozen between -25°C and -15°C (-13°F and 5°F). Each shipment contains 100 doses of vaccine. When unpacking the shipping container:

1. Examine the package for damage.
2. Open the box and remove the TagAlert monitor next to the vaccine.
3. Check the TagAlert for temperature excursions during transit.
4. Press and hold the blue “start and stop” button for 5 seconds.
5. Read the indicator status. If the:
 - a. Left arrow points to a green checkmark, the vaccine is ready to use. Store the vaccine at proper temperatures immediately.
 - b. Right arrow points to an X mark: 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 Rhode Island Department of Health Immunization Team Representative (ITR) immediately.



If you are storing the Moderna COVID-19 vaccine in the freezer, it must be:

- Stored between -25°C and -15°C (-13°F and 5°F)
- Stored in the original carton
- Protected from light
- **Do not store with dry ice!**

Moderna COVID-19 vaccine can be stored at frozen temperatures between -25°C and -15°C (-13°F and 5°F) until its expiration date. RIDOH recommends checking the expiration date by entering the lot number here: modernatx.com/covid19vaccine-eua

If storing the Moderna COVID-19 vaccine in the refrigerator, it must be:

- Stored between 2°C and 8°C (36°F and 46°F)
- Stored in the original carton or similar container.
- Protected from light.



The Moderna COVID-19 vaccine can only be stored in the refrigerator between 2°C and 8°C (36°F

and 46°F) **for up to 30 days.**

You must monitor the temperature of the freezer and/or refrigerator using an approved DDL. Please see the section titled **Certified Calibrated Thermometers** for more information on appropriate DDLs.

Thawing

The vaccine may be thawed in the refrigerator or at room temperature.

- Refrigerator: Between 2°C and 8°C (36°F and 46°F) for 2 hours and 30 minutes
- Room temperature: Between 15°C and 25°C (59°F and 77°F) for 1 hour
- Vials that have not been punctured may be kept between 8°C and 25°C (46°F and 77°F) for up to 12 hours. Do NOT refreeze thawed vaccine.

Janssen (Johnson & Johnson)

The complete CDC Janssen (Johnson & Johnson) COVID-19 vaccine training module can be found at <https://www2.cdc.gov/vaccines/ed/covid19/janssen/index.asp>

The Janssen COVID-19 vaccine will arrive refrigerated between 2°C and 8°C (36°F and 46°F). When unpacking the shipping container:

1. Examine the shipment for signs of damage.
2. Each shipment contains two temperature monitors. Open the box and remove both monitors.
 - a. The WarmMark monitor is located under the frozen gel packs at the top of the cooler.
 - b. The FreezeMark indicator is located inside the inner box, next to the vaccine.



3. Remove the instruction card for each temperature monitor immediately. Follow the guide on the back of each card to read the monitors.
4. The expiration date is NOT printed on the vaccine vial or carton. To determine the expiration date:
 - a. Scan the QR code on the outer carton, or
 - b. Call 1-800-565-4008, or
 - c. Visit www.vaxcheck.jnj.
5. Write the expiration date on the carton.

Refrigeration

You must monitor the temperature of the or refrigerator using an approved DDL. Please see the section titled **Certified Calibrated Thermometers** for more information on appropriate DDLs. See next page for guidance on room temperature storage.

The Janssen COVID-19 vaccine can be stored in the refrigerator between 2°C and 8°C (36°F and 46°F) or at room temperature between 9° C to 25° C (47° F to 77° F). **Do not freeze!**

- Unpunctured vials of the vaccine may be stored in the refrigerator between 2°C and 8°C (36°F and 46°F) until the expiration date.
 - Keep the vials in their original package to protect from light and keep track of the expiration date (write the expiration date on the carton).
- Punctured vials can be kept refrigerated between 2°C and 8°C (36°F and 46°F) for up to 6 hours and at room temperature between

Room Temperature

The Janssen COVID-19 vaccine may be kept at room temperature between 9° C to 25° C (47° F to 77° F) for the following time frames:

- Punctured vials for 2 hours
- Unpunctured vials for 12 hours