

New York State Vaccine Program

Storage and Transport Guidance for Jynneos Vaccine

SEPTEMBER 2022

Store Jynneos vaccine:

<p>Frozen -25°C to -15°C (-13°F to 5°F)</p> <ul style="list-style-type: none"> • Store frozen until expiration date. • NEVER REFREEZE THAWED VACCINE. 	<p>OR</p>	<p>Refrigerated 2°C to 8°C (36°F to 46°F)</p> <ul style="list-style-type: none"> • Store refrigerated for up to 8 weeks. • Count 8 weeks from the date vaccine was <i>first</i> placed in refrigerated storage. Label vaccine vial/carton with this 8-week “beyond use” date. • Vaccine must be discarded after 8-week “beyond use” date or after expiration date, whichever comes first. • Once punctured, vials may be stored refrigerated for up to 8 hours.
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ADDITIONAL CONSIDERATIONS:

- Never store vaccine in a combination refrigerator/freezer or dorm-style unit. **For more information about acceptable vaccine storage units**, see page 8 of [CDC’s Vaccine Storage and Handling Toolkit](#).
- Protect vaccine from light. Keep vials in original packaging whenever possible.
- Expiration date is printed on vaccine carton (not individual vials) or can be looked up at [Monkeypox \(hhs.gov\)](#).
- Note that this storage and handling information differs from the package insert. The information on this document supersedes the package insert.

Transport Jynneos vaccine:

<p>Frozen -25°C to -15°C (-13°F to 5°F)</p> <ul style="list-style-type: none"> • Never use dry ice for frozen transport. • If using CDC’s water bottle transport system, the water bottles must be frozen solid (not conditioned). • If vaccine begins to thaw in transit, store vaccine in a refrigerator at the receiving location. Never refreeze thawed vaccine. 	<p>OR</p>	<p>Refrigerated 2°C to 8°C (36°F to 46°F)</p> <ul style="list-style-type: none"> • Count hours used for transport against maximum allowable refrigerated storage time. • If using CDC’s water bottle transport system, the water bottles must be conditioned (not frozen solid).
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ADDITIONAL CONSIDERATIONS:

- Never use soft-sided or collapsible food/beverage coolers for vaccine transport. **For more information about acceptable vaccine transport containers**, see pages 22-23 of [CDC’s Vaccine Storage and Handling Toolkit](#).
- To the extent possible, **avoid**: leaving the transport container in direct sunlight; leaving the transport container unattended; opening the transport container.
- If using a personal or company vehicle to transport vaccine, bring vehicle to a comfortable temperature before placing transport container inside. Never place transport container in the trunk.
- Protect vaccine from drops, shocks, and vibration. Secure transport container in vehicle. If transporting individual vials or partial cartons, use dunnage (padding material such as bubble wrap) to hold vials in place within the transport container.

- Plan route to minimize transport time. In general, transport time or transport time plus clinic workday should be 8 hours maximum.
- **Every time vaccine is moved, the cold chain is put at risk. Therefore, limit transports to the extent possible.**

Temperature Monitoring Requirements

- You **must** use a digital data logger (DDL) to monitor the temperature of vaccines **at all times during storage and transport.**
- When positioning a DDL in a permanent vaccine storage unit, place the buffered probe in the center of the unit with the vaccines surrounding it, and attach the temperature display to the outside of the unit.
- When packing a DDL in a vaccine transport container:
 - Make sure the buffered probe has been conditioned in the refrigerator or freezer for at least 5 hours prior to transport.
 - Remember to reset the minimum/maximum temperature display.
 - Place buffered probe as close as possible to vaccines in the transport container.
 - Do not place buffered probe directly next to ice packs or other coolants.
 - Attach temperature display to the outer lid of the transport container whenever possible.
- Most digital data loggers (DDLs) have a minimum/maximum temperature display. **If your DDL does not have a “min/max” display, you must check and record temperatures at more frequent intervals. See below.**
- If being transported for use at an off-site clinic or for redistribution, vaccine should be placed in a permanent storage unit immediately after arriving at the destination. **If holding vaccine in a transport container throughout the clinic day, you must check and record temperatures at more frequent intervals. See below.**

SUMMARY TABLE: VACCINE TEMPERATURE MONITORING REQUIREMENTS

Vaccine is stored in a:	DDL displays “min/max” temperature:	DDL does NOT display “min/max” temperature:
Permanent storage unit on site at your location.	Check DDL and record time and min/max temperature on paper log 1x each clinic day (start of business).	Check DDL and record time and current temperature on paper log at least 2x each clinic day (start and end of business).
Transport container traveling from one location to another.	Check DDL and record time and min/max temperature at the beginning of transport and upon arrival at destination.	Check DDL and record time and current temperature at the beginning of transport and upon arrival at destination.
Permanent storage unit during an off-site or satellite clinic.	Check DDL and record time and min/max temperature 1x (when vaccine is moved from transport container to permanent storage unit).	Check DDL and record time and current temperature at least 2x during clinic day (when vaccine is moved from transport container to permanent storage unit and at end of clinic day).
Transport container during an off-site or satellite clinic.	Check DDL and record time and min/max temperature whenever container is opened.	Check DDL and record time and current temperature at least 1x per hour.
Frequency of full DDL temperature data review/download:	Review DDL data at least 1x per week and anytime min or max is outside acceptable range.	Review DDL data for temperature excursions at least 1x per day.

Packing Vaccines for Transport during Emergencies

Be ready BEFORE the emergency

Equipment failures, power outages, natural disasters—these and other emergency situations can compromise vaccine storage conditions and damage your vaccine supply. **It's critical to have an up-to-date emergency plan with steps you should take to protect your vaccine.** In any emergency event, activate your emergency plan immediately. Ideally, vaccine should be transported using a portable vaccine refrigerator or qualified pack-out. However, if these options are not available, you can follow the emergency packing procedures for refrigerated vaccines below:

1 Gather the Supplies



Hard-sided coolers or Styrofoam™ vaccine shipping containers

- Coolers should be large enough for your location's typical supply of refrigerated vaccines.
- Can use original shipping boxes from manufacturers if available.
- Do NOT use soft-sided collapsible coolers.



Conditioned frozen water bottles

- Use 16.9 oz. bottles for medium/large coolers or 8 oz. bottles for small coolers (enough for 2 layers inside cooler).
- Do NOT reuse coolant packs from original vaccine shipping container, as they increase risk of freezing vaccines.
- Freeze water bottles (can help regulate the temperature in your freezer).
- Before use, you must condition the frozen water bottles. Put them in a sink filled with several inches of cool or lukewarm water until you see a layer of water forming near the surface of bottle. The bottle is properly conditioned if ice block inside spins freely when rotated in your hand (this normally takes less than 5 minutes).



Insulating material — You will need two of each layer

- **Insulating cushioning material** – Bubble wrap, packing foam, or Styrofoam™ for a layer above and below the vaccines, at least 1 in thick. Make sure it covers the cardboard completely. Do NOT use packing peanuts or other loose material that might shift during transport.
- **Corrugated cardboard** – Two pieces cut to fit interior dimensions of cooler(s) to be placed between insulating cushioning material and conditioned frozen water bottles.



- **Temperature monitoring device** – Digital data logger (DDL) with buffered probe. Accuracy of $\pm 1^{\circ}\text{F}$ ($\pm 0.5^{\circ}\text{C}$) with a current and valid certificate of calibration testing. Pre-chill buffered probe for at least 5 hours in refrigerator. Temperature monitoring device currently stored in refrigerator can be used, as long as there is a device to measure temperatures for any remaining vaccines.

Why do you need cardboard, bubble wrap, and conditioned frozen water bottles?

Conditioned frozen water bottles and corrugated cardboard used along with one inch of Insulating cushioning material such as bubble wrap keeps refrigerated vaccines at the right temperature and prevents them from freezing. **Reusing vaccine coolant packs from original vaccine shipping containers can freeze and damage refrigerated vaccines.**



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Visit www.cdc.gov/vaccines/SandH
for more information, or your state
health department.

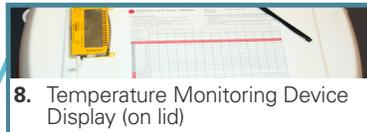
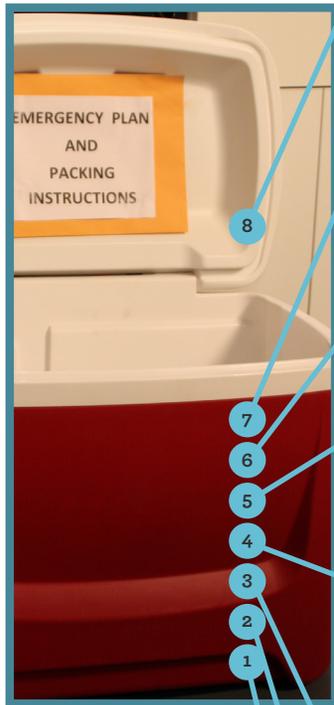
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Packing Vaccines for Transport during Emergencies

2 Pack for Transport

Conditioning frozen water bottles (this normally takes less than 5 minutes)

- Put frozen water bottles in sink filled with several inches of cool or lukewarm water or under running tap water until you see a layer of water forming near surface of bottle.
- The bottle is properly conditioned if ice block inside spins freely when rotated in your hand.
- If ice “sticks,” put bottle back in water for another minute.
- Dry each bottle.
- Line the bottom and top of cooler with a single layer of conditioned water bottles.
- Do NOT reuse coolant packs from original vaccine shipping container.



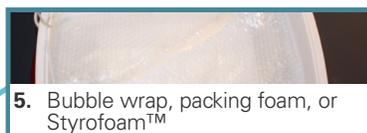
8. Temperature Monitoring Device Display (on lid)



7. Conditioned Water Bottles



6. Cardboard Sheet



5. Bubble wrap, packing foam, or Styrofoam™



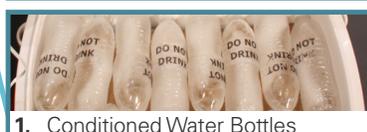
4. Vaccines, Diluents, and Temperature Monitoring Device Probe



3. Bubble wrap, packing foam, or Styrofoam™



2. Cardboard Sheet



1. Conditioned Water Bottles

Close lid – Close the lid and attach DDL display and temperature log to the top of the lid.

Conditioned frozen water bottles – Fill the remaining space in the cooler with an additional layer of conditioned frozen water bottles.

Insulating material – Another sheet of cardboard may be needed to support top layer of water bottles.

Insulating cushioning material – Cover vaccines with another 1 in. layer of bubble wrap, packing foam, or Styrofoam™

Vaccines – Add remaining vaccines and diluents to cooler, covering DDL probe.

Temperature monitoring device – When cooler is halfway full, place DDL buffered probe in center of vaccines, but keep DDL display outside cooler until finished loading.

Vaccines – Stack boxes of vaccines and diluents on top of insulating material.

Insulating cushioning material – Place a layer of bubble wrap, packing foam, or Styrofoam™ on top (layer must be at least 1 in. thick and must cover cardboard completely).

Insulating material – Place 1 sheet of corrugated cardboard over water bottles to cover them completely.

Conditioned frozen water bottles – Line bottom of the cooler with a single layer of conditioned water bottles.

NOTE:

This pack-out can maintain appropriate temperatures for up to 8 hours, but the container should not be opened or closed repeatedly.

3 Arrive at Destination

Before opening cooler – Record date, time, temperature, and your initials on vaccine temperature log.

Storage – Transfer boxes of vaccines quickly to storage refrigerator.

Troubleshooting – If there has been a temperature excursion, contact vaccine manufacturer(s) and/or your immunization program before using vaccines. Label vaccines “Do Not Use” and store at appropriate temperatures until a determination can be made.

JYNNEOS VACCINE TRANSPORT TRACKING SHEET

Email the completed tracking sheet to the NYS Vaccine Program at nyvfc@health.ny.gov. Please include "transport tracking" in the subject line. Completed tracking sheets must be submitted within 24 hours of the vaccine transport. All information must be completed.

Date of Vaccine Transport: _____

SECTION 1: RELEASING PROVIDER INFORMATION

Name of Provider (Usually the name of an organization but may be the name of an individual)	PIN (NYSIIS or CIR PIN)
Full Name and Phone Number of Contact Person	Signature of Contact Person
Vaccines will be transported (Select 1): <input type="checkbox"/> Refrigerated: 2°C to 8°C (36°F to 46°F) <input type="checkbox"/> Frozen: -25°C to -15°C (-13°F to 5°F)	Vaccines were packed for transport at: <div style="text-align: right;"><input type="checkbox"/> AM <input type="checkbox"/> PM</div>

SECTION 2: VACCINE INCLUDED IN TRANSPORT CONTAINER (Submit one form per transport container.)

Lot Number	Expiration Date	# of vials	Where was vaccine stored on site prior to being packed for transport? <i>R = Refrigerator F = Freezer</i>	Specify date and time vaccine was first placed in this on-site storage unit. <i>Receiving provider may use this information to verify vaccine's beyond-use date and time.</i>	What was the temperature of this on-site storage unit at the time vaccine was packed for transport? <i>Specify °C or °F.</i>	Calculate (or verify) the Beyond-Use Date and Time. <i>Count 8 weeks from the date and time vaccine was first placed in refrigerated storage. DO NOT exceed expiration date.</i>

SECTION 3: MINIMUM AND MAXIMUM TRANSPORT TEMPERATURES (If the DDL does not display "min/max" temperature, you must review the full temperature log.)

The minimum (coldest) temperature during transport was: <input type="checkbox"/> °C <input type="checkbox"/> °F	The maximum (warmest) temperature during transport was: <input type="checkbox"/> °C <input type="checkbox"/> °F
Was the cold chain maintained during transport? <input type="checkbox"/> Yes <input type="checkbox"/> No, and the excursion has been reported to vaccinetempexcursion@health.ny.gov	

SECTION 4: RECEIVING PROVIDER INFORMATION

Name of Provider (Usually the name of an organization but may be the name of an individual)	PIN (NYSIIS or CIR PIN)
Full Name and Phone Number of Contact Person	Signature of Contact Person
After being unpacked from the transport container, vaccine was stored on site in (check all that apply): <input type="checkbox"/> refrigerator at _____ °C <input type="checkbox"/> °F <input type="checkbox"/> freezer at _____ °C <input type="checkbox"/> °F <input type="checkbox"/> N/A (Vaccine administered immediately)	
Vaccine was placed in on-site storage unit(s) at: <input type="checkbox"/> AM <input type="checkbox"/> PM	