



INSPECTION GUIDE

Terminal Distributor of Dangerous Drugs COVID-19 Vaccine Storage and Temperature Monitoring

Updated 03/05/2021

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COVID-19 VACCINE STORAGE AND TEMPERATURE MONITORING

OAC = Ohio Administrative Code / ORC = Ohio Revised Code

IMPORTANT REMINDERS: Any deviation from the requirements of this guide should be done based upon consultation with the vaccine's manufacturer, the Ohio Department of Health, or the Centers for Disease Control and Prevention. Such deviations must be properly documented for review by Board of Pharmacy staff upon inspection.

Question	Description / Guidance	Reference ¹
Do you maintain records of receipt of COVID-19 vaccines?	Records of receipt shall contain the name, strength, dosage form, and quantity of the dangerous drugs received, the name and address of the seller, the name and address of the recipient, and the date of receipt.	OAC 4729:5-5-24 (Outpatient Pharmacies) OAC 4729-9-22 (Institutional Pharmacies)
Do you have the appropriate temperature monitoring devices?	<p>For accurate temperature monitoring, use a digital data logger (DDL) with detachable probe designed specifically to measure ultra-cold temperatures.</p> <p>A DDL is recommended. However, temperature monitoring devices (TMD) must meet the following criteria per the Ohio Department of Health (ODH):</p> <p>TMD Minimum Required Functionalities:</p> <ul style="list-style-type: none"> ▪ A temperature probe or sensor ▪ An active temperature display that can be easily read from outside of the unit that can show current, minimum, and maximum temperatures. ▪ Resettable min/max functionality ▪ Alarm for out-of-range temperatures <p>IMPORTANT: If vaccine storage units experience temperatures that are outside of the</p>	Temperature Monitoring Devices (TMD)- ODH Requirements

¹ Please be advised that the information contained in this guide is subject to change. While the Board will attempt to keep this document updated, it is the provider's responsibility to ensure compliance with all current requirements from the manufacturer, ODH, and CDC.

	recommended temperature ranges indicated for vaccines, contact the ODH Immunization Program at 1-844-963-4829 (844-9ODHVAX).	
FROZEN COVID-19 VACCINES: <u>USE OF ULTRA-COLD FREEZER</u> Are vaccines stored appropriately according to the manufacturer's instructions?	Store between -80° C and -60° C (-112° F and -76° F).	CDC Product Info: Pfizer-BioNTech COVID-19 Vaccine
FROZEN COVID-19 VACCINES: <u>USE OF THERMAL SHIPPING CONTAINERS</u> Are vaccines stored appropriately according to the manufacturer's instructions? How often do you replenish the dry ice? How do you monitor your temperature?	<p>Store between -80° C and -60° C (-112° F and -76° F)</p> <p>For the thermal shipping container to maintain the ultra-low temperatures required, it is recommended that the thermal shipping container itself be stored at 15° to 25° Celsius (59° to 77° Fahrenheit).</p> <p>Replenish dry ice pellets within 24 hours of delivery.</p> <p>Dry ice pellets should be replenished every 5 days thereafter.</p> <p>Temperatures should be monitored and recorded each day the site is open. The shipper may need to be recharged more frequently than every 5 days if the temperature is trending warmer.</p> <p><u>Direct Shipments from Pfizer (Quantities equal to or greater than 1170)</u></p>	Pfizer-Biotech COVID-19 Vaccine - Thermal Shipping Container Dry Ice Replenishment Instructions

<p>How often do you open the container?</p>	<p>The Controlant® temperature monitoring device (TMD), included with the thermal shipping container, should be used to monitor the temperature.</p> <p>The TMD will provide daily emails on the status of the containers. Providers should review daily emails and save the final email (full summary of status reports).</p> <p><u>Shipments from ODH RSS Warehouse (quantities less than 1170):</u></p> <p>The Lascar EasyLog Digital Data Logger should be used to monitor the temperature of the thermal shipping container as long as it is used to store vaccine.</p> <p>Temperatures should be monitored and recorded each day the site is open.</p> <p>If there is a flashing red light or out of range temperature, the site must quarantine the vaccine and contact the ODH Provider Call Center (1-844-963-4829).</p> <p>Open the thermal shipping container no more than 2 times per day for up to 3 minute each time. Use packaging tape to seal the outer carton after each entry.</p> <p>If more frequent openings are necessary, more frequent dry ice replenishment will be required. Ensure that the thermal shipping container is re-iced at the end of business on days when the vaccination site will be closed the following day, such as weekends or holidays.</p> <p>Store vaccine vials upright in the tray and protect from light.</p>	
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<p>FROZEN COVID-19 VACCINES: <u>USE OF FREEZER</u></p> <p>Are vaccines stored appropriately according to manufacturer information?</p>	<p>Store between -25° C and -15° C (-13° F and 5° F)</p> <p>Pfizer: Vials may be stored at 25° C and -15° C (-13° F and 5° F) for up to 2 weeks. Vials may be returned one time to recommended storage condition of 80° C and -60° C (-112° F and -76° F).</p> <p>See chart starting on Page 7 of this guide for COVID-19 storage and temperature monitoring requirements.</p>	<p>Moderna COVID-19 Vaccine - Storage and Handling Summary (CDC)</p> <p>Pfizer-BioNTech COVID-19 Vaccine Fact Sheet for Healthcare Providers</p>
<p>THAWED COVID-19 VACCINES: <u>USE OF REFRIGERATORS</u></p> <p>Are vaccines stored appropriately according to manufacturer information?</p>	<p>Thawed vaccine vials may be stored in refrigerator.</p> <p>Store between 2° C to 8° C (36° F to 46° F).</p> <p>See chart starting on Page 7 of this guide for COVID-19 storage and temperature monitoring requirements.</p>	<p>CDC Product Info: Pfizer-BioNTech COVID-19 Vaccine</p> <p>CDC Product info: Moderna COVID-19 Vaccine</p> <p>CDC Product Info: Janssen COVI-19 Vaccine</p>
<p>Are vaccines labeled sufficiently to ensure the integrity of the drug?</p>	<p>Storage areas shall be maintained at temperatures and conditions which will ensure the integrity of the drugs prior to their dispensing or administering as stipulated by the USP/NF and/or the manufacturer's or distributor's labeling.</p> <p>A label, containing date and time when the vaccine is removed from the cold storage or freezer and the date and time of beyond use date (BUD), is placed on the container (resealable plastic bag or similar container) in which the vaccine will be stored in the refrigerator.</p>	<p>OAC 4729:5-5-02 (Outpatient Pharmacies)</p> <p>OAC 4729-17-08 (Institutional Pharmacies)</p> <p>Pfizer-BioNTech COVID-19 Vaccine - Beyond Use Date/Time (BUD) Tracking Label for Vaccine During Refrigerator Storage</p> <p>Moderna COVID-19 Vaccine Storage and Handling Summary</p>

		Moderna COVID-19 Vaccine Storage and Handling Label Janssen COVID-19 Vaccine Storage and Handling Label
Do you prefill syringe with COVID-19 vaccines?	<p>Provider should contact manufacturer for stability and efficacy information.</p> <p>EUA labeling does not specify ISO air quality is required for 6 hours BUD from time of the vial puncture.</p> <p>Syringes not intended for immediate use should be labeled with the drug name, lot number, and BUD date and time.</p> <p>See chart starting on Page 7 of this guide for COVID-19 storage and temperature monitoring requirements.</p>	
Do you maintain appropriate record keeping of temperature monitoring for COVID-19 vaccines?	<p>COVID-19 vaccines have specific temperature record keeping requirements per manufacturer and state/federal requirements.</p> <p>The temperatures of storage units containing COVID-19 vaccine are required to be monitored at all times.</p> <p>Each day the site is open, each Ohio COVID-19 Vaccine provider is required to check and record:</p> <ul style="list-style-type: none"> • The minimum and maximum (min/max) temperatures of cold storage refrigerators and/or freezers • Twice daily temperature checks must be conducted at the beginning and end of the day. <p>This information must be documented on an ODH paper temperature log.</p>	CDC Product Info: Pfizer-BioNTech COVID-19 Vaccine CDC Product info: Moderna COVID-19 Vaccine CDC Product Info: Janssen COVI-19 Vaccine Daily Temperature Monitoring Log (ODH) ODH Vaccine Temperature Monitoring Standards

<p>Does the pharmacy have a policy to respond to temperature excursions?</p>	<p>A terminal distributor shall develop and implement policies and procedures to respond to any out-of-range individual temperature readings or excursions to ensure the integrity of stored drugs.</p> <p>IMPORTANT: If vaccine storage units experience temperatures that are outside of the recommended temperature ranges indicated for vaccines, contact the ODH Immunization Program at 1-844-963-4829 (844-9ODHVAX).</p>	<p>OAC 4729:5-5-24</p>
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COVID-19 STORAGE AND TEMPERATURE MONITORING

	Pfizer- BioNTech	Moderna	Janssen
ULTRA-COLD STORAGE	Store between -80° C and -60° C (-112° F and -76° F).	NA	NA
THERMAL SHIPPING CONTAINER (TEMPORARY STORAGE - REQUIRES DRY ICE)	<p>Store between -80° C and -60° C (-112° F and -76° F).</p> <p>Store container at 15° to 25° C (59° to 77° F).</p> <p>Thermal shipping container may be used as temporary storage for up to 30 days from the delivery date.</p> <p>Dry ice must be replenished within 24 hours after receiving vaccine and every 5 days thereafter.</p>	NA	NA
FREEZER	<p>Store at -25° C to -15° C (-13° F to 5° F) for up to 2 weeks.</p> <p>Vials may be returned one time to the recommended storage conditions -80° C and -60° C (-112° F and -76° F).</p>	Stored between -25° C and -15° C (-13° F and 5° F).	NA
REFRIGERATOR	<p>2° C to 8° C (36° F to 46° F)</p> <p>Time to thaw in refrigerator 2-3 hours.</p> <p>Beyond-Use Date: 120 hours (5 days)</p>	<p>2° C to 8° C (36° F to 46° F)</p> <p>Time to thaw in refrigerator for 2 hours and 30 min.</p> <p>Beyond-Use Date: 30 days</p>	<p>2° C to 8° C (36° F to 46° F)</p> <p>Unpunctured Vials: Beyond-use date- Manufacturer expiration date.</p> <p>Punctured Vials: Beyond-use-date- Up to 6 hours.</p>
ROOM TEMPERATURE (RT))	Undiluted Vaccine: May be thawed in room temperature (RT) (2° C to	Vaccine may be thawed in room temperature (RT) (15° C to 25° C [59° F to 77° F]) for 1 hour.	

	<p>25° C [35° F to 77° F]) between 30 min. and 2 hrs.</p> <p>Beyond-Use Date: 2 hours before mixing. After 2 hours, return unmixed vials to the refrigerator.</p> <p>Mixed Vaccine: can be left at RT (2° C to 25° C [35° F to 77° F])</p> <p>Beyond-Use Date: Up to 6 hours.</p> <p>Do not return to freezer storage.</p>	<p>Punctured Vials: 2° C to 25° C (36° F to 77° F)</p> <p>Beyond-Use Date for Punctured Vials: Up to 6 hours.</p> <p>Do not return to freezer storage.</p>	<p>Punctured Vials: 8° C to 25° C (46° F to 77° F)</p> <p>Beyond-Use Date: 2 hours</p> <p>Do not return to freezer storage.</p>
PRE-FILLED SYRINGES	<p>Pre-filled syringes can be stored between 2° C to 30° C (36° F to 86° F).</p> <p>Any unused vaccine must be discarded 6 hours after dilution.</p>	<p>Syringes may be pre-filled, provided their content is administered within 6 hours of the first pierce.</p> <p>Pre-filled syringes can be either stored in the refrigerator at 2° C to 8° C (36° F to 46° F) or left at room temperature (15° C to 25° C [59° F to 77° F]).</p> <p>Any unused vaccine must be discarded 6 hours after dilution.</p>	<p>Filled syringes can be stored between 2° C to 8° C (36° F to 46° F) for up to 6 hours or at room temperature (maximally 25°C/ 77° F) for up to 2 hours.</p>
BEYOND-USE DATE (BUD)/ EXPIRATION DATE:	<p>Ultra-Cold Storage Freezer: Manufacturer expiration</p> <p>Thermal-shipping container: Manufacturer expiration when stored up to 30 days.</p> <p>Freezer: 2 weeks</p> <p>Refrigerator: 120 hours (5 days)</p>	<p>Freezer: Manufacturer expiration</p> <p>Refrigerator: 30 days</p> <p>Room Temperature:</p> <ul style="list-style-type: none"> Punctured vials: 6 hours <p>Prefilled Syringes: 6 hours</p>	<p>Refrigerator: Manufacturer expiration</p> <ul style="list-style-type: none"> Unpunctured vials: Manufacturer expiration Punctured vials: 6 hours. <p>Room Temperature:</p> <ul style="list-style-type: none"> Punctured vials: 2 hours. <p>Prefilled Syringes:</p>

REFERENCE MATERIAL:	Room Temperature: <ul style="list-style-type: none"> ▪ Undiluted vials: 2 hours ▪ Diluted vials: 6 hours 		<ul style="list-style-type: none"> • 6 hours (stored in 2° C to 8° C (36° F to 46° F). • 2 hours (stored in 8° C to 25° C (46° F to 77° F).
	Prefilled Syringes: 6 hours https://www.cdc.gov/vaccines/covid-19/info-by-product/pfizer/downloads/storage-summary.pdf	https://www.cdc.gov/vaccines/covid-19/info-by-product/moderna/downloads/storage-summary.pdf	https://www.cdc.gov/vaccines/covid-19/info-by-product/janssen-storage-handling-summary.pdf

RULE REFERENCES:

Institutional Pharmacies

OAC 4729-9-11 (D):

All areas where dangerous drugs and device s are stored shall be dry, well-lighted, well-ventilated, and maintained in a clean and orderly condition. Storage areas shall be maintained at temperatures which will ensure the integrity of the drugs prior to their use as stipulated by the USP/NF and/or the manufacturer's or distributor's labeling unless otherwise directed by the board. Records relating to the distribution of dangerous drugs shall be maintained in a secure manner that ensures the integrity of the information.

Outpatient Pharmacies (RULES EFFECTIVE 12/01/2020)

OAC 4729:5-5-02 (E):

(E) Space and fixtures

(1) The library and equipment shall be housed in a suitable, well-lit and well-ventilated room or department and maintained in a clean, sanitary and orderly condition.

(2) All areas where drugs and devices are stored and prepared shall be dry, well-lit, well-ventilated, and maintained in a clean, sanitary and orderly condition. Storage areas shall be maintained at temperatures and conditions which will ensure the integrity of the drugs prior to their dispensing or administering as stipulated by the USP/NF and/or the manufacturer's or distributor's labeling.

OAC 4729:5-5-23 (B):

(B) Refrigerators and freezers used for the storage of dangerous drugs shall comply with the following:

(1) Maintain either of the following to ensure proper refrigeration and/or freezer temperatures are maintained:

(a) Temperature logs with, at a minimum, daily observations; or

(b) A temperature monitoring system capable of detecting and alerting staff of a temperature excursion.

(2) The terminal distributor shall develop and implement policies and procedures to respond to any out-of-range individual temperature readings or excursions to ensure the integrity of stored drugs.

(3) The terminal distributor shall develop and implement a policy that no food or beverage products are permitted to be stored in refrigerators or freezers used to store dangerous drugs.

OAC 4729:5-5-24 (B):

(B) Temperature logs maintained in accordance with paragraph (B) of rule 4729:5-5-23 of the Administrative Code shall include either:

(1) The date and time of observation, the full name or the initials of the individual performing the check, and the temperature recorded; or

(2) For automated systems that provide temperature monitoring, either of the following:

(a) A report that provides, at a minimum, the date and time of observation and the temperature recorded; or

(b) A report that provides temperature excursions, if any, and the date, time, temperature recorded, and length of the noted excursion.