

PFIZER 5 TO 11 YEARS -90°C VACCINE STORAGE AND HANDLING COMPETENCY ASSESSMENT

Note: Stability data on the Pfizer product will continue to be evaluated even after the vaccine begins shipping. Staff should be aware information may be updated and staff should stay abreast of any change in vaccine handling. The competency form will be updated as needed.

This document is used exclusively to evaluate healthcare personnel giving immunizations at DoD facilities or associated field activities.

Employee Name: _____ Assessment Start Date: _____ Completion Date: _____

Required Competency or Skill	Self Assessment	Evaluation Method	Competency Validated by Supervisor (Signature & date)	Comments/Additional Resources
1. Training and Equipment	<i>Demonstrate and recognize training and safety equipment to allow for personnel safety when handling dry ice and the proper equipment needed to store ultra-cold vaccine.</i>			
1.1 Watch the Pfizer handling video for the storage and handling of the Pfizer 5 to 11 years COVID-19 vaccine. https://www.cvdvaccine-us.com/product-storage-and-dry-ice				
1.2 Demonstrate the proper wearing of dry ice protective equipment; safety goggles and thermal gloves (designed to handle dry ice) that allow manual dexterity. All exposed skin must be protected from dry ice exposure.				
1.3 Review the Material Safety Data Sheet (MSDS) for the dry ice pellets and the precautions regarding skin contact, asphyxiation hazard and over-pressurization hazard when working with dry ice.				
1.4 Identify the MTF Vaccine Coordinator and the location of the ultra-cold freezer(s) designated for Pfizer 5 to 11 year COVID-19 vaccine. Vaccine Coordinator: _____ Freezer Location: _____ DHA – IHS: _____ USAMMA-DOC Call line: 301-619-3017/4318 or usarmy.detrick.medcom-usamma.mbx.doc@army.mil				
2. Opening -90°C Pfizer Vaccine Shipping Container	<i>Apply all procedures for safely opening shipping container, transferring vaccine without a temperature excursion and disposition procedures to return the shipping container and GPS.</i>			
2.1 STOP: Before opening the thermal shipping container, make sure the area in which you are working has <u>proper ventilation</u> . Use of dry ice in confined spaces, such as small rooms, walk-in coolers, and/or poorly ventilated areas, <u>can result in depletion of oxygen, resulting in asphyxiation</u> . The dry ice will vaporize into CO2 and can quickly displace O2 in confined space, causing dizziness, headaches, difficulty breathing, loss of consciousness and death.				
2.2 Pfizer pediatric vaccine (orange cap) is shipped on dry ice in smaller disposable shippers. Unlike the adult shippers, these smaller shippers <u>cannot</u> be used for temporary storage. The contents MUST be removed and place in a refrigerator or ultra-cold freezer as soon as the order is received. Do not store Pfizer pediatric vaccine in a				

Self-Assessment

1= Experienced 2=Needs Practice 3= Never Done N/A=Not Applicable

Evaluation/Validation Methodologies:

T = Tests D = Demonstration/Observation V = Verbal I = Interactive Class

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standard freezer.				
<p>2.3 Upon receipt, open the top flap of the box and disable the GPS enabled logger by pressing the “STOP” button on the device. Open the inner lid holding data logger (lid should remain attached to box).</p> <p>If product is indicating a temperature alarm, continue to proceed with storage protocols and mark vaccine in freezer with “DO NOT USE”. Once vaccine is stored at proper temperatures, follow DHA guidelines for reporting potential shipment temperature compromise.</p>				
<p>2.4 STOP: Put on protective equipment (at minimum safety glasses and thermal gloves) to protect skin against dry ice exposure.</p>				
<p>2.5 Carefully remove the dry ice pod from the shipper and put to the side.</p>				
<p>2.6 Take out the payload box and remove the vial trays, inspect for broken vaccine vials and immediately transfer to proper storage. Dry ice gloves do not need to be used when removing vial tray or vials, recommend use of routine nitrile gloves. Transfer of product from the shipper must be done within 5 minutes to prevent premature product thawing. Each shipping box may contain 1-5 vaccine trays.</p> <p>Pediatric (5 to 11 years) orange vial capped vaccine can be placed in Ultra-Cold freezer (-90°C to -60°C) for 6 months or Refrigerator (2°C to 8°C) for 10 weeks.</p>				
<p>2.7 Shipping box should be visually inspected to make sure all vaccine trays have been removed.</p>				
<p>2.8 STOP: Put on protective equipment (at minimum safety glasses and thermal gloves) to protect skin against dry ice exposure. Replace dry ice pod in box.</p>				
<p>2.9 STOP: Sublimating (vaporizing to a gas) of dry ice must occur in <u>well-ventilated area</u>. Do NOT leave box to sublimate in a confined space to include walk in coolers, refrigerators, freezers, closets or vehicles. Do NOT dispose of dry ice in a sink, toilet or other drain. Do NOT dispose of dry ice in trash or garbage. Due to risk of explosion do NOT store dry ice in ultra-low freezers. Do NOT leave dry ice unattended in open areas.</p>				
<p>2.10 Shipping container and temperature data logger will be returned within 10 business days and no later than 20 days after receipt, per the protocol annotated inside the box lid.</p>				
<p>3. Storing Pfizer 5 to 11 years Vaccine in -90°C Ultra-</p>	<p><i>Operate storage equipment and apply proper procedures for storing the vaccine in a (-90°C to -60°C)</i></p>			

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<i>cold Freezer or 2°C to 8°C Refrigerator</i>				<i>ultra-cold freezer or (2°C to 8°C) refrigerator to protect against a temperature compromise.</i>
<p>3.1 Prior to moving vaccine to ultra-cold freezer or refrigerator, confirm the freezer is clearly labeled as “Ultra-Cold -90°C to -60°C” or “Refrigerator 2°C to 8°C” and “For COVID-19 Vaccine Storage”. Visually confirm refrigerator or freezer has capacity to store vials before beginning vaccine transfer.</p>				
<p>3.2 If possible vaccine should be stored in the shipping tray. Vaccine trays may be stacked in the refrigerator or freezer. During storage minimize exposure to room light and avoid exposure to direct sunlight and ultraviolet light.</p>				
<p>3.3 Vaccine will not be stored in an ultra-cold freezer containing human tissue samples. Vaccine may be stored in a refrigerator containing blood and other bodily fluid specimens but the vaccine must be stored <u>above</u> blood/bodily fluids.</p>				
<p>3.4 Orange vial capped vaccine may be stored in ultra-cold freezer at (-90°C to -60°C) until the expiry date printed on the label. Trays should be marked with date placed in storage and the date the vaccine will expire (6 months).</p>				
<p>3.6 Orange vial capped vaccine may be stored in the refrigerator at (2°C to 8°C) for up to 10 weeks. Trays should be marked with the date placed in the refrigerator and the date the vaccine will expire. Do not refreeze thawed vials.</p>				
<p>3.6 Vaccine not used before expiration will be marked as expired, segregated from viable vaccine and reported as waste per DHA MedLog protocol.</p>				
<i>4. Thawing Vaccine in Preparation for Administration</i>				<i>Apply the proper procedures to safely thaw vaccine in preparation for vaccine administration to a recipient.</i>
<p>4.1 Vaccine removed from ultra-cold freezer may thaw in the refrigerator. Orange vial capped vaccine can be stored in the refrigerator for up to 10 weeks. A carton of 10 vials may take up to 4 hours to thaw. If needed for immediate use, a vial will defrost at <u>room temperature in 30 min</u>. Thawed vials may be handled in room light conditions. Once vials are thawed they should not be refrozen.</p>				
<p>4.2 Store pediatric vaccine in a separate marked bin specific for the pediatric COVID-19 vaccine. Bin labels at https://www.health.mil/coldchain</p>				
<p>4.3 Prior to dilution, vaccine may remain at room temperature (8°C to 25°C) for a total of 12 hours. After dilution, the vial should be held between (2°C to 25°C). Vials should be discarded 12 hours after dilution.</p>				

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4.4 Vaccine left out beyond the 12 hours must be marked as expired, segregated from viable vaccine and reported as waste per DHA MedLog protocol.				
5. Transportation of Frozen or Thawed Vials		<i>Apply the proper procedures to safely transport frozen or thawed vaccine to alternate vaccination sites.</i>		
5.1 Transport of Vials: If local redistribution is needed, undiluted vials may be transported at (-90°C to -60°C) or at (2°C to 8°C). Any hours used for transport at (2°C to 8°C) count against the 10 week limit for storage at (2°C to 8°C). Once vials are thawed they should not be refrozen.				

I understand that of all the topics listed, I will be allowed to perform only those for my skill level/scope of practice and only after I have successfully demonstrated competency.

Employee Signature: _____ Date: _____

Annual Review

Date	Competency Review Validated (Supervisor Signature)	Comments
_____	_____	_____
_____	_____	_____
_____	_____	_____

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