

APPENDIX C Vaccine Storage & Handling

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Appendix C

Checklist for Safe Vaccine Storage and Handling

Here are the most important things you can do to safeguard your vaccine supply. Are you doing them all? Review this list to see where you might make improvements in your vaccine management practices. Fill in each box with either YES or NO.

Establish Storage and Handling Policies

- YES NO 1. We have designated a primary vaccine coordinator and at least one back-up coordinator to be in charge of vaccine storage and handling at our facility.
- YES NO 2. Both the primary and back-up vaccine coordinator(s) have completely reviewed either CDC's online vaccine storage and handling guidance or equivalent training materials offered by our state health department's immunization program.
- YES NO 3. We have detailed, up-to-date, written policies for general vaccine management, including policies for routine activities and an emergency vaccine-retrieval-and-storage plan for power outages and other problems. Our policies are based on CDC's vaccine storage and handling guidance and/or on instruction from our state or local health department's immunization program.
- YES NO 4. We review these policies with all staff annually and with new staff, including temporary staff, when they are hired.

Log In New Vaccine Shipments

5. We maintain a vaccine inventory log that we use to document the following:
- YES NO a. Vaccine name and number of doses received
- YES NO b. Date we received the vaccine
- YES NO c. Condition of vaccine when we received it
- YES NO d. Vaccine manufacturer and lot number
- YES NO e. Vaccine expiration date

Use Proper Storage Equipment

- YES NO 6. We store vaccines in refrigerator and freezer units designed specifically for storing biologics, including vaccines. Alternatively, we keep frozen and refrigerated vaccines in separate, free-standing freezer and refrigerator units. At a minimum, we use a household-style unit with a separate exterior door for the freezer and separate thermostats for the freezer and refrigerator. We do NOT use a dormitory-style unit (a small combination freezer-refrigerator unit with a freezer compartment inside the refrigerator).
- YES NO 7. We use only calibrated thermometers with a Certificate of Traceability and Calibration* that are recalibrated as recommended by the manufacturer.
- YES NO 8. We have planned back-up storage unit(s) in the event of a power failure or other unforeseen event. We perform regular maintenance to assure optimal functioning.

Ensure Optimal Operation of Storage Units

- YES NO 9. We have a "Do Not Unplug" sign next to the electrical outlets for the refrigerator and freezer and a "Do Not Stop Power" warning label by the circuit breaker for the electrical outlets. Both include emergency contact information.
- YES NO 10. We keep the storage unit clean, dusting the coils and cleaning beneath it every 3–6 months.

Maintain Correct Temperatures

- YES NO 11. We always keep at least one accurate calibrated thermometer (+/-1°C [+/-2°F]) with the vaccines in the refrigerator; ideally, we have a continuous-temperature logger and/or temperature-sensitive alarm system.
- YES NO 12. We maintain the refrigerator temperature at 35–46°F (2–8°C), and we aim for 40°F (5°C).

(Maintain Correct Temperatures continued on page 2)

*Certificate of Traceability and Calibration with calibration measurements traceable to a testing laboratory accredited by the International Organization of Standardization, to the standards of the National Institute of Standards and Technology, or to another internationally recognized standards agency.

Technical content reviewed by the Centers for Disease Control and Prevention, July 2011.

www.immunize.org/catg.d/p3035.pdf • Item #P3035 (7/11)

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(Maintain Correct Temperatures continued from page 1)

- YES NO 13. We keep extra containers of water in the refrigerator (e.g., in the door, on the floor of the unit where the vegetable bins were located) to help maintain cool temperatures.
- YES NO 14. We always keep at least one accurate calibrated thermometer (+/-1°C [+/-2°F]) with vaccines in the freezer.
- YES NO 15. We maintain the average temperature in the freezer at +5°F (-15°C), preferably colder but no colder than -58°F (-50°C).
- YES NO 16. We keep ice packs or ice-filled containers in the freezer to help maintain cold temperatures.

Store Vaccines Correctly

- YES NO 17. We post signs on the doors of the refrigerator and freezer that indicate which vaccines should be stored in the refrigerator and which in the freezer.
- YES NO 18. We do NOT store any food or drink in any vaccine storage unit.
- YES NO 19. We store vaccines in the middle of the refrigerator or freezer (never in the doors), with room for air to circulate.
- YES NO 20. We have removed all vegetable and deli bins from the storage unit.
- YES NO 21. If we are using a combination refrigerator-freezer unit, we do not store vaccines in front of the cold air outlet that leads from the freezer to the refrigerator (often near the top shelf).
- YES NO 22. We check vaccine expiration dates and rotate our supply of each type of vaccine so that we use the vaccines that will expire soonest.
- YES NO 23. We store vaccines in their original packaging in clearly labeled uncovered containers with slotted sides that allow air to circulate.

Maintain Daily Temperature Logs

- YES NO 24. On days when our practice is open, we document refrigerator and freezer temperatures on the daily log twice a day — first thing in the morning and right before our facility closes.
- YES NO 25. We consistently record temperatures on the log in either Fahrenheit or Celsius. We NEVER mix in any way how we record our temperatures. For example, if the log prompts us to insert an "x" by the temperature that's preprinted on the log, we do not attempt to write in the actual temperature.
- YES NO 26. The logs show whom to call if the temperature in the storage unit goes out of range.
- YES NO 27. When we change the thermostat setting, we document it in the daily log sheet's note section.
- YES NO 28. If out-of-range temperatures occur in the unit, we document in the daily log sheet's note section who responded and when.
- YES NO 29. Trained staff (other than staff designated to record the temperatures) review the logs weekly.
- YES NO 30. We keep the temperature logs on file for at least 3 years.

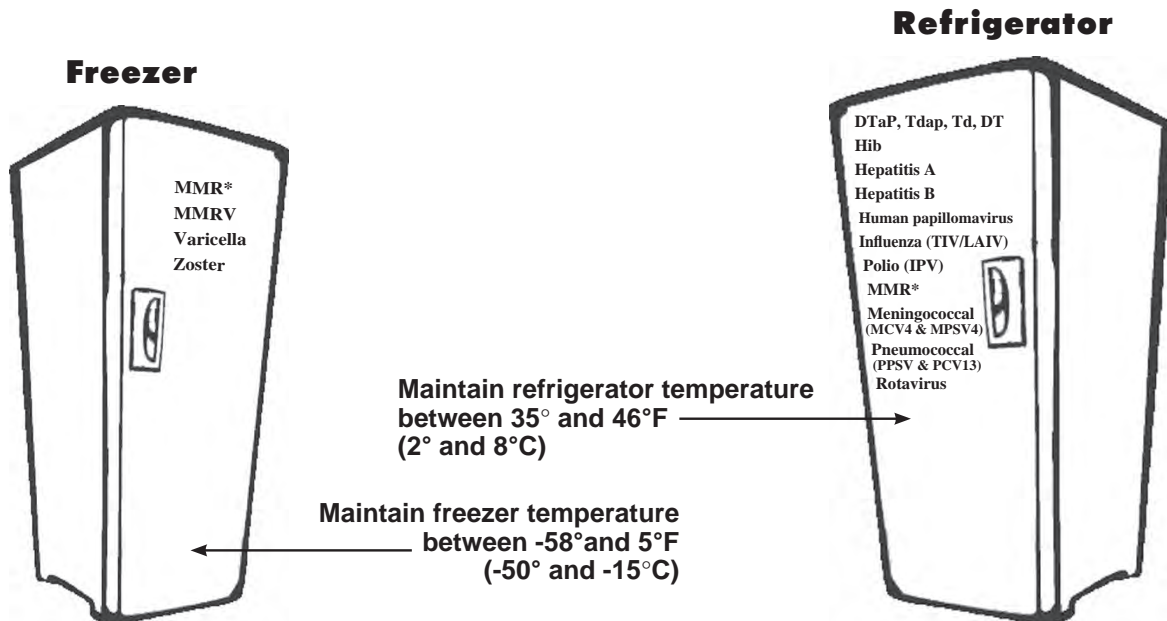
Take Emergency Action As Needed

- 31. In the event that vaccines are exposed to improper storage conditions, we take the following steps:
 - YES NO a. We restore proper storage conditions as quickly as possible; if necessary, we move the vaccine to our planned back-up storage unit. We address the storage unit's mechanical or electrical problems according to guidance from the manufacturer or repair service.
 - YES NO b. In responding to improper storage conditions, we do NOT make frequent or large changes in thermostat settings. After changing the setting, we give the unit at least a day to stabilize its temperature.
 - YES NO c. We temporarily label exposed vaccines "Do not use" and keep them separate from any unexposed vaccines. We do not use exposed vaccines until our state health department's immunization program or the vaccine manufacturer gives us approval.
 - YES NO d. We document exactly what happened, noting the temperature in the storage unit and the amount of time the vaccines were out of proper storage conditions. We contact our state health department's immunization program or the vaccine manufacturer to determine how to handle the exposed vaccines.
 - YES NO e. We follow the health department or manufacturer's instructions and keep a record detailing the event. Where applicable, we mark the exposed vials with a revised expiration date provided by the manufacturer.

If we answer YES to all of the above, we give ourselves a pat on the back! If not, we assign someone to implement needed changes!

Vaccine Handling Tips

Outdated or improperly stored vaccines won't protect patients!



Manage vaccine inventories.

Inventory your vaccine supplies at least monthly and before placing an order. Expired vaccine must never be used and is money wasted!

Always use the vaccine with the soonest expiration date first.

Move vaccine with the soonest expiration date to the front of the storage unit and mark it to be used first. Keep vaccine vials in their original boxes.

Store vaccine appropriately.[†]

Place vaccines in refrigerator or freezer immediately upon receiving shipment. Keep vaccine vials in their original packaging. Place vaccine in clearly labeled wire baskets or other open containers with a 2–3" separation between baskets and from wall of unit. Separate vaccines that have been supplied from your state's Vaccines for Children program from vaccines that are privately purchased. Do not store vaccines in the door or on the floor of the unit.

*MMR may be stored in either the freezer or the refrigerator.

[†]Refer to package insert for specific instructions on the storage of each vaccine. If you have questions about the condition of the vaccine upon arrival, you should immediately place the vaccine in recommended storage, mark it "do not use," and then call your state health department or the vaccine manufacturer(s) to determine whether the potency of the vaccine(s) has been affected. For other questions, call the immunization program at your state or local health department.

Record your health department's phone number here: _____

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www.immunize.org/catg.d/p3048.pdf • Item #P3048 (12/11)

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Recording Refrigerator Temperatures

Record refrigerator temperatures twice a day.

- **Acceptable temperatures are 35°F to 46°F.**
- **Unacceptable temperatures are below 35°F and above 46°F.**

The numbers on the temperature log on the right correspond to step numbers below.

Refrigerator Temperature Log Month/Year: June 2020
Days 1-15

Staff Initials	1	2	3	4	5	6	7	8	9	10	11	12	13	14	15
Day of Month	1	2	3	4	5	6	7	8	9	10	11	12	13	14	15
Time	8:00 a.m.	8:00 p.m.	8:00 a.m.	8:00 p.m.	8:00 a.m.	8:00 p.m.	8:00 a.m.	8:00 p.m.	8:00 a.m.	8:00 p.m.	8:00 a.m.	8:00 p.m.	8:00 a.m.	8:00 p.m.	8:00 a.m.

Danger! Temperatures above 46°F and too warm! Alert any unacceptable temperatures on this form below* and call your VFC representative!

Acceptable Temperatures	46°F	45°F	44°F	43°F	42°F	41°F	40°F	39°F	38°F	37°F	36°F	35°F	34°F	33°F	32°F
MIN															
MAX															

* Write any unacceptable temps (above 46° or below 35°) _____ MIN 34° MAX 33°

Take Action!
If temperature is too cold or too warm (above 46°F or below 35°F):
1. Put a "Do Not Use Vaccine" sign on the refrigerator.
2. Alert your supervisor immediately.
3. Contact your VFC Representative.
4. Record the actions you take.

Record actions taken for unacceptable temperatures:
Date: 6/2/20 Action: Call VFC Representative
6/4/20 Action: Call VFC Representative

1 Start a new log at the beginning of every month. Write the **month** and **year** in the upper right corner of the Refrigerator Temperature Log.

Month/Year June 2020
Days 1-15

2 At the beginning and end of every clinic day, write your **initials** in the Staff Initials a.m. or p.m. space for that day. Then write the a.m. or p.m. **time**.

Staff Initials	<u>PH, LH</u>
Day of Month	<u>1</u>
Time	<u>8:00, 5:00</u> am pm

3 Read the **current temperature** on the refrigerator thermometer.



OR



Write an X next to the **current temperature** on the log.

Danger	
46°F	
45°F	
44°F	
43°F	
42°F	
41°F	X
Aim for 40°F	X
39°F	
38°F	
37°F	
36°F	
35°F	
Danger	

Write the **unacceptable temperature** in the space provided.

Immediately follow the steps under **Take Action!**

* Write any unacceptable temps (above 46° or below 35°) _____ 34°

Take Action!
If temperature is too cold or too warm (above 46°F or below 35°F):
1. Put a "Do Not Use Vaccine" sign on the refrigerator.
2. Alert your supervisor immediately.
3. Contact your VFC Representative.
4. Record the actions you take.

4 Read the **MIN** and **MAX** temperatures.



Temperatures are acceptable

OR



Temperature(s) is NOT acceptable

Do nothing.

Write the **unacceptable temperature** in the space provided.

Write **MIN** or **MAX** next to the unacceptable temperature.

Immediately follow the steps under **Take Action!**

* Write any unacceptable temps (above 46° or below 35°) _____ MIN 33°

Take Action!
If temperature is too cold or too warm (above 46°F or below 35°F):
1. Put a "Do Not Use Vaccine" sign on the refrigerator.
2. Alert your supervisor immediately.
3. Contact your VFC Representative.
4. Record the actions you take.

5 At the end of every clinic day repeat steps 2 3 4.

6 At the end of the day press the **Memory Clear** button on the thermometer.



Vaccine Storage Temperatures

- ☑ Store unopened and opened vaccines in their original box with the lid in place until administration. Many vaccines should be protected from light.
- ☑ Keep calibrated thermometers with *Certificates of Traceability and Calibration* in both the refrigerator and freezer. Read and document refrigerator and freezer temperatures in the morning *AND* at the end of the work day.
- ☑ Have a current emergency vaccine retrieval and storage plan. Exposure of a vaccine to temperatures outside the recommended range requires immediate corrective action. Contact the vaccine manufacturer and/or your state or local health department for guidance.

Vaccine(s)	Diluent – Store Between:	Vaccine – Store Between:
DTaP, DT, Tdap, Td	No diluent	35°F & 46°F (2°C & 8°C)
Hepatitis A	No diluent	
Hepatitis B	No diluent	
Hib (ActHIB, Hiberix)	35°F & 46°F (2°C & 8°C)	
Hib (PedvaxHIB)	No diluent	
HPV	No diluent	
Influenza (LAIV)	No diluent	
Influenza (TIV)	No diluent	
Meningococcal (MCV4 – Menactra)	No diluent	
Meningococcal (MCV4 – Menveo)	35°F & 46°F (2°C & 8°C)	
Meningococcal (MPSV4)	35°F & 46°F (2°C & 8°C)	
Pneumococcal (PCV, PPSV)	No diluent	
Polio (IPV)	No diluent	
Rotavirus (RV-5 RotaTeq)	No diluent	
Rotavirus (RV-1 Rotarix)	68°F & 77°F (20°C & 25°C)	
MMR	35°F & 46°F (2°C & 8°C)	-58°F & 46°F (-50°C & 8°C)*
Varicella	35°F & 77°F (2°C & 25°C)	-58°F & 5°F (-50°C & -25°C)
Zoster	35°F & 77°F (2°C & -25°C)	-58°F & 5°F (-50°C & -25°C)
Combination Vaccines		
DTaP-IPV (Kinrix)	No diluent	35°F & 46°F (2°C & 8°C)
DTaP-HepB-IPV (Pediatrix)	No diluent	
DTaP-IPV/Hib (Pentacel)	35°F & 46°F (2°C & 8°C)	
HepA-HepB (Twinrix)	No diluent	
Hib-HepB (Comvax)	No diluent	
MMRV	35°F & 46°F (2°C & 8°C)	-58°F & 5°F (-50°C & -25°C)

*MMR may be stored in either refrigerator or freezer.

For more information, see CDC's **Vaccine Storage & Handling Guide**
<http://www.cdc.gov/vaccines/recs/storage/guide/vaccine-storage-handling.pdf>

Safeguard Your Power Supply

Protect plug and outlet



Plug in unit to a nearby outlet.

Secure plug with a guard/cover.

Post "Do Not Unplug" signs near outlet.

Always avoid disruption of power



Do not use extension cords.



Do not plug more than one appliance into an outlet. This will prevent tripping of circuit breakers.



Do not use outlets that are controlled by wall switches.



Never unplug the vaccine refrigerator or freezer.

If you experience a power failure, do not open refrigerator/freezer doors. If it lasts more than 4-6 hours, call the VFC Program.

• VFC Program Office (877) 243-8832

• VFC Field Representative

www.eziz.org

Selected Vaccine Storage & Handling Resources

(Materials from CDC, the Immunization Action Coalition and the California Department of Public Health's EZ-IZ website.)

Vaccine Storage & Handling Guide [NEW] (Best practices. Storage and handling recommendations for all U.S. vaccines)
<http://www.cdc.gov/vaccines/recs/storage/guide/vaccine-storage-handling.pdf>

Emergency Response Worksheet (What to do in case of a power failure or another event that results in vaccine storage outside of the recommended temperature range)
<http://www.immunize.org/catg.d/p3051.pdf>

Refrigerator Buying Guide (VFC requirements, tips, and a worksheet for buying a refrigerator for vaccine storage)
<http://eziz.org/assets/docs/IMM-940.pdf>

Setting Up Your Refrigerator and Freezer for Vaccine Storage
<http://eziz.org/assets/docs/IMM-962.pdf> (Refrigerator)
<http://eziz.org/assets/docs/IMM-965.pdf> (Freezer)

Storing Vaccines in Your Refrigerator and Freezer
<http://eziz.org/assets/docs/IMM-963.pdf> (Refrigerator)
<http://eziz.org/assets/docs/IMM-966.pdf> (Freezer)

Temperature Logs for Vaccines
<http://www.immunize.org/catg.d/p3039f.pdf> (Fahrenheit)
<http://www.immunize.org/news.d/3039c.pdf> (Celsius)

Transporting Refrigerated Vaccines (Guidelines for vaccine transport and short-term storage)
<http://eziz.org/assets/docs/IMM-983.pdf>

Contact Information: Selected Vaccine Manufacturers & Distributors

Manufacturer/Website	Phone Number	Products
Centers for Disease Control & Prevention www.cdc.gov/ncidod/srp/drugs/drug-service.htm www.cdc.gov/laboratory/drugservice/index.html	404-639-3670	Distributor for diphtheria antitoxin, VIG, smallpox vaccine
GlaxoSmithKline www.gskvaccines.com	866-475-8222	Infanrix, Kinrix, Pediarix, Havrix, Engerix-B, Twinrix, Hiberix, Cervarix, Fluarix, FluLaval, Rotarix, Boostrix
Massachusetts Biological Labs www.umassmed.edu/massbiolabs/index.aspx	617-474-3000	IGIM, Td, TT
MedImmune, Inc. www.medimmune.com	877-633-4411	FluMist
Merck & Co., Inc. www.merckvaccines.com	800-637-2590	PedvaxHIB, Comvax, Vaqta, Recombivax-HB, Gardasil, M-M-R II, ProQuad, Afluria, Pneumovax 23, RotaTeq, Varivax, Zostavax, Td
Biotest Pharmaceuticals www.biotestpharma.com/products/nabiHB.html	800-458-4244	HBIG
Novartis Vaccines www.novartisvaccines.com/us/index.shtml	877-683-4732	Fluvirin, Agriflu, Menveo, RabAvert (distributor for Ixiaro)
Pfizer (Wyeth Vaccines) www.pfizerpro.com/	800-438-1985	Prevnar 13
sanofi Pasteur www.vaccineshoppe.com	800-822-2463	Daptacel, Tripedia, Pentacel, ActHIB, Fluzone, Menomune, Menactra, IPOL, Imovax, Decavac, Tenivac, Adacel, Typhim Vi, YF-Vax
Talecris Biotherapeutics www.talecris.com/talecris-biotherapeutics-us-home.htm	800-520-2807	HBIG, IGIM, RIG, TIG

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