

School-Located Vaccine Clinics

TOOLKIT

Part 5: VACCINE STORAGE and HANDLING

- 5.1 Proper Maintenance and Storage of Vaccine**
- 5.2 SLVC Checklist for Safe Vaccine Handling and Storage**
- 5.3 Transportation of Vaccine**
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Proper Maintenance and Storage of Vaccine by School Nurses

Special Instructions:

NOTE: The refrigerator must be designated for vaccines, medications and biologicals only. No food or beverage is allowed to be stored in them.

1. One school nurse and a backup person shall be assigned the responsibility for the proper storage and handling of vaccines kept in school offices.
2. Each location that stores vaccine shall have a working refrigerator and a certified calibrated digital data logger suitable for checking internal temperatures of the refrigerator. The refrigerator thermometer must be able to record temperatures at or above 36°F - 46°F (2-8°C).
3. Refrigerator temperature should be maintained between 36° and 46° F. The temperature of the refrigerator must be checked and documented each workday at the beginning of the day. The temperatures shall be recorded on the log sheets that are obtained from the Maine Immunization Program and placed on or near the refrigerator as well as documented in ImmPact. Each log shall be maintained by the school for three years and then destroyed.
4. Upon arrival of the vaccine, the designated school nurse or backup person shall immediately unpack the vaccines and place them in the refrigerator or freezer as appropriate. The lot number and quantity received should be verified and match what is listed in ImmPact and on the packing list. The vaccines shall be stored inside the refrigerator and never placed on the door shelves (there is too much temperature variation when the door is open). The vaccines shall be placed so that the cool air can circulate around the vaccines. The newest vaccine shall be placed behind any of the same type of vaccine that has an earlier expiration date.

5. The vaccines shall be written into the vaccine record book and added to the supply on hand so that the count in the record book matches the count in the refrigerator. Log into ImmPact and accept vaccine transfer. Records shall be retained in the office for three years and then destroyed.
6. The school nurse shall rotate the vaccines monthly so that the ones with the earliest expiration dates are placed in the front of the refrigerator and used first.
7. Ice packs shall be placed inside the freezer to help maintain the temperature when the door is opened.
8. Bottles of cold water shall be placed to line the inside walls of the refrigerator and on the door shelves in order to maintain the internal temperature of the refrigerator when the door is opened.
9. The School Nurse shall place a “Do Not Disconnect” sign on each refrigerator and circuit breaker. The electrical connection shall be protected from accidental disconnect by either a protected location or protective plug cover.
10. If the temperature of the refrigerator or freezer is measuring above or below the allowable temperatures listed above, the school nurse discovering a refrigerator or freezer out of temperature range shall:
 - Label the vaccine that it has been stored out of range and not to use the vaccine until given the permission to use from the manufacturer.
 - Notify the Manufacturer of the product for instructions in handling the vaccines (contact numbers below). Contact the Maine Immunization Program, if obtained from the Maine Immunization Program.
11. In the event of an extended power outage the school nurse shall follow the procedure for extended power outages.
12. For further instructions for storing frozen vaccine, please reference the link below, pages 33-35:
<https://www.maine.gov/dhhs/mecdc/infectious-disease/immunization/documents/MIP-Policies-and-Procedures.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 .	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 https://www.amscomedical.com/brand/listing/massachusetts-biologic-labs/68	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 https://www.biotest.com/de/en/index.cfm	800-458-4244	HBIG
Novartis Vaccines https://www.novartis.com/	877-683-4732	Fluvirin, Agriflu, Menveo, RabAvert (distributor for Ixiaro)
Pfizer (Wyeth Vaccines) www.pfizerpro.com/	800-438-1985	Prennar 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 https://www.grifols.com/en/home#	800-520-2807	HBIG, IGIM, RIG, TIG

Maine Immunization Program: (207)287-3746 or 800-867-4775

School-based Vaccine Clinic Checklist for Safe Vaccine Handling and Storage

Here are the 17 most important things you should do to safeguard your vaccine supply.

Are you doing them all?

- ___ 1. We have a school nurse or a designated person in charge of the handling and storage of our vaccines.
- ___ 2. We have a back-up person in charge of the storage and handling of our vaccines.
- ___ 3. A vaccine inventory log is maintained that documents:
 - _____ Vaccine name and number of doses received
 - _____ Date the vaccine was received
 - _____ Arrival condition of vaccine
 - _____ Vaccine manufacturer and lot number
 - _____ Vaccine expiration date
- ___ 4. Our refrigerator for vaccines is either household-style or commercial-style, NOT dormitory-style. The freezer compartment has a separate exterior door. Alternatively, we use two storage units: a free-standing refrigerator and a separate, free-standing freezer.
- ___ 5. We do NOT store any food or drink in the refrigerator.
- ___ 6. We unpack vaccine immediately upon arrival and place it in the refrigerator.
- ___ 7. We store vaccines in the middle of the refrigerator, and NOT in the door.
- ___ 8. We check vaccine expiration dates before use.
- ___ 9. We post a sign on the refrigerator door showing which vaccines should be stored in the refrigerator and which should be stored in the freezer.
- ___ 10. We always keep a certified calibrated thermometer in the refrigerator that can record temperatures at 36-46°F.
- ___ 11. The temperature in the refrigerator is maintained at 36–46°F.
- ___ 12. We use bottles of cold water to line the inside walls of the refrigerator to help maintain cold temperatures.
- ___ 13. We post a temperature log on the refrigerator door on which we record the refrigerator minimum and maximum temperature once a day—first thing in the morning and we know whom to call if the temperature goes out of range.
- ___ 14. We understand that these temperature logs must be submitted to the Maine CDC Immunization Program at least monthly with copies maintained by the school for three years.
- ___ 15. We have a “Do Not Unplug” sign next to the refrigerator’s electrical outlet.
- ___ 16. In the event of a refrigerator failure, we take the following steps:
 - _____ We call the manufacturer immediately.
 - _____ We notify the Maine CDC Immunization Program.
 - _____ We label the vaccine stating that it has been stored out of range and not to use the vaccine until given the guidance to use from the manufacturer. (this vaccine should be kept in a cold storage unit)
- ___ 17. We keep important phone numbers posted where they are easily accessible including:

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Centers for Disease Control & Prevention www.cdc.gov/ncidod/srp/drugs/drug-service.htm .	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 https://www.amscomedical.com/brand/listing/massachusetts-biologic-labs/68	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 https://www.biotest.com/de/en/index.cfm	800-458-4244	HBIG
Novartis Vaccines https://www.novartis.com/	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, Tenvirax, Adacel, Typhim Vi, YF-Vax
Talecris Biotherapeutics https://www.grifols.com/en/home#	800-520-2807	HBIG, IGIM, RIG, TIG



Transportation of Vaccine

Rationale:

The best assurance of vaccine efficacy is to minimize the number of times vaccines are handled and transported. If vaccine transportation to another location is required, it is critical that the potency is protected by maintaining the cold chain at all times. It is essential that refrigerated vaccine shall be maintained at 36 - 46 degrees Fahrenheit during transportation.

Instructions for all transported vaccine:

1. The school vaccine provider shall pack the vaccine in the appropriately sized cooler the day of the clinic according to quantity guidelines outlined below. The vaccine should remain in their original boxes when transported to the home or clinic site.
2. The school vaccine provider shall attach a label to the outside of the container to clearly identify the contents as fragile Vaccines.
3. The certified calibrated thermometer shall be fixed to the outside of the cooler by velcro and used for all temperature readings.
4. The school vaccine provider shall record the time and temperature inside the cooler on the *Vaccine Transport Temperature Log*.
5. The school vaccine provider shall check the temperature at least hourly to ensure that the cold chain is not broken. Record the time and temperature on the *Vaccine Transport Temperature Log*. Do not open the cooler for hourly temperature readings. Retain these records for three years and then destroy.
6. If the temperature of the cooler falls outside of the recommended guidelines the school vaccine provider shall take the following actions:
 - Label the Vaccine that it has been stored out of range
 - Notify the manufacturer of the product for instructions in handling the vaccine (Manufacturer's contact numbers are listed below)
 - If the vaccine was obtained from the Maine Immunization Program notify the Maine Immunization Program at 287-9972

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/drugsevice/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

Special Instructions for Refrigerated Vaccine Transport:

MIP recommends transporting refrigerated vaccines with a portable refrigeration unit. If this type of unit is not available, a hard-sided insulated cooler with at least 2-inch walls, a Styrofoam vaccine shipping container, or other qualified container may be used as long as it maintains the recommended temperature range (36°F to 46°F [2°C to 8°C]).

- Using a hard-sided cooler, Styrofoam vaccine shipping container, or other qualified container requires the following:
 - o Coolers should be large enough to hold the MIP supply of refrigerated vaccines.

o Label the container with the facility name, “Fragile Vaccines – Do NOT Freeze”, and the date and time the vaccines was removed from the permanent storage unit.

NOTE: Do not use soft-sided collapsible coolers for transporting vaccine.

- Conditioned frozen water bottles are recommended for keeping vaccines cold.
- o Use 16.9 oz. bottles for medium/large coolers and 8 oz. bottles for small coolers
- o Before use, condition the frozen water bottles. This is done by placing them in a sink filled with several inches of cool or lukewarm water until there is a layer of water forming near the inner surface of the bottle. The bottle is properly conditioned when the ice block spins freely within the bottle when rotated.

NOTE: Do not reuse coolant packs from original vaccine shipping containers.

- Insulating material – two each of the following layers is needed:
 - o Corrugated cardboard – two pieces cut to fit the internal dimensions of the coolers(s) and placed between the insulating cushioning material and the conditioned water bottles.
 - o Insulating cushioning material such as bubble wrap, packing foam, or Styrofoam for a layer at least 2-inches thick above and below the vaccines. Ensure this layer covers the cardboard completely.

NOTE: Do not use packing peanuts or other loose material that may shift during transport.

- A data logger with a buffered probe must be used as a temperature monitoring device.
 - o Prepare the probe by pre-chilling it in the refrigerator for at least 5 hours prior to transport.
 - o Ensure the data logger has a current and valid certificate of calibration testing.
 - o Ensure the data logger certificate is documented to be accurate within +/- 1°F (+/- 0.5°C).
 - o The data logger currently stored in the refrigerator can be used for transport, as long as there is a device in place to measure the temperature for any remaining vaccines.

MIP recommends the following packing assembly for refrigerated vaccines:

- Line the bottom of the cooler with a single layer of conditioned water bottles.
- Place a sheet of corrugated cardboard over the water bottles. • Place at least a 2-inch layer of insulating material (i.e., bubble-wrap, packing foam, or Styrofoam) over the cardboard.
- Stack boxes of vaccines on top of the insulating material.
- When cooler is halfway full, place the data logger buffered probe in the center of the vaccines, but keep the display outside the cooler.
- Cover vaccines with another 2-inch layer of insulating material.
- Add the second layer of corrugated cardboard.
- Fill the remaining space in the cooler with conditioned water bottles.
- Close the lid of the cooler securely, and attach the data logger display and a temperature log to the top of the lid to record and monitor the temperature during transport.
- Use the temperature recording form to record the time and temperature inside of the storage unit at the time the vaccines were removed.

- If vaccines are kept in a transport container for longer than an hour, record the temperatures hourly.
- As soon as the destination site is reached, check and record the vaccine temperature.

As long as the vaccine temperature is 36°F to 46°F (2°C to 8°C), place the vaccine in the refrigerator.

If the vaccine is below 36°F (below 2°C) or above 46°F (above 8°C), label the vaccine as “Do Not Use”, place in the refrigerator, and immediately contact the vaccine manufacturer to determine viability.

NOTE: Always keep vaccine properly stored until otherwise instructed by the vaccine manufacturer or MIP.

Special Instructions for Frozen Vaccine Transport:

Varicella and MMRV vaccines are fragile and must be kept frozen. For transporting instructions, please reference the following link, pages 46-48:

<https://www.maine.gov/dhhs/mecdc/infectious-disease/immunization/documents/MIP-Policies-and-Procedures.pdf>



Ordering and Storage of Vaccine FAQ's about School-located Vaccine Clinics (SLVC's)

What forms do I need to fill out in order to receive vaccine from the Maine Immunization Program?

You will need to contact Valerie MacKenzie, our provider relations specialist, for an enrollment packet and other information at 287-3746.

Do I need to fill out a new provider agreement every calendar year?

No. A provider agreement needs to be renewed at the beginning of *every other* calendar year unless there is a change with the medical director.

Why do I need to fill out all these forms every year just to get influenza vaccine?

This is a FEDERAL requirement for any organization that receives vaccine from our program.

What are the storage requirements for properly storing vaccine at our school?

You can use units like this:



A refrigerator unit with no freezer compartment is not considered dormitory-style and **is acceptable** for vaccine storage.

2. You **cannot** use a dorm style refrigerator to store vaccine.



A refrigerator with a built in freezer

Compartment is considered dormitory-style and **is not** acceptable for vaccine settings.

What are the temperature requirements for storing vaccine?

1. Refrigerated vaccine must be stored between 36 °F and 46 °F degrees
(Example influenza vaccine)
2. Freezer vaccine must be stored between -58 °F degrees and +5 °F degrees
(Example varicella vaccine)

How many days of temperatures must I record and submit before I can order vaccine?

You must record and submit through the ImmPact system seven days of temperatures before you will be sent vaccine.

Once I receive vaccine how many times a day do I need to check the temperature?

You (or your designee) must check and record the minimum and maximum temperature of the vaccine storage unit **once** per day in the morning. You do not have to record the temperature if the school is not open or if you do not have any vaccine. (example: weekends, holidays, school vacation week)
School nurses who work part-time in buildings must have designee record temperatures on the days the nurse is not in the building.

Do I really need to keep vaccine until it expires in June?

Yes, you need to keep vaccine until either it expires, or you can transfer it to another provider who may be able to use the vaccine before its expiration date.
Please contact the Maine Immunization Program at the end of the school year for further instructions.
Please remember that we receive money back even for vaccine that is expired so please do not throw out vaccine.

Do I have to complete two webinars in order to receive vaccine?

Yes, all primary and backup vaccine coordinators must complete two webinars. This is a federal requirement. You can access the webinars at <https://www.maine.gov/dhhs/mecdc/infectious-disease/immunization/annual-education-requirement.shtml>.
You need to complete the **Vaccines for Children** and the **Vaccine Storage and Handling** modules.