VACCINE MANAGEMENT

Recommendations for Storage and Handling of Selected Biologicals

June 2005





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DT: Diphtheria, Tetanus Toxoids—Pediatric Td: Tetanus, Diphtheria Toxoids—Adult

Shipping Requirements

Should be shipped in insulated container. Maintain temperature at 35° to 46°F (2° to 8°C). **Do not freeze or expose to freezing temperatures.**

Condition upon Arrival*

Should not have been frozen or exposed to freezing temperatures. Refrigerate upon arrival.

Storage Requirements

Refrigerate immediately upon arrival. Store at 35° to 46°F (2° to 8°C). Do not freeze or expose to freezing temperatures.

Shelf Life

Check expiration date on vial or container.

Instructions for Use

Shake vial vigorously before withdrawal and use.

Shelf Life After Opening

The vaccine should be administered shortly after withdrawal from the vial. Unused portions of multidose vials may be refrigerated at 35° to 46°F (2° to 8°C) and used until outdated, if not contaminated.

Special Instructions

^{*} If you have questions about the condition of the material at the time of delivery, you should 1) immediately place material in recommended storage; and 2) notify the Quality Control office at the vaccine manufacturer; and 3) notify your state health department immunization program if vaccine was publicly purchased vaccine.

DTaP: Diphtheria Toxoid, Tetanus Toxoid, Acellular Pertussis Vaccine—Pediatric

DTaP/Hib: Diphtheria Toxoid, Tetanus Toxoid, Acellular Pertussis Vaccine Combined with *Haemophilus influenzae* type b Conjugate Vaccine*—Pediatric

DTaP/HepB/IPV: Diphtheria Toxoid, Tetanus Toxoid, Acellular Pertussis Vaccine, Hepatitis B Vaccine, Inactivated Polio Vaccine—Pediatric

Tdap: Tetanus Toxoid, Diphtheria Toxoid, Acellular Pertussis Vaccine—Adult

Shipping Requirements

Should be shipped in insulated container. Maintain temperature at 35° to 46°F (2° to 8°C). **Do not freeze or expose to freezing temperatures.**

Condition upon Arrival**

Should not have been frozen or exposed to freezing temperatures. Refrigerate upon arrival.

Storage Requirements

Refrigerate immediately upon arrival. Store at 35° to 46°F (2° to 8°C). **Do not freeze or expose to freezing temperatures.**

Shelf Life

Check expiration date on vial, container, or manufacturer-filled syringe.

Instructions for Reconstitution* or Use

Shake well before withdrawal and use. Do not use if resuspension does not occur with vigorous shaking.

Shelf Life After Reconstitution* or Opening

Single-Dose Vials: The vaccine should be administered shortly after withdrawal from the vial.

Manufacturer-Filled Syringes: The vaccine should be administered shortly after the needle is attached to the syringe.

Special Instructions

^{*} ActHIB® (sanofi pasteur) should be used within 24 hours of reconstitution if used alone. If sanofi pasteur DTaP is used to reconstitute ActHIB®, the TriHibit® vaccine must be used within 30 minutes of reconstitution. Only sanofi pasteur DTaP-Tripedia® or the diluent shipped with the product may be used to reconstitute the sanofi pasteur ActHIB® product. Sanofi pasteur DAPTACEL® is not licensed for use in reconstitution of ActHIB®.

^{**} If you have questions about the condition of the material at the time of delivery, you should 1) immediately place material in recommended storage; and 2) notify the Quality Control office at the vaccine manufacturer; and 3) notify your state health department immunization program if vaccine was publicly purchased vaccine.

HBIG: Hepatitis B Immune Globulin

Shipping Requirements

Should be shipped in insulated container. Maintain temperature at 35° to 46°F (2° to 8°C). **Do not freeze or expose to freezing temperatures.**

Condition upon Arrival*

Should not have been frozen or exposed to freezing temperatures. Refrigerate upon arrival.

Storage Requirements

Refrigerate immediately upon arrival. Store at 35° to 46°F (2° to 8°C). **Do not freeze or expose to freezing temperatures.**

Shelf Life

Check expiration date on vial or container.

Instructions for Reconstitution or Use

Shake vial vigorously before withdrawal and use.

Shelf Life After Reconstitution or Opening

Use until outdated, if not contaminated.

Special Instructions

Rotate stock so that the earliest dated material is used first.

Hepatitis Vaccines: Hepatitis A, Hepatitis B, Hepatitis A/B, Hepatitis B/*Haemophilus influenzae* type b

Shipping Requirements

Should be shipped in insulated container. Maintain temperature at 35° to 46°F (2° to 8°C). **Do not freeze or expose to freezing temperatures.**

Condition upon Arrival*

Should not have been frozen or exposed to freezing temperatures. Refrigerate upon arrival.

Storage Requirements

Refrigerate immediately upon arrival. Store at 35° to 46°F (2° to 8°C). **Do not freeze or expose to freezing temperatures.**

Shelf Life

Check expiration date on vial, container or manufacturer-filled syringe.

Instructions for Use

Shake vial vigorously before withdrawal and use.

Shelf Life After Opening

Single-Dose Vials: The vaccine should be administered shortly after withdrawal from the vial.

Manufacturer-Filled Syringes: The vaccine should be administered shortly after the needle is attached to the syringe.

Special Instructions

^{*} If you have questions about the condition of the material at the time of delivery, you should 1) immediately place material in recommended storage; and 2) notify the <u>Quality Control office at the vaccine manufacturer</u>; and 3) notify your state health department immunization program if vaccine was publicly purchased vaccine.

Hib: *Haemophilus influenzae* type b Conjugate Vaccine

Shipping Requirements

Should be shipped in insulated container. Maintain temperature at 35° to 46°F (2° to 8°C). **Do not freeze or expose to freezing temperatures.**

Condition upon Arrival*

Should not have been frozen or exposed to freezing temperatures. Refrigerate upon arrival.

Storage Requirements

Refrigerate immediately upon arrival. Store at 35° to 46°F (2° to 8°C). **Do not freeze or expose to freezing temperatures.**

Shelf Life

Check expiration date on vial or container.

Instructions for Reconstitution** or Use

Shake vial vigorously before withdrawal and use. Do not use if resuspension does not occur with vigorous shaking.

Shelf Life After Reconstitution** or Opening

The vaccine should be administered shortly after withdrawal from the vial.

Special Instructions

Rotate stock so that the earliest dated material is used first.

IPV: Inactivated Polio Vaccine

Shipping Requirements

Should be shipped in insulated container. Maintain temperature at 35° to 46°F (2° to 8°C). **Do not freeze or expose to freezing temperatures.**

Condition upon Arrival*

Should not have been frozen or exposed to freezing temperatures. Refrigerate upon arrival.

Storage Requirements

Refrigerate immediately upon arrival. Store at 35° to 46°F (2° to 8°C). **Do not freeze or expose to freezing temperatures**.

Shelf Life

Check expiration date on vial or container.

Instructions for Use

Multidose Vials: Shake vial vigorously before withdrawal and use. Withdraw 0.5 mL of vaccine into separate sterile needle and syringe for each immunization.

Shelf Life After Opening

The vaccine should be administered shortly after withdrawal from the vial. Doses remaining in the vial may be used until outdated if not contaminated.

Special Instructions

^{*} If you have questions about the condition of the material at the time of delivery, you should 1) immediately place material in recommended storage; and 2) notify the Quality Control office at the vaccine manufacturer; and 3) notify your state health department immunization program if vaccine was publicly purchased vaccine.

^{**}ActHIB® (sanofi pasteur) should be used within 24 hours of reconstitution if used alone. If sanofi pasteur DTaP is used to reconstitute ActHIB®, the TriHibit® vaccine must be used within 30 minutes of reconstitution. Only sanofi pasteur DTaP-Tripedia® or the diluent shipped with the product may be used to reconstitute the sanofi pasteur ActHIB® product. Sanofi pasteur DAPTACEL® is not licensed for use in reconstitution of ActHIB®.

TIV: Trivalent Inactivated Influenza Vaccine

Shipping Requirements

Should be shipped in insulated container. Maintain temperature at 35° to 46°F (2° to 8°C). **Do not freeze or expose to freezing temperatures.**

Condition upon Arrival*

Should not have been frozen or exposed to freezing temperatures. Refrigerate upon arrival.

Storage Requirements

Refrigerate immediately upon arrival. Store at 35° to 46°F (2° to 8°C). **Do not freeze or expose to freezing temperatures.**

Shelf Life

Formulated for use during current influenza season.

Instructions for Use

Shake vial vigorously before withdrawal and use.

Shelf Life After Opening

Multidose Vials: The vaccine should be administered shortly after withdrawal from the vial.

Manufacturer-Filled Syringes: Sterile until removal of hub cap.

Special Instructions

^{*} If you have questions about the condition of the material at the time of delivery, you should 1) immediately place material in recommended storage; and 2) notify the <u>Quality Control office at the vaccine manufacturer</u>; and 3) notify your state health department immunization program if vaccine was publicly purchased vaccine.

LAIV: Live Attenuated Influenza Vaccine

Shipping Requirements

Should be shipped frozen in insulated container with dry ice. at 4°F (-20°C) or colder. Shipment includes WarmMark™ temperature indicator.

Condition upon Arrival*

Should be frozen at 4°F (-20° C) or colder; **must not have thawed in shipment**. (All windows in WarmMark™ indicator should be white. If any indicator windows are red, do not use the product. Call the manufacturer for further instructions.)

Storage Requirements

Upon arrival, immediately store the vaccine in a freezer with its own exterior door. Must be maintained in a continuously frozen state at 5°F (-15°C) or colder. **No freeze/thaw cycles are permitted with this vaccine.** May be stored in either a manual defrost freezer or in a frost-free freezer compartment.

In order to maintain the temperature of 5°F (-15°C) or colder in the freezer, it will be necessary in most refrigerator/freezer models to turn the temperature dial down to the coldest setting. This may result in the refrigerator compartment temperature being lowered as well. Careful monitoring of the refrigerator temperatures will be necessary to avoid freezing killed or inactivated vaccines.

NOTE: The manufacturer supplied freezer box is no longer required for storage of LAIV vaccine in a frost-free freezer. This new storage requirement applies to the 2005-2006 influenza season, not the 2004-2005 LAIV vaccine supply.

Shelf Life

Formulated for use during current influenza season.

Instructions for Use

Thaw sprayer in palm of hand before administering. Do not roll the vaccine sprayer in your hand, as this may dislodge the dose divider clip. May also be thawed in a refrigerator and stored at 35° to 46°F (2° to 8°C) for no more than 60 hours prior to use. **Do not refreeze after thawing.**

Shelf Life After Thawing

The vaccine should be administered shortly after thawing. Vaccine thawed in the refrigerator and stored at 35° to 46°F (2° to 8°C) that is not used within 60 hours must be discarded in an impenetrable sharps container.

Special Instructions

Rotate stock so that the earliest dated material is used first.

NOTE: all materials used for administering live virus vaccines should be burned, boiled, or autoclaved prior to disposal.

^{*} If you have questions about the condition of the material at the time of delivery, you should 1) immediately place material in recommended storage; and 2) notify the Quality Control office at the vaccine manufacturer; and 3) notify your state health department immunization program if vaccine was publicly purchased vaccine.

MMR: Measles/Mumps/Rubella Vaccine, MR: Measles/Rubella Vaccine, Measles Virus Vaccine, Mumps Virus Vaccine, Rubella Virus Vaccine

Shipping Requirements

Vaccine: Use insulated container. Must be shipped with refrigerant. Maintain at 50°F (10°C) or less. If shipped with dry ice, diluent must be shipped separately.

Diluent: May be shipped with vaccine, but do not place in container with dry ice.

Condition upon Arrival*

Maintain at 50°F (10° C) or less. If above this temperature, see instructions (*) below. **Do not use warm vaccine.** Refrigerate upon arrival.

Storage Requirements

Vaccine may be stored separately from diluent. Store as follows:

Vaccine: Refrigerate immediately upon arrival. Store at 35° to 46°F (2° to 8°C). Protect from light at all times, since such exposure may inactivate the virus.

Diluent: May be refrigerated or stored at room temperature (68° to 77°F [20° to 25°C]). **Do not freeze or expose to freezing temperatures.**

NOTE: Freeze-dried (lyophilized) MMR vaccine may be maintained at freezer temperatures.

Shelf Life

Check expiration date on container or vial

Instructions for Reconstitution and **Use**

Reconstitute just before using. Use only the diluent supplied to reconstitute the vaccine. Inject diluent into the vial of lyophilized vaccine and agitate to ensure thorough mixing. Withdraw entire contents into syringe and inject total volume of vaccine subcutaneously.

Shelf Life After Reconstitution, Thawing or Opening

After reconstitution, use immediately or store in a dark place at 35° to 46°F (2° to 8°C). **Discard if not used within 8 hours.**

Special Instructions

Rotate stock so that the earliest dated material is used first.

NOTE: all materials used for administering live virus vaccines should be burned, boiled, or autoclaved prior to disposal.

^{*} If you have questions about the condition of the material at the time of delivery, you should 1) immediately place material in recommended storage; and 2) notify the <u>Quality Control office at the vaccine manufacturer</u>; and 3) notify your state health department immunization program if vaccine was publicly purchased vaccine.

MCV4: Meningococcal Conjugate Vaccine, Groups A, C, Y, W-135

Shipping Requirements

Should be shipped in insulated container. Maintain temperature at 35° to 46°F (2° to 8°C). **Do not freeze or expose to freezing temperatures.**

Condition upon Arrival*

Should not have been frozen or exposed to freezing temperatures. Refrigerate upon arrival.

Storage Requirements

Refrigerate immediately upon arrival. Store at 35° to 46°F (2° to 8°C). **Do not freeze or expose to freezing temperatures.** Protect from light.

Shelf Life

Check expiration date on vial or container.

Instructions for Use

Follow manufacturer's directions.

Shelf Life After Opening

The vaccine should be administered shortly after withdrawal from the vial.

Special Instructions

Rotate stock so that the earliest dated material is used first. Vaccine should be injected by the intramuscular route. Do not inject intradermally, subcutaneously, or intravenously.

MPSV4: Meningococcal Polysaccharide Vaccine, Groups A, C, Y, W-135

Shipping Requirements

Should be shipped in insulated container. Maintain temperature at 35° to 46°F (2° to 8°C). **Do not freeze or expose to freezing temperatures.**

Condition upon Arrival*

Should not have been frozen or exposed to freezing temperatures. Refrigerate upon arrival.

Storage Requirements

Refrigerate immediately upon arrival. Store at 35° to 46°F (2° to 8°C). **Do not freeze or expose to freezing temperatures.**

Shelf Life

Check expiration date on vial or container.

Instructions for Reconstitution and **Use**

Reconstitute gently. This is a white powder that yields a clear, colorless

liquid when reconstituted with 0.6 ml (single-dose vial) or 6 ml (10-dose vial) of sterile distilled water.

Shelf Life After Reconstitution or Opening

Single-Dose Vials: Use within 30 minutes of reconstitution.

Multidose Vials: Unused portions of multidose vials may be refrigerated at 35° to 46°F (2° to 8°C) and used up to 35 days after reconstitution.

Special Instructions

Diluent to be used is sterile, distilled water for injection; diluent for 10-dose vial also contains 0.01% thimerosal. Reconstituted vaccine should be injected subcutaneously. Do not inject intradermally, intramuscularly, or intravenously.

^{*} If you have questions about the condition of the material at the time of delivery, you should 1) immediately place material in recommended storage; and 2) notify the <u>Quality Control office at the vaccine manufacturer</u>; and 3) notify your state health department immunization program if vaccine was publicly purchased vaccine.

PCV: Pneumococcal Conjugate Vaccine (7-Valent)

Shipping Requirements

Should be shipped in insulated container. Maintain temperature at 35° to 46°F (2° to 8°C). **Do not freeze or expose to freezing temperatures.**

Condition upon Arrival*

Should not have been frozen or exposed to freezing temperatures. Refrigerate upon arrival.

Storage Requirements

Refrigerate immediately upon arrival. Store at 35° to 46°F (2° to 8°C). **Do not freeze or expose to freezing temperatures.**

Shelf Life

Check expiration date on vial or container.

Instructions for Use

Vaccine should appear as a homogenous white suspension after vigorous shaking. The vaccine should be administered intramuscularly only.

Shelf Life After Opening

The vaccine should be administered shortly after withdrawal from the vial.

Special Instructions

This vaccine is a suspension containing adjuvant and should not be used if the particles cannot be resuspended after vigorous shaking.

Rotate stock so that the earliest dated material is used first.

PPV: Pneumococcal Polysaccharide Vaccine (Polyvalent)

Shipping Requirements

Should be shipped in insulated container. Maintain temperature at 35° to 46°F (2° to 8°C). **Do not freeze or expose to freezing temperatures.**

Condition upon Arrival*

Should not have been frozen or exposed to freezing temperatures. Refrigerate upon arrival.

Storage Requirements

Refrigerate immediately upon arrival. Store at 35° to 46°F (2° to 8°C). **Do not freeze or expose to freezing temperatures.**

Shelf Life

Check expiration date on vial or container.

Instructions for Use

Follow manufacturer's directions.

Shelf Life After Opening

Single-Dose Vials: The vaccine should be administered shortly after withdrawal from the vial.

Multidose Vials: Unused portions of multidose vials may be refrigerated at 35° to 46°F (2° to 8°C) and used until outdated, if not contaminated.

Special Instructions

Do not inject intravenously. Intradermal administration may cause severe local reactions and should be avoided.

^{*} If you have questions about the condition of the material at the time of delivery, you should 1) immediately place material in recommended storage; and 2) notify the <u>Quality Control office at the vaccine manufacturer</u>; and 3) notify your state health department immunization program if vaccine was publicly purchased vaccine.

Varicella (Chickenpox) Vaccine

Shipping Requirements

Vaccine: Use insulated container. Must be shipped with dry ice only, at 4°F (-20°C) or colder. Should be delivered within 2 days.

Diluent: May be shipped with vaccine, but do not place in container with dry ice.

Condition upon Arrival*

Should be frozen. Vaccine should remain at 4°F (-20°C) or colder until arrival at the healthcare facility. Dry ice should still be present in the shipping container when vaccine is delivered.

Storage Requirements

Vaccine: Freeze immediately upon arrival. Maintain vaccine in a continuously frozen state at 5°F (-15°C) or colder. No freeze/thaw cycles are allowed with this vaccine. Vaccine should only be stored in freezers or refrigerator/freezers with separate doors and compartments. Acceptable storage may be achieved in standard household freezers purchased in the last 10 years, and standard household refrigerator/freezers with a separate, sealed freezer compartment. "Dormitory-style" units are not appropriate for the storage of varicella vaccine.

In order to maintain temperatures of 5°F (-15°C) or colder, it will be necessary in most refrigerator/freezer models to turn the temperature dial down to the coldest setting. This may result in the refrigerator compartment temperature being lowered as well. Careful monitoring of the refrigerator temperature will be necessary to avoid freezing killed or inactivated vaccines.

Diluent: May be refrigerated or stored at room temperature (68° to 77°F [20° to

25°C]). Do not freeze or expose to freezing temperatures.

Shelf Life

Check expiration date on container or vial.

Instructions for Reconstitution and Use

Reconstitute just before using. Use only the diluent supplied to reconstitute the vaccine.

Shelf Life After Reconstitution, Thawing or Opening

Protect from light. Discard if not used within **30 minutes** of reconstitution.

Special Instructions

If this vaccine is stored at a temperature warmer than 5°F (-15°C), it will result in a loss of potency and a reduced shelf life. If a power outage or some other situation occurs that results in the vaccine storage temperature rising above the recommended temperature, the healthcare provider should contact Merck, the vaccine manufacturer, at 1-800-609-4618 for a reevaluation of the product potency before using the vaccine.

Rotate stock so that the earliest dated material is used first.

NOTE: all materials used for administering live virus vaccines should be burned, boiled, or autoclaved prior to disposal.

^{*} If you have questions about the condition of the material at the time of delivery, you should 1) immediately place material in recommended storage; and 2) notify the <u>Quality Control office at the vaccine manufacturer</u>; and 3) notify your state health department immunization program if vaccine was publicly purchased vaccine.

Manufacturer Quality Control Office Telephone Numbers

Manufacturer/Distributor	Telephone Number	Products
sanofi pasteur www.us.aventispasteur.com	800-822-2463	DTaP, DTaP-Hib, DT, Td, TT, Hib, MCV4, MPSV4, Influenza (TIV), IPV
Bayer Biological Products www.bayerbiologicalsusa.bayerhealthcare.com/products.asp	800-288-8371	IGIM, HBIG, TIG
Centers for Disease Control & Prevention Drug Service www.cdc.gov/ncidod/srp/drugs/drug-service.html	404-639-3670	Distributor for Diphtheria antitoxin
Chiron www.chiron.com/products/vaccines/index.html	800-200-4278 (medical information pharmacist) 800-244-7668 (customer support)	Influenza (TIV)
GlaxoSmithKline www.gsk.com/products/vaccines.jsp	866-475-8222 (customer support) 888-825-5249 (customer support)	DTaP, DTaP-HepB- IPV, HepA, HepB, HepA-HepB
Massachusetts Biological Labs	617-983-6400	Td, TT, IGIM, VZIG
MedImmune, Inc. www.medimmune.com	877-358-6478 (LAIV customer support) 877-633-4411 (general customer support)	Influenza (LAIV)
Merck www.merck.com	800-609-4618 (customer support) 800-672-6372 (customer support)	Hib, Hib-HepB, PPV23, HepA, HepB, MMR, Measles, Mumps, Rubella, Varicella
Nabi Biopharmaceuticals www.nabi.com	800-635-1766	HBIG
Wyeth www.wyeth.com	800-999-9384 (storage) 800-934-5556 (customer support) 800-666-7248 (customer support)	Hib, PCV7

