

Temperature monitors for vaccines and the cold chain

Cold-chain monitor

Vaccine vial monitor

Freeze Watch™

Stop!Watch™

DT and TT shipping indicator



**DEPARTMENT OF VACCINES AND
OTHER BIOLOGICALS**



World Health Organization
Geneva
1999

**The Department of Vaccines and Other Biologicals
thanks the donors whose financial support
has made the production of this document possible.**

This document was produced by the
Access to Technologies Team
of the Department of Vaccines and Other Biologicals

Ordering code: WHO/V&B/99.15
Printed: July 1999

This document is available on the Internet at:
<http://www.who.int/gpv-documents/>

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Contents

<i>Abbreviations</i>	<i>iv</i>
1. Introduction	1
2. The cold-chain monitor	2
2.1 How temperatures are monitored	3
2.2 How to interpret temperature readings (indexes)	4
2.3 Information for health workers	5
2.4 Information for vaccine manufacturers	6
2.5 Availability, price and purchase details.....	6
3. The vaccine vial monitor	7
4. Freeze Watch™	8
5. Stop!Watch™	10
6. DT and TT shipping indicator	11
7. Supporting materials available from WHO	13
7.1 Documentation.....	13
7.2 Audiovisual materials.....	13
Annex 1: Supplier	14
Annex 2: Vaccine potency testing	15
Annex 3: Examples of audiovisual materials	16

Abbreviations

BCG	bacille Calmette-Guérin (vaccine)
DTP	diphtheria-tetanus-pertussis vaccine
DT	diphtheria-tetanus vaccine
OPV	oral polio vaccine
PIS	product information sheet
TT	tetanus toxoid
VVM	vaccine vial monitor

1. Introduction

This document describes the cold-chain monitor, the vaccine vial monitor (VVM), *Freeze Watch™*, *Stop!Watch™* and the diphtheria-tetanus vaccine (DT) & tetanus toxoid (TT) shipping indicator.

Table 1: Recommended temperature ranges

Vaccines	Stages of the cold chain	Maximum temperatures	Minimum temperatures
OPV, BCG, measles, yellow fever	All	+8°C	-20°C
Hepatitis B, DTP	All	+8°C	0°C
DT, TT	Transport	+40°C	0°C
DT, TT	Storage	+8°C	0°C
Diluent	Transport	Ambient	0°C
Diluent	Storage	Ambient	0°C
Diluent	Point of use	+8°C	0°C

To retain maximum potency a vaccine should be kept in its safe temperature range. The safe range varies between vaccines and between stages of the cold chain, as shown in Table 1.

The cold-chain monitor, *Freeze Watch™* and the DT and TT shipping indicator are intended to help managers and health workers ensure that the cold chain functions correctly from the point of manufacture to the point of use.

Stop!Watch™ monitors temperatures inside refrigerators.

The vaccine vial monitor monitors vaccine potency, registering the effect of heat on individual vials of vaccine.

2. The cold-chain monitor

The cold-chain monitor is used to show exposure to temperatures above the safe range during transportation and storage. It has an indicator that responds to two different temperatures: the first part—marked ABC—responds to temperatures above +10°C; the second part—marked D—responds to temperatures above +34°C. The indicator (marked 2 in Figure 1) is mounted on a card.

Figure 1: Front and back of the cold-chain monitor (PIS code E6/16)¹

1 Vaccine Cold Chain Monitor

Date in	Index	Location	Date out	Index

2

3

	If A all blue	If B all blue	If C all blue	If A & B & C & D all blue
Polio	Use within 3 months	TEST VACCINE BEFORE USE	Use within 3 months	Use within 3 months
Measles & Yellow Fever	Use within 3 months			
DPT & BCG	Use within 3 months			
TT & DT & Hepatitis B	These vaccines may be used			

4 SUPPLIER
FOURNISSEUR

Name: _____
Nom: _____
Date of dispatch: _____
Date d'expédition: _____
Vaccine: _____
Vaccin: _____

5

Keep the Cold Chain Monitor with your vaccine

When the Monitor arrives
complete the top part of the card
– fill in the date
– fill in the index (–, A, B, C and/or D)
– fill in the location

When the Monitor leaves
complete the top part of the card
– fill in the date
– fill in the index (–, A, B, C and/or D)

If windows A, B, C & D are all white use vaccines normally.

If the windows A to C are completely blue, but window D is still white it means that the vaccine has been exposed to a temperature above 10°C but below 34°C for the following number of days:

	INDEX		
	A	AB	ABC
At a temperature of 12°C	3 days	8 days	14 days
At a temperature of 21°C	2 days	6 days	11 days

6

If window D is blue it means that there has been a break in the cold chain of a temperature higher than 34°C for a period of at least two hours. Check the cold chain.

The instruction «use within three months» should not be followed if either the expiry date or any local cold chain policy require a shorter period before use or disposal of the vaccine.

Assembled & distributed by Berlinger Ganterschwil Switzerland

¹ Each product described in this document has a PIS code, its reference number in the EPI product information sheets, 1997 edition and 1998 supplement (WHO/EPI/LHIS/97.01 and WHO/EPI/LHIS/98.03).

The front of the cold-chain monitor has:

- (1) A record form that health workers fill in to show when vaccine shipments are received and despatched.
- (2) An indicator that is a heat-sensitive strip (*Monitor MarkTM*) with four windows, marked A, B, C and D.
- (3) An interpretation guide explaining what to do with vaccines that have been exposed to high temperatures.
- (4) A space for filling in the following information: name of supplier/manufacturer, date of dispatch, type of vaccine. For cold-chain monitors packed with vaccines supplied by UNICEF this space is already filled in by the manufacturer.

The back of the cold-chain monitor has:

- (5) Instructions on use.
- (6) A table giving information on the time and temperature characteristics of the indicator (*Monitor MarkTM*).

2.1 How temperatures are monitored

The cold-chain monitor is entirely heat-stable until it is activated by pulling out the small tab on the left side of the indicator (see paragraph 2.4.1), which then registers temperatures above +10°C in windows A, B, and C and temperatures above +34°C in window D.

When the indicator is exposed to temperatures above +10°C:

- A blue colour starts to appear in the first window, marked “A”. If the temperature then drops below +10°C the blue colour stops spreading.
- Each time the indicator is exposed to temperatures over +10°C the blue colour spreads further across the windows from A to C. This colour change is irreversible; the colour can stop spreading but never disappears.
- The higher the temperature, the faster the blue colour spreads.

When the indicator is exposed to temperatures above +34°C:

- Window D turns blue within two hours.
- Once D has changed colour to blue it never changes back to white.

2.2 How to interpret temperature readings (indexes)

A simplified interpretation guide (labelled 3 in Figure 1) explains how to interpret the colour changes (referred to as “indexes”) on the indicator in relation to the vaccines with which the cold-chain monitor is packed. The following combinations of colour change are possible:

- **Windows A, B, C and D all white, no blue showing:**

This means the cold chain is good; temperatures have been kept below +10°C and the vaccines have been stored safely.

Polio:	Vaccine may be used.
Measles and yellow fever:	Vaccines may be used.
DTP and BCG:	Vaccines may be used.
TT, DT and hepatitis B:	Vaccines may be used.

- **Window A all blue, the other windows white:**

Polio:	If vaccine vial monitors (VVMs) are attached, follow VVM guidance. If no VVMs are attached, use vaccine within three months.
Measles and yellow fever:	Vaccines may be used.
DTP and BCG:	Vaccines may be used.
TT, DT and hepatitis B:	Vaccines may be used.

- **Windows A and B all blue, the other windows white:**

Polio:	If VVMs are attached, follow VVM guidance. If no VVMs are attached, test vaccine before use ² .
Measles and yellow fever:	Use vaccines within three months.
DTP and BCG:	Vaccines may be used.
TT, DT and hepatitis B:	Vaccines may be used.

- **Windows A, B and C all blue, window D white:**

Polio:	If VVMs are attached, follow VVM guidance. If no VVMs are attached, test vaccine before use. ²
Measles and yellow fever:	Test vaccines before use. ²
DTP and BCG:	Use vaccines within three months.
TT, DT and hepatitis B:	Vaccines may be used.

- **Windows A, B, C and D all blue:**

Polio:	If VVMs are attached, follow VVM guidance. If no VVMs are attached, test vaccine before use. ²
Measles and yellow fever:	Test vaccines before use. ²
DTP and BCG:	Test vaccines before use. ²
TT, DT and hepatitis B:	Test vaccines before use. ²

² See Annex 2 for minimum quantities of vaccine justifying vaccine potency testing.

Enter the index or colour change in the Index column of the record form as follows:

- If there is no blue colour in any window, fill in a dash (-).
- If window **A** is entirely blue, write "A" in the Index column.
- If windows **A** and **D** are entirely blue, write "AD".
- If windows **A** and **B** are entirely blue, write "AB".
- If windows **A**, **B** and **D** are entirely blue, write "ABD".
- If windows **A**, **B** and **C** are entirely blue, write "ABC".
- If windows **A**, **B**, **C** and **D** are entirely blue, write "ABCD".
- If window **D** is blue, write "D".

Note: Only record the index for a window when the window is entirely blue. For example if window **A** is blue and window **B** is partly blue, enter "A".

2.3 Information for health workers

2.3.1 *How to use the cold-chain monitor in routine forwarding of vaccine shipments*

The storekeeper is responsible for entering information on the record form in the top half of the cold-chain monitor at each level of the cold chain.

- **When a cold-chain monitor arrives with a vaccine shipment, the storekeeper fills in:**
 - the date the shipment arrives;
 - the index (**A**, **B**, **C** or **D**) registered on the indicator (see box above);
 - the location of the store.
- **When a cold-chain monitor leaves a store with a vaccine shipment, the storekeeper fills in:**
 - the date the shipment leaves;
 - the index (**A**, **B**, **C** or **D**) registered on the indicator (see box above).

2.3.2 *What action to take if there is a break in the cold chain*

- **Vaccines:** Consult the interpretation guide (labelled 3 in Figure 1) on the front of the cold-chain monitor and, if VVMs are supplied, check their readings.
- **Cold chain:** By reading the record form at the top of the front of the cold-chain monitor, the weak parts of the cold chain can be identified. Every break in a cold chain should be investigated and action should be taken to prevent a further breakdown. Priority should be given to the higher levels of the cold chain: the central store, regional stores and their transport facilities. These stores are relatively easy to visit and supervise and the volume of vaccine stored is larger than elsewhere.

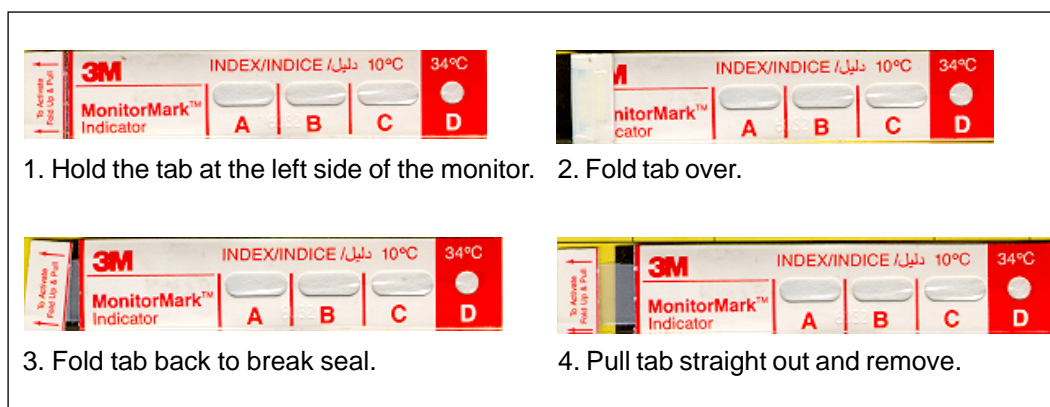
2.4 Information for vaccine manufacturers

2.4.1 What to do when packing the cold-chain monitor with consignments of vaccine

- Select a cold-chain monitor in an appropriate language.
- Fill in the bottom part of the cold-chain monitor, labelled “SUPPLIER”, with the name of the vaccine supplier or manufacturer, the date of dispatch and the type of vaccine being dispatched.
- Select sufficient monitors so that you have:
One cold-chain monitor per 3000 doses of DTP, measles or yellow fever vaccine; and/or one cold-chain monitor per shipment of polio vaccine.
- Precool the cold-chain monitors to a temperature of less than +10°C for at least 30 minutes. This is essential for accurate functioning. If the indicator is activated at normal room temperature some blue colour will begin to show even if there is immediate cooling.
- Activate the cold-chain monitors you will be using. See Figure 2.
- Pack the cold-chain monitors with the vaccine.

Figure 2: Steps to activate the indicator (*Monitor Mark™*)

2.4.2 How to store monitors



No special precautions need to be taken during storage or transport as the indicator (*Monitor Mark™*) is entirely heat-stable until it has been activated.

2.5 Availability, price and purchase details

Vaccine cold-chain monitors are available in Arabic, Bulgarian, Chinese, English, French, Greek, Polish, Portuguese, Russian and Spanish. Each language is printed on a different coloured card.

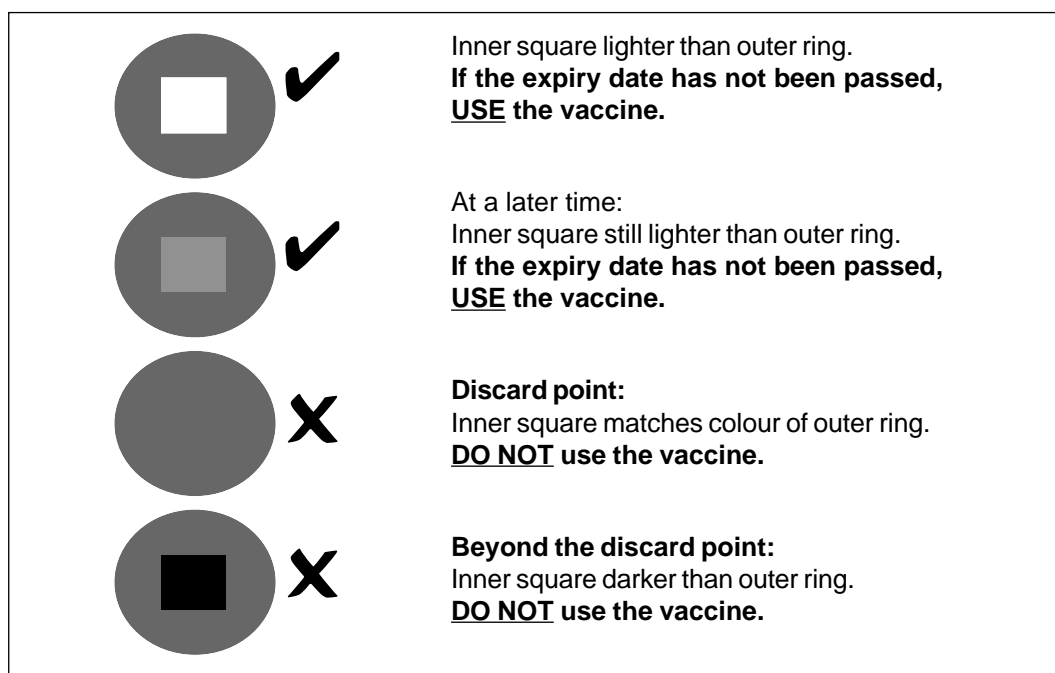
The 1998 price of a cold-chain monitor (PIS code E6/16) was US\$ 2.74, for a minimum order of 500 cards. This price, which includes packaging but not shipping, is subject to change without notice. See Annex 1 for the address of the supplier.

3. The vaccine vial monitor

The vaccine vial monitor (VVM) is a round disc of heat-sensitive material placed on a vaccine vial to register cumulative heat exposure. A direct relationship exists between rate of colour change and temperature: the lower the temperature, the slower the colour change; the higher the temperature, the faster the colour change. VVMs can be used on vaccine vials or ampoules. Details on the use of VVMs are given in a question-and-answer document entitled *Vaccine vial monitor and multidose vial policy* (currently being revised).

The VVM shows the health worker if a specific vial of polio vaccine can be used. The combined effects of time and temperature cause the VVM to change colour gradually and irreversibly. A VVM on one vial cannot be used to indicate whether the vaccine in another vial lacking a VVM is suitable for use. Figure 3 shows the VVM's four colour-changes.

Polio vaccine may be packed with a cold-chain monitor in the shipment and with VVMs on the vials. The cold-chain monitor shows the effect of the environment on the whole shipment of vaccine, while the VVMs indicate its effect on the vaccine in each vial.



4. Freeze Watch™

Freeze Watch™ is an irreversible temperature indicator. It consists of a white backing card and a small vial of red liquid, both enclosed in a plastic casing, with an adhesive strip on the back. If *Freeze Watch™* is exposed to temperatures below 0°C for more than one hour the vial bursts and the red liquid is released, staining the backing card. *Freeze Watch™* is used to warn of freezing and is packed with DTP, TT and DT (freezing point -6.5°C) as well as with hepatitis B vaccine (freezing point -0.5°C).

Figure 4:
Freeze Watch™ (PIS code E6/45)



The current *Freeze Watch™* model supersedes a model (PIS code E6/14) in which the vial burst at -4.5°C. This change became necessary when hepatitis B vaccine, with its higher freezing point, was introduced into the EPI vaccination schedule.

Every refrigerator that stores vaccines should be supplied with *Freeze Watch™* unless *Stop!Watch™* is in use (see Section 5). *Freeze Watch™* can also be placed in vaccine carriers and cold boxes, where it should be used as a matter of routine in low-temperature environments.

Freeze Watch™ should be placed with freeze-sensitive vaccines by removing the protective strip from the adhesive backing and sticking the device in place. In an upright refrigerator, stick it to the side wall; in a top-opening refrigerator, stick it to the basket—not the side wall.

If the *Freeze Watch™* breaks, all the freeze-sensitive vaccines in the refrigerator should be subjected to the shake test³ to determine which should be discarded.

The 1998 price of *Freeze Watch™* (PIS code E6/45) was US\$ 2.81 for a minimum order of 400; this price, which includes packaging but not shipping, is subject to change without notice. See Annex 1 for the address of the supplier.

³ The shake test is described in a poster (See Annex 3).

5. Stop!Watch™

This device combines the *Monitor Mark™* indicator from the cold-chain monitor with *Freeze Watch™*. It is used to monitor temperatures in a refrigerator over time. The present model replaces the original version (PIS code E6/40) and its *Freeze Watch™* is set to burst at 0°C so that it can be used with hepatitis B vaccines.

Figure 5: Stop!Watch™ (PIS code E6/46)



The back of *Stop!Watch™* has a space for the indicator readings⁴ and the date to be recorded. This information should be filled in monthly by the supervisor, when he or she visits the clinic. When the space is full the *Stop!Watch™* should be replaced by a new one. The used device should be returned for analysis to the person responsible for operations management. If the *Freeze Watch™* is broken, the *Stop!Watch™* should be replaced at once.

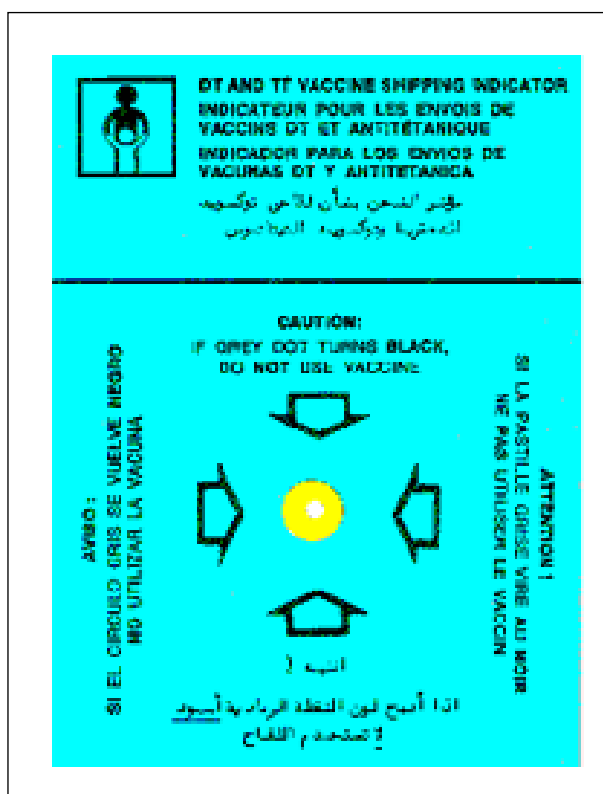
The 1998 price of *Stop!Watch™* (PIS code E6/46) was US\$ 5.72 for a minimum order of 400; this price, which includes packaging but not shipping, is subject to change without notice. See Annex 1 for the address of the supplier.

⁴ See paragraph 2.2 on interpreting the indicator readings.

6. DT and TT shipping indicator

This device consists of a blue card with a temperature-sensitive dot in the centre. It does not require activation and the dot turns from silver-grey to black instantaneously at temperatures above +48°C. The change is irreversible.

Figure 6: DT and TT shipping indicator
(PIS code E6/15)



DT and TT vaccines are very resistant to heat and are shipped from the manufacturer without insulation. They are, however, damaged by temperatures above +48°C, and the device is therefore used to monitor temperatures during shipment. One indicator is included with each shipment of 3000 doses of DT and TT.

The shipping indicator should be kept with DT and TT vaccines if they have to be stored outside the cold chain.

Note that, in cold climates, DT and TT vaccines should be protected from freezing during transport. They should therefore be packed with a cold-chain monitor and *Freeze WatchTM*, according to the procedures described above .

The 1998 price of the DT and TT shipping indicator (PIS Code E6/15) was US\$ 0.60 for a minimum order of 600; this price, which includes packaging but not shipping, is subject to change without notice. See Annex 1 for the address of the supplier.

7. Supporting materials from WHO

7.1 Documentation

How to use the cold-chain monitor : This is a training module from the Logistics and Cold Chain for Primary Health Care series. It includes detailed guidelines and practical exercises on using the monitor.

(Ordering code: WHO/EPI/LOG/84.27)

Protocol for a cold-chain survey: This document describes the steps involved in a cold-chain survey based on the use of cold-chain monitors.

(Ordering code: WHO/EPI/LHIS/94.09)

Vaccine vial monitor and multidose vial policy: This document revises and replaces the original document, which included questions and answers on the costs and advantages of the VVM and on its integration into immunization procedures.

(In preparation.)

7.2 Audiovisual materials

The following materials are useful for training purposes and can be permanently displayed on health centre walls for reference. See Annex 3 for examples.

Shake-test poster: Illustrates the simple test indicating whether DTP or TT vaccines have been frozen. *(Ordering code: CCPS/02)*

Stop!WatchTM poster: A two-colour guide to the parts and functions of Stop!WatchTM. It includes instructions on when and what to record on the monitor. *(Ordering code: CCPS/17)*

Cold-chain monitor poster: Shows the front and back of the cold-chain monitor, explains the different parts and indicates what to fill in.

(Ordering code: CCPS/16)

Vaccine vial monitor sticker: This small sticker shows the different stages of colour change registered by the vaccine vial monitor and is a handy guide on interpreting the readings. *(Ordering code: CCST/05)*

Annex 1: Supplier

Orders for each of the items described in this document should be sent to:

Berlinger & Co. AG
Postfach 67
9608 Ganterschwil
Switzerland

Telephone: +41 (71) 982-8811
Fax: +41 (71) 982-8839
E-mail: berlinger@blnet.ch

Annex 2:

Vaccine potency testing

Minimum quantities of vaccine justifying vaccine potency testing

Vaccine	Number of doses justifying a test	Number of doses needed for a test	Interval after which report expected	Conditions of transport
Poliomyelitis (oral)	20 000	20	1 month	0°C to +8°C
Measles (freeze-dried)				
Yellow fever (freeze-dried)				
BCG (freeze-dried)	20 000		3 months	
Diphtheria-tetanus-pertussis	200 000			
Tetanus toxoid	50 000			
Hepatitis B	10 000			
Poliomyelitis (inactivated)	Until potency test is established, do not retest			

Annex 3: Examples of audiovisual materials

HAS YOUR DPT, DT OR TT VACCINE BEEN FROZEN?

To check if vaccines DPT, DT or TT vaccine has been frozen? and assess their quality, visually and sense the flow of a light on the vial with a candle which is brought next to frozen vials.

Una vacuina DPT, DT o TT que haya estado congelada.

VOTRE VACCIN DT ODD DT OU ANTI-TÉTANIQUE A-T-IL ÉTÉ CONGELÉ?


Pour vérifier si vos vaccins DPT, DT ou anti-tétanique ont été congelés, regardez visuellement le contenu de la ampoule devant une bougie lumineuse. Possibilité de sentir aussi le fluide qui n'a pas été congelé.

Un vaccin DPT, DT ou anti-tétanique qui a été congelé.

¿HAN ESTADO CONGELADAS LA VACUNA DPT, DT O LA ANATOXINA TETÁNICA?




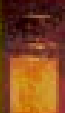








Para verificar si los vacunos DPT, DT o la anatoxina tetánica están o han sido congelados, observe visualmente el contenido de la ampolla con una vela encendida que se haya acercado a ella.


Unas vacunas DPT, DT o de anatoxina tetánica que han estado congeladas.




PERSON
PERSONE
PERSONA

VACCINES NON-FROZEN / VACCINIS QUI NON SUPT CONGELATI / VACCINI CONGELADOS Y DESCONGELADOS

<p>Bonch and slowly. Usa un trovulo. Usa y huela.</p>		 <p>NOT FROZEN/CONGELÉ</p>		<p>Comença huela en granular partícula e support. Use slowly. Empieza con la vela en la partícula granulada, puede moverse fácilmente. Comienza huela a gota sobre partícula granular.</p>
<p>Still somewhat not slowly. Noi anochi haca el trovulo. Seguir hue y huela.</p>		 <p>AFTER UNFROZEN VACCINE IS NOT AN FROZEN</p>		<p>It is sediment settling on the bottom of the vial. It does not appear as food in floor. Tiene un sedimento en el fondo del frasco.</p>
<p>Not begin to clear it at first no sediment. Comenzó a no clarificar, más como tener de clarificar. Empieza a clarificar pero no tiene sedimentos.</p>		 <p>AFTER UNFROZEN VACCINE IS NOT AN FROZEN</p>		<p>Almost completely clear it is a clear sediment. But there is just a very small amount of sediment, it does not clear. Casi completamente clara, con un sedimento claro.</p>
<p>Still clear with a little bit of white sediment which moves when the vial is tilted. Aunque está clara y si un sedimento blanco se mueve al inclinar el frasco. Mientras está clara un sedimento blanco se mueve cuando se inclina el frasco.</p>		 <p>AFTER UNFROZEN VACCINE IS FROZEN</p>		<p>Completely not clear, sediment floats inside when the vial is tilted. La mezcla está completamente opaca, el sedimento flota cuando se inclina el frasco. Completamente opaca, el sedimento flota cuando se inclina el frasco.</p>



✓
NOT FROZEN / CONGELÉ
NI FROZEN / CONGELÉ
NI FROZEN / CONGELÉ



✗
FROZEN / CONGELÉ
FROZEN / CONGELÉ
FROZEN / CONGELÉ

(1) (2) (3) (4) (5) (6) (7) (8) (9) (10) (11) (12) (13) (14) (15) (16) (17) (18) (19) (20) (21) (22) (23) (24) (25) (26) (27) (28) (29) (30) (31) (32) (33) (34) (35) (36) (37) (38) (39) (40) (41) (42) (43) (44) (45) (46) (47) (48) (49) (50) (51) (52) (53) (54) (55) (56) (57) (58) (59) (60) (61) (62) (63) (64) (65) (66) (67) (68) (69) (70) (71) (72) (73) (74) (75) (76) (77) (78) (79) (80) (81) (82) (83) (84) (85) (86) (87) (88) (89) (90) (91) (92) (93) (94) (95) (96) (97) (98) (99) (100)

The shake-test poster:
 Ordering code: CCPS/02.
 Size 42 x 30 cm.
 Available as a trilingual presentation in English, French and Spanish.



VACCINE COLD CHAIN MONITOR

Recording part.
To be filled in by
the health worker.

The index

Guide to what to
do with vaccines
exposed to heat.

Information about
the vaccine.

Front

Write the date that the vaccine arrives at the store here.

Write the incoming index here.

Write the name of the store here.

Write the date that the vaccine leaves the store here.

Write the outgoing index here.

Read the index. A, B, and C change to blue at 10° C. D changes to blue at 34° C.

The supplier writes the vaccine information here.

Instructions on how
to use the monitor.


Information on the
time and temperature
characteristics of the
monitor card.

Back

Section	TEMPERATURE		
	A	B	C
Color change	10°C	10°C	10°C
Color	Blue	Blue	Blue

Expanded Programme on Immunization

Cold-chain monitor poster:
Ordering code: CCPS/16.
Size 40x60 cm.
Available in English and French.

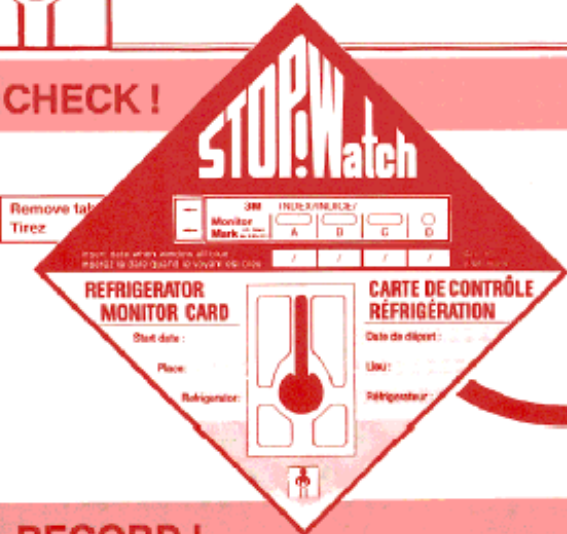


REFRIGERATOR / REFRIGERATEUR

STOP!Watch

CHECK !

CONTROLEZ !




Remove tab / Tirez

3M INDEX/INDICE / Monitor Mark / Carte de contrôle

Start date / Date de départ

Place / Lieu

Refrigerator / Réfrigérateur




RECORD !

ENREGISTREZ !

At each supervision visit :

- Fill in the date.
- Read the index on the Monitor Mark and note it down (A, B, C and/or D).
- Note whether Freeze-Watch is red or white.



Cool a refrigerator 30 minutes then remove activation tab. Laisser refroidir pendant 30 minutes puis tirer l'onglette.

A chaque visite de supervision :

- Inscrivez la date.
- Vérifiez l'état de l'indice et inscrivez le (A, B, C ou/et D).
- Indiquez l'état de la FreezeWatch (rouge ou blanc).

3M INDEX/INDICE / Monitor Mark / Carte de contrôle


Refrigerator at 12°C for 3 days / Réfrigérateur à 12°C pendant 3 jours

3M INDEX/INDICE / Monitor Mark / Carte de contrôle


Refrigerator at 12°C for 8 days / Réfrigérateur à 12°C pendant 8 jours

3M INDEX/INDICE / Monitor Mark / Carte de contrôle

Refrigerator at 12°C for 11 days / Réfrigérateur à 12°C pendant 11 jours



White above -4°C / Blanc supérieure à -4°C



Red below -4°C / Rouge inférieure à -4°C

STOP!Watch ■ STOP!Watch ■ STOP!Watch

Stop!Watch™ poster:
 Ordering code: CCPS/17.
 Size 30 x 42 cm.
 Available as a bilingual presentation in English and French.

22

Temperature monitors for vaccines and the cold chain

Vaccine Vial Monitor VVM says . . .



The square is lighter than the circle.
If the expiry date is not passed, use the vaccine



The square is lighter than the circle.
If the expiry date is not passed, use the vaccine



The square matches the circle.
Do not use the vaccine. Inform your supervisor



The square is darker than the circle.
Do not use the vaccine. Inform your supervisor

Vaccine vial monitor sticker:

Ordering code: CCST/05.

Size 10.5 x 11 cm.

Available in English, French, Russian, Spanish.