Temptime Corporation
Protecting Patients – Reducing Risk
Through Full-Life Monitoring of Temperature-Sensitive Medicines

Michael Rush, MBA
Executive Director - Global Health Policy

15 October 2015
Temptime Corporation

• Working Globally to Improve Public Health:
  – More than 600 Million HEATmarker devices used per year
  – Vaccine manufacturers worldwide apply HEATmarker at the time of manufacture to monitor the vaccine until use
  – HEATmarkers are used worldwide on vaccine and other heat-sensitive medical products

• Only company able to develop a time-temperature indicator (TTI) to meet strict requirements of the World Health Organization

• Experts in technologies that monitor temperature-sensitive medical products

• Our expertise and customer-satisfaction have made Temptime the world-leader in chemical time-temperature indicators

• Privately held company; headquartered in Morris Plains, NJ
  – Spin-off from Allied-Signal in 1987

• Temptime’s core VVM technology identified by Harvard School of Public Health as one of a handful of essential tools for solving critical global health challenges – e.g., cold-chain and vaccine distribution issues in developing world countries
Quality Systems

- Temptime's quality management system is consistent with FDA’s Quality System Regulations (QSR) 21 CFR 820 (GMP for medical devices)

- ISO 9001:2008
- ISO 13485:2003
- WHO Prequalified Device
New State of the Art Manufacturing Equipment
New State of the Art Manufacturing Equipment
# Temptime Core Technologies

## Applied to Address Unmet Market Needs

<table>
<thead>
<tr>
<th>Core Products</th>
<th>Image</th>
</tr>
</thead>
<tbody>
<tr>
<td>Freeze Indicator</td>
<td><img src="image1" alt="Freeze Indicator Image" /></td>
</tr>
<tr>
<td>Cumulative Heat Indicator</td>
<td><img src="image2" alt="Cumulative Heat Indicator Image" /></td>
</tr>
<tr>
<td>Delayed-Heat Threshold Indicator</td>
<td><img src="image3" alt="Delayed-Heat Threshold Indicator Image" /></td>
</tr>
<tr>
<td>Instant Heat Threshold Indicator</td>
<td><img src="image4" alt="Instant Heat Threshold Indicator Image" /></td>
</tr>
</tbody>
</table>

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<table>
<thead>
<tr>
<th>Product</th>
<th>Image</th>
</tr>
</thead>
<tbody>
<tr>
<td>TransTracker™ C</td>
<td><img src="image5" alt="TransTracker™ C Image" /></td>
</tr>
<tr>
<td>TransTracker™ H</td>
<td><img src="image6" alt="TransTracker™ H Image" /></td>
</tr>
<tr>
<td>TransTracker™ F</td>
<td><img src="image7" alt="TransTracker™ F Image" /></td>
</tr>
</tbody>
</table>

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The HEATmarker Vaccine Vial Monitor (VVM) is Easy To Interpret

When the Active Square is lighter than the Reference Circle, if the expiry date has not passed, USE the vaccine.

If the Active Square matches or is darker than the Reference Circle, DO NOT USE the vaccine.
## HEATmarker VVM for Use on Vaccines

<table>
<thead>
<tr>
<th>Temperature-Sensitive Product</th>
<th>Indications</th>
<th>Customers</th>
<th>Temptime Product</th>
<th>Value Delivered</th>
</tr>
</thead>
</table>
| Children’s Immunization Campaigns and routine program use for a range of vaccine-preventable diseases: | GSK, Sanofi Pasteur, Merck, Crucell, Pfizer, Novartis, Serum Institute of India, Biofarma, Japan BCG, BB-NCIPD, Bharat Biotech, Statens Serum Institute, Biological E, Bharat Serums and Vaccines, Haffkine, Bio-Manguinhos, BioCel, WalVax, Chengda, & others | VVM2, VVM7, VVM14, VVM30 (4 designated WHO categories) | • Prevents immunization with heat-damaged vaccines  
• Identifies and preserves vaccines that are still viable for use  
• Expands reach of immunization programs to remote populations  
• Increases immunization programs’ efficiency  
• Serves as effective stock-management tool |
| • BCG  
• Diphtheria  
• Tetanus  
• Pertussis  
• DTP  
• Hep B  
• HiB  
• Meningococcal A and C  
• Measles  
• Mumps, Pneumococcal  
• OPV  
• Rotavirus  
• Rubella  
• Tetanus Toxoid  
• Yellow Fever  
Other Campaigns: | | | | |
| • HPV  
• IPV  
• Rabies  
• Typhoid |
### Temptime Products Used in Over 150 Countries from the USA to the Most Challenging Environments

<table>
<thead>
<tr>
<th>Pharmaceutical Product</th>
<th>Indication</th>
<th>Customer</th>
<th>Temptime Product</th>
<th>Value Delivered</th>
</tr>
</thead>
<tbody>
<tr>
<td>Oxytocin</td>
<td>Oxytocin, Post-partum hemorrhaging</td>
<td>BIOL Gland</td>
<td></td>
<td>• Help avoid morbidity/mortality rates of new mother by preventing administration of heat damaged medicine</td>
</tr>
<tr>
<td>Diagnostic tests</td>
<td>Diagnostic tests for HIV, AIDS, Hepatitis</td>
<td>Standard Diagnostics</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Lotion for decontamination of skin exposed to chemical weapons</td>
<td>EZ-EM Canada (Bracco)</td>
<td></td>
<td></td>
<td>• Ensures test effectiveness and accurate results</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td>• Helps protect troops from health consequences of chemical warfare</td>
</tr>
</tbody>
</table>
FREEZEmarker® - Monitoring Freeze Events

- The FREEZEmarker® is a single use freeze indicator that signals whether or not there has been a freeze event during a shipment.

**Response Temperatures**

- -1°C ±1°C
- 0°C ±1°C
- -6°C ±2°C

Before Freezing

![FREEZEmarker® indicator before freezing](image1)

After Freezing

![FREEZEmarker® indicator after freezing](image2)

“Magnified view of the FREEZEmarker® indicator”
# FREEZEmarker: Full-Life Monitoring

<table>
<thead>
<tr>
<th>Pharmaceutical Product</th>
<th>Indication</th>
<th>Customer</th>
<th>Temptime Product</th>
<th>Value Delivered</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Anemia</td>
<td>Amgen</td>
<td></td>
<td>• Quality system extension to patient</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td>• Full-Life Monitoring</td>
</tr>
<tr>
<td></td>
<td>Anemia</td>
<td>Janssen</td>
<td></td>
<td>• Quality system extension to patient</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td>• Full-Life Monitoring</td>
</tr>
<tr>
<td></td>
<td>Post surgical analgesia</td>
<td>Pacira</td>
<td></td>
<td>• Protects patients from receiving ineffective analgesia</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td>• Supports launch of more effective analgesia, improving patient recovery</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td>• Full-Life Monitoring</td>
</tr>
<tr>
<td></td>
<td>Corneal Transplants</td>
<td>Numedis</td>
<td></td>
<td>• Prevents transplant with failed cornea, improving surgical outcomes</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td>• Geographical expansion (ex US) to more patients who can benefit from corneal implants</td>
</tr>
</tbody>
</table>
Peak Threshold Indicators

• Single use threshold indicators.

• Multiple unit secondary packages or shipping boxes.

• Ability to customize temperature thresholds.

**LIMITmarker F/L™**

Formulated to signal short excursions above the set response temperatures: 9°C, 17°C, 21°C, 25°C (all +/- 1°C).

**LIMITmarker I™**

Formulated to immediately signal upon excursions above the set response temperatures: 40°C ±1°C, 44°C ± 1°C, and 50°C ±2°C

Before Exposure to 40°C

After Exposure to 40°C
## TransTracker for Monitoring Shipments

<table>
<thead>
<tr>
<th>Pharmaceutical Product</th>
<th>Indication</th>
<th>Customer</th>
<th>Temptime Product</th>
<th>Value Delivered</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Medical Imaging Contrast Media</td>
<td>Lantheus</td>
<td></td>
<td>• Ensures enhanced imaging quality for more precise diagnosis</td>
</tr>
<tr>
<td></td>
<td>Childhood vaccines for VFC Program</td>
<td>Novartis Sanofi Pasteur</td>
<td></td>
<td>• Prevent vaccination with freeze damaged vaccines</td>
</tr>
<tr>
<td></td>
<td>Rheumatoid Arthritis</td>
<td>Abbott</td>
<td></td>
<td>• Protect patients from self-administering heat damaged medicines</td>
</tr>
<tr>
<td></td>
<td>Migraine headaches</td>
<td>Zogenix</td>
<td></td>
<td>• Improved drug delivery for chronic migraines</td>
</tr>
<tr>
<td></td>
<td>M.S. Psoriasis Crohn's Anemia</td>
<td>Value Drug and London Drug for:</td>
<td></td>
<td>• Protect patients from administering temperature damaged medicines</td>
</tr>
<tr>
<td></td>
<td></td>
<td>• Biogen</td>
<td></td>
<td>• Reduces risk of adverse affects, ineffective treatment</td>
</tr>
<tr>
<td></td>
<td></td>
<td>• Janssen</td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td>• Amgen</td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td>• Teva</td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>For shipments in specialty pharmacy</td>
<td></td>
</tr>
</tbody>
</table>

**Pharmaceutical Products**: Medical Imaging Contrast Media, Childhood vaccines for VFC Program, Rheumatoid Arthritis, Migraine headaches, M.S. Psoriasis Crohn's Anemia, Value Drug and London Drug for: Biogen, Janssen, Amgen, Teva

**Customers**: Lantheus, Novartis Sanofi Pasteur, Abbott, Zogenix, Value Drug and London Drug for: Biogen, Janssen, Amgen, Teva

**Temptime Products**: None listed

**Value Delivered**: Enhanced imaging quality, preventing vaccination with freeze damaged vaccines, protecting patients from self-administering heat damaged medicines, improved drug delivery, protecting patients from administering temperature damaged medicines, reducing risk of adverse affects, ineffective treatment.
Safe-T-Vue® Temperature Indicators for Blood Products, Plasma and RBCs

Expansion into Blood Monitoring Solutions with Acquisition of William Laboratories

- Safe-T-Vue® is a temperature-sensitive indicator that easily adheres directly to blood bags during refrigeration and temporary storage.
- Ideally suited for use by blood banks and transfusion services to maintain quality control in transport and storage of blood products.
- It is available for 6°C, 8°C and 10°C temperature indications.
- US FDA 510(k) cleared medical device.
- CE mark.
Global Health Partners & Market Leaders Using Temptime Technologies
Not currently available for sale. Not cleared for sale as a medical device in the U.S.
Typical Product and Information Flow

MedTracker - Vaccine Public Market Pilot

- Vaccine Manufacturer
- National Store
- Regional Store
- District Store
- Facilities

User smart phone interprets barcode and indicator. Information sent to host computer.

Host computer communicates with user.

Captive Database

Web Portal
Global Health Policies related to Temperature-Monitoring

- WHO, UNICEF & GAVI (global/regional policies)
- India, Indonesia & Pakistan (national policies)
- China (provincial policies)
- US (state-level policies)
- Gulf Cooperation Council: Saudi Arabia, UAE, Oman, Kuwait, Bahrain, Qatar (regional policy – unimplemented)
- PAHO/Americas – Brazil & Peru (MoHs considering national policies); Argentina (national policy – unimplemented)
- Other Products: e.g. – Oxytocin, Blood Products
UNICEF/WHO Policies on Criticality of VVMs

2007 UNICEF/WHO Joint Policy Statement Requiring Member States, Donor Agencies and NGOs to Include VVMs As Minimum Requirement for Purchase of Vaccine

2012 WHO Includes VVMs As Critical Characteristic for Vaccine Prequalification

<table>
<thead>
<tr>
<th>Vaccine vial monitor (VVM)</th>
<th>All vaccines</th>
</tr>
</thead>
<tbody>
<tr>
<td>Proof of feasibility and intent to apply a VVM to the proposed vaccine, as defined below. The vaccine presented for prequalification presents data confirming that it has a thermostability profile that will enable it to be matched to a current WHO-approved VVM type (VVM2, VVM7, VVM14 or VVM30) or a future VVM type approved by WHO(WHO/V&amp;B/99.187, WHO/IVB/07.048). Signed declaration, as part of the cover letter submitted along with the file for prequalification confirming that the manufacturer will apply a VVM to the vaccine, and has the technical capacity to do so if requested by the purchasing specifications.</td>
<td></td>
</tr>
</tbody>
</table>
VVM Continued Expansion in China
Beijing CDC Launches HEATmarker® VVM for 2014 Flu Vaccine Program

Beijing CDC requiring VVM on all private vaccines
VVM Continued Expansion in China
Beijing CDC Launches HEATmarker® VVM for 2014 Flu Vaccine Program

- NCDC launched a study covering 5 vaccines in three provinces
- Beijing CDC requiring VVM on all private vaccines
## Cold Chain Problems are Global

Vaccines – US San Francisco Bay Area 10 County Region (2006)

<table>
<thead>
<tr>
<th>Category</th>
<th># of Incidences</th>
<th>Loss (dollars)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Refrigeration Problems</td>
<td>16</td>
<td>$42,958</td>
</tr>
<tr>
<td>Shipping/Receiving</td>
<td>4</td>
<td>$34,772</td>
</tr>
<tr>
<td>Improper Storage</td>
<td>6</td>
<td>$187,133</td>
</tr>
<tr>
<td>Expired Vaccines</td>
<td>51</td>
<td>$127,289</td>
</tr>
<tr>
<td><strong>Total Losses</strong></td>
<td><strong>77</strong></td>
<td><strong>$392,717</strong></td>
</tr>
</tbody>
</table>

**Extrapolation to state**

$2,352,426

Source: California Department of Public Health
Vaccines for Children (VFC) program provides free vaccines to eligible children

82 million VFC vaccine doses were administered to an estimated 40 million children at a cost of $3.6 billion in 2010

Study

Vaccine storage unit temperatures were monitored in 45 providers for a 2-week period

Finding

76 percent of the 45 selected providers were exposed to inappropriate temperatures for at least 5 cumulative hours during that period

Impact

Exposure to inappropriate temperatures can reduce vaccine potency and efficacy, increasing the risk that children are not provided with maximum protection against preventable diseases.

1 https://oig.hhs.gov/oei/reports/oei-04-10-00430.pdf
Obrigado
Gracias

Thank You
Back-Up Slides
The Global Framework is Being Developed
Logistics Management Information System (LMIS)\textsuperscript{1}

- Capturing accurate routine administration, dispensing, and consumption data.
- Real-time end-to-end logistics management from the point of origin to service-delivery point.
- Demand forecasting, capacity planning and modeling based on consumption
- MedTracker used as a data capture device
The Next Challenge – Controlled Temperature Chain (CTC)

Current definition of CTC

• Allowing specific vaccines to be kept and administered at ambient temperatures, up to 40°C
  • For one, limited period of time (length of time will vary by antigen and setting) immediately preceding administration
  • For vaccines meeting a number of pre-determined conditions
  ▶ Up until this excursion, the vaccine should continue to be kept in the traditional 2°C-8°C cold chain.

■ Current focus: vaccines administered during campaigns and special strategies, in ‘single antigen’ settings.
Objective: on-label use of vaccines in a CTC

- First pilot conducted on MenAfriVac in Banikoara, Benin in November 2012.
  - Over 155,000 people vaccinated using MenAfriVac in a CTC
- VVM on each vial
- And Temptime’s LIMITmarker™ in each vaccine carrier

Before Exposure to 40°C  After Exposure to 40°C
Comparison of VVM+ and VVM at 40°C
<table>
<thead>
<tr>
<th>Device</th>
<th>Int. transport</th>
<th>Primary store</th>
<th>In-country transport</th>
<th>Intermediate store</th>
<th>In-country transport</th>
<th>Service level</th>
</tr>
</thead>
<tbody>
<tr>
<td>Electronic temperature monitor with LCD screen</td>
<td>![Image]</td>
<td>![Image]</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Vaccine cold chain monitor</td>
<td>![Image]</td>
<td>![Image]</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Vaccine vial monitor</td>
<td>![Image]</td>
<td>![Image]</td>
<td>![Image]</td>
<td>![Image]</td>
<td>![Image]</td>
<td></td>
</tr>
<tr>
<td>Freeze indicator</td>
<td>![Image]</td>
<td>![Image]</td>
<td>![Image]</td>
<td>![Image]</td>
<td>![Image]</td>
<td></td>
</tr>
<tr>
<td>Multi-channel computerized temperature recording sys.</td>
<td>![Image]</td>
<td>![Image]</td>
<td>![Image]</td>
<td>![Image]</td>
<td>![Image]</td>
<td></td>
</tr>
</tbody>
</table>

Examples and main use of WHO recommended temperature monitoring devices for storage and transportation of vaccines.
Monitor Cumulative Heat with HEATmarker VVM

- The Active Square is the color changing reactive portion
- It is light at the start and progressively and irreversibly darkens
- The color change is faster at higher temperatures
- End point is reached when the color of the Active Square area is equal to the Reference Circle
The HEATmarker Is Easy To Read

The Active Square is lighter than the Reference Circle.
If the expiry date is not passed, USE the vaccine.

The Active Square matches or is darker than the Reference Circle.
DO NOT USE the vaccine.
The Chemistry of the HEATmarker TTI

**Polymerization Reaction**

- The principle of operation is based on the solid-state polymerization of substituted diacetylenic monomers
- The combined effects of time and temperature cause a gradual, predictable, cumulative and irreversible color change from clear to dark

(Colorless)

\[ R-C≡C-C≡C-R \]
\[ R-C≡C-C≡C-R \]
\[ R-C≡C-C≡C-R \]
\[ \downarrow \]
**Polymerization**

\[ R-C≡C-C≡C-R \]
\[ R-C≡C-C≡C-R \]
\[ R-C≡C-C≡C-R \]
\[ (Black) \]
The VVM (Vaccine Vial Monitor) is the TTI used by WHO/UNICEF in the global immunization program. Temptime has more than 17 different categories of TTIs available from days at refrigerated temperature to years at room temperature.
VVM Response is Correlated with Vaccine Stability

- VVM should reach endpoint before vaccine potency drops below efficacy requirements.
- Dossier with these stability data supports VVM7.
- For WHO prequalified vaccines, WHO makes decision on VVM category and sends letter to vaccine manufacturer and Temptime.
- For other applications, vaccine manufacturer makes VVM category decision.
# HEATmarker VVM for Use on Vaccines

<table>
<thead>
<tr>
<th>Pharmaceutical Product</th>
<th>Indication</th>
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</table>
|                         | Children’s Immunization Campaigns for a range of contagious diseases:  
• BCG  
• Diphtheria  
• Tetanus  
• Pertussis  
• DTP  
• Hep B  
• HiB  
• Meningococcal A and C  
• Measles  
• Mumps, Pneumococcal  
• OPV  
• Rotavirus  
• Rubella  
• Tetanus Toxoid  
• Yellow Fever  
Other Campaigns:  
• HPV  
• IPV  
• Rabies  
• Typhoid | GSK, Sanofi Pasteur, Merck, Crucell, Pfizer, Novartis, Serum Institute of India, Biofarma, Japan BCG, BB-NCIPD, Bharat Biotech, Statens Serum Institute, Biological E, Bharat Serums and Vaccines, Haffkine, plus others | VVM2, VVM7, VVM14, VVM30 |  
• Prevents immunization with heat damaged vaccines  
• Expands reach of immunization programs to remote populations  
• Increases immunization programs efficiency |
Time temperature indicator known as vaccine vial monitor (VVM) absolutely vital to eradication effort, allowing health workers to know vaccine has not been exposed to excessive heat.
Improving vaccine effectiveness.
• Inspection of VVMs on JE vaccine in outlying district was at the endpoint
• The local health officials conducted an investigation and found that the 450,000 doses of JE vaccine were stored in a walk-in refrigerated storage facility at the Government Medical Store Depot outside of Delhi that had experienced power interruptions for an unknown amount of time, and the back-up generator failed to function properly
• VVMs avoided administration of vaccine exposed to excessive heat due to equipment failures and identified equipment problems
Enabling vaccine outreach.
Expanding vaccine coverage.
Objective: To evaluate the feasibility and effectiveness of a village-based, out-of-cold-chain strategy for improving the on-time administration (within 24 hours) of the HB vaccine birth dose in remote areas of China, especially among children born at home. Strategy possible because of use of VVM.
Conclusions of Study in China

• Village health workers using an out-of-cold-chain immunization strategy can improve the on-time administration of the hepatitis B birth dose among home-born infants.

• Simple tools such as VVMs, AD syringes, and Uniject can ensure vaccine quality and injection safety when vaccines are administered by village health workers.

• Taking vaccine out of the cold chain could potentially decrease the risk of vaccine damage due to inadvertent freezing (this study did not follow up on the children who were given potentially frozen vaccine).
Facilitating stock management.

use this first

D. Kristensen
PATH
WHO Global Learning Opportunities for Vaccine Quality (GLO/VQ)

- e-VVM Based Vaccine Management Course – coming soon

http://epela.net/epela_web/
Preventing vaccine wastage.
Yogyakarta earthquake 2006.
Example: Reduce Wastage of Vaccine
Earthquake in Yogyakarta, Indonesia

- Damaged the infrastructure, including the cold store facilities at the district and health centers
- Electricity was out for several days and generators were either not used or not functioning.
- Vaccine in 5 districts and more than 50 health centers was saved from being discarded prematurely (wasted) due to the presence of the VVM on the vials
Over the last 10 years\textsuperscript{1}, it is estimated that VVMs have:

- Saved developing country immunization programs $140 million in vaccines that are no longer discarded due to suspected heat exposure.
- Facilitated the delivery of 1.46 billion doses of vaccine through outreach.
- Averted 100,824 deaths from potential heat exposed vaccine and avert 57,725 deaths by extending vaccine delivery.

\textsuperscript{1} PATH 2013
Helping to save lives!
UNICEF/WHO Policies on Criticality of VVMs

2007 UNICEF/WHO Joint Policy Statement Urging Member States, Donor Agencies and NGOs to Include VVMs As Minimum Requirement for Purchase of Vaccine

2012 WHO Includes VVMs As Critical Characteristic for Vaccine Prequalification

### Vaccine vial monitor (VVM)

- Proof of feasibility and intent to apply a VVM to the proposed vaccine, as defined below.

The vaccine presented for prequalification presents data confirming that it has a thermostability profile that will enable it to be matched to a current WHO-approved VVM type (VVM2, VVM7, VVM14 or VVM30) or a future VVM type approved by WHO (WHO/V&B/99.187, WHO/IV/B/07.048).

Signed declaration, as part of the cover letter submitted along with the file for prequalification confirming that the manufacturer will apply a VVM to the vaccine, and has the technical capacity to do so if requested by the purchasing specifications.
Participants from MoH, SFDA, National CDC, Six Institutes of Biologic Products, WHO and PATH

The need to improve vaccine quality, enhance the vaccine cold chain and strengthen the public’s opinion of vaccine quality and safety was discussed.

It was concluded that implementation of VVMs would help to achieve these goals.

Some Institutes have started implementation of VVMs for domestic vaccines.
Feasibility of VVM implementation in China
Lanzhou Institute Study

• In the first semester of 2010, Lanzhou Insititute carried out a feasibility study on the VVM implementation in China
  • 20,000 VVM were labeled on Hib vaccines which were distributed in 13 municipal CDCs, 16 district CDCS and 14 POV in Guangdong Province
  • The feasibility of the VVM implementation from manufacturing by Temptime, through each step of the supply chain from vaccine manufacturer, to vaccine distributor, to vaccine users
FREEZEmarker® Used in US CDC Vaccines for Children Program

• In shipments of vaccine from distributor to each provider’s practice

Before Freezing  After Freezing

IMPORTANT CHANGES TO SHIPMENTS BEGINNING September 14, 2009

Centers for Disease Control & Prevention
Vaccines for Children Program

The cold temperature monitor indicator included in all vaccine shipments to providers will be changed beginning September 14, 2009. The TransTracker® C FREEZEmarker® temperature indicator will replace the ColdMark™ Freeze Indicator. The FreezeMarker indicator has been tested by McKesson and proved to be effective in consistently and accurately assessing the exposure to temperature variants during the shipping process. The heat indicator (3M MonitorMark™) will not be changing.

Please review the instructions attached to the new FreezeMarker temperature indicator to ensure you are reading the device correctly.

• If you have any questions about this change or the FreezeMarker temperature indicator, please feel free to contact McKesson 877-TEMP123 (877-836-7123) or your Project Grantee PPOC.

McKesson Specialty Care Solutions
FREEZEmarker® Used in US CDC Vaccines for Children Program

Studied for use during vaccine storage in providers’ practices

Visual Freeze Indicators On Each Box of Vaccine Are An Early Warning Tool to Identify Potential for Freeze Damage¹

Monday, October 28, 2013

Ronald Angoff, M.D., Yale University School of Medicine, Department of Pediatrics and The Child Study Center, New Haven, CT
Jillian Wood, Connecticut Chapter American Academy of Pediatrics, Hartford, CT, Maria Chernock and Diane Tipping