British Columbia Mass Immunization Clinic Cold Chain Project 2005-06

A collaboration between the BC Centre for Disease Control, BC Health Authorities, Cryopak Industries and sanofi pasteur

Final Report

November 2006

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Table of Contents

Appendix 1. Site visits 2005-06 10

Background

In recognition of British Columbia's (BC) cooperation throughout the Pentacel/Quadracel allocation plan in the fall of 2004, sanofi pasteur offered funding for a project to improve vaccine management in BC. A brainstorming session with BC Centre for Disease Control (BCCDC) and sanofi pasteur health professionals held in February 2005 identified a list of 5 possible projects. This list was circulated to the BC Public Health Nurse Leaders and Communicable Disease Nurses for their input in March 2005. The project selected in May 2005 was "the measurement of vaccine temperature in various mass clinic scenarios to recommend the equipment needed to maintain the cold chain throughout the mass clinic".

Goal

To enhance cold chain maintenance by public health staff in mass immunization clinic settings in BC

Objectives

1. To provide (enhanced) recommendations on types of insulated coolers that will maintain the cold chain during vaccine transport and handling in mass clinic settings in BC
2. To provide (formal) limited documentation data on one or more coolers for summer and winter configurations that provide scientific/legal evidence to support required temperature maintenance of vaccines throughout transport and handling in mass clinic settings
3. To provide a limited number of recommended standard insulated coolers to Health Authorities (HA) that need them for mass clinics
4. To provide educational in-services to BCCDC and HA designated staff on recommendations for the maintenance of the cold-chain throughout transport and handling in mass clinic settings based on results of the project

Methods

The project was a collaboration between sanofi pasteur, Cryopak Industries, the BCCDC and the BC HA. Funding was provided by sanofi pasteur for the limited documentation testing by Cryopak, HA nurses' time and travel, the purchase of coolers and cold chain supplies and overhead costs (Appendix 1). The project team was composed of Joan Rousseau (sanofi pasteur), Don Easterbrook (formerly of Cryopak Industries and now co-owner of Thermal & Protective Packaging Inc.), Cheryl McIntyre and Eleni Galanis (BCCDC).

- The project team reviewed data the BCCDC had collected in the past on cold chain practices and equipment used.
- The team developed a survey to assess current vaccine transport and handling practices and equipment used for school, community health centres (CHC) and

mass immunization clinics (influenza, outbreak control). The survey was self-administered via the web to one nurse per Health Unit (HU)/Branch in September 2005. Survey results were analysed by Sophie Robov and Jason Parsons of sanofi pasteur and reviewed by the project team.

- Joan Rousseau and Don Easterbrook conducted site visits to observe vaccination clinics and to interview field staff/managers about their vaccine transport and handling practices. This was done to validate/clarify the survey data and gain insight regarding cold chain challenges as well as innovative management strategies in mass immunization clinics. The visits occurred in 11 immunization clinics in four HA between December 2005 and April 2006 (Appendix 2).
- The project team reviewed the data collected from the survey, clinic observations and interviews. Preliminary results were presented to HA representatives in February 2006. Based on these discussions, the frequency of use, acceptability and cold-chain reliability, the group selected the following coolers for testing for limited documentation:
  - 16 qt Coleman cooler
  - 16 qt Igloo cooler (Appendix 3)
  - 34 qt Coleman cooler
  - 38 qt Igloo wheelie cooler (Appendix 4)
- The group determined the temperature and time conditions for testing based on the parameters reported in the survey and during the site visits (Appendix 5).
- Micom Laboratories, Quebec, tested the selected coolers under the predetermined conditions to provide limited documentation. The final report was prepared by Linda A. Walker.
  - Testing was conducted in an environmental chamber which allowed temperature modifications to simulate the predetermined conditions.
  - Eight (small coolers) or 12 (large coolers) temperature probes (thermocouples) were placed in the coolers to monitor the internal cooler temperatures and two probes were placed on the exterior of the cooler to monitor the external temperature (Appendix 6)
  - Temperatures were monitored continuously for up to 24 hrs. Temperatures from the 11 probes were plotted over time.
  - Time to first fail (time at which the first probe ≥8.1C) and time to 50% fail (time when 50% of the probes ≥8.1C) were determined. **Time to 50% fail was considered representative of the time that the temperature of the vaccine reached ≥8.1C** according to the project team.
  - Lids were opened every 10 minutes for 5-10 seconds during times when coolers were in simulated clinics.
- One 38 qt Igloo Wheelie cooler (Appendix 4), 2-36oz soft sided gel packs and 3-12ml flexible insulating blankets were provided to each Health Unit/Branch (total of 125 units).
- Joan Rousseau and Don Easterbrook provided educational in-services for HA staff in four HA between May and June 2006.

Results

Survey

- Seventy-one of 118 nurses responded to the survey (61% response rate)
    - 13 from NHA
    - 18 from IHA
    - 13 from VCH
    - 11 from VIHA
    - 16 from FHA
- Storage
    - 93% of respondents stated that all their regular vaccine fridges were temperature-monitored
    - 85% respondents never stored vaccine in off-site fridges
- Number of clinics
    - Average number of vaccine clinics: 1-10 clinics/wk for 83% of respondents
    - Maximum number of vaccine clinics: >15 clinics/wk for 17%
- Transport time
    - Average one-way transit time: <30min for 90% of respondents
    - Maximum one-way transit time: >1h for 24%
    - Average time vaccine is in the field: 1-4h for 80%
    - Maximum time vaccine is in the field: >8h for 20%
- Only 18% of HU had a single dedicated biological packer
- Configuration
    - 28% packed coolers differently in summer and winter
- Pre-conditioning
    - 99% always pre-conditioned their ice packs
    - 73% always pre-conditioned their insulating materials
    - 10% always pre-conditioned their coolers
- Re-conditioning (in the field)
    - 52% always re-conditioned their ice packs
    - 37% always re-conditioned their insulating materials
    - 7% always re-conditioned their coolers
- Cooler monitoring
    - 49% never monitored cooler temperatures during transport and handling; 34% sometimes did; 10% always did
    - Chemical indicators and digital thermometers were equally used
    - Monitors were placed in various areas of coolers, but mostly beside or near vaccines
- Handling at clinics
    - 83% always used smaller coolers at nursing stations
    - Average number of times lid was opened during a clinic: 83% opened lids 1-10 times
    - Maximum number of times lid was opened during a clinic: 46% opened >10 times
    - Average time lid was left open each time: 85% < 30 sec
    - Maximum time lid was left open each time: 7% >1min

- Types of coolers used
  - > 80 different coolers described
  - Igloo and Coleman hard-sided were most common brands
  - 16 qt size was most common size (range 6-62 qt range)
  - Generally 8 qt size used at immunization station; 16, 32 or 64 qt used for transport
  - Coolers on wheels (20% used), comments:
    - Great for mass clinics
    - Weight/size were drawbacks for lift/transport (injury)
    - Tended to pack too much vaccine
    - Good idea/liked to know more about them
  - A/C adaptor coolers (6% used), comments:
    - Would like more information/nice to have
  - Styrofoam coolers (38% used), comments:
    - Rarely used - mostly for power failures
    - Used to re-transport vaccine to BCCDC
    - Awkward to carry – no handles
    - Not purchased
  - Soft-pouched coolers (44% used), comments:
    - For short term storage at nurses station – refilled every 30 minutes
    - Easy to carry for small baby clinics
    - “Were told not to use them” due to poor insulation properties
    - Many liked them
  - Re-use of manufacturer shipping cartons (48% used), comments:
    - Not used often and only used when sending vaccines back to BCCDC, manufacturer, other branch offices or hospital (power failure)
    - Not always in good condition as reused many times
    - Difficult to maneuver in vehicles
- Comments and wishes:
  - Supply of recommended temperature monitors
  - Vaccine coolers on wheels and larger coolers
  - Resources for transporting vaccines and equipment to field clinics
  - Body mechanics/injury focus when lifting
  - Better fridges with glass doors/continuous read thermometer
  - Back-up generator
  - Supply of flexible ice blankets and gel packs
  - Plug-in A/C adaptor coolers
  - Coolers with built-in ice compartments
  - Soft-sided coolers and recommendations around use

Site visit observations

- For the most part, site visits validated the survey findings:
  - Maintaining the cold chain was of high priority to the Public Health Nurse teams observed.

    - Approximately 50% of teams monitored the temperature in their main vaccine cooler, similar to what was found in the survey.
    - Most times, coolers were opened for less than 5 sec at a time, which is less than what was found by the survey.
    - Numerous vaccine packing configurations were used (no standard).
        - Frozen ice packs were usually placed in the bottom and seldom in the top of the cooler.
- Innovative techniques were used to enhance clinic function, including to streamline workflow, to minimize the time vaccine was exposed to temperatures outside 2-8C and to support the vaccinees:
    - Sequential or simultaneous immunization ("Car Wash Approach") of an individual with multiple vaccines in a highly coordinated and relaxed technique utilizing a 2 nurse approach.
    - Use of a designated staff person to dispatch/re-pack vaccine from the main vaccine cooler to nursing stations in order to minimize cooler opening and to maintain cooler packing configuration.
    - Use of several small labeled coolers to differentiate vaccines at the nursing stations to minimize vaccine handling and clinical error.
    - Use of "Nurse vaccinator team huddles" to communicate various issues including vaccine needs from central cooler supply.

Cooler testing

Cooler testing results are found in Appendix 7 and Table 1. The graphs in Appendix 7 include 2h conditioning time followed by actual testing time. Table 1 includes only testing time.

Table 1. Time to first and 50% fail of the probes in the coolers

	16qt Igloo	16qt Coleman	38qt Igloo	34qt Coleman
	Summer cycle			
time to first fail	7.3h	1.8h	2.3h	2.0h
time to 50% fail	13.8h	3.3h	7.8h	4.6h
	Winter cycle			
time to first fail	18.3h	7.2h	6.0h	7.2h
time to 50% fail	20.2h	14.5h	19.5h	13.2h

The first probe to fail was usually the one closest to the surface. Time to 50% fail was deemed to be a more accurate measurement of the temperature of the vaccine product.

Testing revealed that the four coolers maintained the cold chain near the vaccine product (time to 50% fail) for the duration of a normal working day and more (13.2 to 20.2h) in the winter cycle. However, only the Igloo coolers maintained the cold chain for the duration of a normal working day (7.8-13.8h) during the summer cycle. In fact, the 16qt Igloo cooler outperformed all other coolers on all parameters.

Advice on cooler configuration
Cryopak Industries developed figures to help configure vaccines and packing materials in such a way that the cold chain is maintained in the winter and the summer for 16qt and 38qt coolers (Appendix 8). Some findings included:

- Different packing configurations should be used in warm/summer weather and cold/winter weather.
- The configuration should be maintained when re-packing the cooler.
- Consider re-conditioning some of the material or adding newly pre-conditioned material during a long clinic, especially in the summer.
    - In temperatures > 38C, consider re-conditioning if offsite for > 8 hrs (Igloo 16 qt) or > 4 hrs (Igloo 38Qt).
    - In temperatures < -15C, consider adding 1 room temperature gel pack for every 5C below this temperature.
- In extreme temperatures or during long clinics or transports, monitor cooler temperature to ensure the cold chain is maintained.
- Frozen gel/ice packs should be placed on top in the cooler since cold air drops. Placement of frozen gel/ice packs in the bottom of the cooler could result in freezing the product.
- Paper and cardboard should not be used as insulating material as they absorb water and change temperature.
- Packaging materials should be kept at the following temperatures prior to packing:
    - Gel/ice packs on top: frozen
    - Gel/ice packs on bottom: fridge temperature
    - Flexible insulating blankets or other insulating material: fridge temperature
    - Cooler: room temperature
- The proposed configurations are slightly heavier than what may be current practice. Safety of vaccine transporters should be kept in mind and ergonomic practices should be used.

Limitations

Laboratory testing of the selected coolers was performed only on one cooler of each type and only once per cooler. The results may not be reproducible or representative of all coolers of the same size and brand. The results do not apply to times and conditions other than those that were tested.

There were discussions about the use of other types of coolers and soft-sided coolers during the visits and in-services. This issue was beyond the scope of the project.

Conclusions

This project determined that the 16 qt and 38 qt Igloo coolers maintained the cold chain for a reasonable period of time in the laboratory under practice and temperature conditions reflective of BC. The testing also provided evidence that the use of specific packaging practices will help maintain the cold chain.

If coolers other than these are used or if these coolers are used under different conditions, temperature monitoring is recommended.

A 38 qt Igloo Wheelie and packaging materials were provided to each BC health unit. An educational session was conducted in each of the Health Authorities where it could be arranged. Results will be presented at various scientific and public health venues.

This project was a successful private-public partnership which supported public health and was mutually beneficial for all parties involved.

Findings from this project will lead to the review of certain aspects of Biologicals Management in BC.

Appendix 1. Site visits 2005-06

Number	Clinic	Name	Date	City	HA
1	CHC	Guildford Health Unit	14-Dec	Surrey	FHA
2	school	Blundell Elementary	14-Dec	Richmond	VCHA
3	school	Talmey Elementary	14-Dec	Richmond	VCHA
4	school	Point Grey Secondary	26-Jan	Vancouver	VCHA
5	school	St. Thomas Aquinas Private Catholic School	14-Feb	North Vancouver	VCHA
6	school	Maple Creek Middle School	21-Feb	Coquitlam	FHA
7	CHC	Prince George Health Unit	23-Feb	Prince George	NHA
8	school	Duchess Park Secondary	23-Feb	Prince George	NHA
9	school	Peace Secondary	24-Feb	Fort St. John	NHA
10	CHC	Parksville-Qualicum Health Unit	04-Apr	Parksville	VIHA
11	school	Nanaimo District Secondary School	05-Apr	Nanaimo	VIHA

Appendix 2. 16 qt Cooler Specifications

Cool 16 - 10847
RHA Vaccine Transporter CHC's, Baby Clinics and School Clinics Programs

16 Quart

Available Colors:

Holds 2- and 3-liter bottles upright. Recessed area on the underside of lid doubles as a tray. Contoured lid makes opening easy. Easy-clean stain & odor resistant liner.

Sale Price Unit FOB: Toronto $21.76
Sale Price Unit FOB Ontario RHA
Sites and Clinics: $24.40

Minimum Purchase 300 Kits

Features

- Holds 2-L Bottle Upright
- Handles - Carrying handle folds away for storage
- Insulation - Body

Specifications

Product Dimensions: 14.63"L x 10.38"W x 13.63"H

Capacity: 16 Qt. (15L)

System Application
RHA Clinical Programs

Church Clinics
School Clinics
Baby Clinics

Vaccine Payload
up to 160 x 0.5-5mL
40 per row / 4 high

Vaccine Weight 5mL, 160 Count 4.86 lbs

Internal Thermal Packaging Configuration
2- 22 oz Soft Sided Gel Pak
2- 12 mL 12 x 4
Flexible Insulating Blanket

Vaccine Transporter
Maximum Weight Configuration
Net Weight Vaccines – 4.86 lbs
Net Weight Shipping Materials – 8.0 lbs

Gross Weight - 12.86 lbs

Appendix 3. 38qt Cooler Specifications

Wheelie Cool 38 - 5048
RHA Vaccine Transporter
Mass Flu Clinics and Disease Outbreak Control Programs

38 Quart

Available Colors:

Roll out to the perfect outing. Convenient 38-quart size. Durable all-terrain wheels. Exclusive Ultratherm® Insulation fills the body. Tow handle plus carry handles. Recessed lid cavity holds supplies.

Sale Price Unit FOB: Toronto $37.03
Sale Price Unit FOB Ontario RHA Sites and Clinics: $42.27

Minimum Purchase: 300 Kits

Features

- Wheeled Cooler
- Handles - Ergonomic tow handle
- Insulation - Body
- X-tra Handles - (2) Molded-in handles for easy access

Specifications

Product Dimensions: 22.94"L x 13.5"W x 15.75"H

Capacity: 38 Qt. (36L)

System Application

RHA Clinical Programs

Mass Flu Clinics
Disease Outbreak Control Clinics

Vaccine Payload

up to 400 x 0.5-5mL

100 per row / 4 high

Vaccine Weight 5mL, 400 Count 12.5 lbs

Vaccine Transporter Maximum Weight Configuration

Net Weight Vaccines – 12.5 Lbs
Net Weight Shipping Materials – 15.5 lbs

Gross Weight – 28.0 lbs

Internal Thermal Packaging Configuration

2- 36 oz Soft Sided Gel Pak
3- 12 mL 12 x 4
Flexible Insulating Blanket

Appendix 4. Time and Temperature Conditions used for Cooler Testing

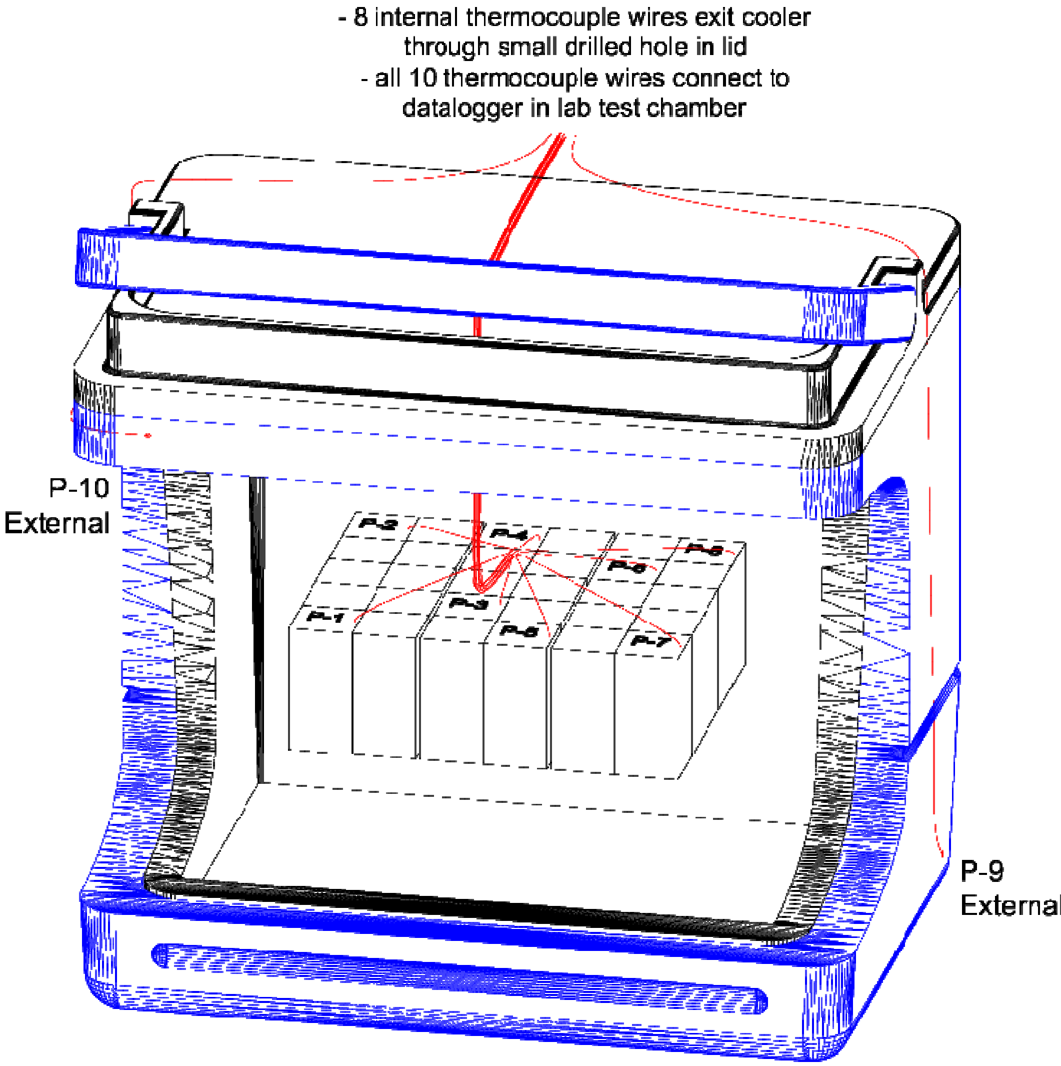
Temp/Time Segments	Summer Scenario		Winter Scenario	
Health Unit (HU) packing	0.5 hr	22 C	0.5 hr	22 C
Transport from HU to vehicle	0.25 hr	35 C	0.25 hr	(-15 C)
Travel to site	3 hr 3 hr	38 C 28 C	6 hr	22 C
Transport from vehicle to HU	0.25 hr	38 C	0.25 hr	(-15 C)
Site duration	6.0 hr	22 C	6.0 hr	22 C
Transport from site to vehicle	0.25 hr	38 C	0.25 hr	(-15 C)
Travel back to HU	6 hr	25 C	6.0 hr	22 C
Transport from vehicle to HU	0.25 hr	38 C	0.25 hr	(-15 C)
Unpack biologicals to HU fridge	0.25 hr	22 C	0.25 hr	22 C
Total time	19.75 hr		19.75 hr	

Notes:
1. Average time to package biologicals is 5-10 minutes.
2. Site Duration – cooler lids opened and closed approximately every 10 minutes x 5-10 seconds.
3. Additional cooler configuration adaptations will be provided (outside of the testing) to accommodate temperature extremes outside of these parameters. (-15 C/winter & +38 C/summer).

Revised Feb 27-06
J.Rousseau /D. Easterbrook

Appendix 5. Temperature Probe Placement

16 Quart Insulated Hard Sided Cooler
30 Vials (3 Bundles of 10) 5 mL Liquid Fill
Cutaway View Showing Thermocouple
Probe Placement
*Componentry not shown for visualization ease

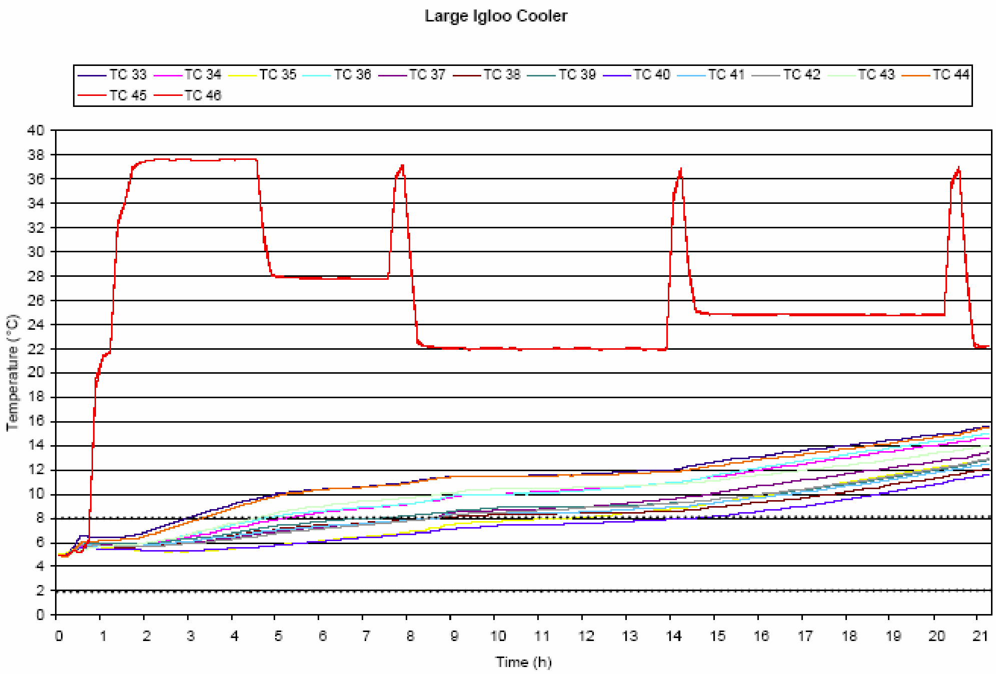


Probe #	1	2	3	4	5	6	7	8	9	10
Vial Position #	1	5	12	15	16	24	26	30	External Bottom Rear	External Top Front
ThermoCouple #	2	3	4	5	6	7	8	9	10	11

Appendix 6. Cooler testing results

Test # MI-6-1788
2006-04-24

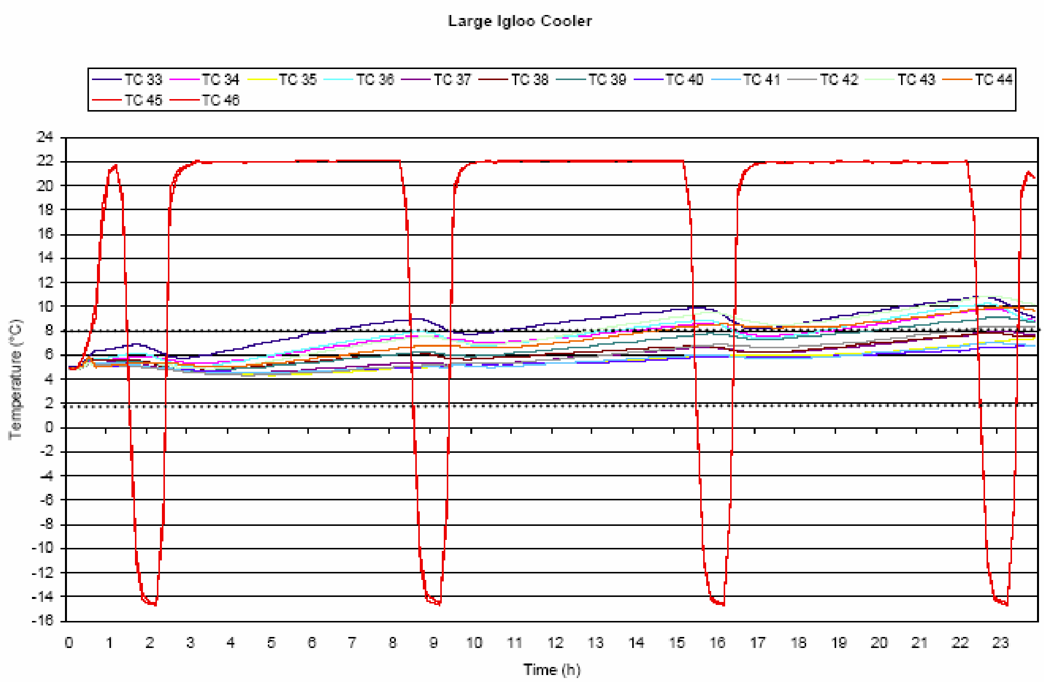
Summer Cycle



Micom Laboratories Inc.

Test # MI-6-1788
2006-04-27

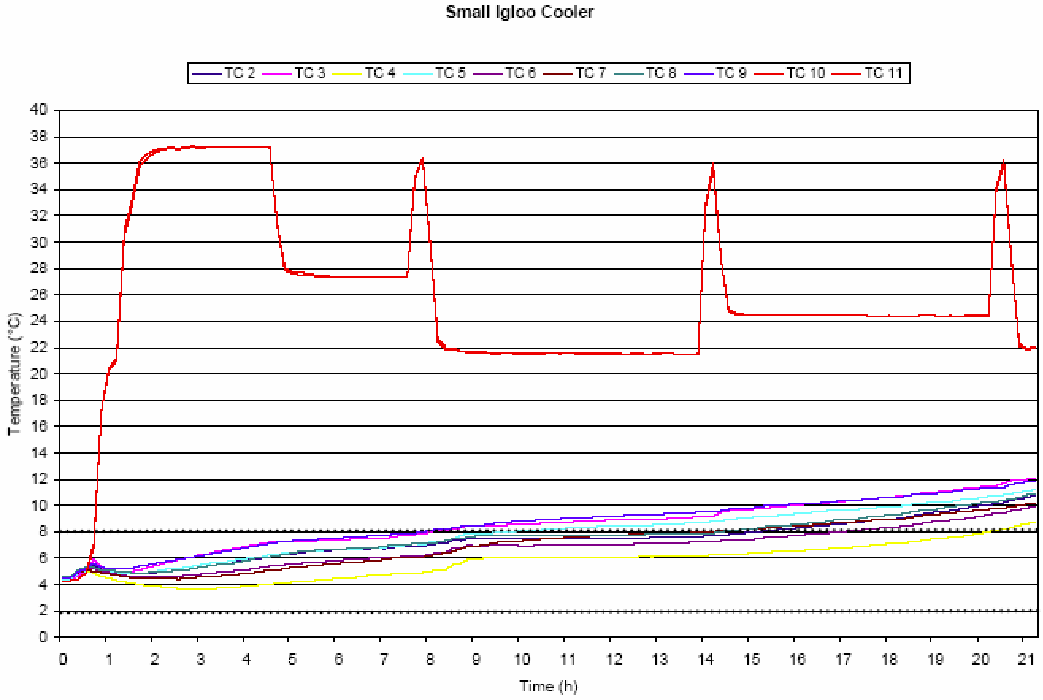
Winter Cycle



Micom Laboratories Inc.

Test # MI-6-1788
2006-04-24

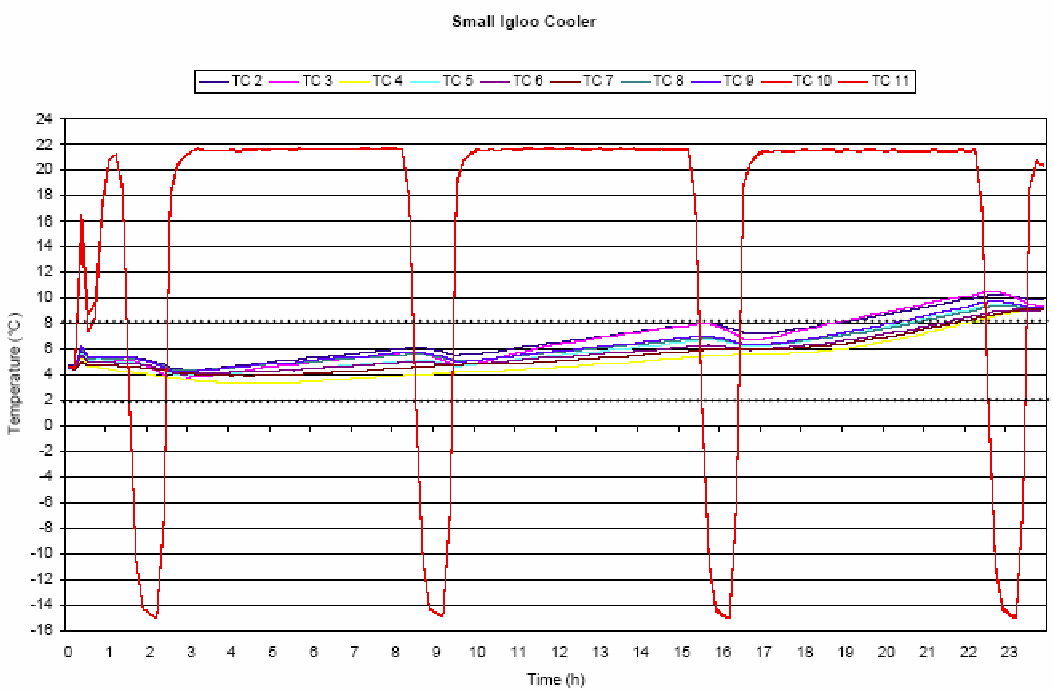
Summer Cycle



Micom Laboratories Inc.

Test # MI-6-1788
2006-04-27

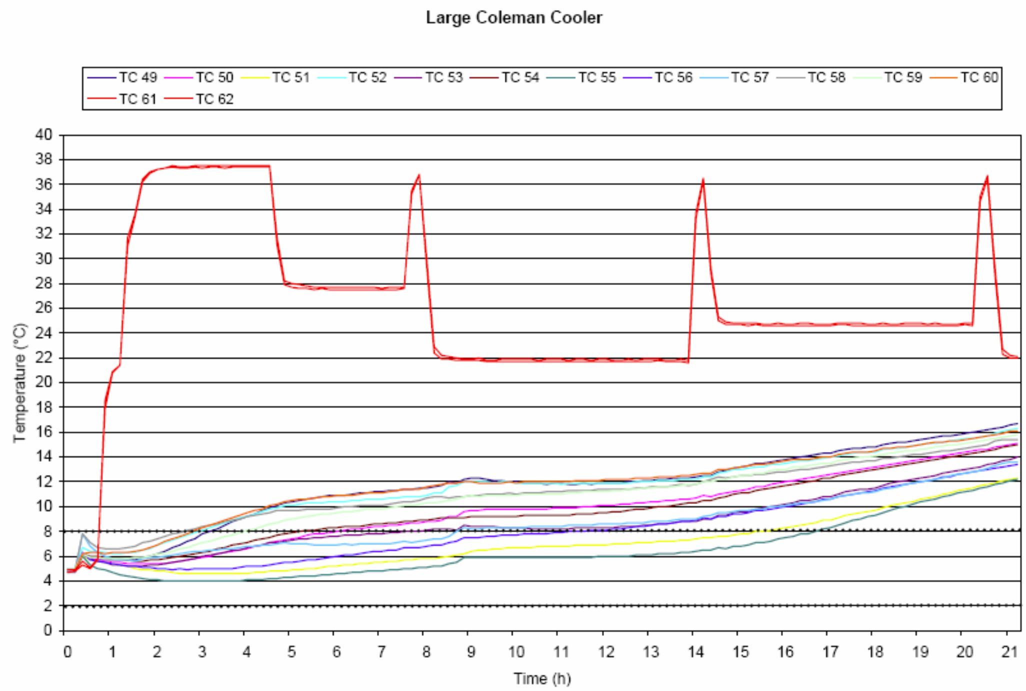
Winter Cycle



Micom Laboratories Inc.

Test # MI-6-1788
2006-04-24

Summer Cycle



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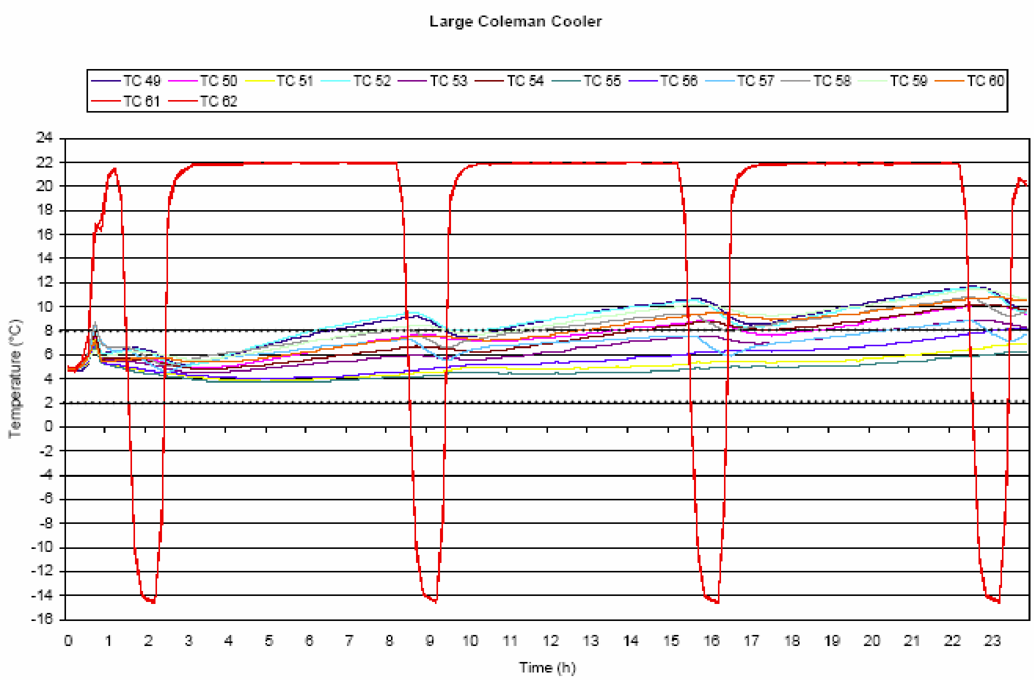
2006-04-27

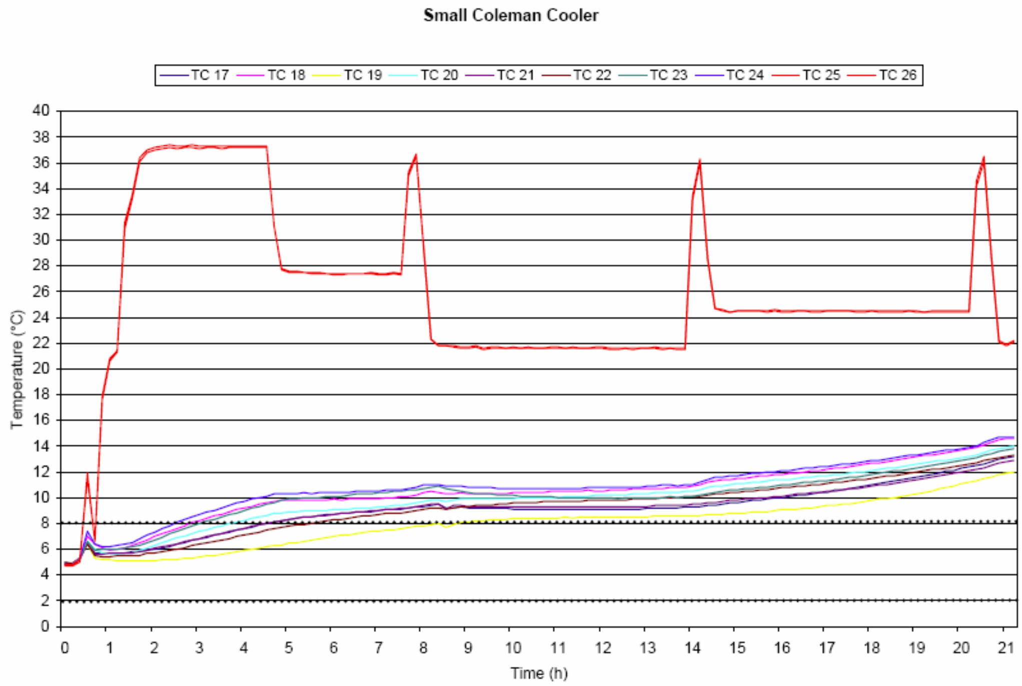
Winter Cycle



Micom Laboratories Inc.

Test # MI-6-1788
2006-04-24

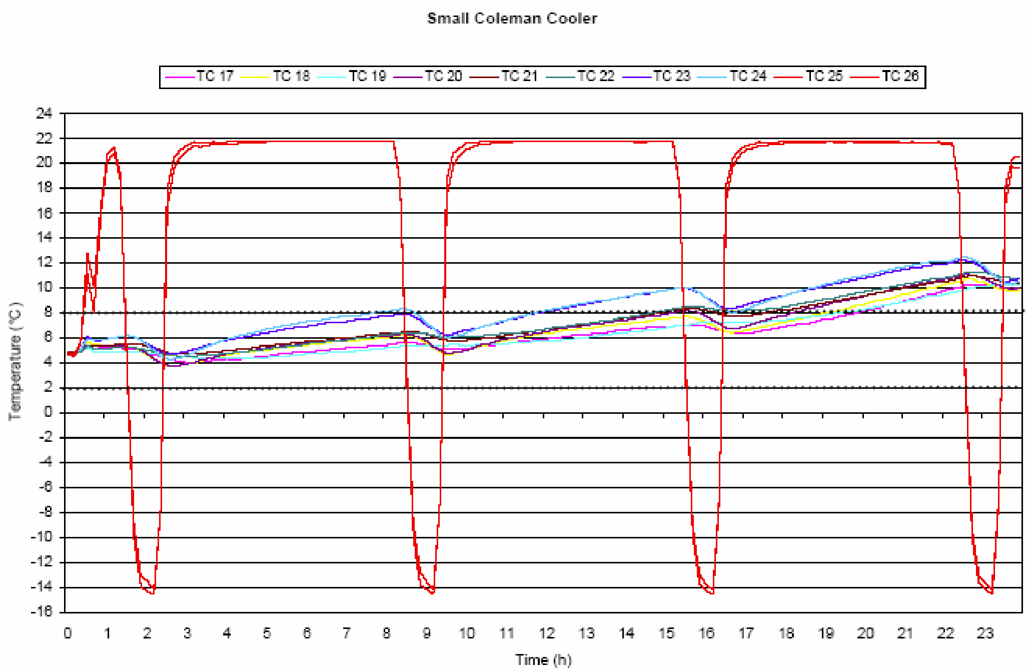
Summer Cycle



Micom Laboratories Inc.

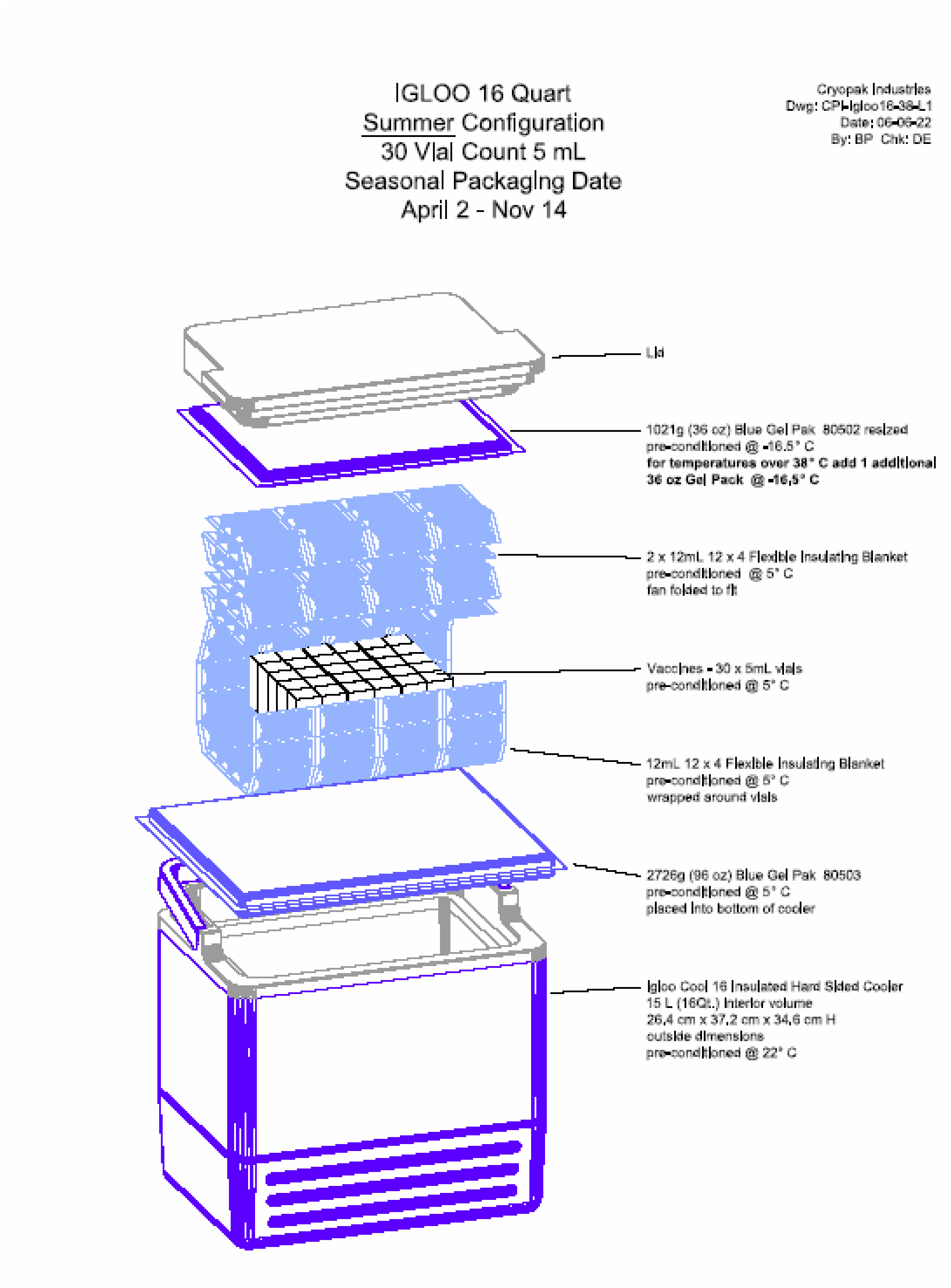
Test # MI-6-1788
2006-04-27

Winter Cycle

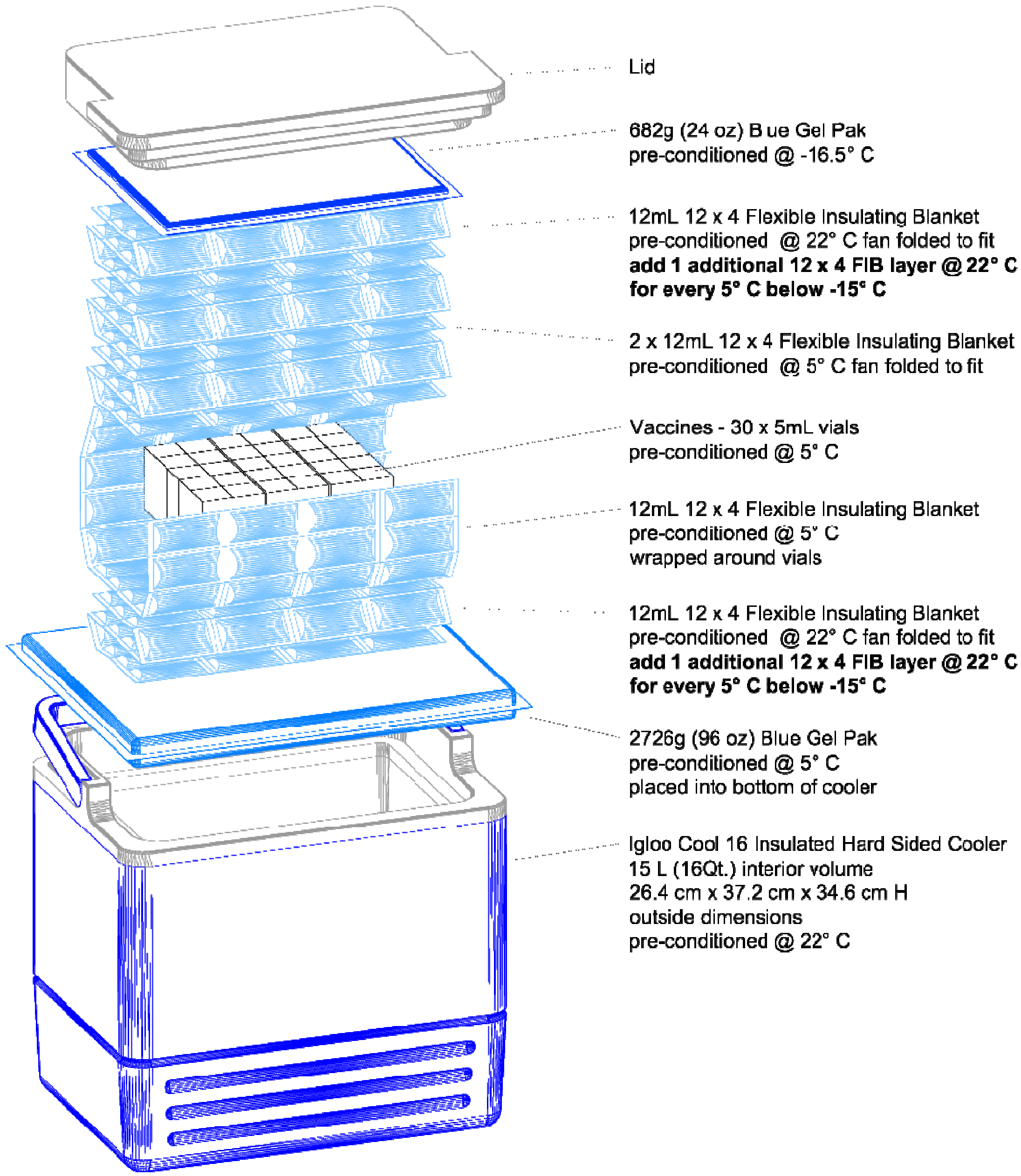


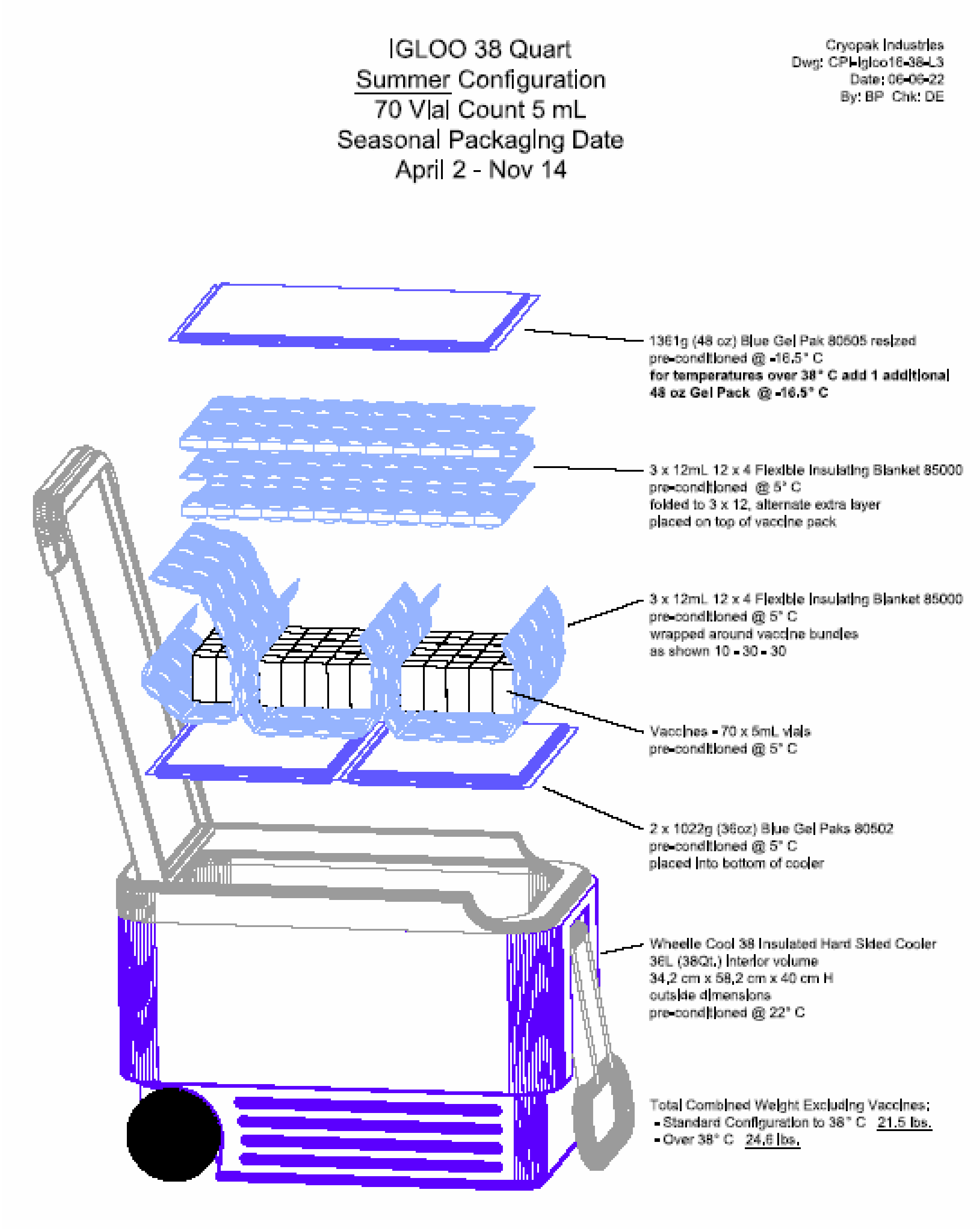
Micom Laboratories Inc.

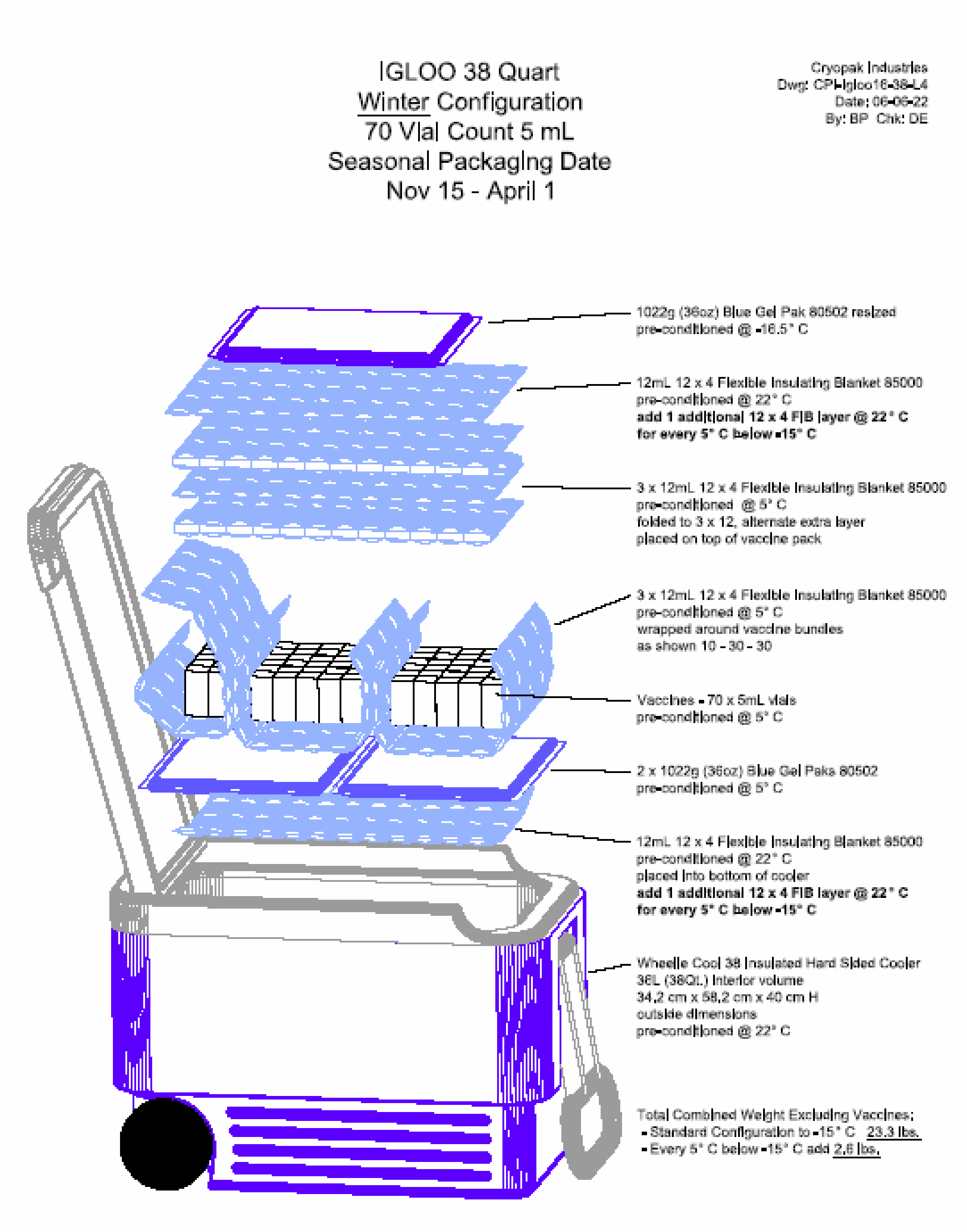
Appendix 7. Cooler Packing Configurations



16 Quart Cooler - Winter Configuration
30 Vial Count 5 mL Liquid Fill
Seasonal Packaging Date Nov 15 - April 1




IGLOO 38 Quart
Summer Configuration
70 Vial Count 5 mL
Seasonal Packaging Date
April 2 - Nov 14
Cryopak Industries
Dwg: CPI-Igloo16-38-L3
Date: 06-06-22
By: BP Chk: DE
1361g (48 oz) Blue Gel Pak 80505 resized
pre-conditioned @ -16.5° C
for temperatures over 38° C add 1 additional
48 oz Gel Pack @ -16.5° C
3 x 12mL 12 x 4 Flexible Insulating Blanket 85000
pre-conditioned @ 5° C
folded to 3 x 12, alternate extra layer
placed on top of vaccine pack
3 x 12mL 12 x 4 Flexible Insulating Blanket 85000
pre-conditioned @ 5° C
wrapped around vaccine bundles
as shown 10 - 30 - 30
Vaccines - 70 x 5mL vials
pre-conditioned @ 5° C
2 x 1022g (36oz) Blue Gel Paks 80502
pre-conditioned @ 5° C
placed into bottom of cooler
Wheelie Cool 38 Insulated Hard Sided Cooler
36L (38Qt.) Interior volume
34,2 cm x 58,2 cm x 40 cm H
outside dimensions
pre-conditioned @ 22° C
Total Combined Weight Excluding Vaccines;
- Standard Configuration to 38° C 21.5 lbs.
- Over 38° C 24.6 lbs.


IGLOO 38 Quart
Winter Configuration
70 Vial Count 5 mL
Seasonal Packaging Date
Nov 15 - April 1
Cryopak Industries
Dwg: CPI-Igloo16-38-L4
Date: 06-06-22
By: BP Chk: DE
1022g (36oz) Blue Gel Pak 80502 resized
pre-conditioned @ -16.5° C
12mL 12 x 4 Flexible Insulating Blanket 85000
pre-conditioned @ 22° C
add 1 additional 12 x 4 FIB layer @ 22° C
for every 5° C below -15° C
3 x 12mL 12 x 4 Flexible Insulating Blanket 85000
pre-conditioned @ 5° C
folded to 3 x 12, alternate extra layer
placed on top of vaccine pack
3 x 12mL 12 x 4 Flexible Insulating Blanket 85000
pre-conditioned @ 5° C
wrapped around vaccine bundles
as shown 10 - 30 - 30
Vaccines - 70 x 5mL vials
pre-conditioned @ 5° C
2 x 1022g (36oz) Blue Gel Paks 80502
pre-conditioned @ 5° C
12mL 12 x 4 Flexible Insulating Blanket 85000
pre-conditioned @ 22° C
placed into bottom of cooler
add 1 additional 12 x 4 FIB layer @ 22° C
for every 5° C below -15° C
Wheelie Cool 38 Insulated Hard Sided Cooler
36L (38Qt.) Interior volume
34.2 cm x 58.2 cm x 40 cm H
outside dimensions
pre-conditioned @ 22° C
Total Combined Weight Excluding Vaccines:
- Standard Configuration to -15° C 23.3 lbs.
- Every 5° C below -15° C add 2.6 lbs.