

Cold Chain Transport of the COVID-19 Vaccines

REPLACING DRY ICE

THERMAL CUSTOM PACKAGING LLC ULTRA-
COLD PC-21, -21 CENTIGRADE PHASE
CHANGE MATERIAL OR PCM.



New Messenger RNA Vaccines

- Different vaccines have different temperature requirements for storage and transport
- The messenger RNA (mRNA) vaccines wrap lipids nanoparticle around a piece of genetic material to improve the lifespan of the vaccine. The lipids give mRNA protection during production and storage. Lipids shield mRNA from enzymes in the blood. These lipids degrade at room temperature and need to be frozen at various temperatures depending on the vaccine. The lipid nanoparticle designed to degrade slowly so it won't do harm.
- Pfizer vaccine requires -70 Centigrade
- Moderna vaccine requires -20 Centigrade

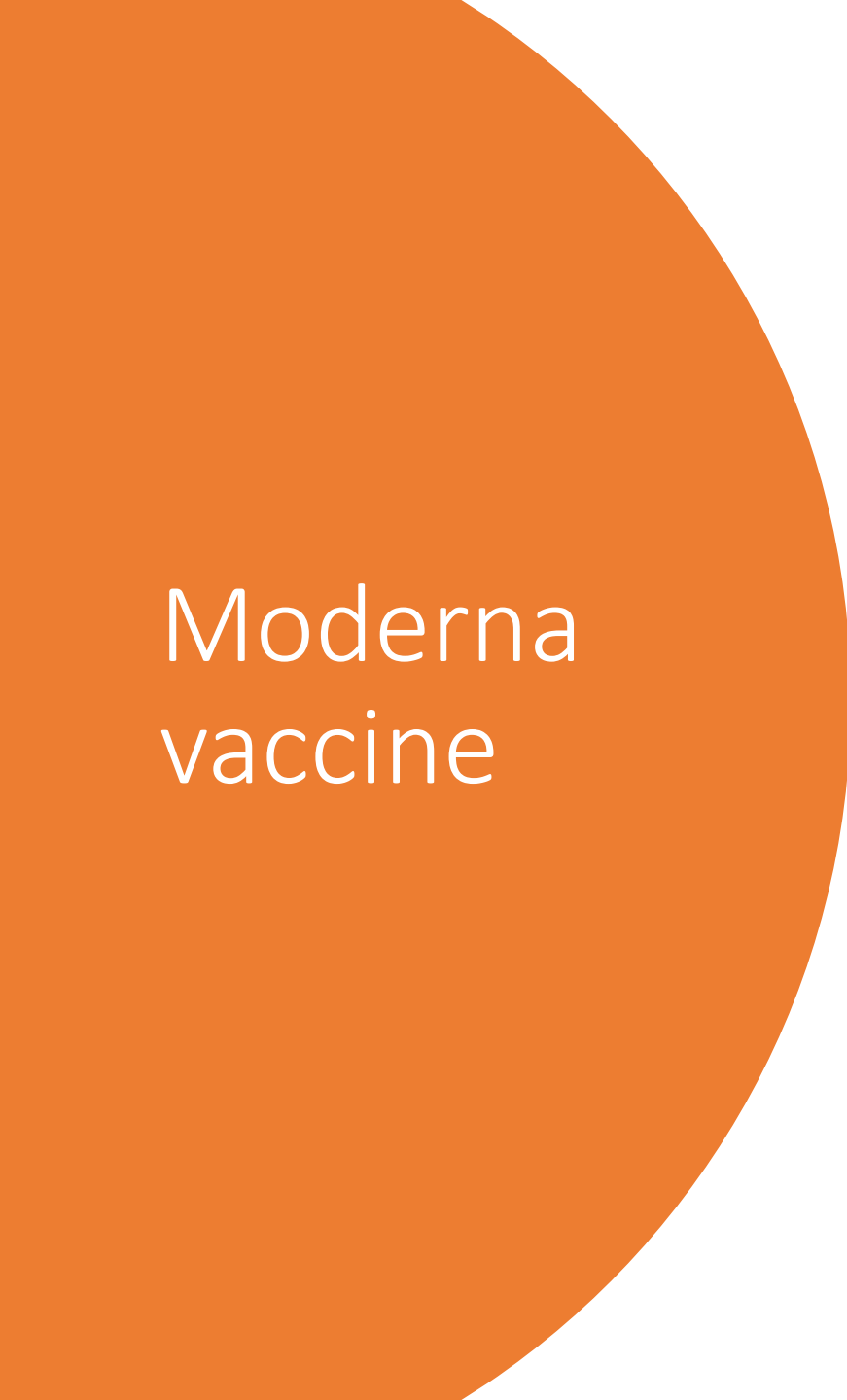


How Messenger Vaccines work


- mRNA stands for messenger ribonucleic acid, a molecule in cells which carry codes from DNA to make proteins
- mRNA vaccine encodes proteins of a virus and when inserted in a cell trigger an immune response to create antibodies. mRNA vaccine provide the instructions for the cells in the body to start producing the “spike” protein of the corona virus. The spike protein is on the surface of the corona virus and allows it to infiltrate and hijack cells.
- On its own the spike protein isn’t harmful. But it will trigger the immune system to begin defensive response.
- With 90-95% efficacy if we vaccinate 60-70% of the population we can stop transmission of the virus.

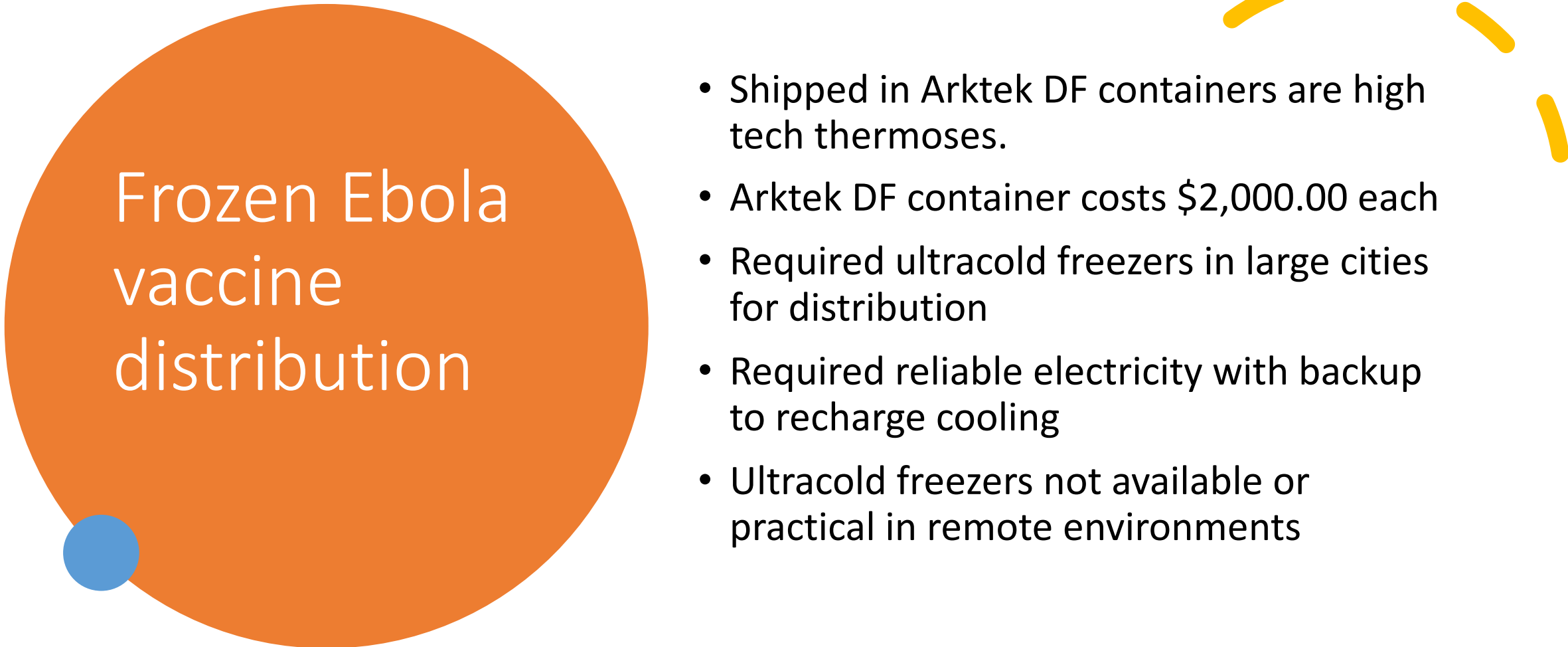
Pfizer vaccine

- Storage and transport -70 centigrade
- 200-1000 vials in insulated boxes filled with dry ice. Each vial 5 doses
- Requires \$15,000 ultracold freezers or replenishment with dry ice. Once refrigerated vaccine is good for 5 days
- Dry Ice toxic substance, requires proper ventilation or can cause headaches, confusion, disorientation and death
- Dry ice sublimates quickly and can rupture containment container
- Dry ice can burn tissues without protective gear
- Dry ice must constantly be procured and may be not available plus it cannot be stored without sublimating to CO₂




Moderna vaccine

- Stable 6 months at -20 centigrade or in a standard household freezer
 - Stable 30 days in a refrigerator
 - Easier to distribute and store particularly in rural areas of developed countries and developing countries that lack ultracold storage.
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Frozen Ebola vaccine distribution

- Shipped in Arktek DF containers are high tech thermoses.
- Arktek DF container costs \$2,000.00 each
- Required ultracold freezers in large cities for distribution
- Required reliable electricity with backup to recharge cooling
- Ultracold freezers not available or practical in remote environments

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- Bulk storage and transport to regional hubs from manufacturer
 - Distribution from hubs to hospitals, pharmacies, medical clinics, etc. in Urban locations
 - Each of which may have different storage capabilities
 - Distribution to Rural / Remote/ Underdeveloped countries have even more Cold Chain Storage issues



Challenges of Cold Chain Vaccine -

Endpoint Distribution Issues.

Challenges of Cold Chain Transport

- Moderna COVID-19 mRNA vaccine advantage over Pfizer mRNA COVID-19 vaccine. The logistics of -70 centigrade Cold Chain Transport in developed countries is a challenge and more so in third world countries.
- Nearly 3 billion of the worlds 7.8 billion people live where temperature-controlled storage is insufficient for an immunization campaign to bring COVID-19 under control
- Most vaccines must be stored with 1 degree Fahrenheit of ideal temperature.
- Study 2019 estimated 25% of vaccines are degraded by time arrive at their destination. Noticed discarded, not noticed decreased protection or no protection. Cost estimated 34.1 billion annually, not include cost of illnesses.

Thermal Custom Packaging Cold Chain Solutions

- Light weight, durable **Totes** that are easily sanitized in three sizes
- Non-Toxic, Reusable, Durable Phase Change Materials (PCMs) that can be stored for multiple years.
- TCP's PCMs allow for a complete system to transport Refrigerated (0-10 C) Frozen (-7, -16 C) and for the **Moderna COVID-19 vaccine ULTRA-COLD -21 C**





LIBERO Summary Report

Additional Information

Download the LIBERO software free of charge from www.elpro.com/downloads

- Use liberoCONFIG to configure LIBERO with your own settings
- Use elproVIEWER to access all recorded data and create own reports

Device Configuration

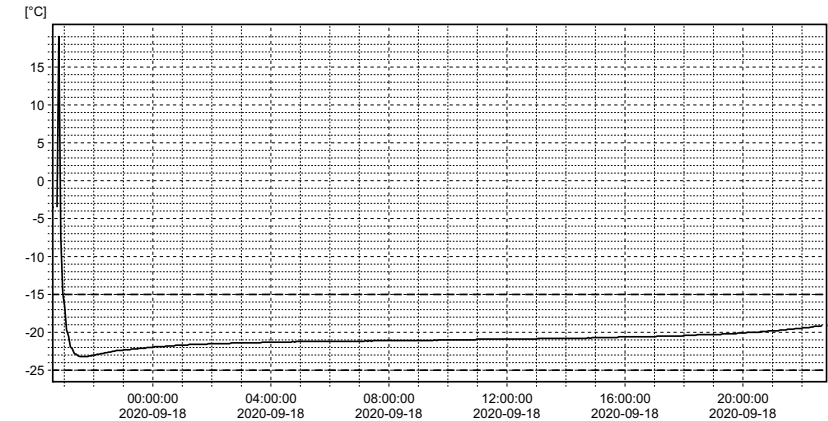
Type:	Libero Ti1-L V1.36	Inspection Range:	Last Transit to Arrived
Logger ID:	15033606	Current State:	Logging Arrived
Log Interval / Duration:	2 m / 22.2 d	Remaining Battery:	396 d
Log Mode:	Loop	Logger Start:	2020-09-10 20:41:13
Report Time Base:	GMT -05:00	Checksum:	P001 / 2.445.677.023
Configured by:	C1361, WPHA2143/tuplingb, 2020-09-10 20:13:30		

Alarm Conditions

Alarm Conditions	Total Time	Status
Upper Threshold: -15.0 °C	Time above Threshold: 16 m	ALARM
Lower Threshold: -25.0 °C	Time below Threshold: 0 s	OK
Alarm Delay: 2 m		

Logging Results

Highest Temperature:	19.1 °C; 2020-09-17 20:43:13	Transit Start at:	2020-09-17 20:42:13
Lowest Temperature:	-23.2 °C; 2020-09-17 21:31:13	Arrived at:	2020-09-18 22:42:26
Average Temperature:	-20.9 °C	Alarm at:	2020-09-17 20:45:13
MKT	-18.6 °C	File created:	2020-09-18 22:43:03



PC-21 ULTRA-COLD TRANSPORT

- Sloan Kettering Hospital in New York City has tested and uses our PC-21 to transport Biological Pharmaceuticals. Their testing shows **-20.9 average** temperature in our large TOTE for **30 hours**.

PC-21 can properly transport Moderna's new mRNA COVID vaccine

TCP's Refrigerated PCO

- 0 Centigrade Refrigerated PCM
- Many Biological pharmaceuticals which include cancer treatment drugs or any pharmaceutical extracted from or semi synthesized from biological sources require refrigerated Cold Chain Transport
- Many specimens (blood, organs, tissue) require refrigerated transport
- Many test samples require Refrigerated Transport including COVID nasal swabs. However the new COVID-19 throat swabs can travel ambient and are stable for 7 days.



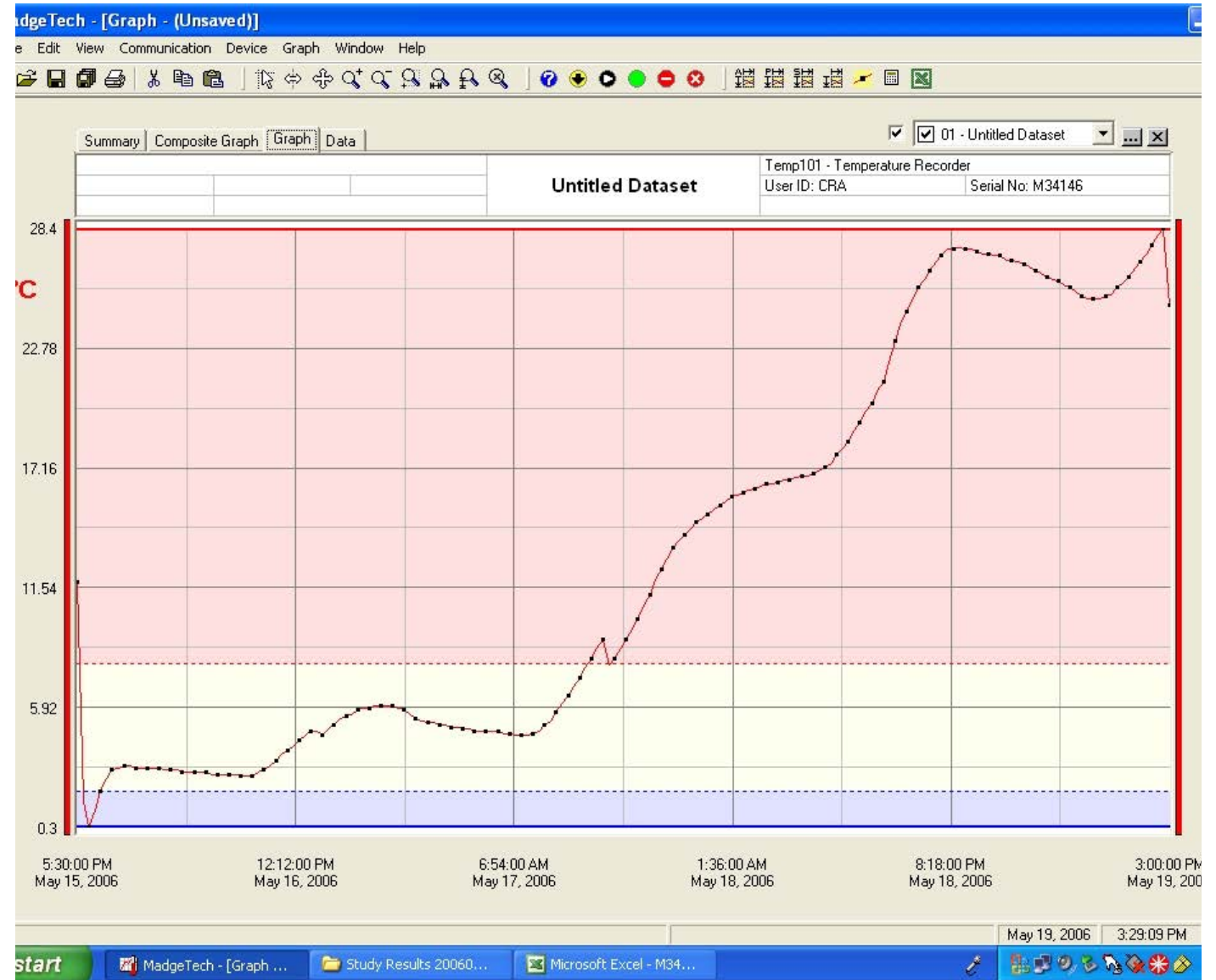
TCP Frozen PCMs

- PC-7, -7 C and PC-16, -16 C maintain frozen specimens along with PC-21
- PC-21 is also used to transport allografts (bone, tendon, etc. transplants)



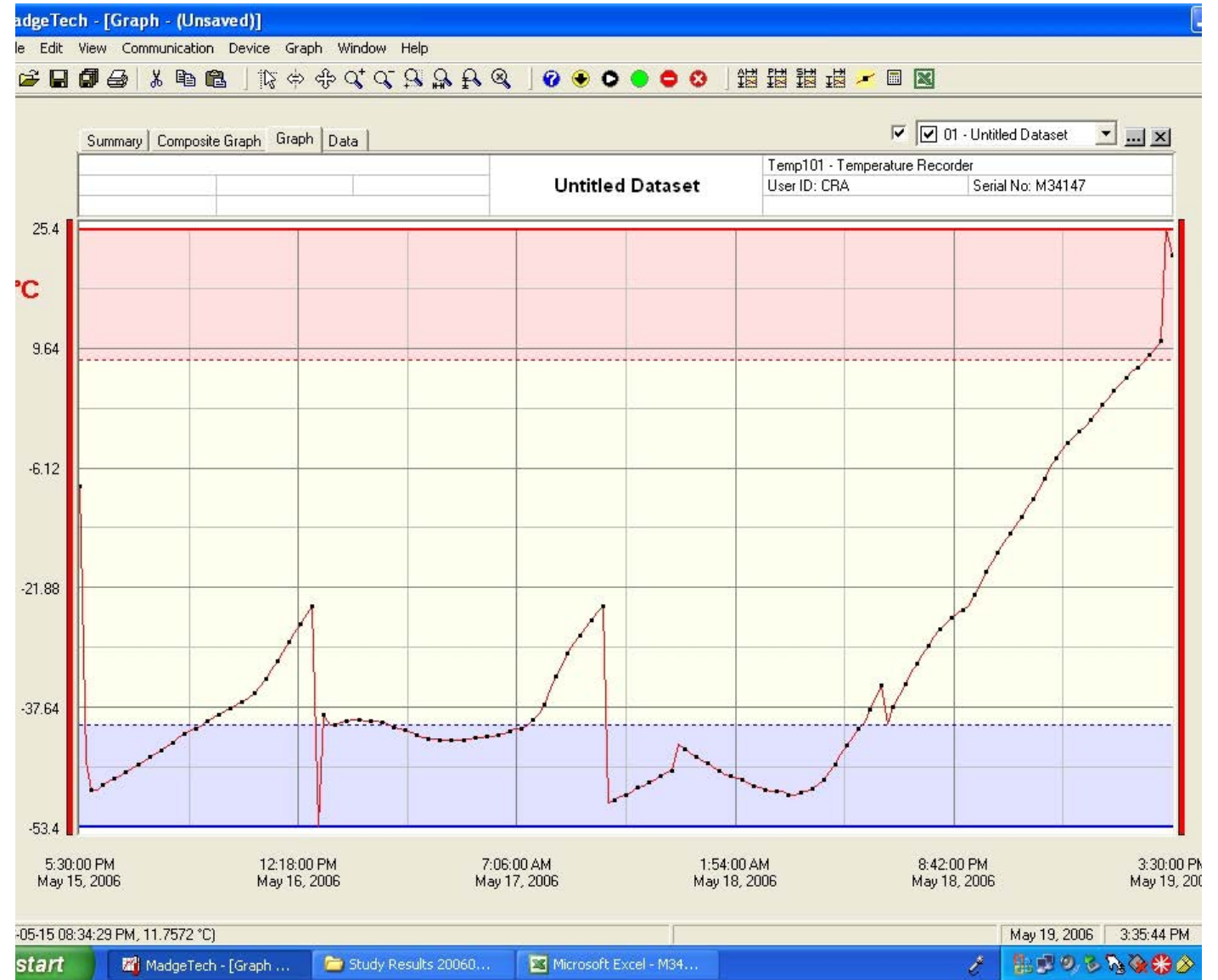
US Air Force Study

- Linda Canas, Chief virologist of the US Air Force tested gel packs, dry ice and our PCMs for long term transport of viruses.
- Testing was done from Guam to Texas
- Data from other company's gel packs less than 50% efficiency and unstable



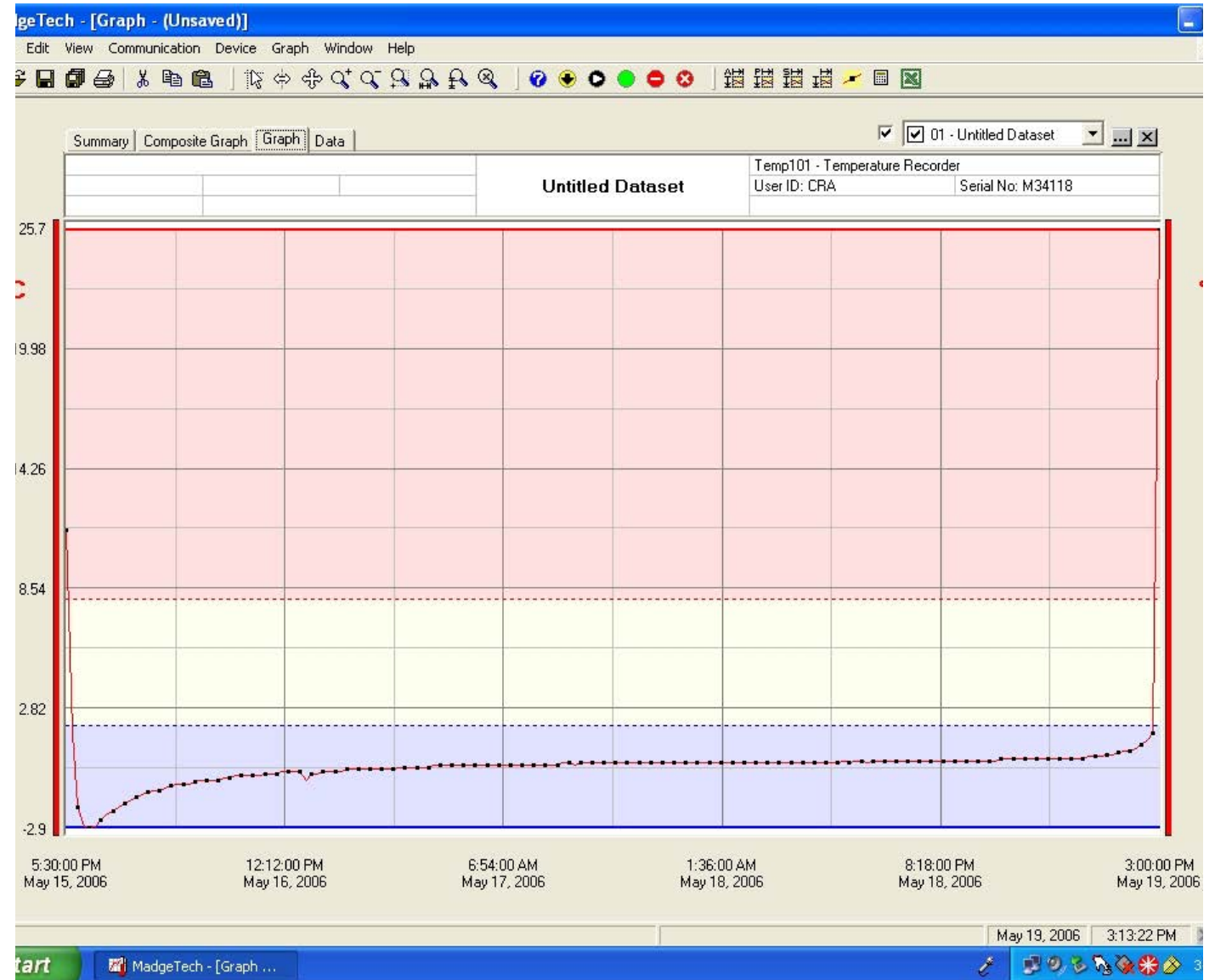
Dry Ice

- Texas to Guam Failure



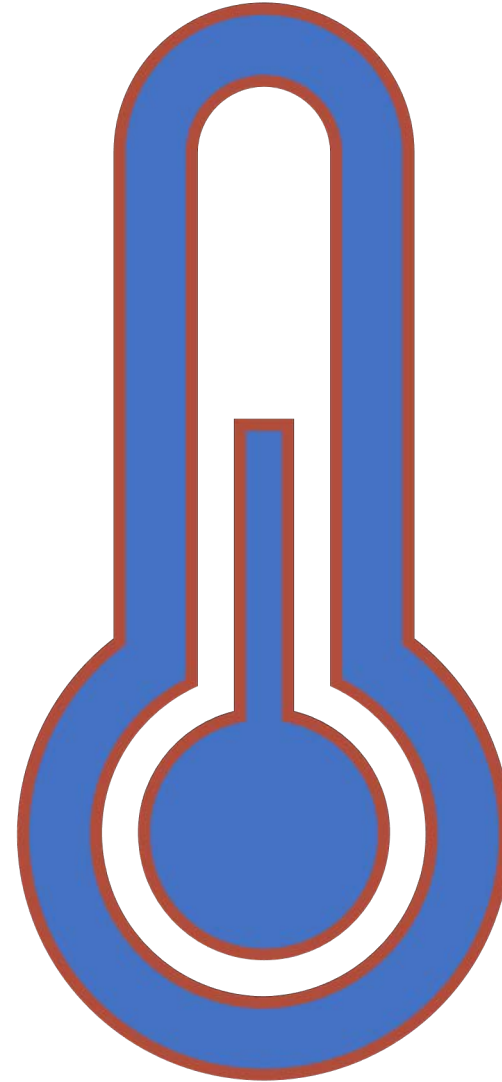
TCP's PCMS

- 96+ hours in our disposable Wizard
- TCP also can build a disposable wizard for any temperature as well as modify the payload size
- Center of Disease Control or CDC used our Totes and PCMs to maintain pharmaceuticals and vaccine refrigerated or frozen in Africa



About TCP's PCMs

- Our PCMs provides specific temperatures for a variety of applications. The “phase” temperatures are the temperatures at which each product undergoes the phase change, or melting, from solid to liquid. These temperatures are 0°C (32°F), -7°C (19.4°F), -16°C (3.2°F), and -21°C (-5.8°F). The latent heat of each product allows all heat absorbed to be used in the melting process, or phase change, without any temperature change, providing a stable passive cooling system.



TCP's Totes

- Small Medium and Large
- All light weight, durable, easy to sanitize
- All can have carrying strap
- TCP makes different size hard shell PCM's to fit different size Totes
- Complete solution for Cold Chain Transport
- Totes work well with our robotic test tube racks
- Small and Medium Tote one 3# PCM on top of payload
- Large Tote has one 4# PCM below and one 4# PCM above the payload

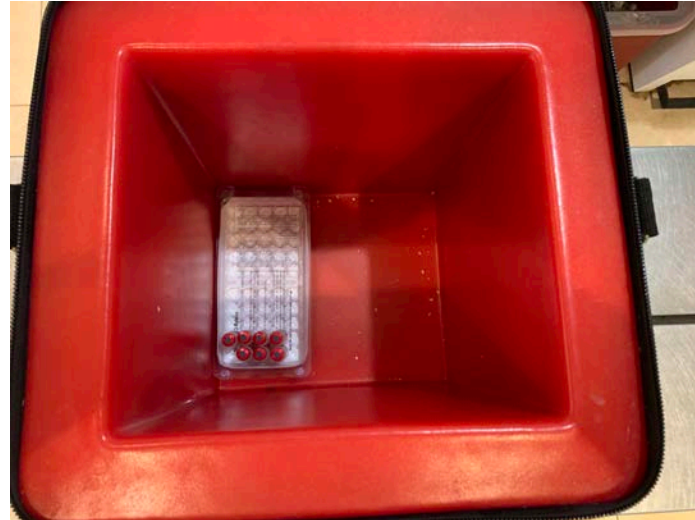


Vaccine Transport in TCP Various Totes

- Small Tote is a 4.3-pound Tote (1.95 KG) which should carry 7 boxes of 50 vaccines per box or 350 doses with one 3# PCM (1.36 KG). One box per layer. Estimated total weight with payload and PCM 10 pounds or 4.55 KG
- Medium Tote is a 5.3-pound (2.4 KG) which should carry 20 boxes of 50 vaccines per box or 1000 doses with one 3# PCM (1.36 KG). Two boxes per layer. Estimated total weight with payload and PCM 12 pounds or 5.45 KG.
- Large Tote is an 8-pound (3.63 KG) which should carry 42 boxes of 50 vaccines per box or 2100 doses with two 4# PCMs (1.82 KG). Seven boxes per layer with divider out. Estimated total weight with payload and two PCMs 25 pounds or 9.54 KG



Small Medium & Large Tote Totes with Vaccines



A large, irregular green splash graphic with a textured, watercolor-like appearance, featuring various shades of green and some darker spots, located on the left side of the slide.

Additional Points

- Our products are NOT Medical devices and do not require government certification such as FDA
- The United States Military places our frozen PCMs (PC-16 or PC-21) in their freezers with important frozen viruses. If power is lost, the first backup is generators to run the freezers. The final safety is when the generators run out of fuel or do not work properly our PCMs maintain the freezers for several days depending on; the amount of PC-21, the environmental temperature and if the freezer is being opened. OUR PCM just sits in the freezer alongside the payload of vaccines in this cases.

A large orange circle is positioned on the left side of the slide, containing the title text.

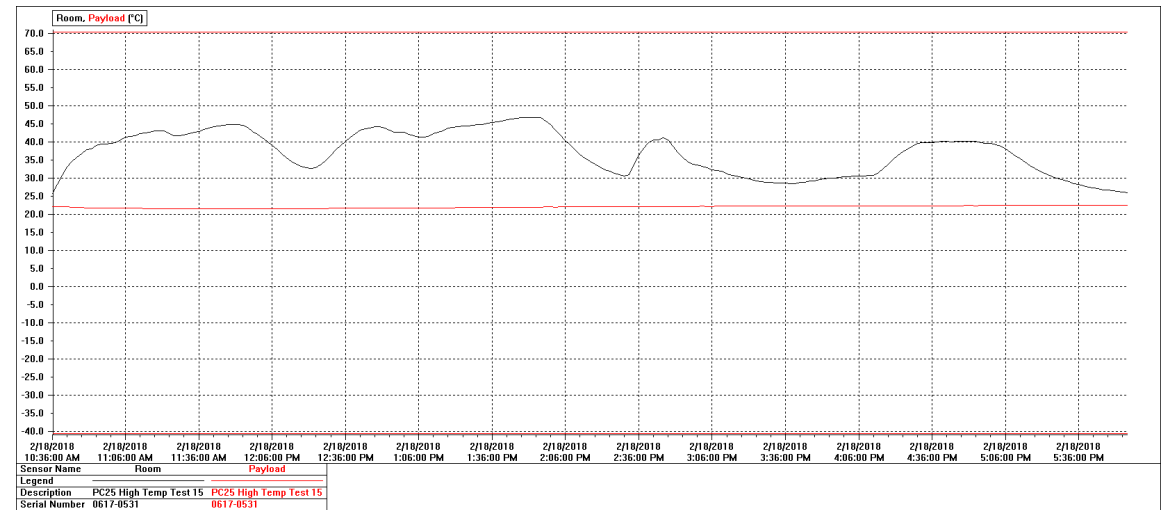
Transport for the *LAST Mile*

- We offer the COMPLETE solution for transporting the vaccines frozen at -21 C or refrigerated (Moderna good for 30 days once thawed, Pfizer 5 days) from the distribution point OUT INTO THE FIELD where vaccination takes place, think rural, senior citizen homes, persons unable to be transported to a hospital for vaccination, etc.
- We Offer the same solution for transporting pharmaceuticals, aside from the vaccines, for treatment into the field. In third world countries we can provide the same link into the villages for vaccination and treatment

New Product PC25

PC25 6 Pound High Temperature Test 9

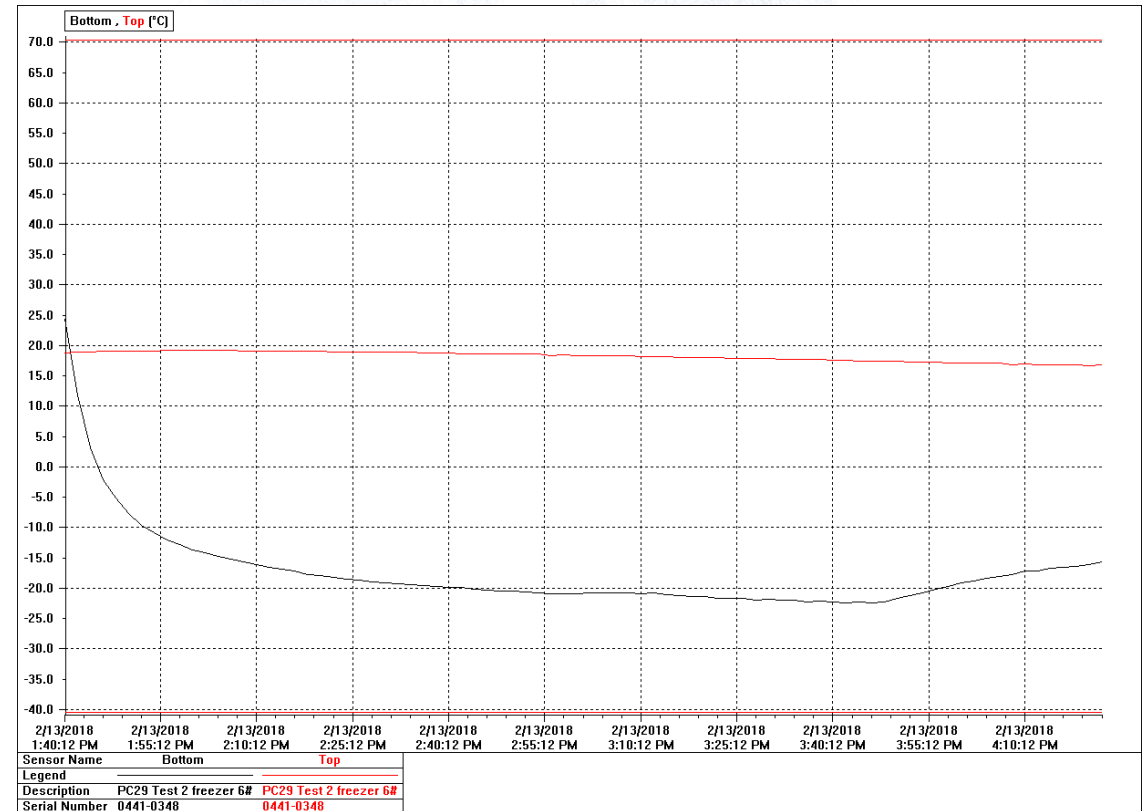
- PC25 used to maintain a payload at 25 Centigrade in hot weather (Black line environmental temperature red line is the payload)



New Product PC29

PC29 Test 2 Freezer 6#

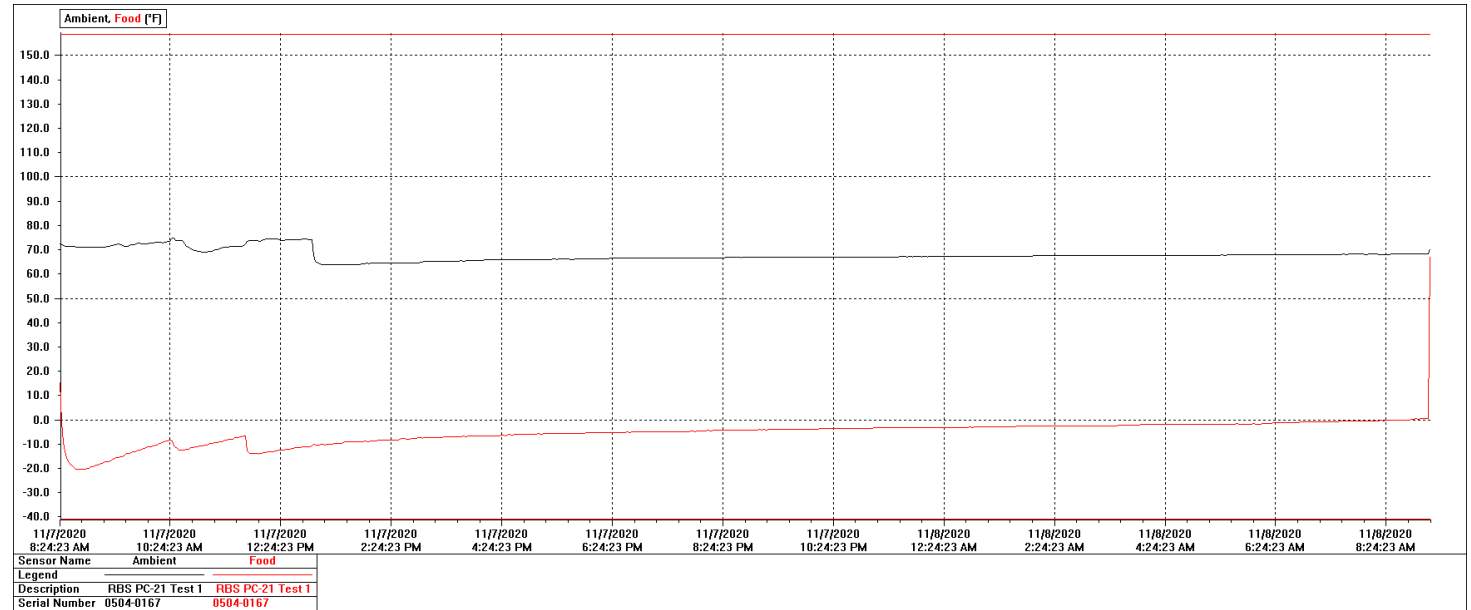
- PC25 maintains payload at 29 Centigrade in cold environments (Red line is the payload and black line the environmental temperature)



Frozen Food Transport

- COVID-19 has increased frozen food deliveries direct to the home.
- TCP is working with company that owns multiple food chains and wishes to do frozen food deliveries.

RBS Test 1 8# PC-21



TCP Website

All of our brochures and data can be found on our TCP website:

WWW.THERMALCUSTOMPACKAGING.COM

Our new Virtual Booth is being updated with products this month

<http://www.virtually-anywhere.net/tours/tcp/booth1/index.htm>

DR Glade's email
cglade@thermalcustompackaging.com