Advancing Transfusion and Cellular Therapies Worldwide

Considerations for Shipment of COVID-19 Convalescent Plasma to Surge Storage

September 2020

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Scope and Goals

- A brief review of BCA's COVID-19 Surge Storage Capacity Plan
- A **Checklist of Considerations** as you plan for shipment to Surge Storage.
- Key steps for processes and SOPs:

  1) Validation plan for shipping containers
     - Determines packing scheme and volume of dry ice needed
     - Must be approved by the Medical Director prior to validation and found acceptable following completion of the validation
     - Traceable thermometer

Scope and Goals for this presentation

2) Dry ice source – simplify!

3) Development of SOPs:

- Packing and shipping procedures ***as determined during the validation process***
- **To reflect BCA's instructions**

4) Staff training:

- Packing process
- Safety (dry ice is a hazardous material)
- Documentation of Competency
- Courier training?

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BCA's COVID-19 Surge Storage Capacity Plan

Jennifer Kapral

Moving excess CCP units to the BCA Surge Supply

CCP Surge Storage Plan for Hospital Collectors:

- Hospital collectors contact Jennifer Kapral when they have reached freezer storage capacity.
- Determine number of units to ship by blood type and by titer.
- Determine if the hospital collector has a local blood provider.
    - Yes, who?
    - No, does the hospital collector have SOPs, boxes and dry ice to ship to a surge center?
- BCA to determine best solution for shipping (local blood supplier, SSC, BPL)
    - If local blood supplier – contact your supplier to arrange for CCP shipment
        - Local blood supplier arrange for pick up and will provide materials and dry ice
        - Depending on local blood supplier, hospital staff or blood supplier driver will pack CCP
        - Cost to hospital provider for this service is $43 per box (includes dry ice) + $150 shipping (per box)
    - If to a surge center (SSC) or deep freeze (BPL) see attached flow chart.
- Shipping paid for by the hospital collector, a shipping fee is included in the cost recovery rate

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CCP Surge Storage Capacity Plan

Centers contact **Jennifer Kapral** when CCP doses are ready to move to Surge Center

Do you have **over 500** units ready to leave your center?
Are units **Low Titer?**

Units will move to BPL for storage. **Sam Keith** will coordinate shipments

All boxes sent to BPL will contain 20 units of the same ABO type

Units will be picked up once schedule

BPL will confirm receiving the product

Have 24 hours to report if product is damaged.

Do you have **under 500** units to more or are units **High Titer?**

Before shipment occurs centers must:

i. Contact BCA 72 hours prior to ship
ii. Give BCA the E-Codes
iii. Confirm # of boxes will be shipped
    - 20 units to a box
iv. Set up shipping information with MNX

All shipments must contain
✓ 9 type O's
✓ 9 type A's
✓ 1 B and 1 AB

Jennifer & BCA Resource Sharing team will alert SSC of incoming shipment, tracking information and box count

SSC will confirm receiving the product

Have 24 hours to report if product is damaged.

NOTE: Collection centers shipping to assigned SSC' should utilize MNX as the preferred next flight out service provider

If you need to set up an MNX account please contact **Sam Keith**

REMEMBER: Once units leave your center, the distribution of these units (whether to SSC or BPL) need to be reported on your CSV file. This allows for tracking and reporting purposes.

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Reminder: Critical Information on Labeling

Shipment of CCP for Surge Storage:

- Under the EUA, CCP is an authorized product but “not an approved product.” It is *not labeled as investigational CCP under the EUA*.
- FDA has confirmed CCP may be shipped across state lines by both licensed and non-licensed (registration-only) collection facilities.
- CCP must be appropriately labeled as described in section III.B.3 on page 8 of the Sept 2020 Investigational CCP Guidance.
- CCP must not be labeled with a license number - Recommendation III.B.3.b on page 8.

Checklist: Shipping with Dry Ice - *Keep it SIMPLE*

____ Identify a source of dry ice

- ➢ **Find another department in your facility with an established contract with a vendor!!**
- ✓ It will be easier and provide potential savings if you can identify another dept that is an existing user of dry ice on your medical campus unless you are anticipating frequent and/or large shipments.
  - Collaborate with another department to use an existing dry ice supplier contract to avoid contract negotiation and approval, with existing storage, and the safety training developed by your institution.
  - Adjust joint supply volume and deliveries according to your plans for collections/shipments.
  - Adopt/revise or develop your policies and procedures, staff training.

OR

- ➢ **Contract as a new customer**
- ✓ Establish a new account for your supply of dry ice with the volume and deliveries according to your plans for collections/shipments.
  - Establish policies, procedures and
  - Establish staff safety training for handling dry ice.

Source: UPS

Resources for Shipping with Dry Ice

____ Resources for shipping with dry ice:

- **DOT-Check the Box: Is it Hazmat?**
- **49 CFR 173.217 Carbon dioxide, solid (dry ice)**
- **UPS – Coolants and Refrigerants (Dry Ice)**
- **UPS-How to Ship with Dry Ice (video)**
- **Dangerous Goods (FedEx Express)**
- **Shipping Dry Ice (FedEx)**
- **USPS Packaging Instruction 9A**

- *Examples of Boxes Available:* **Uline Shipping Containers**, **FedEx order Boxes**

Checklist: Shipping Containers

_____ Shipping containers must be:

- Suitable to transport dry ice (properly ventilated) and maintain temperatures ≤ -18 C
- Capable of maintaining temperatures for the appropriate timeframe necessary to ship frozen plasma from a facility to the final destination.

____ Obtain/purchase appropriate number of shipping containers:

- Purchase appropriate shipping containers OR make arrangements with a local supplier/BCA supplier – how many will you need?
- *Considering collaborating* with local suppliers if possible.

____ Obtain/purchase traceable data logger or temperature device for validation process

- Capable of accurate temperature readings in the appropriate temperature range (≤ -18 C)
- *Examples* of models available: Traceable Products, Fisher Scientific, Dickson, SensoScientific

Checklist: Shipment Method

____ Determine shipment method **according to BCA instructions** for various purposes - see slide 7, flowchart for details of shipping

- Air/Ground
  - FedEx Service – Boxes go on a flight and are delivered the next day (First, AM or Standard) based on shipper selection. Part of general shipments.
  - MNX Service – Boxes are put on commercial flights, driven or a combination based on best route and timeframe. Handled “with care.”
  - BCA has rates with both services, and both offer competitive rates.
  - BCA extends their discount to any shipper during the CCP agreement period to ensure they are receiving the discounts.

  NOTE: Collection centers shipping to assigned SSC should utilize MNX as the preferred next flight out service provider.
- If you need to set up an MNX account, please contact Sam Keith at BCA.

Checklist: Shipment Method

____ Does your facility require courier training on transport of frozen plasma packed on dry ice??

- REVIEW: Dry ice is classified as a hazardous material by the Department of Transportation.
- **Drivers should be aware:** U.S. Department of Transportation states, “Packaging: Dry ice is solid carbon dioxide that releases carbon dioxide gas as it cools. Because of this, dry ice and the other contents of your package need to be packaged securely in a sturdy packaging that permits the release of carbon dioxide gas. This will prevent the buildup of pressure from the dry ice that could rupture the packaging.”

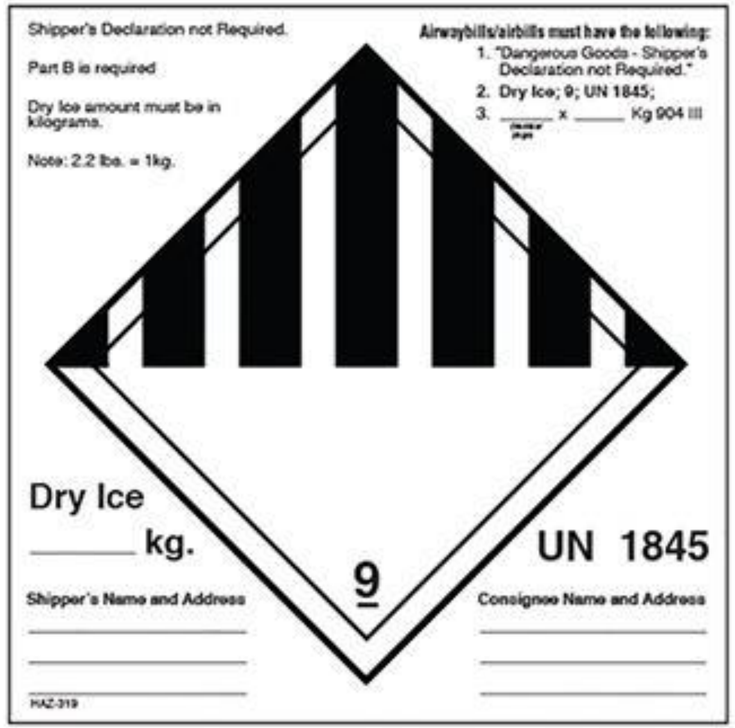
Checklist: Packaging and Labeling of the Shipping Container

_____ Is there proper ventilation in the courier vehicle?

_____ REVIEW: 49 CFR 173.217 Carbon dioxide, solid (dry ice)

_____ Labeling of a shipping container containing dry ice

- Depending on the method of transportation and the carrier, additional hazardous material labeling may be needed. (i.e. hazard Class 9 DOT Miscellaneous Dangerous Good label UN 1845, and net weight of dry ice in kilograms)
- **Refer to instructions from BCA**



Checklist: Validation Plan

____ Write a validation plan for the shipping container

- Include forms for recording results
- Packing scheme - Dry ice above and below?
- Amount of dry ice
  - 5-10 lbs. of dry ice will sublimate every 24 hours. The exact sublimation rate will depend on the density of the insulating container used (source: UPS)
  - Assume there will be shipping delays
- Maximum number of units per box
- Maximum transportation time
- Temperature recording (acceptable limits)
- SOP for shipping (including necessary forms)
- Staff training and competency
  - Including safety and handling of dry ice
- Acceptance criteria and corrective action for failure

Challenges: FDA Requirements for Validation

AABB asked FDA:

Is it possible for a hospital-based blood donor center to adopt another center's validated SOPs and use that center's validated boxes as their own without repeating the validation, or with only a minimal validation?

FDA response:

"Yes, a hospital-based center could share their standard operating procedures and validation plans for shipping COVID-19 convalescent plasma (CCP) with another licensed or registered blood center. Hospitals that adopt the procedures as their own would still be required to comply with the requirements in 21 CFR 606.100 (b) (10) and they should establish a validation plan for maintaining the temperature of the frozen plasma at -18C or colder during shipment as required in 21 CFR 600.15 (a). In addition, if the CCP is collected under the EUA, registered or licensed blood establishments must ensure that storage and cold chain procedures are maintained and consistent with the conditions outlined in the EUA.

We do not agree with omitting the box validation process. A validation plan should consider the maximum transit time, external environmental conditions, the number of packed units, the amount and placement of the coolant, and the properties of the shipping container. A useful resource may be the ISBT Blood Transport Container Validation Guidelines (June 2019). https://www.isbtweb.org/fileadmin/user_upload/ISBT_Blood_Transport_Container_Validation_Guidelines_v1.0_June__2019_final.pdf "

Checklist: Medical Director Review and Approval Prior to Start of Validation

____ Obtain Medical Director review and approval with signature prior to start of validation and as defined in your Quality Plan:

- Validation plan
- SOP for packing and shipping
- Plan for staff training and competency

Checklist - Perform Shipping Container Validation

____ Perform shipping container validation as outlined in plan

____ Review results of validation against acceptability criteria defined in the validation plan

____ Determine whether the validation was acceptable or unacceptable.

____ If acceptable, send for final review and approval as defined by your quality plan and outlined in the validation.

____ If unacceptable, determine corrective action and repeat the validation.

Challenges, Tips and Lessons Learned

Why we shipped out of state

- As the first collector in the state, initially we couldn't keep up with demand—but orders slowed when the local blood supplier Vitalant was able to get up and running.
- During an AABB call, I mentioned that our demand had slowed and we had excess units.
- Requests that I share those units in areas that were struggling came in quickly

Challenges, Tips and Lessons Learned

Validation Plan

- Registered, not licensed FDA facility-no shipping over state lines
- Our shipping boxes were only validated for 6 hours
  - Never had to get them further than Grand Junction ~4 hours away
  - COVID-19 Convalescent plasma is an unlicensed product
  - FDA will allow a registered facility to ship across state lines for urgent medical need, with documentation
- First step—I confirmed with FDA that this was an acceptable use for "urgent medical need"

Challenges, Tips and Lessons Learned

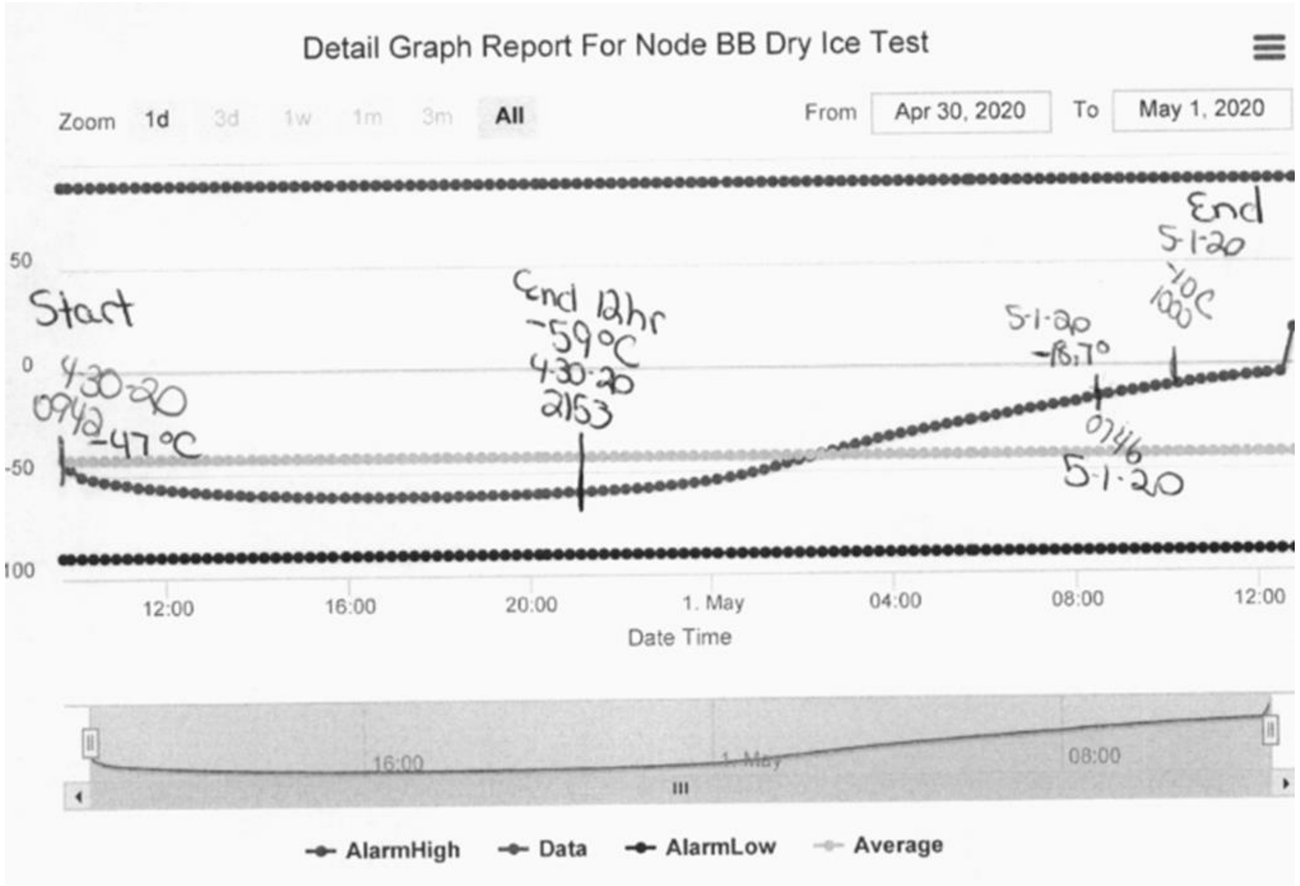
Validation Design

- Blood boxes 14x14 inch box insulted with ½ inch foam panels on all sides
- Establish that a shipping temperature of less than -18 C can be maintained
  - Extreme Temperature Validation
  - Ambient Temperature validation
    - 20 units of expired or near expired FFP
    - Monitor for 24 hours using Senso ULF probe

Challenges, Tips and Lessons Learned

Validation Results

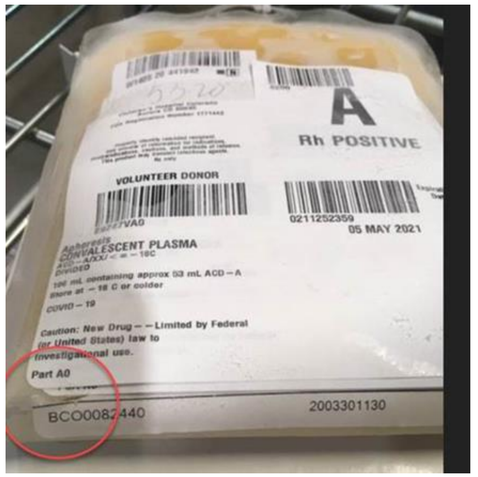
- Ambient Temperature
  - Passed without issues
- Extreme Temperature (46 C)
  - Put the packed box in the blanket warmer!
  - Box failed at 22 hours
  - Could be due to amount of dry ice, or use different shipping boxes
  - Decided to proceed with validating for up to 22 hours
  - Repeated validation and was acceptable up to 22 hours

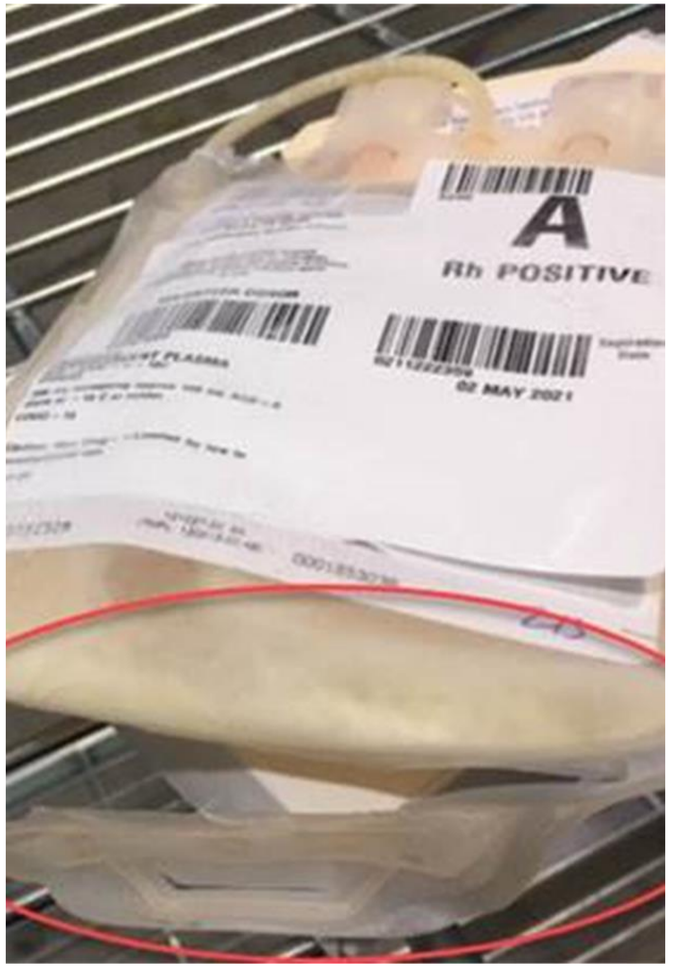


Challenges, Tips and Lessons Learned

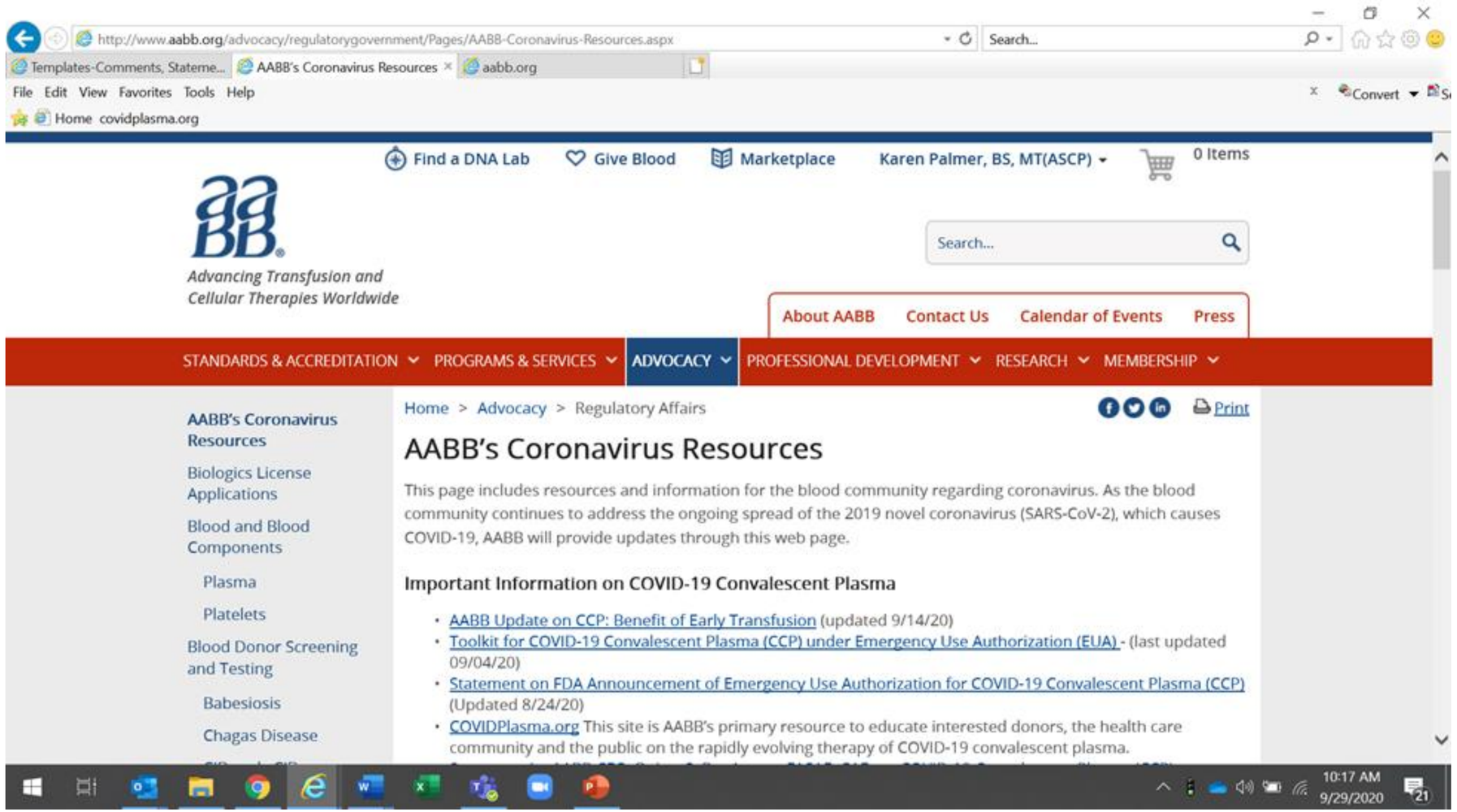
Real world results

- All units maintained appropriate temperature when shipped
  - UT, IL, CA
- Unexpected—some units were cracked
  - Feedback from facilities is that this happens under the best of circumstances sometimes—it is an expected loss
  - We plan to re-validate using individual bubble wrap sleeves for extra cushioning





Where to Find this Information



Questions?

Contact AABB's Regulatory Affairs staff:

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