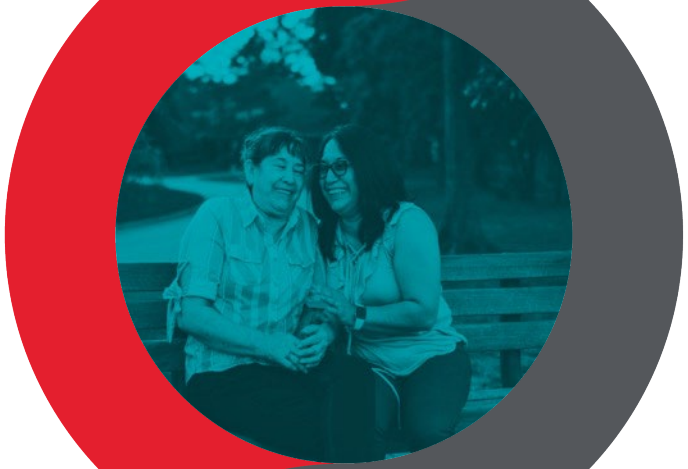
# Impact of SD plasma to Alberta

ALBERTA PRECISION LABORATORIES

Leaders in Laboratory Medicine



# SD plasma roll out

- Only the following sites have a small stock of thawed SD plasma to allow urgent provision of plasma:
  - Foothills
  - University of Alberta / Stollery Children's Hospital (same TM lab)
  - Royal Alexandra Hospital
  - Peter Lougheed Hospital
  - Grey Nuns Community Hospital

Trauma Sites

Vascular Surgery sites

- The remaining sites thaw standard AB (patients of any weight) or low titre group A plasma( >25 kg patients only) for urgent unmatched use.  Group specific SD plasma thawed for non-urgent situations.

# SD Plasma – Increased discards

- Between April 1st to October 23rd, 2023 Alberta has seen plasma discards increase significantly to 11% of thawed. 69% of units discarded are directly due to the SD plasma roll out

**Discards by Final Disposition Facility**

| Count of Unit # Column Labe | | | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|---|---|
| Row Labels | CGYAC | CGYFH | CGYPL | CGYRV | CGYSH | EDMGR | EDMMI | EDMRA | EDMUA | Grand Total | |
| 60M | | 5 | | | | | | 3 | 17 | 25 | Out of controlled temp >60 minutes |
| BROKE | | | | | | | | 1 | | 1 | Broken-Reagents only |
| EXP | | 13 | | | | | | | 97 | 110 | Intact unit reached expiry Date/Time |
| FVI | | 12 | 3 | 2 | | 152 | | 31 | 142 | 342 | Failed vis inspection/CBS visual assessment guide |
| HOSPBROKEN | | | | | | | | | 2 | 2 | Unit broken while in hospital facility |
| MHPWASTE | | 2 | | | | | | | | 2 | Unit wastage due to return from MHP |
| MOD EXP | | 1 | | | | | | | 15 | 16 | Modification Expiry Date/Time reached |
| NULL | | 3 | | | | | | | 8 | 11 | |
| PTREL | | | | | 3 | | | 1 | 4 | 8 | Patient did not require component |
| RECBROKEN | | | | | 1 | | | | | 1 | Unit discovered broken upon receipt from CBS |
| SPIKE | 1 | | | | | | | | 2 | 3 | Bag spiked, not transfused |
| STOR | | | | | | 1 | | | | 1 | Discard due to hospital storage/process deviations |
| THAWEXP | | 28 | | | | | 1 | | 13 | 42 | Unit thawed for general use and past thaw expiry |
| TPT | | 2 | | | | | | | 3 | 5 | Discard due to transport errors |
| **Grand Total** | **1** | **66** | **3** | **2** | **4** | **153** | **1** | **36** | **303** | **569** | |

# SD Plasma – Failed visual inspection

# SD Plasma – Sept Octapharma letter

- Octaplasma must be allowed to be brought to ‘at or around +37°C’.
  - Thaw it adequately at +37°C, use it quickly, thereafter, and it is best not to under or overheat the product at any time.
  - If, however, the product cannot be administered after thawing, it can be stored at 2°C to 8°C for up to 5 days or at +20°C to 25°C for up to 8 hours. Pre-thawed, long-term-stored Octaplasma should therefore be used only as an exception in cases where time plays a crucial role, such as e.g., massive transfusions caused by major trauma.

- If the thawed product cannot be used immediately, it is important to let the product reach 37°C, and then let the product rest at room temperature (temperature prevailing in a work area) to gradually cool down to reach ambient temperature (15°C to 25°C) before placing it in the fridge at 2°C to 8°C for up to 5 days of storage. This reduces the chance for protein precipitates to form later-especially after 3-5 days.

- When the plasma, upon rewarming to reach 37°C in a water bath becomes clear (i.e. fibrinogen/cryoprecipitate resolved), the product can be used.
  - In general, the time required to dissolve the cryo-precipitate in a pre-thawed Octaplasma bag that was previously stored in the fridge may take anywhere between 7-12 minutes when placed in a circulating water bath.

# SD Plasma – Thaw Time Impact

Thaw time challenge

a. Took frozen SD plasma units and thawed with Helmer Quickthaw D16 for 25 minutes.
b. Measured internal temperature of the SD unit with LogTag TRED with RBC internal probe @ 25 minutes
c. Allowed the TRED to record data q 30 seconds for 35 minutes (to maximum of 60minute thaw)

- Findings:
  - A 30 minute thaw is within the internal 30-37C but at lower end
  - A 35 minute thaw consistently gives  36 C internal temp
  - A 40 minute thaw equilibrates to plasma thawer temperature of 36.6 C
  - A >40 minutes – no additional changes to internal temperature

# SD Plasma – Room Temp Conditioning

Room Temperature Rest Challenge

a. SD plasma was thawed in the Helmer QuickThaw until the desired internal temperature was obtained (as close to 37C as possible), as measured using a TRED with an internal RBC probe.

b. The SD plasma was removed from the plasma thawer and left at room temperature (22C) until the unit's internal temperature was measured between 20-25C.

- Findings:
  - After 1 hour, the temperature was 29.5- 30 C
  - It took >3.25 hours for thawed SD plasma to reach 22C

# SD Plasma – Rewarming

## Two Challenges as part of the Rewarming step

1. **4→37 challenge**
    a. A SD plasma unit which had previously been noted to have failed visual inspection due to large particulate agglutination, has its internal temperature monitored using a TRED with internal RBC probe
    b. The SD plasma was re-warmed in 5 minute intervals using a Helmer Quickthaw D16
    c. After each interval and attempt to photograph the particular and grade its size was performed
        a. 4+ - large and easy to notice and photograph,
        b. 3+ - Large aggregate but additional time is required to identify and photograph,
        c. 2+ - small aggregate requiring some scrutinization to identify and difficult to photograph,
        d. 1+ - very small aggregate(s) required large amounts of effort to identify, very hard to photograph,
        e. 0+ no aggregate(s) identified
    d. This was repeated until the internal temperature met the desired internal temperature (as close to 37C as possible).
2. **37→4 challenge** ( in case the unit doesn't get issued or used following rewarming)
    a. The SD plasma that was re-warmed is placed into a refrigerated environment, until the internal temperature of the unit reached refrigerated temperature (2-6oC)
    b. A visual inspection of the unit was performed to identify if the aggregates were reformed (the same grading criteria was used)

# SD Plasma – Rewarming

Two Challenges as part of the Rewarming step Findings

1. 4-37 Challenge
    a. 0 minutes – 7C, 4+ aggregation
    b. 5 minutes – 28.9C, 3+ aggregation
    c. 10 minutes – 34.5C C, 2+ aggregation
    d. 15 minutes – 35.2C, 1+ aggregation
    e. 20 minutes – 35.6C, 1+ aggregation
    No matter how long they were rewarmed they could still be found if the techs looked hard enough. How small is okay?

a. 37→4 Challenge
    a. Fridge Temp– reached ~4C in 4.5hr and demonstrated 3+ aggregation

# Impact

- The 80% target for SD plasma use in the province of Alberta is leading to increased discards which results in:
  - Significant stress to the staff needing plasma in urgent situations
  - Increased cost to the system overall

- We never had the same issue with 5- day storage of single unit CBS produced plasma.

- **Need to have CBS reconsider the recommendations regarding the 80% transition goal to SD plasma.**