

Blood Derivative Distribution: Role of the Hospital Blood Bank

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What is a Blood Product?

- Blood components
 - Whole blood, RBCs, platelets, plasma, cryoprecipitate, cryosupernatant
 - Provided to hospitals free of charge by federally-licensed Blood Operators (CBS, HemaQuébec) with annual billing to provincial Ministries of Health
 - Products manufactured within hospitals paid for by hospital budget
 - Autologous (pre-operative deposit, intra/post-operative salvage)
 - Modifications of CBS/HQ-supplied products: washing, pooling, aliquoting, irradiation, etc
 - Federal licensing of hospital-manufactured blood products with implementation of standard CSA Z902.04



What is a Blood Product?

- Cellular therapeutics
 - Derived from bone marrow or collected from peripheral blood via apheresis
 - Autologous vs allogeneic (directed, designated, pooled/random)
 - May be modified prior to reinfusion (T-cell depletion, targeted differentiation)
 - May be supplied by CBS/HQ (eg., UBMDR) with cost shared by supplier and hospital; manufactured in-house at hospital; or purchased by hospital from commercial third party
 - Examples: hematopoietic stem cells, granulocytes, lymphocytes, dendritic cells, mesenchymal cells



What is a Blood Product?

- Plasma derivatives/fractionated plasma products
 - Purchased from private sector fractionation industry either by CBS/HQ (cost passed on to provincial MOH) or directly by hospital/physician (eg., topical thrombin)
 - CBS/HQ offsets cost in part by supplying source/recovered plasma from volunteer blood donors, remainder generally from paid American donors
 - Manufacturing economies requires 1000s of donors per lot
 - Many examples: coagulation factors (eg., FVIII, FIX), immune globulins (eg., IVIG, HBIG, VZIG), colloids (eg., albumin)
 - Not all licensed in Canada due to small market size; access requires Health Canada SAP
 - CBS/HQ also provides alternatives to derivatives in order to avoid financial disincentive for hospital (eg., HES, recombinant coagulation factor concentrates)



What is a Blood Product?

- Pharmaceutical products containing human plasma/derivative (eg., albumin) as excipient:
 - Examples: vaccines (MMR) enzymes (Aldurazyme), cytokines (Betaseron), bacterial proteins (Botox, streptokinase), monoclonal antibodies (Rituximab), growth hormones (Erythropoietin)
 - Almost all purchased directly from manufacturer by hospital with rare exceptions
 - Eg., Synagis (recombinant anti-RSV Ab) provided by CBS/HQ



What is a Blood Product?

- All of the aforementioned under jurisdiction of Health Canada's Biologics and Genetic Therapies Directorate
 - Referenced in different regulations (eg., blood and blood components to be covered by CSA-Z902, while plasma derivatives covered by Part C/Division 4/Schedule D of Food and Drugs Act)
 - All require maintenance of audit trail from donor to recipient (“vein-to-vein”)
 - Does NOT stipulate which products are the responsibility of the hospital blood bank



UHN Blood Transfusion Laboratory

- Scope of practice defined mainly by those products provided by Canadian Blood Services
 - Prior to amalgamation, Princess Margaret Hospital issued plasma derivatives through hospital pharmacy
 - Evolving standards require BTL oversight over all autologous blood and components as well (eg., intraoperative cell salvage)
 - Cellular therapeutics mostly managed outside of blood transfusion lab by various clinical areas
 - Most pharmaceuticals with human excipients handled by hospital pharmacy, with occasional products purchased directly by clinical areas

UHN Blood Transfusion Laboratory

- BTL laboratory information system (LIS) has two primary functions:
 - Management of patient samples used for compatibility testing
 - Management of blood products issued to patients



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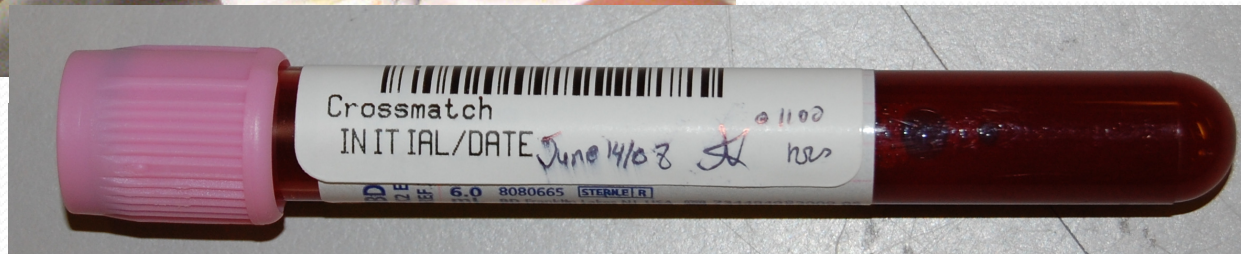


Patient Samples

- Currently, all tubes must be re-labeled as LIS does not recognize barcode generated by hospital information system (HIS)
 - LIS upgrade in Dec 2008 to avoid need for re-labeling except for non-HIS-orderable tests
 - Most accessioned patient samples can be tested by automation; for manual tests, samples must be aliquoted into separate specimen tubes labeled with handwritten identifiers (eg., last 4 digits of accession #)



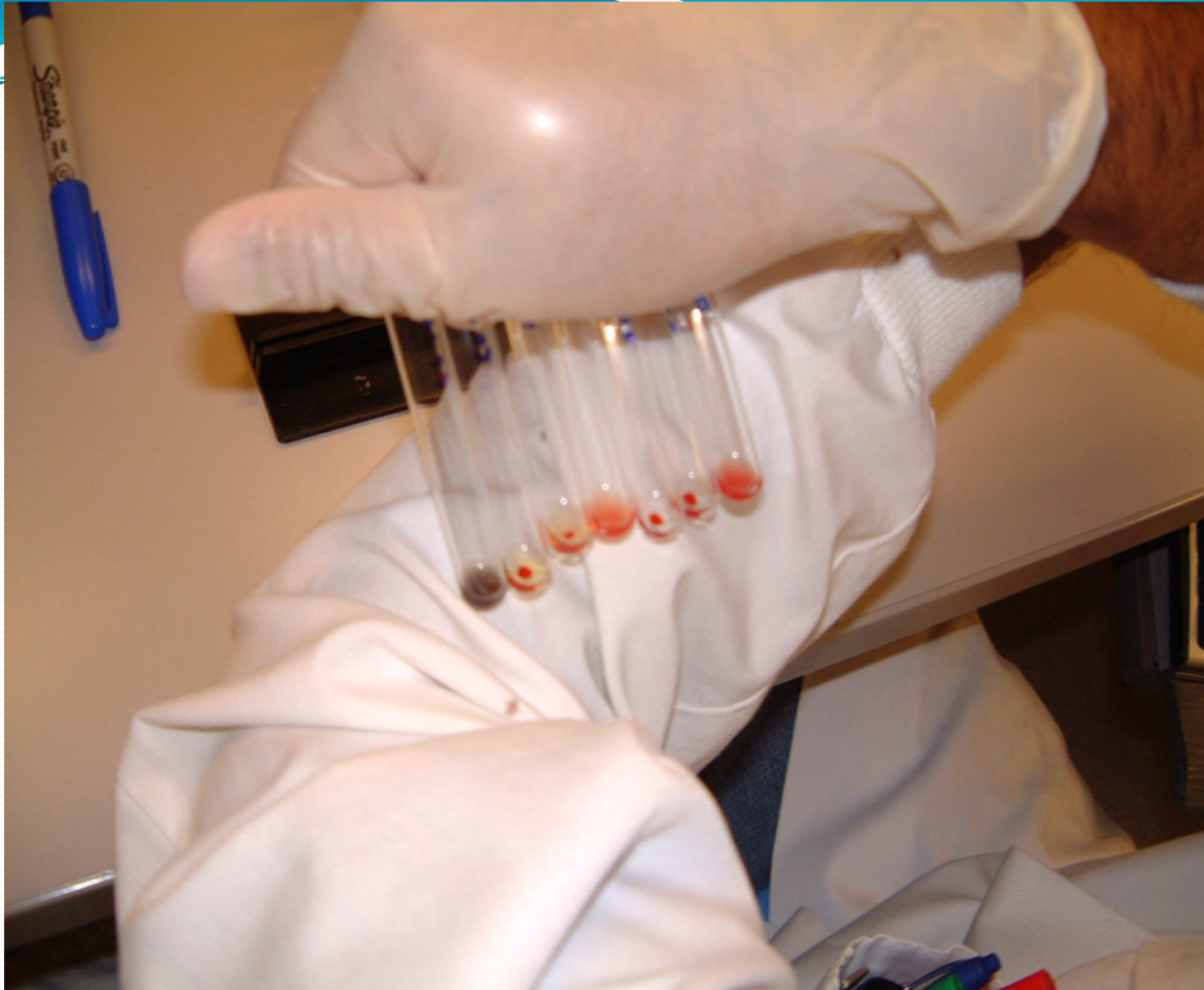
Hospital ID Wristband



HIS-generated specimen label

LIS-generated specimen over-label



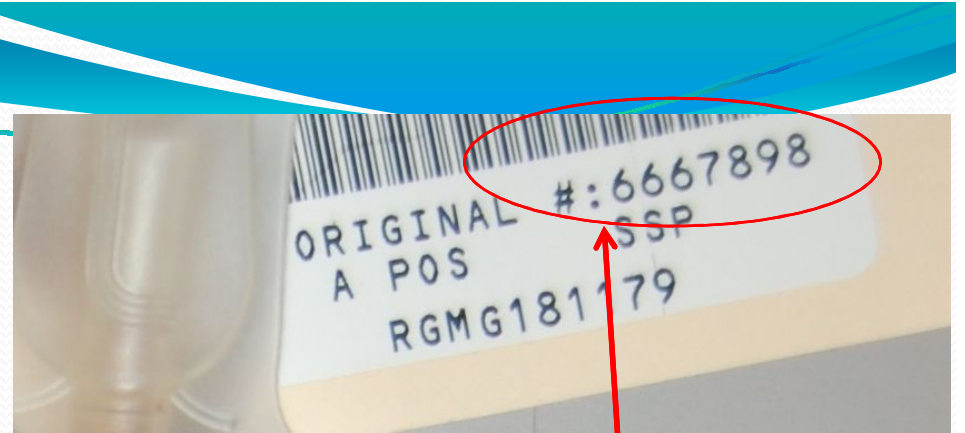


Specimen aliquots for manual ABO/Rh grouping

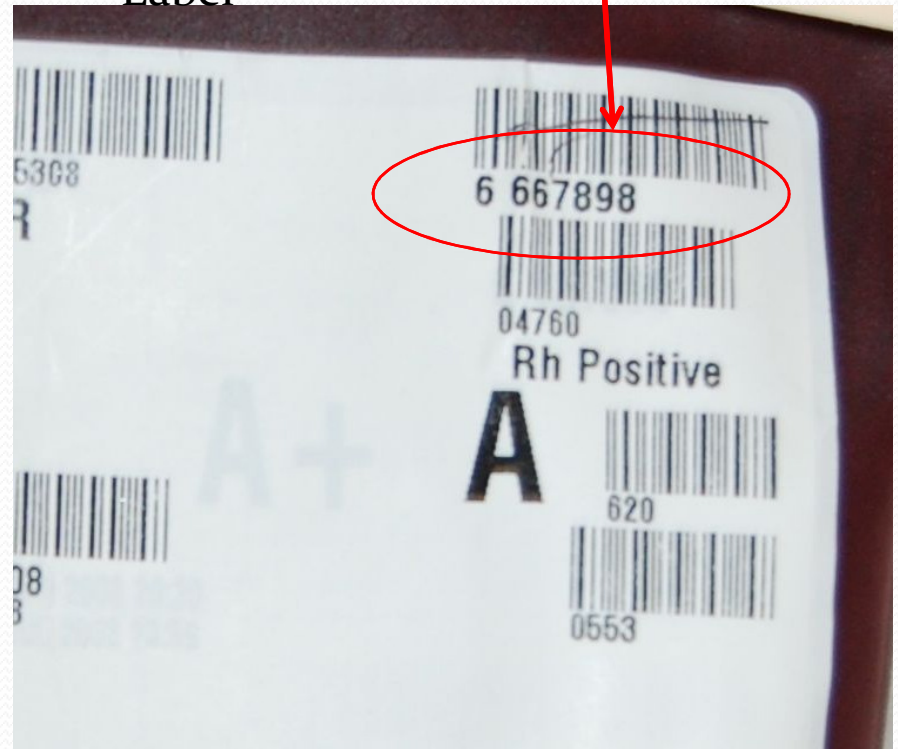


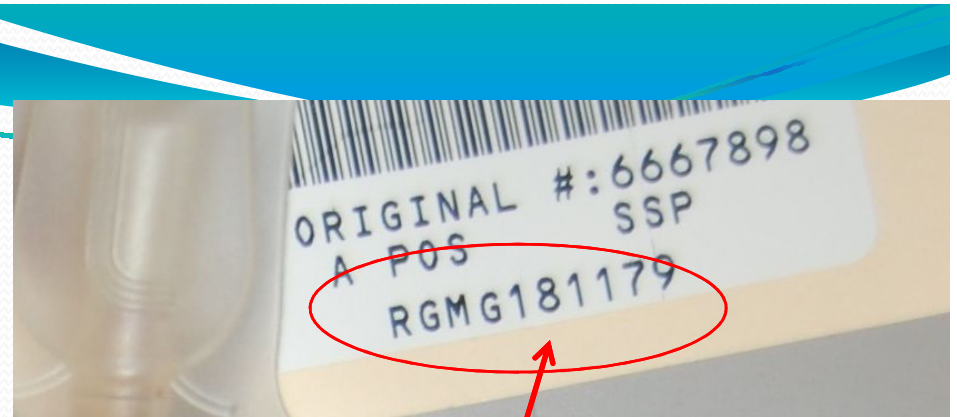
Products

- Blood and blood components
 - Barcodes on supplier label are recognizable by LIS; however, due to frequency of repeating numbers from CBS, ~70% of products must be re-labeled with new system-assigned unit number and barcode
 - Eventual transition to ISBT 128 standard by CBS (already achieved by HQ) will guarantee unique unit # for all blood products; re-labeling will still be required for product modifications)
 - Compatibility label currently printed from two sources:
 - LIS (with barcode provided in future versions)
 - Remote-allocation blood fridge (with barcode)

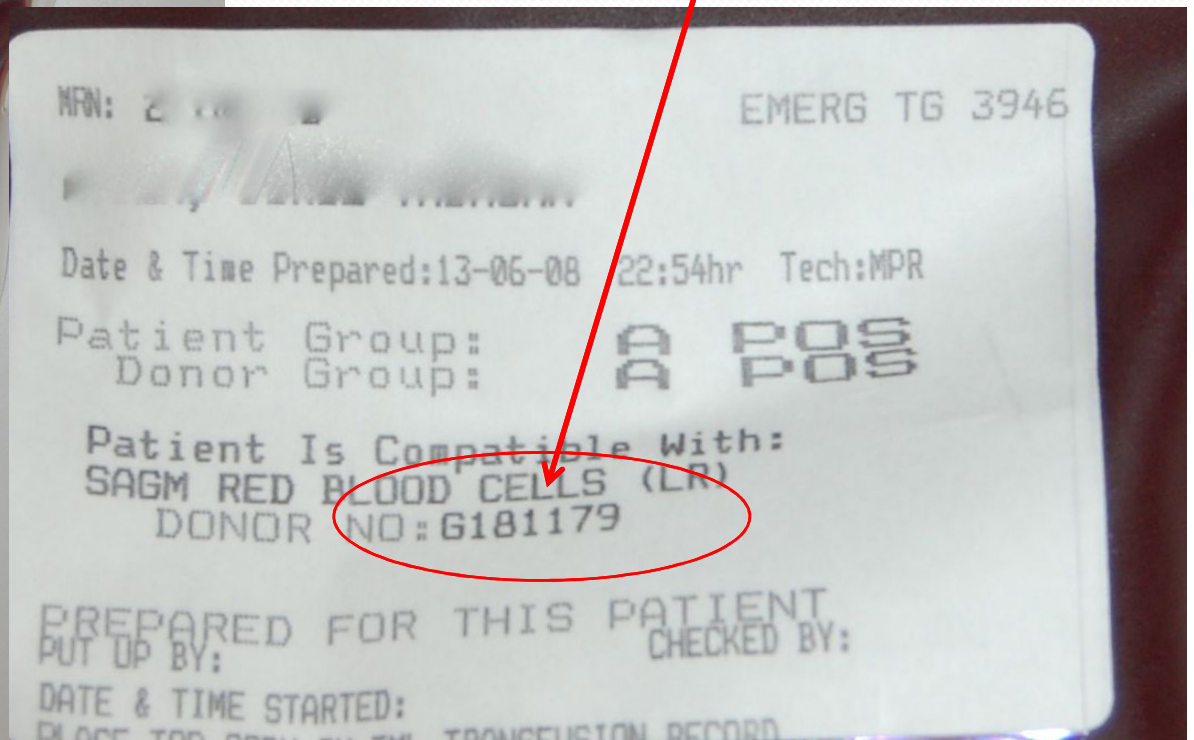


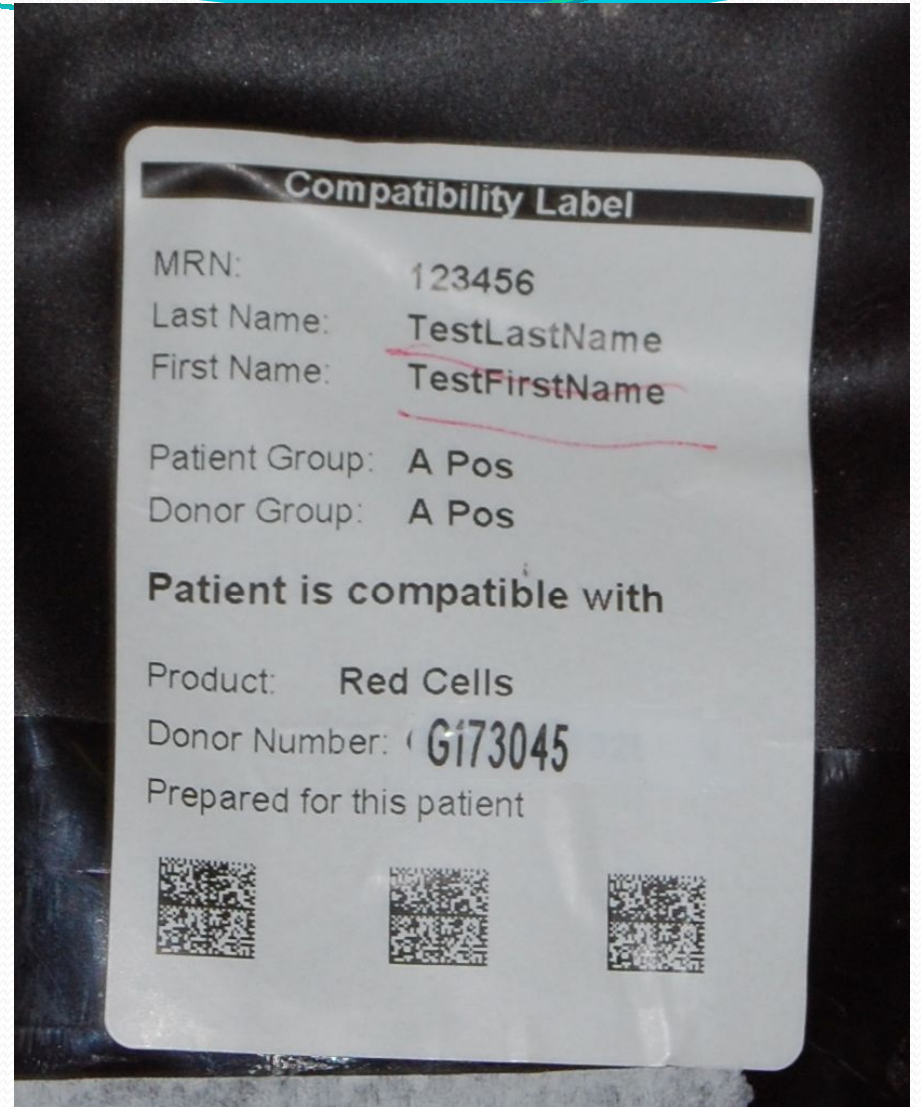
Original Unit # On Supplier Label





LIS Unit # On Compatibility Label





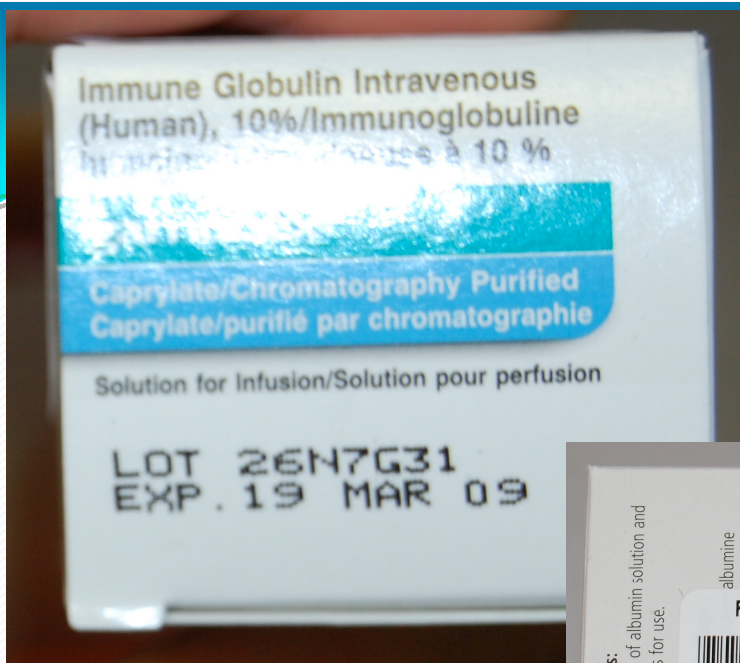
Compatibility Label with Barcode from Remotely-Allocated RBC



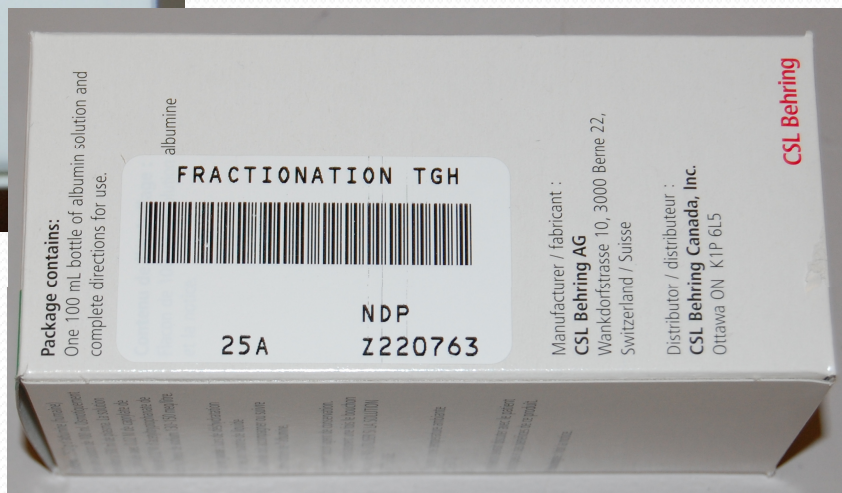
Products

- Fractionated Plasma Products
 - All products relabeled when accessioned into inventory; new system assigned-number and barcode includes manufacturer code, product code, lot#, unit#, expiry date
 - Compatibility label printed by LIS currently have no barcode; may be achievable with next LIS upgrade
 - Until recently compatibility label previous printed with patient identifiers hand-written

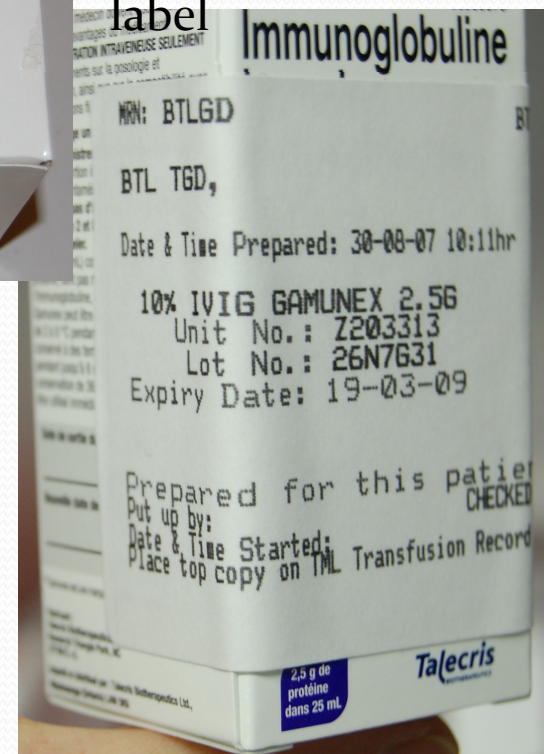
Original product label



LIS product label



LIS compatibility label



Completing The Loop

- Once a product is issued from the blood bank, disposition in LIS set to “presumed transfused”
- Hospital staff visually check compatibility label against patient wristband before infusion
- Compatibility label placed in patient chart as record of transfusion



MFN: 2 10 2

EMERG TG 3946

SIMPSON, HOMER - MRN 1234567

Date & Time Prepared: 13-06-28 22:54hr Tech: MPR

Patient Group: A POS
Donor Group: A POS

Patient Is Compatible With
SAGM RED BLOOD CELLS (LR)
DONOR NO: 6181179

PREPARED FOR THIS PATIENT
PUT UP BY: CHECKED BY:

DATE & TIME STARTED:

PLACE TOP COPY IN THE TRANSFUSION RECORD

SIMPSON, HOMER
1234567

System Prone to Error

- In UK SHOT database (1996-2004), 34.3% of transfusion incidents resulting in major morbidity were incorrect blood component transfused
 - Overall, 70% of all reported incidents were IBCT
- 70% of errors occurred in clinical area, 30% in laboratory
 - Highest risk error: wrong blood in tube at time of collection
 - Commonest single error: inadequate final patient identification check at time of infusion