



Red Blood Cells – In-date for In Vitro Diagnostic Use

Product # PS260

- Red Blood Cells, drawn from qualified human blood donors, provided prior to expiration date collected at FDA registered Blood Establishments.
- Red Blood Cell units will be:
 - ~250 mL
 - within normal expiration date for anticoagulant used (specify days from draw to delivery)
 - collected and maintained in the original FDA approved collection container in FDA approved anticoagulant
 - prepared from separated whole blood or from apheresis collection, collected under normal aseptic conditions, and stored at 1 - 6 C.
 - May be leukoreduced, non-leukoreduced, or with additive solutions to extend shelf life as below.
- Anticoagulants
 - CPD or CP2D (21 day shelf life),
 - CPDA-1 (35 day shelf life)
 - ACD-A, CPD, CP2D with Additive (AS-1, AS-3, AS-5) (42 day shelf life)
- Labeling: Each unit labeled with the product description, unit number, anticoagulant, collection date and/or expiration date, and the name of blood establishment.
- Appearance: Normal in color, free of hemolysis and clots.
- Included with each shipment:
 - Signed Certificate of Compliance with the following information:
Certification of testing.
Each donor unit tested by an FDA licensed laboratory with FDA licensed test kits.
Test results Negative or Non-Reactive for HBsAg, anti-HBc, anti-HIV 1/2, anti-HTLV I/II, anti-HCV, and Syphilis, HIV -1 RNA and HCV RNA. Results for other viral tests if performed such as HBV NAT, West Nile Virus and Chagas (T. cruzi) Negative or Non-Reactive.
Certification of Storage Temperature. The red cell units have been maintained at 1 - 6 C.
- Collection Data: A record listing the unit number, collection date and / or expiration date will accompany each shipment. Each unit will be cross-referenced to the box in which it is packed.
- Packing: Red Blood Cell units packed in validated shipping containers suitable for 48 hour temperature control.
- Shipping: Depends on customer specification.
Shipped at 1 - 10 C with cold packs with an insulating barrier between the units and the cold packs to protect from freezing, Next Day Delivery by Federal Express with cold packs to maintain temperature.
- Order Lead Time: Depends on required quantity. Contracts and Standing Orders available.