

Clerical error during label re-print.

W2276 23 005340 S R

IU Health Apheresis
550 N University Blvd
Indianapolis IN 46202

FOR AUTOLOGOUS USE ONLY

Collection Date/Time: 08 DEC 2023 13:02 EST
(08 DEC, 2023 18:02 UTC)

Do Not Irradiate
Do Not Use Leukoreduction Filters

S1168100 AUTOLOGOUS 0233421662 Expiration Date/Time
MNC, APHERESIS 08 DEC 2023 16:02 EST
(08 DEC, 2023 21:02 UTC)

Volume: 229 mL containing 40 mL Citrate

Storage: 2 - 6° C

Donor/Recipient: [Redacted]

IU Health Cellular Therapy Lab
550 N University Blvd
Indianapolis IN 46202

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CONFIDENTIAL

WARNING – Hematrax CT defaults to 23:59.

Cell Immunotherapy and Transfusion

Directions: Verify the recipient/donor name and medical record number of the recipient or product in by filling out this form. Write 'N/A' if the information is not available. For example, an autologous product will only need recipient information completed. Affix a duplicate ISBT or the one from the product bag to the product or specimen is deemed unacceptable.

W2276 23 005340 S R

IU Health Apheresis
550 N University Blvd
Indianapolis IN 46202

FOR AUTOLOGOUS USE ONLY

Collection Date/Time: 08 DEC 2023 23:59 EST
(09 DEC, 2023 04:59 UTC)

Do Not Irradiate
Do Not Use Leukoreduction Filters

S1303100 AUTOLOGOUS 0233442359 Expiration Date/Time
MNC, APHERESIS 10 DEC 2023 23:59 EST
For Further Processing (11 DEC, 2023 04:59 UTC)

Total Volume: 211 mL containing approx 40 mL Citrate
Store at 1 to 10 C

Donor/Recipient: [Redacted]

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Product / Specimen Information

Appearance (no hemolysis, clumping or signs of contamination)

Labeling (label is accurate and legible)

Label verification form was used but the error was not caught.

Indiana University Health
Cellular Therapy Lab UH 3453
550 N. University Blvd.
Indianapolis, IN 46202


DIN

Interim Label

Verification of Product Labeling: Autologous MNC(A) F-406 v09.08.2020

Signature of Product Labeler: _____ Date: _____

Label Verification: Verify (using a source document) that each element on the product bag label and tags is accurate, legible and complete.

| | |
|-----|--|
| (✓) | |
| | DIN |
| | Proper name of product affixed to bag. ISBT 128 product code is appropriate for product type, anticoagulant, storage temperature and attributes. |
| | "FOR AUTOLOGOUS USE ONLY" |
| | Donor Name: Last, First, Middle Initial (if included) |
| | Donor MRN |
| | Donor date of birth |
| | IU Health Apheresis Collection Facility |
| | IU Health Cellular Therapy Lab Processing Facility |
| | Collection date and end times (including time zone)  |
| | Expiration date and time |
| | Total product volume |
| | Anticoagulant volume |
| | Applicable biohazard and/or warning labels (s) and statements printed on the affixed product label or attached on the tie tag. |
| | "Not evaluated for infectious substances" on tie tag. |
| | Manufacturer label affixed to bag according to manufacturer specific SOP or study SOP. |

Signature of Labeling Verifier: _____ Date: _____

When you sign this form you're stating that you verified all applicable data points.