| DEPARTMENT OF HEALTH AND HUMAN SERVICES PUBLIC HEALTH SERVICE FOOD AND DRUG ADMINISTRATION BLOOD ESTABLISHMENT REGISTRATION AND PRODUCT LISTING FOR MANUFACTURERS OF BLOOD PRODUCTS AND LICENSED DEVICES | FEI: 1828129<br>DUNS: 619073489<br>U.S. License Number:<br>2132                                 | REASON FOR SUBMISSION Annual Registration | DISTRICT OFFICE: Detroit  VALIDATED BY FDA: 12/06/2024 |
|--|---|---|--|
| Versiti Indiana, Inc. Market Square 2200 Elmwood Ave. Suite D 16 Lafayette, IN 47904 USA   | REPORTING OFFICIAL: Megan McShea, Regulatory Ma Indiana Blood Center 3450 North Meridian Street | nager                                     | U.S. AGENT:  |
| 708-359-2058   | Indianapolis, IN 46208 USA<br>317-916-5070<br>versitiregulatoryaffairs@versiti.o                | org                                       |  |
| OTHER NAMES USED IN THIS LOCATION:  Central Indiana Regional Blood Center, Inc.; Indiana Blood Center - Lafayette Donor Center; Indiana Blood Center - Lafayette Substation                              | TYPE OF OWNERSHIP: CORPORATION  DONOR/RECIPIENT RELATIO ALLOGENIC, AUTOLOGOUS,                  |   | ESTABLISHMENT TYPE:  COLLECTION FACILITY               |

| PRODUCT               | COLLECT | MANUAL<br>APHERESIS | AUTOMATED<br>APHERESIS | PREPARE | LEUKOCYTES<br>REDUCED | IRRADIATED | DONOR<br>RETESTED | TEST | STORE AND<br>DISTRIBUTE<br>TO OTHERS | BACTERIAL<br>TESTING | PATHOGEN<br>REDUCED | POOLED |
|-----------------------|---------|---------------------|------------------------|---------|-----------------------|------------|-------------------|------|--------------------------------------|----------------------|---------------------|--------|
| WHOLE BLOOD           | Х       |                     |                        |         |                       |            |                   |      |                                      | ·                    |                     |        |
| RED BLOOD CELLS (RBC) |         |                     | Х                      |         | Х                     |            |                   |      |                                      |                      |                     |        |
| PLATELETS             |         |                     | Х                      |         | Х                     |            |                   |      |                                      |                      |                     |        |
| PF24 PLASMA           |         |                     | Х                      |         |                       |            |                   |      |                                      |                      |                     |        |
| FRESH FROZEN PLASMA   |         |                     | Х                      |         |                       |            |                   |      |                                      |                      |                     |        |

\*\*\*\*\* End Of Report \*\*\*\*\*

FDA information collection OMB Control number: 0910-0052, Expiration Date: 7/31/2024