| 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: 1573778 DUNS: 017730458 U.S. License Number: | REASON FOR SUBMISSION Annual Registration | VALIDATED BY FDA: 12/06/2023 |
|--|---|---|---|
| LEGAL NAME AND LOCATION: Cleveland Clinic Desk Q6-2, Attn: Medical Director 9500 Euclid Avenue Cleveland, OH 44195 USA 216-444-6539 | REPORTING OFFICIAL: Zaher Otrock, MD, PhD Cleveland Clinic 9500 Euclid Avenue Desk Q6-2 Cleveland, OH 44195 USA 216-444-6539 martinm2@ccf.org | | U.S. AGENT: |
| OTHER NAMES USED IN THIS LOCATION: | TYPE OF OWNERSHIP: CORPORATION DONOR/RECIPIENT RELATIO | NSHIP: | ESTABLISHMENT TYPE: HOSPITAL BLOOD BANK |

| PRODUCT | COLLECT | MANUAL APHERESIS | AUTOMATED APHERESIS | PREPARE | LEUKOCYTES REDUCED | IRRADIATED | DONOR RETESTED | TEST | STORE AND DISTRIBUTE TO OTHERS | BACTERIAL TESTING | PATHOGEN REDUCED | POOLED |
|---|---------|---------------------|------------------------|---------|-----------------------|------------|-------------------|------|--------------------------------------|----------------------|---------------------|--------|
| RED BLOOD CELLS (RBC) | | | | | | Х | | Х | Х | , | | |
| RBC DEGLYCEROLIZED | | | | | | Х | | Х | | | | |
| RBC RECONSTITUTED | | | | Х | | Х | | Х | | | | |
| RBC WASHED | | | | Х | | Х | | Х | | | | |
| CRYOPRECIPITATED AHF | | | | | | | | | Х | | | |
| PLATELETS | | | | | | Х | | | Х | | | |
| PLATELETS PAS (PLATELETS ADDITIVE SOLUTION) | | | | | | Х | | | Х | | | |
| GRANULOCYTES | | | | | | Х | | Х | | | | |
| PLASMA | | | | | | | | | Х | | | |
| PF24 PLASMA | | | | | | | | | Х | | | |

| 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: 1573778 DUNS: 017730458 U.S. License Number: | REASON FOR SUBMISSION Annual Registration | DISTRICT OFFICE:Cincinnati VALIDATED BY FDA: 12/06/2023 |
|--|---|---|--|
| LEGAL NAME AND LOCATION: Cleveland Clinic Desk Q6-2, Attn: Medical Director 9500 Euclid Avenue Cleveland, OH 44195 USA 216-444-6539 | REPORTING OFFICIAL: Zaher Otrock, MD, PhD Cleveland Clinic 9500 Euclid Avenue Desk Q6-2 Cleveland, OH 44195 USA 216-444-6539 martinm2@ccf.org | | U.S. AGENT: |
| OTHER NAMES USED IN THIS LOCATION: | TYPE OF OWNERSHIP: CORPORATION DONOR/RECIPIENT RELATIO | NSHIP: | ESTABLISHMENT TYPE: HOSPITAL BLOOD BANK |

| PRODUCT | COLLECT | MANUAL APHERESIS | AUTOMATED APHERESIS | PREPARE | LEUKOCYTES REDUCED | IRRADIATED | DONOR RETESTED | TEST | STORE AND DISTRIBUTE TO OTHERS | TESTING | PATHOGEN REDUCED | POOLED |
|---------------------------------|---------|---------------------|------------------------|---------|-----------------------|------------|-------------------|------|--------------------------------------|---------|---------------------|--------|
| PF24RT24 PLASMA | | | | | | | | | Х | | | |
| FRESH FROZEN PLASMA | | | | | | | | | Х | | | |
| PLASMA CRYOPRECIPITATED REDUCED | | | | | | | | | Х | | | |

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

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