

DEPARTMENT OF HEALTH AND HUMAN SERVICES
WASHINGTON, D.C.

ESTABLISHMENT LICENSE

FOR THE MANUFACTURE OF
BIOLOGICAL PRODUCTS

This is to certify that Establishment License No. 634 is hereby issued
to Central Kentucky Blood Center, Inc., the manufacturer,
located at Lexington, Kentucky
identified as Central Kentucky Blood Center, Inc., through the establishment
located at Lexington, Kentucky **DUPLICATE**

pursuant to Section 351 of the Public Health Service Act, approved July 1, 1944 (58 Stat. 702, 42 U.S.C. 262), as amended, and the regulations thereunder. The license authorizes the manufacturer to maintain an establishment for the preparation or manufacture and preparation for sale, barrier, or exchange in the District of Columbia, or for sending, carrying, or bringing for sale, barrier, or exchange from any State or possession into any other State or possession or into any foreign country, or from any foreign country into any State or possession, any virus, therapeutic serum, toxin, antitoxin, vaccine, blood, blood component or derivative, allergenic product, an analogous product, or antipernanone or its derivatives, for which the manufacturer holds an unexpired and unrevoked product license issued by the Secretary of Health and Human Services pursuant to said Act and regulations.

Date July 7, 1976



William B. ...
Director, Center for Biologics
Evaluation and Research
Food and Drug Administration

**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: 1070402
DUNS:
U.S. License Number:
1836

REASON FOR SUBMISSION
Change in Information

DISTRICT OFFICE: Cincinnati
VALIDATED BY FDA: 07/30/2018

LEGAL NAME AND LOCATION:

Kentucky Blood Center, Inc.
3121 Beaumont Centre Circle
Lexington, KY 40513-1709 USA

REPORTING OFFICIAL:

Kim Turner, Vice President of Quality and Regulatory Affairs
Kentucky Blood Center, Inc.
3121 Beaumont Centre Circle

U.S. AGENT:

Lexington, KY 40513-1709 USA

859-519-3785

kiturner@kybloodcenter.org

OTHER NAMES USED IN THIS LOCATION:

TYPE OF OWNERSHIP:
CORPORATION

DONOR/RECIPIENT RELATIONSHIP:
ALLOGENIC, AUTOLOGOUS, DIRECTED

ESTABLISHMENT TYPE:
COMMUNITY (NON-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
WHOLE BLOOD	X					X			X			
RED BLOOD CELLS (RBC)			X	X	X	X			X			
RBC FROZEN				X					X			
RBC DEGLYCEROLIZED				X		X			X			
RBC REJUVENATED FROZEN									X			
RBC REJUVENATED DEGLYCEROLIZED				X		X			X			
CRYOPRECIPITATED AHF				X					X			
PLATELETS			X		X	X			X			
GRANULOCYTES			X			X			X			
FRESH FROZEN PLASMA			X	X		X			X			

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: 1070402
 DUNS:
 U.S. License Number:
 1836

REASON FOR SUBMISSION
 Change in Information

DISTRICT OFFICE: Cincinnati
 VALIDATED BY FDA: 07/30/2018

LEGAL NAME AND LOCATION:

Kentucky Blood Center, Inc.
 3121 Beaumont Centre Circle
 Lexington, KY 40513-1709 USA

REPORTING OFFICIAL:

Kim Turner, Vice President of Quality and Regulatory Affairs
 Kentucky Blood Center, Inc.
 3121 Beaumont Centre Circle

U.S. AGENT:

Lexington, KY 40513-1709 USA

859-276-2534

859-519-3785
 kiturner@kybloodcenter.org

ESTABLISHMENT TYPE:

COMMUNITY (NON-HOSPITAL) BLOOD BANK

OTHER NAMES USED IN THIS LOCATION:

TYPE OF OWNERSHIP:
 CORPORATION
 DONOR/RECIPIENT RELATIONSHIP:
 ALLOGENIC, AUTOLOGOUS, DIRECTED

PRODUCT	COLLECT	MANUAL APHERESIS	AUTOMATED APHERESIS	PREPARE	LEUKOCYTES REDUCED	IRRADIATED	DONOR RETESTED	TEST	STORE AND DISTRIBUTE TO OTHERS	BACTERIAL TESTING	PATHOGEN REDUCED	POOLED
PLASMA CRYOPRECIPITATED REDUCED				X					X			
RECOVERED PLASMA				X					X			
POOLED CRYOPRECIPITATE				X					X			

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

**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: 3007689681
DUNS:
U.S. License Number:
1836

REASON FOR SUBMISSION
Change in Information

DISTRICT OFFICE: Cincinnati
VALIDATED BY FDA: 07/30/2018

LEGAL NAME AND LOCATION:

Kentucky Blood Center, Inc.
3130 Maple Leaf Dr.
Lexington, KY 40509 USA

REPORTING OFFICIAL:

Kim Turner, Vice President of Quality and Regulatory Affairs
Kentucky Blood Center, Inc.
3121 Beaumont Centre Circle

U.S. AGENT:

859-327-3223

Lexington, KY 40513 USA
859-519-3785
kiturner@kybloodcenter.org

OTHER NAMES USED IN THIS LOCATION:

Central Kentucky Blood Center - Andover; Kentucky Blood Center -
Andover; Kentucky Blood Center Inc.

TYPE OF OWNERSHIP:

CORPORATION

ESTABLISHMENT TYPE:

COLLECTION FACILITY

DONOR/RECIPIENT RELATIONSHIP:

ALLOGENIC, AUTOLOGOUS, DIRECTED

PRODUCT	COLLECT	MANUAL APHERESIS	AUTOMATED APHERESIS	PREPARE	LEUKOCYTES REDUCED	IRRADIATED	DONOR RETESTED	TEST	STORE AND DISTRIBUTE TO OTHERS	BACTERIAL TESTING	PATHOGEN REDUCED	POOLED
WHOLE BLOOD	X											
RED BLOOD CELLS (RBC)			X									
PLATELETS			X		X							
PLASMA			X									

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

**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: 3011192341
DUNS:
U.S. License Number: 1836

REASON FOR SUBMISSION
Change in Information

DISTRICT OFFICE: Cincinnati
VALIDATED BY FDA: 07/30/2018

LEGAL NAME AND LOCATION:

Kentucky Blood Center, Inc.
12905 Shelbyville Rd
Suite 4
Louisville, KY 40243 USA

502-290-0537

REPORTING OFFICIAL:

Kim Turner, Vice President of Quality and Regulatory Affairs
Kentucky Blood Center
3121 Beaumont Centre Circle

Lexington, KY 40513 USA
859-519-3785
kiturner@kybloodcenter.org

U.S. AGENT:

OTHER NAMES USED IN THIS LOCATION:

TYPE OF OWNERSHIP:

Kentucky Blood Center - Middletown; Kentucky Blood Center, Inc
CORPORATION
DONOR/RECIPIENT RELATIONSHIP:
ALLOGENIC, AUTOLOGOUS, DIRECTED

ESTABLISHMENT TYPE:
COLLECTION FACILITY

PRODUCT	COLLECT	MANUAL APHERESIS	AUTOMATED APHERESIS	PREPARE	LEUKOCYTES REDUCED	IRRADIATED	DONOR RETESTED	TEST	STORE AND DISTRIBUTE TO OTHERS	BACTERIAL TESTING	PATHOGEN REDUCED	POOLED
WHOLE BLOOD	X											
RED BLOOD CELLS (RBC)			X									
PLATELETS			X		X							
PLASMA			X									

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

**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: 1000220419
DUNS:
U.S. License Number:
1836

REASON FOR SUBMISSION
Change in Information

DISTRICT OFFICE: Cincinnati
VALIDATED BY FDA: 07/30/2018

LEGAL NAME AND LOCATION:

Kentucky Blood Center, Inc.
472 South Mayo Trail
Pikeville, KY 41501 USA

REPORTING OFFICIAL:

Kim Turner, Vice President of Quality and Regulatory Affairs
Kentucky Blood Center, Inc.
3121 Beaumont Centre Circle

U.S. AGENT:

Lexington, KY 40513-1709 USA
859-519-3785
kiturner@kybloodcenter.org

OTHER NAMES USED IN THIS LOCATION:

Central Kentucky Blood Center, Inc.; Kentucky Blood Center -
Pikeville; Kentucky Blood Center Inc.

TYPE OF OWNERSHIP:

CORPORATION

DONOR/RECIPIENT RELATIONSHIP:

ALLOGENIC, AUTOLOGOUS, DIRECTED

ESTABLISHMENT TYPE:

COLLECTION FACILITY; DISTRIBUTION CENTER

PRODUCT	COLLECT	MANUAL APHERESIS	AUTOMATED APHERESIS	PREPARE	LEUKOCYTES REDUCED	IRRADIATED	DONOR RETESTED	TEST	STORE AND DISTRIBUTE TO OTHERS	BACTERIAL TESTING	PATHOGEN REDUCED	POOLED
WHOLE BLOOD	X								X			
RED BLOOD CELLS (RBC)			X						X			
PLATELETS			X						X			
PLASMA			X									

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

**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: 1048401
DUNS:
U.S. License Number:
1836

REASON FOR SUBMISSION
Change in Information

DISTRICT OFFICE:Cincinnati
VALIDATED BY FDA: 07/30/2018

LEGAL NAME AND LOCATION:

Kentucky Blood Center, Inc.
10 Stonegate Centre
Somerset, KY 42503 USA

REPORTING OFFICIAL:

Kim Turner, Vice President of Quality and Regulatory Affairs
Kentucky Blood Center, Inc.
3121 Beaumont Centre Circle

U.S. AGENT:

Lexington, KY 40513-1709 USA

859-519-3785

kiturner@kybloodcenter.org

OTHER NAMES USED IN THIS LOCATION:

Central Kentucky Blood Center, Inc.; Kentucky Blood Center -
Somerset; Kentucky Blood Center Inc.

TYPE OF OWNERSHIP:

CORPORATION

DONOR/RECIPIENT RELATIONSHIP:

ALLOGENIC, AUTOLOGOUS, DIRECTED

ESTABLISHMENT TYPE:

COLLECTION FACILITY

PRODUCT	COLLECT	MANUAL APHERESIS	AUTOMATED APHERESIS	PREPARE	LEUKOCYTES REDUCED	IRRADIATED	DONOR RETESTED	TEST	STORE AND DISTRIBUTE TO OTHERS	BACTERIAL TESTING	PATHOGEN REDUCED	POOLED
WHOLE BLOOD	X											
RED BLOOD CELLS (RBC)			X									
PLATELETS			X		X							
PLASMA			X									

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

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: 3013450009
 DUNS:
 U.S. License Number:

REASON FOR SUBMISSION
 Change in Information

DISTRICT OFFICE: Cincinnati
 VALIDATED BY FDA: 07/30/2018

LEGAL NAME AND LOCATION:

Kentucky Blood Center, Inc.
 2605 Kentucky Ave.
 MP3 Suite 104
 Paducah, KY 42003 USA
 270-557-7821

REPORTING OFFICIAL:

Kim Turner, Vice President of Quality and Regulatory Affairs
 Kentucky Blood Center, Inc.
 3121 Beaumont Centre Circle
 Lexington, KY 40513 USA
 859-519-3785
 kiturner@kybloodcenter.org

U.S. AGENT:

OTHER NAMES USED IN THIS LOCATION:

Kentucky Blood Center - Paducah

ESTABLISHMENT TYPE:
 DISTRIBUTION CENTER

TYPE OF OWNERSHIP:

CORPORATION

DONOR/RECIPIENT RELATIONSHIP:

PRODUCT	COLLECT	MANUAL APHERESIS	AUTOMATED APHERESIS	PREPARE	LEUKOCYTES REDUCED	IRRADIATED	DONOR RETESTED	TEST	STORE AND DISTRIBUTE TO OTHERS	BACTERIAL TESTING	PATHOGEN REDUCED	POOLED
WHOLE BLOOD									X			
RED BLOOD CELLS (RBC)									X			
CRYOPRECIPITATED AHF									X			
PLATELETS									X			
FRESH FROZEN PLASMA									X			

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

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: 3014276808
DUNS:
U.S. License Number:
1836

REASON FOR SUBMISSION
Change in Information

DISTRICT OFFICE: Cincinnati
VALIDATED BY FDA : 07/30/2018

LEGAL NAME AND LOCATION:

Kentucky Blood Center, Inc.
Kentucky Blood Center, Inc
5406 Antle Drive
Suite 101
Louisville, KY 40229 USA
502-915-0999

REPORTING OFFICIAL:

Kim Turner, Vice President of Quality and Regulatory Affairs
Kentucky Blood Center
3121 Beaumont Centre Circle
Lexington, KY 40513 USA
859-519-3785
kiturner@kybloodcenter.org

U.S. AGENT:

OTHER NAMES USED IN THIS LOCATION:
Kentucky Blood Center - HillView

TYPE OF OWNERSHIP:
CORPORATION

DONOR/RECIPIENT RELATIONSHIP:
ALLOGENIC, AUTOLOGOUS, DIRECTED

ESTABLISHMENT TYPE:
COLLECTION FACILITY

PRODUCT	COLLECT	MANUAL APHERESIS	AUTOMATED APHERESIS	PREPARE	LEUKOCYTES REDUCED	IRRADIATED	DONOR RETESTED	TEST	STORE AND DISTRIBUTE TO OTHERS	BACTERIAL TESTING	PATHOGEN REDUCED	POOLED
WHOLE BLOOD	X											

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

DEPARTMENT OF HEALTH AND HUMAN SERVICES
 PUBLIC HEALTH SERVICE
 FOOD AND DRUG ADMINISTRATION
 ESTABLISHMENT REGISTRATION AND LISTING FOR HUMAN CELLS,
 TISSUES, AND CELLULAR AND TISSUE-BASED PRODUCTS
 DESCRIBED IN 21 CFR 1271.10

FEI: 0001070402

Other FDA Registrations:
 Blood: FEI: 0001070402
 Devices:
 Drugs:

Reason For Last Submission: Annual Registration/Listing
 Last Annual Registration Year: 2019
 Last Registration Receipt Date: 12/04/2018
 Summary Report Print Date: 02/01/2019

Legal Name and Location:
 Kentucky Blood Center
 3121 Beaumont Centre Circle
 Lexington, Kentucky 40513-1709
 USA
 Phone: 859-276-2534

Ext:

Reporting Official:
 Kim Turner, Vice President, Quality & Regulatory
 3121 Beaumont Centre Circle
 Lexington, Kentucky 40513-1709
 USA
 Phone: 859-519-3785 Ext:
 kturner@kybloodcenter.org

Satellite Recovery Establishment: No
 Parent Manufacturing Establishment FEI No.:
 Testing For Micro-Organisms Only: No

Note: FDA acceptance of an establishment registration and HCT/P listing does not constitute a determination that an establishment is in compliance with applicable rules and regulations or that the HCT/P is licensed or approved by FDA (21 CFR 1271.27(b)).

HCT/P(s)	Donor Type(s)	Establishment Functions							Date of Discontinuance	Date of Resumption	Proprietary Name(s)
		Recover	Screen	Donor Testing	Package	Process	Store	Label			
Amniotic Membrane											
Blood Vessel											
Bone											
Cardiac Tissue - non-valved											
Cartilage											
Cornea											
Dura Mater											
Embryo											
Fascia											
Heart Valve											
HPC Apheresis	Family Related	X	X		X	X	X	X	X		
HPC Cord Blood											
Ligament											
Nerve Tissue											
Oocyte											
Ovarian Tissue											
Pancreatic Islet Cells - autologous											
Parathyroid											
Pericardium											
Peripheral Blood Mononuclear Cells	Autologous	X	X		X	X	X	X	X		
Peritoneal Membrane											
Sclera											
Semen											
Skin											
Tendon											
Testicular Tissue											
Tooth Pulp											
Umbilical Cord Tissue											

Additional Information: No additional information provided.
Proprietary Name(s):

FBI: 0001070402

FDA information collection OMB Control number: 0910-0543, expiration date: 6/30/2020

Page 2 of 2

Legal Name:

Kentucky Blood Center