

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, through the establishment  
identified as Central Kentucky Blood Center, Inc.  
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 propagation or manufacture and preparation for sale, barter, or exchange in the District of Columbia, or for sending, carrying, or bringing for sale, barter, 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, or analogous product, or arsenamine or its derivatives, for which the manufacturer holds an unsuspended and unrevoked product license issued by the Secretary of Health and Human Services pursuant to said Act and regulations.

Date July 7, 1976



*W. Mark D. ...*  
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	<b>FEI:</b> 1070402 <b>DUNS:</b> 074099904 <b>U.S. License Number:</b> 1836	<b>REASON FOR SUBMISSION</b> Annual Registration	<b>DISTRICT OFFICE:</b> Cincinnati <b>VALIDATED BY FDA :</b> 11/18/2019
<b>LEGAL NAME AND LOCATION:</b>  Kentucky Blood Center, Inc. 3121 Beaumont Centre Circle Lexington, KY 40513-1709 USA  859-276-2534	<b>REPORTING OFFICIAL:</b> Kim Turner, Vice President of Quality and Regulatory Affairs Kentucky Blood Center, Inc. 3121 Beaumont Centre Circle  Lexington, KY 40513-1709 USA 859-519-3785 kiturner@kybloodcenter.org		<b>U.S. AGENT:</b>
<b>OTHER NAMES USED IN THIS LOCATION:</b>	<b>TYPE OF OWNERSHIP:</b> CORPORATION  <b>DONOR/RECIPIENT RELATIONSHIP:</b> ALLOGENIC, AUTOLOGOUS, DIRECTED		<b>ESTABLISHMENT TYPE:</b> 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			

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<b>LEGAL NAME AND LOCATION:</b>  Kentucky Blood Center, Inc. 3121 Beaumont Centre Circle Lexington, KY 40513-1709 USA  859-276-2534	<b>REPORTING OFFICIAL:</b> Kim Turner, Vice President of Quality and Regulatory Affair: Kentucky Blood Center, Inc. 3121 Beaumont Centre Circle  Lexington, KY 40513-1709 USA 859-519-3785 kiturner@kybloodcenter.org		<b>U.S. AGENT:</b>
<b>OTHER NAMES USED IN THIS LOCATION:</b>	<b>TYPE OF OWNERSHIP:</b> CORPORATION  <b>DONOR/RECIPIENT RELATIONSHIP:</b> ALLOGENIC, AUTOLOGOUS, DIRECTED		<b>ESTABLISHMENT TYPE:</b> 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
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	<b>FEI:</b> 3007689681 <b>DUNS:</b> 963971770 <b>U.S. License Number:</b> 1836	<b>REASON FOR SUBMISSION</b> Annual Registration	<b>DISTRICT OFFICE:</b> Cincinnati <b>VALIDATED BY FDA:</b> 11/18/2019
<b>LEGAL NAME AND LOCATION:</b>  Kentucky Blood Center, Inc. 3130 Maple Leaf Dr. Lexington, KY 40509 USA  859-327-3223	<b>REPORTING OFFICIAL:</b> Kim Turner, Vice President of Quality and Regulatory Affair Kentucky Blood Center, Inc. 3121 Beaumont Centre Circle  Lexington, KY 40513-1709 USA 859-519-3785 kiturner@kybloodcenter.org	<b>U.S. AGENT:</b>	
<b>OTHER NAMES USED IN THIS LOCATION:</b> Central Kentucky Blood Center - Andover; Kentucky Blood Center - Andover; Kentucky Blood Center Inc.	<b>TYPE OF OWNERSHIP:</b> CORPORATION  <b>DONOR/RECIPIENT RELATIONSHIP:</b> ALLOGENIC, AUTOLOGOUS, DIRECTED	<b>ESTABLISHMENT TYPE:</b> 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 \*\*\*\*\*

<b>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</b>	<b>FEI:</b> 1048401 <b>DUNS:</b> 125276147 <b>U.S. License Number:</b> 1836	<b>REASON FOR SUBMISSION</b> Annual Registration	<b>DISTRICT OFFICE:</b> Cincinnati <b>VALIDATED BY FDA:</b> 11/18/2019
<b>LEGAL NAME AND LOCATION:</b>  Kentucky Blood Center, Inc. 10 Stonegate Centre Somerset, KY 42503 USA  606-679-7413	<b>REPORTING OFFICIAL:</b> Kim Turner, Vice President of Quality and Regulatory Affairs Kentucky Blood Center, Inc. 3121 Beaumont Centre Circle  Lexington, KY 40513-1709 USA 859-519-3785 kiturner@kybloodcenter.org		<b>U.S. AGENT:</b>
<b>OTHER NAMES USED IN THIS LOCATION:</b> Central Kentucky Blood Center, Inc.; Kentucky Blood Center - Somerset; Kentucky Blood Center Inc.	<b>TYPE OF OWNERSHIP:</b> CORPORATION  <b>DONOR/RECIPIENT RELATIONSHIP:</b> ALLOGENIC, AUTOLOGOUS, DIRECTED		<b>ESTABLISHMENT TYPE:</b> 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: 010967889 U.S. License Number: 1836	REASON FOR SUBMISSION Annual Registration	DISTRICT OFFICE:Cincinnati VALIDATED BY FDA: 11/18/2019
<b>LEGAL NAME AND LOCATION:</b>  Kentucky Blood Center, Inc. 472 South Mayo Trail Pikeville, KY 41501 USA  606-432-4979	<b>REPORTING OFFICIAL:</b> Kim Turner, Vice President of Quality and Regulatory Affairs Kentucky Blood Center, Inc. 3121 Beaumont Centre Circle  Lexington, KY 40513-1709 USA 859-519-3785 kiturner@kybloodcenter.org		<b>U.S. AGENT:</b>
<b>OTHER NAMES USED IN THIS LOCATION:</b> Central Kentucky Blood Center, Inc.; Kentucky Blood Center - Pikeville; Kentucky Blood Center Inc.	<b>TYPE OF OWNERSHIP:</b> CORPORATION  <b>DONOR/RECIPIENT RELATIONSHIP:</b> ALLOGENIC, AUTOLOGOUS, DIRECTED		<b>ESTABLISHMENT TYPE:</b> 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				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	<b>FEI:</b> 3011192341 <b>DUNS:</b> 109873442 <b>U.S. License Number:</b> 1836	<b>REASON FOR SUBMISSION</b> Annual Registration	<b>DISTRICT OFFICE:</b> Cincinnati <b>VALIDATED BY FDA :</b> 11/18/2019
<b>LEGAL NAME AND LOCATION:</b>  Kentucky Blood Center, Inc. 12905 Shelbyville Rd Suite 4 Louisville, KY 40243 USA  502-290-0537	<b>REPORTING OFFICIAL:</b> Kim Turner, Vice President of Quality and Regulatory Affair: Kentucky Blood Center 3121 Beaumont Centre Circle  Lexington, KY 40513-1709 USA 859-519-3785 kiturner@kybloodcenter.org		<b>U.S. AGENT:</b>
<b>OTHER NAMES USED IN THIS LOCATION:</b> Kentucky Blood Center - Middletown; Kentucky Blood Center, Inc	<b>TYPE OF OWNERSHIP:</b> CORPORATION  <b>DONOR/RECIPIENT RELATIONSHIP:</b> ALLOGENIC, AUTOLOGOUS, DIRECTED		<b>ESTABLISHMENT TYPE:</b> 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	<b>FEI:</b> 3014276808 <b>DUNS:</b> 116918360 <b>U.S. License Number:</b> 1836	<b>REASON FOR SUBMISSION</b> Annual Registration	<b>DISTRICT OFFICE:</b> Cincinnati <b>VALIDATED BY FDA:</b> 11/18/2019
<b>LEGAL NAME AND LOCATION:</b> Kentucky Blood Center, Inc. Kentucky Blood Center, Inc 5406 Antle Drive Suite 101 Louisville, KY 40229 USA  502-915-0989	<b>REPORTING OFFICIAL:</b> Kim Turner, Vice President of Quality and Regulatory Affair: Kentucky Blood Center 3121 Beaumont Centre Circle  Lexington, KY 40513-1709 USA 859-519-3785 kiturner@kybloodcenter.org	<b>U.S. AGENT:</b>	
<b>OTHER NAMES USED IN THIS LOCATION:</b> Kentucky Blood Center - Hillview	<b>TYPE OF OWNERSHIP:</b> CORPORATION  <b>DONOR/RECIPIENT RELATIONSHIP:</b> ALLOGENIC, AUTOLOGOUS, DIRECTED	<b>ESTABLISHMENT TYPE:</b> 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	<b>FEI:</b> 3013450009 <b>DUNS:</b> 096999969 <b>U.S. License Number:</b>	<b>REASON FOR SUBMISSION</b> Annual Registration	<b>DISTRICT OFFICE:</b> Cincinnati <b>VALIDATED BY FDA :</b> 11/18/2019
<b>LEGAL NAME AND LOCATION:</b>  Kentucky Blood Center, Inc. 2605 Kentucky Ave. MP3 Suite 104 Paducah, KY 42003 USA  270-557-7821	<b>REPORTING OFFICIAL:</b> Kim Turner, Vice President of Quality and Regulatory Affair: Kentucky Blood Center, Inc. 3121 Beaumont Centre Circle  Lexington, KY 40513-1709 USA 859-519-3785 kiturner@kybloodcenter.org		<b>U.S. AGENT:</b>
<b>OTHER NAMES USED IN THIS LOCATION:</b> Kentucky Blood Center - Paducah	<b>TYPE OF OWNERSHIP:</b> CORPORATION  <b>DONOR/RECIPIENT RELATIONSHIP:</b>		<b>ESTABLISHMENT TYPE:</b> 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			
RED BLOOD CELLS (RBC)									X			
CRYOPRECIPITATED AHF									X			
PLATELETS									X			
FRESH FROZEN PLASMA									X			

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