

Notification of a change in Laboratory Director must be made **within 60 days** to New York State Department of Health.

**PLEASE RETURN THIS COMPLETED AND SIGNED FORM BY ONE METHOD ONLY:**

**Fax (518) 449-6901 or email [plasma@health.ny.gov](mailto:plasma@health.ny.gov).**

SOURCE PLASMA DONATION CENTER INFORMATION		
SPDC PFI Number: PA ____		
SPDC Name:		
SPDC Address:		
City:	State:	ZIP Code:
FORMER Laboratory Director Name:		
Effective Date of Change:		

**NEW LABORATORY DIRECTOR INFORMATION:** Complete this section in its entirety for the **NEW** individual. Identify the individual who meets the federal requirements to direct the testing for hematocrit and moderate complexity total protein. Laboratory Director is responsible for the overall operation and administration of the laboratory, in accordance with 42 CFR 493.1407. Laboratory Director may direct no more than a total combination of five high and moderate complexity laboratories, including laboratories outside of New York State.

First Name:	M.I.:	Last Name:
Effective Date:	Average Weekly On-site Presence (hours):	
Home Address:		
City:	State:	ZIP Code:
Work E-mail Address:	Work Phone Number:	

**LABORATORY DIRECTOR QUALIFICATION (Check appropriate box and attach supporting documents as indicated)**

- Doctor of Medicine or Osteopathy in New York State** and: 1) certified in Anatomic or Clinical Pathology (or both) or 2) possess qualifications that are equivalent to those required for board certification.  
**\*Attach** copy of New York State license registration AND board certification and board certification renewal (as appropriate); or current eligibility for board certification in Anatomic or Clinical pathology.
- Doctor of Medicine, Osteopathy, Podiatric Medicine in New York State** with at least one year training or experience, or both, in non-waived testing in the specialty of chemistry.  
**\*Attach** copy of New York State license registration AND memorandum attesting to above experience, from the laboratory director where experience was acquired (include CLIA number and types of tests).
- Doctor of Medicine, Osteopathy, Podiatric Medicine in New York State** with at least 20 hours of continued medical education (CME) in laboratory director responsibilities or 20 hours of training in laboratory director responsibilities acquired during medical residency/fellowship training.  
**\*Attach** copy of New York State license registration and proof of 20 hours acquired via CME or residency/fellowship training.
- Earned a **doctoral degree in chemical, physical, biological, or clinical laboratory science** from an accredited institution and be certified by American Board of Medical Microbiology, American Board of Clinical Chemistry, or American Board of Laboratory Immunology.  
**\*Attach** copy of doctorate diploma (and transcript if degree does not list field) and current board certification.
- Earned a **doctoral degree in chemical, physical, biological, or clinical laboratory science** from an accredited institution with least one year experience directing or supervising non-waived testing.  
**\*Attach** copy of doctoral degree (and transcript if degree does not list field) **AND** memorandum attesting to above experience, from the laboratory director where experience was acquired (include CLIA number and types of tests).
- Earned a **master's degree in a chemical, physical, biological, or clinical laboratory science, or medical technology** from an accredited institution with at least one year training or experience (or both) in non-waived testing, and at least one separate year of supervisory laboratory experience in non-waived testing.  
**\*Attach** a copy of master's degree (and transcript if degree does not list major) **AND** memorandum attesting to above experience, from the laboratory director where experience was acquired (include CLIA number and types of tests).
- Earned a **bachelor's degree in a chemical, physical, biological, or clinical laboratory science, or medical technology** from an accredited institution with at least two years training or experience (or both) in non-waived testing and at least two separate years of supervisory laboratory experience in non-waived testing.  
**\*Attach** a copy of bachelor's degree (and transcript if degree does not list major) **AND** memorandum attesting to above experience, from the laboratory director where experience was acquired (include CLIA number and types of tests).

**LABORATORY TECHNICAL CONSULTANT:** The Technical Consultant is responsible for the technical and scientific oversight of the laboratory, in accordance with 42 CFR 493.1413. The Technical Consultant may be the Laboratory Director, if properly qualified.

Will the Laboratory Director also serve as the Technical Consultant?  YES  NO

If NO, please fill out the information below for Technical Consultant.

Name of Technical Consultant:

**TECHNICAL CONSULTANT QUALIFICATION (check appropriate box and attach supporting documents as indicated)**

- Doctor of Medicine or Osteopathy in New York State, and certified in Anatomic or Clinical Pathology** (or both), or possess qualifications that are equivalent to those required for board certification.  
**\*Attach** copy of NYS license registration **AND** board certification and board certification renewal (as appropriate); or current eligibility for board certification in Anatomic or Clinical pathology.
- Doctor of Medicine, Osteopathy, Podiatric Medicine in New York State** with at least one year training or experience, or both, in non-waived testing in the specialty of chemistry.  
**\*Attach** copy of NYS license registration **AND** memorandum attesting to above experience, from the laboratory director where experience was acquired (include CLIA number and types of tests).
- Earned a doctoral degree or master's degree in chemical, physical, biological, or clinical laboratory science or medical technology** from an accredited institution with at least one year laboratory training or experience, or both, in non-waived testing in the specialty of chemistry.  
**\*Attach** copy of doctoral or master's diploma; transcripts if diploma does not state major; **AND** memorandum attesting to above experience, from the laboratory director where experience was acquired (include CLIA number and types of tests).
- Earned a bachelor's degree in a chemical, physical, biological, or clinical laboratory science, or medical technology** from an accredited institution with at least two years training or experience (or both) in non-waived testing in the specialty of chemistry.  
**\*Attach** copy of bachelor's diploma; transcripts if diploma does not state major; **AND** memorandum attesting to above experience, from the laboratory director where experience was acquired (include CLIA number and types of tests).

**CERTIFICATION:**

I understand that by signing this Source Plasma Donation Center Change of Laboratory Director form:

1. Subpart 58-4 of Title 10 (Health) of the Official Compilation of Codes, Rules, and Regulations of the State of New York (NYCRR) establishes regulatory requirements for source plasma donation centers. The source plasma donation center responsible physician and laboratory director shall be jointly responsible for ensuring compliance with the Subpart. The source plasma donation center responsible physician shall be responsible for ensuring compliance with the Code of Federal Regulation (CFR), Title 21, Parts 630 and 640. The laboratory director shall be responsible for ensuring compliance with CFR, Title 42, Part 493.
2. I agree to any investigation made by the Department of Health (Department) to verify or confirm the information provided herein or adjunctive to this application, and any investigation in connection with the registration, a complaint or incident report made known to the Department. Further, I understand that, should this application or my status be investigated at any time, I agree to cooperate in such an investigation and provide the Department with immediate access to all facilities, equipment, records, and personnel as required by the Department to determine compliance with this subdivision.
3. I attest that the information I have given the Department is true and correct, that I have read the relevant rules and regulations, and I accept responsibility for the activities performed at the applying facility.
4. I understand that if the source plasma donation center wishes to perform testing other than hematocrit or total protein for donor eligibility, including all other donor eligibility testing and mandated infectious disease testing on the donated plasma, a New York Clinical Laboratory Permit is required. I further understand that the collection, storage, processing or distribution of a blood component for any purpose other than use as source material for manufacture requires a New York Blood Bank Permit.

**Wet signature only. Signature stamps will not be accepted.**

Date:	Signature, NEW Laboratory Director:	Name, NEW Laboratory Director (Print):
Date:	Signature, Owner/Representative:	Name, Owner/Representative (Print):