

NEW YORK STATE DEPARTMENT OF HEALTH  
 WADSWORTH CENTER  
 CLINICAL LABORATORY EVALUATION PROGRAM  
 EMPIRE STATE PLAZA, P.O. BOX 509  
 ALBANY, NEW YORK 12201-0509  
 Telephone: (518) 485-5378 Fax: (518) 485-5414  
 E-mail: CLEP@health.ny.gov  
 Web: www.wadsworth.org/clep

**FOR OFFICE USE ONLY**

Received \_\_\_\_\_  
 PFI No. \_\_\_\_\_  
 PSC No. \_\_\_\_\_  
 Consultant \_\_\_\_\_  
 Initial/Amendment \_\_\_\_\_  
 Issued Eff. \_\_\_\_\_

## APPLICATION / LOCATION CHANGE FORM FOR PATIENT SERVICE CENTER (PSC)

Complete Sections 1, 2, 3, 4 and 6 of this application and attach a scale floor plan of the PSC that illustrates the relationship between the PSC and any other health services purveyor(s).

### SECTION 1: REASON FOR NOTIFICATION Please check appropriate box.

<input type="checkbox"/> New Expected opening date: _____	<input type="checkbox"/> Change in Location – PSC Number: _____ Effective Date: _____ Former Address: _____
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### SECTION 2: PATIENT SERVICE CENTER (PSC) INFORMATION

NAME OF PARENT LABORATORY:	PFI
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### PATIENT SERVICE CENTER ADDRESS ADDRESS (NUMBER AND STREET)

CITY, TOWN OR VILLAGE	STATE	ZIP CODE	COUNTY
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PSC TELEPHONE NUMBER	PSC FAX NUMBER	<b>DAYS AND HOURS OF OPERATION</b> M _____ to _____ F _____ to _____ Tu _____ to _____ Sa _____ to _____ W _____ to _____ Su _____ to _____ Th _____ to _____
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CONTACT PERSON
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CONTACT TELEPHONE NUMBER
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CONTACT PERSON EMAIL
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### SECTION 3: PERSONNEL

Will or do PSC phlebotomists or other employees of the parent laboratory perform duties for any referring health services purveyor? If so, please describe such duties on a separate sheet. ☐ Yes ☐ No

# APPLICATION/LOCATION CHANGE FORM FOR PATIENT SERVICE CENTER (PSC)

## SECTION 4 – PATIENT SERVICE CENTER SELF-ASSESSMENT

Answer the questions below for each Patient Service Center pending approval.

		Yes	No
1.	Is the PSC located within the offices of, or otherwise share space with, the practice of a physician or other health services purveyor in a position to make referrals of specimens to the laboratory? ("Referral" implies that the health services purveyor is not under the same ownership as the PSC.)		
2.	Is the PSC located in a building in which a physician or other health services purveyor in a position to make referrals to the laboratory has an ownership or investment interest? ("Referral" implies that the health services purveyor is not under the same ownership as the PSC.)		
3.	Is PSC space subleased from a physician or other health services purveyor, i.e., one who has leasehold interest in the building, in a position to make referrals to the laboratory? ("Referral" implies that the health services purveyor is not under the same ownership as the PSC.)?		
4.	Is the PSC located in a building owned or leased by the same laboratory that operates the PSC?		
5.	Do you have a lease/rental agreement? <u>Please enclose a copy of the lease/rental agreement.</u>		
6.	Is the PSC open to the general public?		
7.	Are the hours the PSC is open independent and not restricted to the hours of any health services purveyor indicated in question 1 or 2 above?		
8.	Are specimens drawn from health services purveyors other than those indicated in question 1 or 2 above?		
9.	Does the PSC have its own entrance and exit?		
10.	Does the PSC:		
	(A) have its own waiting area?		
	(B) use a waiting area that is generally shared by all occupants or tenants of the building?		
11.	Do advertisements and notices by the clinical laboratory list the address and phone number of this PSC?		
12.	Does the PSC have its own telephone line, separate and distinct from that of any health care purveyor?		
13.	Do PSC patients referred by health services purveyors other than those in the building have unrestricted access to restrooms?		

		Yes	No
14.	Does the PSC post conspicuously, in the waiting area or other place visible to all visitors, a sign which states:		
	(A) the services at the site are limited to collection of specimens and/or preparation of the specimens for transport;		
	(B) the name and address of the laboratory which will test the specimens;		
	(C) information on billing practices, including the name and address of the establishment from which bills will originate and to which billing questions can be directed.		
15.	Does the PSC:		
	(A) create and maintain a record of the daily accession of specimens containing the following information (except that a fixed station which accepts specimens from a mobile station may use a copy of the mobile station's accession record in lieu of creating its own for specimens provided by the mobile station):		
	(a) the name and address or other identification of the person from whom the specimen was taken;		
	(b) the name and address or other identifier of the licensed physician or other authorized person who requested the test;		
	(c) the date and hour when the specimen was taken;		
	(e) the type of test requested; and		
	(f) the date and hour when each specimen was forwarded to the clinical laboratory for testing;		
16.	(B) forward a copy of the accession record to the clinical laboratory together with the specimens.		
	Does the PSC:		
	(A) have on the premises an operating refrigerator and/or freezer which:		
	(a) maintains appropriate temperature range;		
	(b) is equipped with an accurate thermometer; and		
	(c) shall be used exclusively for the storage of patient specimens for clinical laboratory testing;		
	(B) store each specimen requiring refrigeration in the refrigerator at all times until removed for forwarding to the clinical laboratory;		
17.	(C) store each specimen so as to maintain its original condition as much as possible, and assure that it will not become unsatisfactory as a patient specimen.		
	Does the PSC transport, or arrange for the transportation of:		
	(A) each specimen which requires refrigeration, in a manner that will assure that its temperature will remain within established acceptable range for testing until it reaches the clinical laboratory;		
	(B) all specimens not requiring refrigeration, so as to maintain their original condition as much as possible and assure that they will not become unsatisfactory as patient specimens;		
	(C) all specimens in a manner designed to minimize the likelihood of exposing personnel or the public to any source of infection or hazard.		

			Yes	No
18.	Does the PSC have on its premises:			
	(A) a properly operating centrifuge equipped with a latch-lock lid to prevent release of aerosols;			
	(B) records of centrifuge inspection and preventive maintenance for two years.			
19.	Does the PSC:	NA		
	(A) limit testing to the screening of glucose and/or ketones, if performed prior to the administration of glucose for a glucose tolerance test;			
	(B) have a policy that if sugar or ketones are present, the physician ordering such a test must be advised and the collection of blood for the tests may not be performed without his or her approval, and document this approval in the accession record.			
20.	Does the PSC have available <u>on-site</u> a current standard operating procedure manual (SOPM) that includes:			
	(A) approval for all PSC procedures, changes to PSC procedures and effective date of each procedure by laboratory director's signature and date;			
	(B) specimen accessioning procedures;			
	(C) requirements for collection, preservation and transportation of specimens;			
	(D) procedures for handling specimens and contaminated or potentially contaminated materials or supplies in a manner designed to minimize the likelihood of transmission of infectious agents to personnel and/or to the public;			
	(E) proper sterilization and/or disinfection procedures for contaminated or potentially contaminated materials or surface;			
	(F) a procedure to obtain physicians' approval to collect blood for tests from persons who are found to be positive for glucose and/or ketones in screening tests, if the glucose tolerance test procedure indicates that screening tests are to be conducted prior to collecting blood;	NA		
	(G) procedures concerning all quality control required for glucose screening;	N/A		
	(H) material safety data sheets (MSDS) for all chemicals used by PSC.			
21.	Does the PSC maintain <u>on-site</u> documentation of quality control (QC) for glucose and/or ketones screening test(s) for a period of two (2) years, including:	NA		
	(A) lot number and expiration date of QC materials;			
	(B) lot number and expiration date of testing material;			
	(C) results of the QC materials for each day of use.			
22.	Does the PSC use only collection devices that are within the expiration date. This includes, but is not limited to:			
	(A) vacutainer tubes and/or micro collection devices;			
	(B) preservatives and/or collection devices with preservatives.			

		Yes	No
23	Does the PSC maintain an inventory control system for supplies and reagents that documents, at a minimum, the expiration date and proper storage conditions?		
24	Does the PSC monitor the environmental conditions (e.g., temperature) of supplies and reagents to ensure these materials are maintained in accordance with the manufacturer requirements?		
25.	Do phlebotomists:		
	(A) have the required in-service training concerning confidentiality and safety;		
	(B) have documented training in acceptable specimen collection and storage Procedures <u>which is on-site for review by the Department</u> ;		
	(C) store and/or process specimens to preserve their integrity and reliability for transport;		
	(D) prepare specimens for transportation in a manner that assures maintenance of proper temperature;		
	(E) wear personal protective clothing, such as a lab coat, when performing phlebotomy and/or handling specimens;		
	(F) wash their hands:		
	(a) if their hands are contaminated with specimens;		
	(b) following completion of their duties, such as removal of protective clothing or before leaving the premises;		
	(G) not eat/drink/smoke/apply cosmetics/insert contact lenses in areas where patient specimens are drawn.		
26.	Do phlebotomists promptly place needles or other sharps in puncture-resistant containers specifically for such disposal, and not cut or bend needles or other sharps after use, or reinsert needles into original sheaths before discarding them?		
27.	(A) Will the PSC be monitored or inspected by the laboratory at least annually?		
	(B) Are there documented inspection records available <u>on-site</u> for review by the Department?		

		Yes	No
28.	Does the PSC:		
	(A) dispose of all specimens and contaminated or potentially contaminated materials or supplies in a manner that would minimize the likelihood of transmission of infectious agents to personnel or to the public;		
	(B) store regulated medical waste in a manner and location which affords protection from the environment and limits exposure to the public;		
	(C) <u>arrange for regulated medical waste removal from the premises at least every 60 days, or more frequently if greater than 50 lbs per month is generated;</u>		
	(D) utilize containers for medical waste which have prominent warning signs using the word "Biohazard";		
	(E) dispose of medical waste, except for discarded sharps, in clearly marked bags which are impervious to moisture and have strength sufficient to resist ripping, tearing, or bursting under normal conditions of usage and handling; and secure them in a manner that prevents leakage during storage, transport, or handling;		
	(F) dispose of potentially infectious articles that might cause punctures or cuts in leakproof, rigid, puncture-resistant containers that are secured in a manner to preclude content loss.		
29.	Does the PSC collect specimens requiring chain of custody protocols (i.e. pre-employment, incident/accident related, return-to-work or paternity testing)?		
30.	(A) Has this PSC been inspected by the laboratory prior to opening?		
	(B) Is the inspection record available on-site for review by the Department?		

## SECTION 5 – POLICY FOR REVOKING AN INTERIM APPROVAL TO OPERATE A PATIENT SERVICE CENTER

Approval to operate a Patient Service Center (PSC) or to receive interim approvals may be rescinded when one of the following conditions occurs:

1. When on-site survey identifies that the responses to questions answered on the PSC application and self-assessment were inaccurate or misrepresented and deficiencies are cited as a result;
2. When there is a repeated pattern of deficiencies that indicates the parent laboratory is not routinely monitoring the PSCs to demonstrate compliance with Department requirements;
3. When more than five (5) deficiencies have been cited for any one PSC during a survey event; and
4. A physical and/or structural change has been made to the PSC without notification to the Department such that the original application is no longer reflective of the actual circumstances of the PSC.

## SECTION 6 - SIGNATURE AND ATTESTATION STATEMENT

I declare, subject to the penalties of perjury, that the information in this application (including any attachments) has been examined by me and to the best of my knowledge and belief is true and correct. I understand that the clinical laboratory that operates Patient Service Centers (PSC) is responsible for their operation and that any misrepresentation made in this application by the undersigned may be punishable by revocation or suspension of (a) the approval to operate any PSC described in Section I and (b) the permit of the clinical laboratory making this application. Any such misrepresentation will also be subject to other such penalties as may be provided by law. I also agree that I will notify the Department of any changes to this application, including a change in the expected opening date, within 5 business days of such change.

\_\_\_\_\_  
Date

\_\_\_\_\_  
Name of Owner/Corporation Officer

\_\_\_\_\_  
Signature

\_\_\_\_\_  
Date

\_\_\_\_\_  
Name of Director

\_\_\_\_\_  
Signature