

## Patient Service Center Self-Assessment Questions

<ul style="list-style-type: none"><li>• 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.</li></ul>
<ul style="list-style-type: none"><li>• 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.)</li></ul>
<ul style="list-style-type: none"><li>• 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.)</li></ul>
<ul style="list-style-type: none"><li>• 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.)</li></ul>
<ul style="list-style-type: none"><li>• Is the PSC located in a building owned or leased by the same laboratory that operates the PSC?</li></ul>
<ul style="list-style-type: none"><li>• Do you have a lease/rental agreement? Please upload a copy of the lease/rental agreement using the upload feature on the left of the screen.</li></ul>
<ul style="list-style-type: none"><li>• Is the PSC open to the general public?</li></ul>
<ul style="list-style-type: none"><li>• Are the hours the PSC is open independent and not restricted to the hours of any health services purveyor indicated in question 1, 2 or 3 above?</li></ul>
<ul style="list-style-type: none"><li>• Are specimens drawn from health services purveyors other than those indicated in question 1, 2 or 3 above?</li></ul>
<ul style="list-style-type: none"><li>• Does the PSC have its own entrance and exit?</li></ul>
<ul style="list-style-type: none"><li>• Does the PSC have its own waiting area?</li></ul>
<ul style="list-style-type: none"><li>• Does the PSC use a waiting area that is generally shared by all occupants or tenants of the building?</li></ul>
<ul style="list-style-type: none"><li>• Do advertisements and notices by the clinical laboratory list the address and phone number of this PSC?</li></ul>
<ul style="list-style-type: none"><li>• Does the PSC have its own telephone line, separate and distinct from that of any health care purveyor?</li></ul>
<ul style="list-style-type: none"><li>• Do PSC patients referred by health services purveyors other than those in the building have unrestricted access to restrooms?</li></ul>
<ul style="list-style-type: none"><li>• Does the PSC post conspicuously, in the waiting area or other place visible to all visitors, a sign which states: the services at the site are limited to collection of specimens and/or preparation of the specimens for transport?</li></ul>
<ul style="list-style-type: none"><li>• Does the PSC post conspicuously, in the waiting area or other place visible to all visitors, a sign which states: the name and address of the laboratory which will test the specimens?</li></ul>
<ul style="list-style-type: none"><li>• Does the PSC post conspicuously, in the waiting area or other place visible to all visitors, a sign which states: 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?</li></ul>

<ul style="list-style-type: none"> <li>Does the PSC 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): the name and address or other identification of the person from whom the specimen was taken?</li> </ul>
<ul style="list-style-type: none"> <li>Does the PSC 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): the name and address or other identification of the person from whom the specimen was taken?</li> </ul>
<ul style="list-style-type: none"> <li>Does the PSC 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): the name and address or other identifier of the licensed physician or other authorized person who requested the test?</li> </ul>
<ul style="list-style-type: none"> <li>Does the PSC 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): the date and hour when the specimen was taken?</li> </ul>
<ul style="list-style-type: none"> <li>Does the PSC 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): the type of test requested?</li> </ul>
<ul style="list-style-type: none"> <li>Does the PSC 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): the date and hour when each specimen was forwarded to the clinical laboratory for testing?</li> </ul>
<ul style="list-style-type: none"> <li>Does the PSC forward a copy of the accession record to the clinical laboratory together with the specimens?</li> </ul>
<ul style="list-style-type: none"> <li>Does the PSC have on the premises an operating refrigerator and/or freezer?</li> </ul>
<ul style="list-style-type: none"> <li>Does it maintain appropriate temperature range?</li> </ul>
<ul style="list-style-type: none"> <li>Is it equipped with an accurate thermometer?</li> </ul>
<ul style="list-style-type: none"> <li>Is it used exclusively for the storage of patient specimens for clinical laboratory testing?</li> </ul>
<ul style="list-style-type: none"> <li>Does the PSC store each specimen requiring refrigeration in the refrigerator at all times until removed for forwarding to the clinical laboratory?</li> </ul>
<ul style="list-style-type: none"> <li>Does the PSC 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?</li> </ul>
<ul style="list-style-type: none"> <li>Does the PSC transport, or arrange for the transportation of 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?</li> </ul>
<ul style="list-style-type: none"> <li>Does the PSC transport, or arrange for the transportation of 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?</li> </ul>

<ul style="list-style-type: none"> <li>Does the PSC transport, or arrange for the transportation of all specimens in a manner designed to minimize the likelihood of exposing personnel or the public to any source of infection or hazard?</li> </ul>
<ul style="list-style-type: none"> <li>Does the PSC have on its premises a properly operating centrifuge equipped with a latch-lock lid to prevent release of aerosols?</li> </ul>
<ul style="list-style-type: none"> <li>Does the PSC have on its premises records of centrifuge inspection and preventive maintenance for two years?</li> </ul>
<ul style="list-style-type: none"> <li>Does the PSC limit testing to the screening of glucose and/or ketones, if performed prior to the administration of glucose for a glucose tolerance test?</li> </ul>
<ul style="list-style-type: none"> <li>Does the PSC 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?</li> </ul>
<ul style="list-style-type: none"> <li>Does the PSC have available on-site a current standard operating procedure manual (SOPM) that includes approval for all PSC procedures, changes to PSC procedures and effective date of each procedure by laboratory director's signature and date?</li> </ul>
<ul style="list-style-type: none"> <li>Does the PSC have available on-site a current standard operating procedure manual (SOPM) that includes specimen accessioning procedures?</li> </ul>
<ul style="list-style-type: none"> <li>Does the PSC have available on-site a current standard operating procedure manual (SOPM) that includes requirements for collection, preservation and transportation of specimens?</li> </ul>
<ul style="list-style-type: none"> <li>Does the PSC have available on-site a current standard operating procedure manual (SOPM) that includes 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?</li> </ul>
<ul style="list-style-type: none"> <li>Does the PSC have available on-site a current standard operating procedure manual (SOPM) that includes proper sterilization and/or disinfection procedures for contaminated or potentially contaminated materials or surface?</li> </ul>
<ul style="list-style-type: none"> <li>Does the PSC have available on-site a current standard operating procedure manual (SOPM) that includes a procedure to obtain physicians' approval to collect blood for tests from persons</li> </ul>
<ul style="list-style-type: none"> <li>Does the PSC have available on-site a current standard operating procedure manual (SOPM) that includes procedures concerning all quality control required for glucose screening?</li> </ul>
<ul style="list-style-type: none"> <li>Does the PSC have available on-site a current standard operating procedure manual (SOPM) that includes material safety data sheets (MSDS) for all chemicals used by PSC?</li> </ul>
<ul style="list-style-type: none"> <li>Does the PSC maintain on-site documentation of quality control (QC) for glucose and/or ketones screening test(s) for a period of two (2) years, including lot number and expiration date of QC materials?</li> </ul>
<ul style="list-style-type: none"> <li>Does the PSC maintain on-site documentation of quality control (QC) for glucose and/or ketones screening test(s) for a period of two (2) years, including lot number and expiration date of testing material?</li> </ul>
<ul style="list-style-type: none"> <li>Does the PSC maintain on-site documentation of quality control (QC) for glucose and/or ketones screening test(s) for a period of two (2) years, including results of the QC materials for each day of use?</li> </ul>
<ul style="list-style-type: none"> <li>Does the PSC use only collection devices that are within the expiration date. This includes, but is not limited to vacutainer tubes and/or micro collection devices?</li> </ul>
<ul style="list-style-type: none"> <li>Does the PSC use only collection devices that are within the expiration date. This includes, but is not limited to preservatives and/or collection devices with preservatives?</li> </ul>

<ul style="list-style-type: none"> <li>• Does the PSC maintain an inventory control system for supplies and reagents that documents, at a minimum, the expiration date and proper storage conditions?</li> </ul>
<ul style="list-style-type: none"> <li>• 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?</li> </ul>
<ul style="list-style-type: none"> <li>• Do phlebotomists have the required in-service training concerning confidentiality and safety?</li> </ul>
<ul style="list-style-type: none"> <li>• Do phlebotomists have documented training in acceptable specimen collection and storage procedures which is on-site for review by the Department?</li> </ul>
<ul style="list-style-type: none"> <li>• Do phlebotomists store and/or process specimens to preserve their integrity and reliability for transport?</li> </ul>
<ul style="list-style-type: none"> <li>• Do phlebotomists prepare specimens for transportation in a manner that assures maintenance of proper temperature?</li> </ul>
<ul style="list-style-type: none"> <li>• Do phlebotomists wear personal protective clothing, such as a lab coat, when performing phlebotomy and/or handling specimens?</li> </ul>
<ul style="list-style-type: none"> <li>• Do phlebotomists wash their hands if their hands are contaminated with specimens?</li> </ul>
<ul style="list-style-type: none"> <li>• Do phlebotomists wash their hands following completion of their duties, such as removal of protective clothing or before leaving the premises?</li> </ul>
<ul style="list-style-type: none"> <li>• Do phlebotomists not eat/drink/smoke/apply cosmetics/insert contact lenses in areas where patient specimens are drawn?</li> </ul>
<ul style="list-style-type: none"> <li>• 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?</li> </ul>
<ul style="list-style-type: none"> <li>• Will the PSC be monitored or inspected by the laboratory at least annually?</li> </ul>
<ul style="list-style-type: none"> <li>• Are there documented inspection records available on-site for review by the Department?</li> </ul>
<ul style="list-style-type: none"> <li>• Does the PSC 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?</li> </ul>
<ul style="list-style-type: none"> <li>• Does the PSC store regulated medical waste in a manner and location which affords protection from the environment and limits exposure to the public?</li> </ul>
<ul style="list-style-type: none"> <li>• Does the PSC 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?</li> </ul>
<ul style="list-style-type: none"> <li>• Does the PSC utilize containers for medical waste which have prominent warning signs using the word "Biohazard"?</li> </ul>
<ul style="list-style-type: none"> <li>• Does the PSC 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?</li> </ul>
<ul style="list-style-type: none"> <li>• Does the PSC 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?</li> </ul>
<ul style="list-style-type: none"> <li>• Does the PSC collect specimens requiring chain of custody protocols (i.e. pre-employment, incident/accident related, return-to-work or paternity testing)?</li> </ul>
<ul style="list-style-type: none"> <li>• Has this PSC been inspected by the laboratory prior to opening?</li> </ul>
<ul style="list-style-type: none"> <li>• Is the inspection record available on-site for review by the Department?</li> </ul>