

You should be able to answer "yes" to each question. This list will be utilized as part of our inspection checklist.

Compliance Checklist

This assessment program must be operated per Section 1244 of the California Business and Professions Code. Use the following checklist to ensure that your program is operating legally:

- | YES | NO | |
|--------------------------|--------------------------|--|
| <input type="checkbox"/> | <input type="checkbox"/> | 1. This program will be a Nondiagnostic General Health Assessment program, whose purpose will be to refer individuals to licensed sources of care as indicated. |
| <input type="checkbox"/> | <input type="checkbox"/> | 2. This program will utilize only those devices which comply with all of the following: <ul style="list-style-type: none"> A. Meet applicable state and federal performance standards pursuant to Section 2 of the Health and Safety Code. B. Are not adulterated as specified in Article 2 (commencing with Section 26610) of Chapter 6 of Division 21 of the Health and Safety Code. C. Are not misbranded as specified in Article 3 (commencing with Section 26630) of Chapter 6 of Division 21 of the Health and Safety Code. D. Are not new devices unless they meet the requirements of Section 26670 of the Health and Safety Code. |
| <input type="checkbox"/> | <input type="checkbox"/> | 3. This program maintains a supervisory committee consisting of at a minimum, a California licensed physician and surgeon and a laboratory technologist licensed pursuant to the California Business and Professions Code. |
| <input type="checkbox"/> | <input type="checkbox"/> | 4. The supervisory committee for the program has adopted written protocols which shall be followed in the program. Written protocols & other required documentation is available testing sites. |
| <input type="checkbox"/> | <input type="checkbox"/> | 5. The protocols contain provision of written information to individuals to be assessed. |
| <input type="checkbox"/> | <input type="checkbox"/> | 6. Written information to individuals includes the potential risks and benefits of assessment procedures to be performed in the program. |
| <input type="checkbox"/> | <input type="checkbox"/> | 7. The written information includes the limitations, including the nondiagnostic nature, of assessment examinations of biological specimens performed in the program. |
| <input type="checkbox"/> | <input type="checkbox"/> | 8. The written information includes information regarding the risk factors or markers targeted by the program. |
| <input type="checkbox"/> | <input type="checkbox"/> | 9. The written information includes the need for follow up with licensed sources of care for confirmation, diagnosis, and treatment as appropriate. |
| <input type="checkbox"/> | <input type="checkbox"/> | 10. The written protocols contain the proper use of each device utilized in the program including operation of analyzers, maintenance of equipment and supplies, and performance of quality control procedures including the determination of both accuracy and reproducibility of measurements in accordance with instructions provided by the manufacturer of the assessment device used. |
| <input type="checkbox"/> | <input type="checkbox"/> | 11. The written protocols contain the proper procedures to be employed when collecting blood samples, if blood specimens are to be obtained. |
| <input type="checkbox"/> | <input type="checkbox"/> | 12. The written protocols contain proper procedures to be employed in handling and disposing of all biological specimens to be obtained and material contaminated by those biological specimens. |
| <input type="checkbox"/> | <input type="checkbox"/> | 13. The written protocols contain proper procedures to be employed in response to fainting, excessive bleeding, or other medical emergencies. |
| <input type="checkbox"/> | <input type="checkbox"/> | 14. The written protocols contain procedures for reporting of assessment. |
| <input type="checkbox"/> | <input type="checkbox"/> | 15. The written protocols contain procedures for referral and follow up to licensed sources of care as indicated. |
| <input type="checkbox"/> | <input type="checkbox"/> | 16. All individuals performing the skin puncture are authorized to do so under and/or the Business and Professions Code.
(or) All individuals performing skin puncture possess a signed statement signed by a California licensed physician and surgeon which attests that the named person has received adequate training in the proper procedure to be employed in skin puncture. |
| <input type="checkbox"/> | <input type="checkbox"/> | 17. Testing institution is registered with County & County has been notified of even using provided forms. |