Medical Laboratories Supplement

Note: Supplement must be dated and signed by owner, partner, officer, or administrator.

Please type or print in ink.

1. Applicant Name (including DBAs): ____________________

2. Describe fully the operations, activities, services, and professional procedures administered:
____
____

3. Attach a list by major category of all tests performed in the last annual period. Indicate percentage breakdown of all tests by type.

4. Employees:
_______Total Number of Full-time (including all employees)
_______Total Number of Part-time (including all employees)
_______Number/FTE Professional Type
_______Physicians employed (other than Medical Director)*
_______Physicians contracted (attach copy of contract)*
_______Bioanalysts
_______Cytotechnicians
_______Technologist
_______Technologist-trainee
_______Other; Describe: ____________________
*If any, please complete Physician's Exposure Supplement

5. Does the laboratory own or operate any mobile laboratories? _______ Yes _______No
If yes, indicate manufacturer and the gross receipts from each unit: ____________________
____

6. Is your facility owned by an M.D.? _______ Yes _______No
If yes, owner name(s) ____________________
If yes, indicate annual number and % of facility total that represents the owner's patient's tests: _______# _______%

7. If the answer to any part of this question is yes, attach a separate sheet and provide the following details: specific tests performed, number of tests performed per year, and percentage of gross annual receipts.
a) Are you involved in any blood banking or crossmatching? _______ Yes _______No
b) Are you involved in any intravenous transfusion or in the procurement of blood and/or its components? _______ Yes _______No
c) Are you involved in any medical, genetic, or drug research? _______ Yes _______No
d) Are you involved in the manufacturing, dispensing, or testing of pharmaceuticals? _______ Yes _______No
e) Do you manufacture and/or sell laboratory equipment or supplies? _______ Yes _______No
f) Do you perform any type of environmental analyses? _______ Yes _______No
g) Are you involved in any services open to the public (health fairs, shopping mall exhibits)? _______ Yes _______No
h) Do you send tests to reference labs? _______ Yes _______No
If yes, please state % of receipts: ____________________
Reference lab name: ____________________
Location: ____________________

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8. Does your staff perform arterial sticks? _______ Yes ______No
   If yes, who performs? ____
   ____
   If yes, what restrictions and precautions are utilized? ____
   ____

9. Does your staff perform Pap smears? _______ Yes ______No
   If yes, who performs the test?_____________
   If yes, who reads and interprets the results? ______________

10. Does the applicant provide drug screening for any entity? _______ Yes ______No
    If yes, please attach copies of all applicable contract types and a copy of the applicant's policy on confidentiality.

11. Does the applicant perform HIV testing? _______ Yes ______No
    If yes, please attach consent/disclosure form, copies of any contracts, and the applicant's policy on confidentiality.

12. Are biopsies performed by the applicant? _______ Yes ______No
    If yes, specify type and number: ____

13. Does applicant prepare any immunological, pharmaceutical, or similar agents? _______ Yes ______No
    If yes, describe: ____

14. Does your facility manufacture or distribute any "test kits" used by others, including any "home test kits"? _______ Yes ______No
    If yes, describe in detail each type of kit, indicate gross receipts for each type of kit, and specify which kits your facility manufactures: ____
    ____

15. Are test results interpreted or diagnosed by applicant? _______ Yes ______No
    If yes, who diagnoses/interprets? ____

16. Are diagnoses made by any non-physician members of your staff? _______ Yes ______No
    If yes, please provide, on a separate sheet, their qualifications and who else reviews the diagnoses.

17. Are any patients ever present at the laboratory premises for the purpose of testing, obtaining specimens, or any other reason? _______ Yes ______No
    If yes, are any of the patient transfers from a health care facility? _______ Yes ______No
    If yes, who is responsible for these patients while they are on your premises?
    ___ Your staff ___ Accompanying staff

18. Describe the occupied building fully, including: Age _________ Construction _______ No. of stories _________
    Last remodeled ______________ Sprinklered: __ Fully __ Partially __ None
    Smoke Alarms ______________ Fire Alarms ______________________________

19. Does applicant provide any services under contract? _______ Yes ______No
    If yes, attach explanation and a copy of the contract.

20. Does applicant, or any agency or association on its behalf, advertise its professional services in any manner other than a simple listing in the telephone directory? _______ Yes ______No
    If yes, attach a copy of all advertisements.

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21. Is your facility owned by, or operated in, a hospital? _______ Yes ______No
If yes, which hospital? ____

22. Name, qualifications, and number of years of experience of the Medical Director, all managers, and supervisors:

Name	Title	Experience/Training	Association Membership

23. Are your technologist graduates of medical technology programs? _______ Yes ______No
If not, indicate exceptions and cite qualifications: ______________________________

24. Is your facility eligible for certification or accreditation? _______ Yes ______No
If yes, is applicant certified and/or accredited? _______ Yes ______No
If yes, by whom? ____
If no, explain the reason: ____

25. Describe the method and frequency of internal quality assurance screens of test results: __________________
____

26. Are random tests performed to audit false positive results? _______ Yes ______No
False negatives? _______ Yes ______No
If no, to either question, please explain the reason: ______________________________
____

27. How long does your lab retain blood, tissue, other specimens for future reference? ______________________
____

28. What professional organization's standards are followed by your lab? ______________________
____

29. How frequently are reagents checked? ____

30. Who calibrates the precision equipment in your facility? ______________________________
What is the frequency of those calibrations? ______________________________

31. Who services and maintains the precision equipment in your facility? ______________________
What is the frequency of servicing? ______________________________

32. Are logs kept of the calibration and servicing of precision instruments? _______ Yes ______No

33. Is your staff trained in CPR? _______ Yes ______No

34. Describe the referral source(s) by which patients are directed to the entity.
____

__________________________ Date

__________________________ Applicant Signature/Title

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