# Request for Confirmatory Laboratory Approval

# Private Sector Drug Testing

## Self-Inspection Checklist

## Application for Approval

## Laboratory Personnel Report

## Laboratory Personnel Appraisal Form

Iowa Department of Public Health
Division of Behavioral Health
Private Sector Drug Testing Program
Lucas State Office Building
321 E. 12th Street
Des Moines, Iowa 50319-0075
(515) 242-6162

# Self-Inspection Checklist

**Extent of Services**

1. List below the alcohol or other drugs or their metabolites for which confirmatory testing is conducted in your laboratory:

2. Check the types of samples that can be analyzed in your laboratory:
   ☐ Urine ☐ Breath ☐ Blood ☐ Saliva/Oral Fluid

3. Laboratory facilities consist of _____ rooms, with a total floor space of _____ square feet.

4. Type of laboratory (check only one principle type):

   ☐ state institution ☐ government

   ☐ hospital ☐ commercial

5. If applicable, work is also done for:

   ☐ cities and towns ☐ hospitals

   ☐ counties ☐ private physicians

   ☐ industries (via company physicians)

   ☐ others (explain)_____

6. Approximate number of samples for which confirmatory testing is conducted on an annual basis:

   _____ samples per year.

**Personnel**

7. Does your laboratory have job descriptions for all technical and non-technical personnel?

   ☐ Yes ☐ No

8. Does your laboratory provide, or arrange for, in-service continuing education programs related to alcohol or drug testing to laboratory directors, supervisors, and analysts on an annual basis?

   ☐ Yes ☐ No

9. Does the laboratory director provide annual evaluations for personnel?

   ☐ Yes ☐ No

10. Name of the Medical Review Officer (MRO) and MRO Certification Details_____

**Quality Assurance**

11. Is your laboratory enrolled in a recognized proficiency testing program?

    ☐ Yes ☐ No

12. Is there a written "Quality Assurance Plan" that encompasses all aspects of the alcohol or drug testing process?

    ☐ Yes ☐ No

13. Does the "Quality Assurance Plan" provide for written standard operating procedure manuals that are reviewed annually for all confirmatory tests conducted?

    ☐ Yes ☐ No

14. Do the written procedure manuals address the following:

| | | |
|---|---|---|
| a. Sample acquisition | ☐ Yes | ☐ No |
| b. Chain of custody protocols | ☐ Yes | ☐ No |
| c. Sample and Report security | ☐ Yes | ☐ No |
| d. Test performance | ☐ Yes | ☐ No |
| e. Reporting of test results | ☐ Yes | ☐ No |
| f. Confidentiality protocols | ☐ Yes | ☐ No |
| g. Confirmation procedures | ☐ Yes | ☐ No |
| h. Detection and rejection of adulterated samples | ☐ Yes | ☐ No |

14. Does the chain of custody documentation for each sample address:

| | | | | |
|---|---|---|---|---|
| a. | Collection & identification of samples | ☐ | Yes | ☐ No |
| b. | Person(s) handling or transferring samples | ☐ | Yes | ☐ No |
| c. | Person(s) receiving or testing samples | ☐ | Yes | ☐ No |
| d. | Time & date of transfer or testing of samples | ☐ | Yes | ☐ No |
| e. | Recipient of destination of samples | ☐ | Yes | ☐ No |
| f. | Storage of samples | ☐ | Yes | ☐ No |
| g. | Disposal of samples | ☐ | Yes | ☐ No |

15. Are "positive" and "negative" controls used in testing each batch of specimens?
☐ Yes ☐ No

Specify approximate batch size_____.

16. Is there a procedure to assure against carryover from a positive specimen to present contamination of subsequent specimens in a test batch?
☐ Yes ☐ No

17. Is there documentation of remedial action in response to controls that exceed defined tolerance limits?
☐ Yes ☐ No

**Equipment**

18. Is there a schedule to regularly check the critical operating characteristics of all laboratory equipment?
☐ Yes ☐ No

19. Is there a schedule to regularly check the critical operating characteristics of all instruments and laboratory equipment?
☐ Yes ☐ No

20. Are all temperature-controlled spaces monitored and are temperature readings documented?
☐ Yes ☐ No

21. Indicate below the essential equipment used by your laboratory:

☐ Balance make & model_____

☐ Refrigerator make & model_____

☐ Other (specify)_____ make & model_____

☐ Other (specify)_____ make & model_____

**Testing**

22. Are all confirmatory tests for drugs or their metabolites (other than alcohol) confirmed by gas chromatography/mass spectrometry before being reported as positive or negative to the medical review officer?

    ☐ Yes ☐ No

23. Type of GC/MS instrumentation: Make_____

    Model_____

    Year_____

24. Are all confirmatory tests for alcohol confirmed by gas chromatography before being reported as positive or negative to the medical review officer?

    ☐ Yes ☐ No

25. Does your laboratory have available a written summary of the established sensitivity levels used for the confirmatory tests conducted for alcohol or other drugs or their metabolites?

    ☐ Yes ☐ No

26. If the first portion of a split sample yields a confirmed positive test result, will your laboratory store the second portion of that sample until receipt of a confirmed negative test result or for a period of at least forty-five calendar days following completion of the initial confirmatory testing?

    ☐ Yes ☐ No

27. Will all samples with a negative test result be disposed of by your laboratory within five working days after issuance of the negative test result report?

    ☐ Yes ☐ No

28. Are urine and blood samples retained in secure storage at freezing temperatures?

    ☐ Yes ☐ No

29. Does your laboratory retain documentation for a period of at least two years for the following:

Chain of custody documentation for:

| | | | | | |
|---|---|---|---|---|---|
| a. | Each sample tested | ☐ | Yes | ☐ | No |
| b. | Identification of the sample | ☐ | Yes | ☐ | No |
| c. | Person(s) handling and testing the sample | ☐ | Yes | ☐ | No |
| d. | Storage of the sample | ☐ | Yes | ☐ | No |
| e. | Disposal of the sample | ☐ | Yes | ☐ | No |

Documents regarding:

| | | | | | |
|---|---|---|---|---|---|
| a. | Analytical information for each batch assayed | ☐ | Yes | ☐ | No |
| b. | Instrument identification | ☐ | Yes | ☐ | No |
| c. | Calibration records | ☐ | Yes | ☐ | No |
| d. | Identification of regent lot numbers and expiration dates | ☐ | Yes | ☐ | No |
| e. | Quality control results | ☐ | Yes | ☐ | No |
| f. | Any other pertinent information | ☐ | Yes | ☐ | No |

**Reporting of Test Results**

30. Are all test results reviewed and signed by the laboratory director or a qualified designee before being reported to the medical review officer?

☐ Yes ☐ No

31. Are there written procedures for making both written and telephone reports to the medical review officer?

☐ Yes ☐ No

32. Will test results be reported as:

| | | | | |
|---|---|---|---|---|
| a. | Positive/negative? | ☐ | Yes | ☐ No |
| b. | Detected/non-detected? | ☐ | Yes | ☐ No |

33. Will each report identify the alcohol or other drugs or their metabolites for which the sample was being tested?

☐ Yes ☐ No

## Application for Approval

Laboratory Name:_____

Lab Address (number & street):_____

City:_____ State:_____ Zip Code_____

Laboratory Director's Name:_____

Phone number (include area code):_____

Fax Number (include area code):_____

Contact Person (if different from lab director):_____

Phone number (include area code):_____

Fax Number (include area code):_____

CLIA License Number:_____

Comments:

_____

_____

Signature of Laboratory Director Date

## Laboratory Personnel Report

(make additional copies of this page as necessary)

Laboratory Name:_____

Laboratory Address (number & street):_____

City:_____ State:_____ Zip Code_____

List all personnel serving as a Director, Supervisor, or Analyst in the laboratory.

D = Director S = Supervisor A = Analyst

| Last Name, First Name Middle Initial | Functioning As: (circle appropriate letter) |
|---|---|
| _____ | D S A |
| _____ | D S A |
| _____ | D S A |
| _____ | D S A |
| _____ | D S A |
| _____ | D S A |
| _____ | D S A |
| _____ | D S A |
| _____ | D S A |
| _____ | D S A |

_____ _____

Signature of Laboratory Director Date

## Laboratory Personnel Report

(make additional copies of this page as necessary)

Laboratory personnel employed by a lab seeking approval to conduct confirmatory testing of samples for the detection of alcohol or other drugs, or their metabolites in Iowa employees or prospective employees must qualify pursuant to Iowa Administrative Code 641, Chapter 12, *Approval of Confirmatory Laboratories for Private Sector Drug-Free Workplace Testing.*

Name (last, first, middle)_____

Maiden Name if Married:_____

Home Address:_____

City:_____ State:_____ Zip Code_____

Present Employer (name & address)_____

_____

_____

Present laboratory position: ☐ Director ☐ Supervisor ☐ Analyst

Employment status: ☐ Full Time ☐ Part Time:_____hours per week

Education: ☐ High School Graduation/Equivalent ☐ Collage/University

| Name and Address of Institution(s) Attended | Dates Attended | | Major Area of Study | Degree or Diploma Received |
|---|---|---|---|---|
| | From mo/yr | To mo/yr | | |
| | | | | |
| | | | | |

| | | | | |
|---|---|---|---|---|
| | | | | |

**Laboratory Training**

| Name and Address of Training Institution(s) | Dates Attended | | Title of Training Program | Degree or Diploma Received |
|---|---|---|---|---|
| | From mo/yr | To mo/yr | | |
| | | | | |
| | | | | |
| | | | | |

Laboratory Experience (from earliest employment since education/training to the present)

| Name and Address of Laboratory(s) or Institution(s) | Employment Dates | | Title of Position Held |
|---|---|---|---|
| | From mo/yr | To mo/yr | |
| | | | |
| | | | |
| | | | |

Licensure/Certification **(Directors only)**

| Name and Address or Certifying Agency | Date Awarded Month & Year | License / Certificate Number |
|---|---|---|
| | | |
| | | |
| | | |

I certify that all statements of this from are true, complete and correct to the be of my knowledge and belief, and are made in good faith.

Signature Date