

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
G. Dean Austin
Division of Behavioral Health
Private Sector Drug Testing Program
Lucas State Office Building
321 E. 12th Street
Des Moines, Iowa 50319-0075
(515) 242-6514

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

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 | <input type="checkbox"/> | Yes | <input type="checkbox"/> | No |
| b. Identification of the sample | <input type="checkbox"/> | Yes | <input type="checkbox"/> | No |
| c. Person(s) handling and testing the sample | <input type="checkbox"/> | Yes | <input type="checkbox"/> | No |
| d. Storage of the sample | <input type="checkbox"/> | Yes | <input type="checkbox"/> | No |
| e. Disposal of the sample | <input type="checkbox"/> | Yes | <input type="checkbox"/> | No |

Documents regarding:

- | | | | | |
|---|--------------------------|-----|--------------------------|----|
| a. Analytical information for each batch assayed | <input type="checkbox"/> | Yes | <input type="checkbox"/> | No |
| b. Instrument identification | <input type="checkbox"/> | Yes | <input type="checkbox"/> | No |
| c. Calibration records | <input type="checkbox"/> | Yes | <input type="checkbox"/> | No |
| d. Identification of reagent lot numbers and expiration dates | <input type="checkbox"/> | Yes | <input type="checkbox"/> | No |
| e. Quality control results | <input type="checkbox"/> | Yes | <input type="checkbox"/> | No |
| f. Any other pertinent information | <input type="checkbox"/> | Yes | <input type="checkbox"/> | 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? | <input type="checkbox"/> | Yes | <input type="checkbox"/> | No |
| b. Detected/non-detected? | <input type="checkbox"/> | Yes | <input type="checkbox"/> | 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 form are true, complete and correct to the best of my knowledge and belief, and are made in good faith.

Signature

Date