## PURPOSE:

To provide a guideline for reporting a laboratory result, the submission of a statistical summary annually and the review of invalid test results.

## LEVEL:

Drug Testing Personnel

## POLICY:

### GUIDELINES FOR REPORTING A LABORATORY RESULT:

1 All specimen submitted shall have a corresponding laboratory result issued within 15 days.
2 A positive result shall be based on an initial and confirmatory drug test.
3 An adulterated or substituted test result shall be based on an initial and confirmatory validity test.
4 All confirmatory drug test results shall specify the concentration of the drug or metabolites.
5 All laboratory reports shall bear the signature of the Analyst and the Head of the Laboratory.
6 All test results shall be reported using the DOH standard electronic laboratory report. The electronic report shall be transmitted in a manner that ensures the confidentiality and security of the information.
7 A laboratory must fax, mail, or transmit a scanned image of a completed Copy 1 of the CCF to the BHFS when the result is reported as either positive for a specific drug, adulterated, substituted, rejected for testing, or an invalid result.
8 No result can be relayed through telephone.

## STATISTICAL SUMMARY OF THE LABORATORY REPORT:

1 A laboratory shall submit annually to the BHFS a report containing the following:

1.1 The total number of specimens received and examined as classified according to:

1.1.1 Mandatory

1.1.2 Random

1.1.3 Other reasons

1.2 The number of specimens that were reported as:

1.2.1 Positive for each drug

1.2.2 Adulterated

1.2.3 Substituted

1.2.4 Rejected for Testing

1.2.5 Invalid Result

1.3 The number of specimens sent for confirmatory testing (for the screening laboratory)

2 The report shall be submitted to the BHFS by mail, fax, or email within 10 working days after the end of the year.

## REVIEWING A POSITIVE, ADULTERATED, SUBSTITUTED OR INVALID TEST RESULT:

1 Prior to making a final decision on a specimen that has been reported positive, adulterated, substituted, or an invalid test result by the laboratory, the Head of the Laboratory shall:

1.1 Allow the donor to explain any circumstances leading to the test result.

1.2 Evaluate alternative medical explanations for the positive test result.

1.3 Review current medical records of the donor that could have resulted from taking legally prescribed medication.

2 When the laboratory reports an invalid result due to the possible presence of interfering substance or adulterant, the Head of the Laboratory shall:

2.1 Send the specimen to another DOH-licensed and accredited laboratory capable of identifying the interfering substance/adulterant;

2.2 Report the result as "Test Canceled" if the explanation provided by the donor is:

2.2.1 If accepted, then an immediate direct observed collection is not required.

2.2.2 If that is not acceptable, then an immediate direct observed collection is required.

**ON TESTING FOR ADDITIONAL DRUGS:**

Requesting a test for drugs other than those stated in the license can be done. However, the donor must be informed that the specimen is not being tested under the guidelines and the procedures are not subject to review by NRL.

**ON REQUESTING FOR A RE-TEST OF SPECIMEN:**

1. For a confirmed positive, adulterated, or substituted result reported, a donor may request through the Head of the Laboratory that the same specimen be re-tested at another DOH-licensed and accredited confirmatory laboratory to verify the result.
2. The donor has 72 hours from the time of notification of a positive, adulterated, or substituted result to request a re-test.

**ON DONOR'S REQUEST FOR OTHER DOCUMENTS:**

The donor must submit a written request addressed to the Head of the Drug Testing Laboratory to obtain a certified true copy of the Chain of Custody and pertinent analytical data.

**ON CHALLENGE TEST:**

1 After the result has been reported by the Drug Testing Laboratory, a donor has the right to request through the Head of the Laboratory that the specimen be re-tested at another DOH-licensed and accredited confirmatory laboratory.

2 A donor shall submit a written request addressed to the Head of the Laboratory within 15 days from receipt of the result.
Note: NRL shall test to resolve any conflicting and unsatisfactory results.

3 Specimen used for challenge. A portion of the original specimen submitted shall be used as a challenge.

4 Persons present during the challenge.
- 4.1 The donor or an authorized representative
- 4.2 The Analyst who conducted the examination that produced the rest in question. In the absence of the analyst, the Head of the Drug Testing Laboratory shall be present.

5 Conditions to challenge a test:
- 5.1 The testing of a challenge test for a drug or metabolite is not subject to the testing cut-off concentrations established for the original testing of a specimen.
- 5.2 The laboratory is only required to provide data that is sufficient to confirm the presence of the drug or metabolite that was reported to be present in the primary specimen.
- 5.3 If the second laboratory fails to reconfirm the presence of the drug or drug metabolite that was reported by the first laboratory, the second laboratory shall conduct validity tests in an attempt to determine the reason for being unable to reconfirm the presence of the drug or drug metabolite. The second laboratory shall conduct the same validity tests as it would conduct on a primary specimen and report those results to the Head of the Laboratory. If the second laboratory fails to determine that the challenge test is adulterated or substituted, the Head of the Laboratory may request the second laboratory to transmit the challenge test to another DOH-licensed and accredited laboratory for further testing. If adulterated or substituted,

the Head of the Laboratory must direct the primary laboratory to test the primary specimen for the adulterant or substitution that was identified by the second laboratory for the challenge test.

6 The challenged test result can only be released to the requesting party.

7 Requirements for handling, transport, and storage of challenged specimens

7.1 Handling and transport

7.1.1 Collection devices and procedures

7.2 Storage Requirement

7.2.1 Shall maintain the required conditions appropriate for each type of specimen.

**APPROVAL:**

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