



---

## TABLE OF CONTENTS

Table of Contents .....	1
Revision History .....	2
Active Deviations.....	2
01 Overview.....	3
OSD-TST-01 Standard Operating Procedures: Evidential Breath Alcohol Testing.....	3
02 Forms.....	9
Directory of Forms .....	9
Breath Alcohol Testing Reference Solution Lot Preparation Notes.....	9
Directory of Workbooks .....	9
Solution Traceability Worksheet.....	9



### REVISION HISTORY

Effective Date	Brief Description of Change(s)
10/17/2022	Original Issue Previous revision history for individual chapters included in archived documents

### ACTIVE DEVIATIONS

This list reflects deviations that are active as of 10/18/2022.

Deviation	Related Chapter(s)	Deviation From
<a href="#">Dev-BAL-OSD-TST-01-2022-1017</a>	OSD-TST-01	Policy



## 01 OVERVIEW

### OSD-TST-01 STANDARD OPERATING PROCEDURES: EVIDENTIAL BREATH ALCOHOL TESTING [\[DEVIATION\]](#)

#### 1 Scope

To describe evidential breath alcohol testing program policies and procedures for instrument testing and location management, reference solution traceability, and record keeping.

#### 2 Related Documents

CRM Manual: Use of the CRM Laboratory for the Production of Breath Alcohol Testing Reference Solutions

#### 3 Terms

##### 3.1 Definitions

**ABA** – An instrument testing sequence which analyzes a series of air blanks (A) and breath samples (B).

**ACA** – An instrument testing sequence which analyzes a series of air blanks (A) and vapor samples (C).

**Adjustment** – A set of operations carried out on a measuring system so that it provides prescribed indications corresponding to given values of the quantity to be measured.

**Certified reference material (CRM)** – Reference material characterized by a metrologically valid procedure for one or more specified properties, accompanied by a reference material certificate that provides the value of the specified property, its associated uncertainty, and a statement of metrological traceability. Note: In this document “CRM” refers to the certified reference materials produced by the Breath Alcohol CRM Laboratory.

**Nominal value** – The rounded or approximate value, which is reported to three decimal places for a solution lot.

**Reference material (RM)** – Material, sufficiently homogenous and stable with respect to one or more specified properties, which has been established to be fit for its intended use in a measurement process.

**Simulator (SIM)** – A device designed to heat an aqueous solution to a specific temperature and used to deliver a vapor sample, usually ethanol, to a breath alcohol testing instrument.

**Solution lot** – A large volume of reference material that is mixed in a single container and considered to be uniform in concentration once the material is divided into smaller containers.

**Traceability** – The property of a measurement result whereby it can be related to a national authoritative standard through an unbroken chain of comparisons with each level having estimated uncertainties.

**Vapor concentration** – The concentration in the vapor above a solution contained in the simulator (expressed in g/210 L).

##### 3.2 Abbreviations

**COBRA** Computer Online BReath Archive

**DPS** Texas Department of Public Safety



<b>ETOH</b>	Ethanol (ethyl alcohol)
<b>H<sub>2</sub>O</b>	Water
<b>IRPCM</b>	Infra-Red Preamp Control Module
<b>ITP</b>	Internal Test Procedure
<b>NIST</b>	National Institute of Standards and Technology
<b>OSD</b>	Office of the Scientific Director
<b>QA</b>	Quality Assurance
<b>RF, RFI</b>	Radio frequency, radio frequency interference
<b>SN</b>	Serial number
<b>Std Dev</b>	Standard deviation

## **4 Instrument and Testing Location Management**

### **4.1 General Requirements**

- A. An instrument inspection is only conducted at the evidential testing location.
- B. An inspection is conducted by a certified technical supervisor and includes not only the instrument, but the associated devices and the test environment.
- C. A technical supervisor may conduct an evidential subject test if the need arises. A technical supervisor is not required to maintain a separate certification as a breath test operator.

### **4.2 Instrumental Procedures**

- A. During an inspection, the technical supervisor conducts a breath test. Select “Other” as the type of test and enter “QA INSPECTION” in the subject last name field.
- B. In order for the test to be considered properly completed, the analytical report meets the following criteria:
  - 1. The analytical report is complete;
  - 2. All air blank results are 0.000;
  - 3. Both subject results are 0.000; and
  - 4. The analytical report is signed by the technical supervisor.
- C. An inspection is performed each time an instrument is placed into or returned to evidential service.
- D. Each active testing location should have an inspection performed at least once per calendar month.
  - 1. If an inspection is not completed during a calendar month, the evidentiary tests conducted during that month are not automatically invalidated.
    - a) *The technical supervisor makes notification to the appropriate BAL regional manager regarding an instrument inspection that was not completed.*
    - b) *Potential impacts to the validity of the tests conducted on the instrument are determined by the scientific director.*



- c) *Documentation regarding the missed inspection and evaluation of potential impacts are retained in the instrument maintenance record.*
- E. The reference solution at each active evidential testing location should be replaced with a new solution at least once per calendar month. The lot number of the solution is recorded in the subject name field of the analytical report.
1. The result of an analysis of a reference solution conducted on a certified instrument at an evidential testing location must agree within  $\pm 0.010$  g/210 L of the nominal value.
- F. Additional tests or checks of the instrument and associated devices may be conducted as determined by the technical supervisor.
- G. The technical supervisor notes in the instrument maintenance record when an instrument is permanently removed from evidential service.
1. Instruments permanently removed from evidential service cannot be returned to evidential service at a later date.

## 5 Reference Solution Traceability

The vapor concentration and uncertainty of the alcohol concentration of the breath alcohol testing reference solution is determined using the Solution Traceability Worksheet (OSD-TST-02) for each reference solution lot.

### 5.1 Reference Solution Traceability Procedure

- A. Using an unexpired 0.080 CRM and three samples of the breath alcohol testing reference solution, conduct the following:
1. Place the solution into the simulator and heat to  $34.00^{\circ}\text{C} \pm 0.20^{\circ}\text{C}$ ;
  2. Connect the simulator to the instrument and conduct twenty consecutive ACAs; and
  3. Enter the last fifteen ACAs of the solution into the applicable column of the Solution Traceability Worksheet.
- B. The 0.080 CRM and the three samples of the breath alcohol testing reference solution may be run in any order.
- C. When the Solution Traceability Worksheet is complete, the technical supervisor affixes their electronic signature and sends the worksheet to a reviewing analyst for technical/administrative review, along with the following:
1. Instrument ACA printouts;
  2. Breath Alcohol Testing Reference Solution Lot Preparation Notes (LAB-CRM-15), as applicable;
  3. Ethanol certificate of analysis; and
  4. CRM certificate of analysis.
- D. Discrepancies noted during the technical/administrative review are brought to the attention of the technical supervisor and resolution takes place prior to use of the solution at an evidential testing location(s).
- E. When the technical/administrative review is complete, the reviewing analyst affixes their electronic signature to the Solution Traceability Worksheet and returns the completed documentation to the technical supervisor.



## 5.2 Reference Solution Traceability Acceptance Criteria

- A. The nominal value of the reference solution must be within  $\pm 0.0030$  when compared to the reference solution vapor concentration.
- B. Reference solutions expire no later than the end of the month, two years from the date of preparation (e.g., a solution prepared 12/15/2019 expires no later than 12/31/2021).

## 6 Technical Records

### 6.1 General Requirements

- A. The technical supervisor maintains all breath alcohol testing records (e.g., analytical report; instrument maintenance, solution, and simulator maintenance records; etc.) and fulfills the role of records custodian on behalf of DPS.
- B. Records are maintained in paper and/or electronic form separate from the COBRA database.
- C. All analytical reports are maintained regardless of whether generated in the laboratory or at a testing location.
- D. Records are organized and detailed enough to allow another technical supervisor to render an opinion.
- E. Where abbreviations or codes are used, the meaning of the abbreviations or codes is defined in this manual or in each associated record (e.g., instrument maintenance record, simulator maintenance record, or reference solution record).
- F. All breath alcohol testing records are retained by DPS per the DPS Records Retention Schedule.
- G. Records are made available on the DPS Breath Alcohol Laboratory website for convenience. Subject dates of birth are excluded from the publicly available records, if present.

### 6.2 Analytical Report Records

- A. Analytical reports are uniquely identified by report number and date.
- B. No alterations are made to the data on an analytical report.
- C. If an analytical report is missing, the technical supervisor makes a reasonable effort to retrieve the missing record. If the record is permanently lost, documentation pertaining to the missing record is retained.

### 6.3 Instrument Maintenance Records

- A. Instruments are uniquely identified by serial number.
- B. Instrument maintenance records contain the required technical records generated during an inspection, evaluation, or maintenance/repair of each certified instrument. Types of documentation which may be found in an instrument maintenance record includes, but is not limited to:
  - 1. Records generated by the technical supervisor during an inspection, instrument installation, instrument removal, or laboratory practice test;
  - 2. Calibration adjustment records and documentation of adjustment solutions used;
  - 3. Flow calibration adjustment records;



4. Records for repairs completed by a technical supervisor, the DPS Breath Alcohol Electronics Laboratory, or the instrument manufacturer; and
  5. Administrative records (e.g., addendums or maintenance notes), as applicable.
- C. Instrument maintenance records include, but are not limited to:
1. Instrument serial number;
  2. Date the inspection, evaluation, or maintenance/repair was performed;
  3. Initials/signature or name of the individual who performed the inspection, evaluation, or maintenance/repair;
  4. Documentation of what evaluation or maintenance/repair was performed; and
  5. Reference to instrument specific deviation requests and/or quality incidents/quality action plans, as applicable.

#### **6.4 Reference Solution Records**

- A. Reference solutions are uniquely identified by lot number.
- B. Reference solution records for each lot include, but are not limited to the:
1. Solution Traceability Worksheet (OSD-TST-02);
  2. Instrument ACA printouts;
  3. Breath Alcohol Testing Reference Solution Lot Preparation Notes (LAB-CRM-15), as applicable;
  4. Ethanol certificate of analysis; and
  5. CRM certificate of analysis
- C. Each page of the reference solution records for each lot contain the:
1. Lot number; and
  2. Identity (e.g., signature or initials) of the individual(s) responsible for the lot preparation, analysis, and/or traceability.

#### **6.5 Simulator Maintenance Records**

- A. Simulators are uniquely identified by serial number.
- B. Simulator maintenance/repair records include, but are not limited to:
1. Simulator serial number;
  2. Date the maintenance/repair was performed;
  3. Initials/signature or name of the individual who performed the maintenance/repair;
  4. Documentation of what maintenance/repair was performed; and
  5. Location of the simulator.

### **7 COBRA Database and Reports**

- A. COBRA is the approved database for collection, recording, reporting, and storage of data.



- B. Breath alcohol personnel are prohibited from using or sharing COBRA information for personal interest, personal gain, or in ways not otherwise authorized for the performance of their assigned duties.
- C. Modification or creation of COBRA reports
  - 1. All breath alcohol personnel may recommend changes to report formats or suggest the creation of new reports.
  - 2. Any recommended changes to reports are submitted in writing to the OSD deputy scientific director (calibration laboratories).
  - 3. Once approved, only authorized users are able to create or modify COBRA reports.





---

## 02 FORMS

### DIRECTORY OF FORMS

#### CRM

	Document Name	FRN
1	Breath Alcohol Testing Reference Solution Lot Preparation Notes	LAB-CRM-15

### DIRECTORY OF WORKBOOKS

#### OSD

	Document Name	FRN
1	Solution Traceability Worksheet	<a href="#">OSD-TST-02</a>