Canadian Society of Forensic Science
La Société canadienne des sciences judiciaires

Canadian Society of Forensic Science Drugs and Driving Committee (DDC)
Drug Screening Equipment – Oral Fluid Standards and Evaluation Procedures

Effective: November 1, 2017

Drug Screening Equipment Standards - Definitions

- "Drug Screening Equipment" means equipment of a kind that is designed to ascertain the presence of specific drugs of interest in the oral fluid of a subject.
- "Error message" means any message displayed by the drug screening equipment that either indicates a malfunction or notification of a situation that affects the operation and needs to be remedied.
- "Oral fluid collection system" means the component of the drug screening equipment which collects the oral fluid sample of the subject.
- "Reader" means the component of the drug screening equipment which interprets and displays the results of the subject test.
- "Testing laboratory" means a laboratory approved by the Drugs and Driving Committee to undertake the testing of drug screening equipment according to the evaluation procedures.

General Guidelines

1. Before submitting their drug screening equipment for evaluation, manufacturers shall first indicate their intention in writing to:

   Chair, Drugs and Driving Committee
   Canadian Society of Forensic Science
   P.O. Box 37040, 3332 McCarthy Road
   Ottawa, Ontario (Canada)
   K1V 0W0

2. Manufacturers must indicate their intention to submit drug screening equipment for approval evaluation by November 30th of any given calendar year for consideration in the following calendar year. The DDC reserves the right to consider submissions at additional times.

3. In order for the DDC to decide whether to accept drug screening equipment for evaluation, the manufacturer shall provide free of charge to the Chair of the DDC or designate(s), the following:

a. Sufficient written operator instructions in both official languages (English and French) to allow proper use of the drug screening equipment, including any specific analytical procedures required and any precautions that should be observed in its use;
b. Performance data relating to the appropriate DDC standards (standards 1, 5-9, 11, 13, 14, 20-22, 27-30, 33, and 34);
c. Specific identification of the drug screening equipment sufficient to distinguish it by name from other equipment, including any other versions of the drug screening equipment; and
d. Details pertaining to the theory and operation of the drug screening equipment. These details shall be sufficient to permit identification of potential malfunctions which could adversely affect the results.

The DDC or designate(s) shall rely upon the above-noted submissions to determine whether to accept the drug screening equipment for evaluation. The DDC shall notify the manufacturer in writing of their decision.

4. Once the manufacturer receives authorization to submit their drug screening equipment for evaluation they shall submit the following free of charge to the DDC or designate(s):
    a. Sufficient oral fluid collection systems, reagents and/or consumables to permit completion of the evaluation;
    b. Two identical readers with all of the specific versions of software, firmware, and/or accessories required for evaluation and proposed for field use of the drug screening equipment if approved;
    c. Confirmation that this drug screening equipment is commercially available; and,
    d. Any specific procedures for use of the synthetic oral fluid outlined in Appendix B on oral fluid collection systems during evaluation.

    The submitted drug screening equipment shall be retained by the DDC or designate(s) as exemplar equipment and may be used to test any proposed equipment modifications.

5. During the testing process, the testing laboratory shall comment on each standard, and each standard shall be considered separately.

6. All test results shall be reported by the testing laboratory to the DDC. All test results shall be retained by the DDC in confidence.

7. The DDC shall accept no liability for breakage or damage to drug screening equipment and/or accessories.

8. The DDC reserves the right to review the manufacturer's English or French translation on any manuals, instructions for use and/or results, and may require changes.

Drug Screening Equipment Evaluation Procedures

These procedures are to be used for determining whether drug screening equipment meets the associated evaluation standards. Each applicable standard shall be addressed either by the manufacturer or testing laboratory, as appropriate, and commented on in the evaluation. Evaluations will be performed at laboratories approved by the DDC for these purposes. Drug screening equipment being evaluated shall be operated according to the instructions for use submitted by manufacturers.

1. ***Drug screening equipment shall have tetrahydrocannabinol (THC), cocaine, and methamphetamine as the target compounds for analysis. This drug screening equipment shall not analyze for any other target compounds. NOTE: The DDC may consider drug screening equipment for evaluation that has a subset of these target compounds for analysis. If so, evaluation procedures will be adjusted accordingly.***

Manufacturers shall submit documentation detailing all of the target compounds in their drug screening equipment. This standard shall be evaluated through testing of positive and negative controls as outlined in subsequent evaluation procedures. The manufacturer shall provide details of all of the interfering substance testing, including cross-reactivity, which they have conducted. Details shall include the concentrations of substances tested. These data shall be evaluated by the DDC or designates as part of the evaluation process.

2. ***In vitro tests of THC, cocaine and methamphetamine-negative oral fluid shall produce negative results using drug screening equipment.***

Twenty (20) separate tests of THC, cocaine and methamphetamine-negative oral fluid shall be performed. All of these tests shall produce a negative result by the drug screening equipment. Synthetic oral fluid shall be used to perform these tests according to the formulation detailed in Appendix B.

3. ***Drug screening equipment shall reliably identify oral fluid with specific target drug concentrations above their respective cut-off concentrations as positive and oral fluid with specific target drug concentrations below their respective cut-off concentrations as negative.***

This standard shall be evaluated by the testing of synthetic oral fluid samples containing each of the specific identified drugs of interest at the concentrations specified in evaluation procedure #4. These tests shall produce a "positive" or "negative" result as appropriate.

4. ***Drug screening equipment cut-off concentrations shall be as follows:***
    a. ***THC 25 ng/mL***
    b. ***Cocaine 50 ng/mL***
    c. ***Methamphetamine 50 ng/mL***

Individual synthetic oral fluid solutions shall be prepared to 25%, 60%, 140% and 175% of the cut-off concentrations for each of the individual specific drugs of interest. Concentrations shall be verified.

Twenty (20) separate tests shall be performed at each concentration (25%, 60%, 140%, and 175% of the cut-off concentration) for each specific drug of interest. At 25% of the cut-off concentration, all test results shall be "negative" for each drug. At 60% of the cut-off concentration, at least 90% of test results shall be "negative" for each drug. At 140% of the cut-off concentration, at least 90% of test results shall be "positive" for each drug. At 175% of the cut-off concentration, all test results shall be "positive" for each drug. In all tests, results shall be negative for the other drugs which have not been added to the synthetic oral fluid solutions.

Drug screening equipment response to a mixture of drugs of interest shall also be tested. Individual synthetic oral fluid solutions shall be prepared and concentrations verified as follows:

- Solution 1: THC at 1,000 ng/mL, cocaine at 1,000 ng/mL, and methamphetamine at 1,000 ng/mL;
- Solution 2: THC at 25% of cut-off concentration, cocaine at 25% of cut-off concentration, and methamphetamine at 25% of cut-off concentration;
- Solution 3: THC at 1,000 ng/mL, cocaine at 1,000 ng/mL, and methamphetamine at 1,000 ng/mL;
- Solution 4: THC at 60% of cut-off concentration, cocaine at 60% of cut-off concentration, and methamphetamine at 60% of cut-off concentration; and,
- Solution 5: THC at 140% of cut-off concentration, cocaine at 140% of cut-off concentration, and methamphetamine at 140% of cut-off concentration

Solutions 1 to 5 shall be tested in sequence. Twenty (20) such test sequences shall be performed. For solutions 1 and 3, all test results shall be "positive". For solution 2, all test results shall be "negative". For solution 4, at least 90% of test results shall be "negative". For solution 5, at least 90% of test results shall be "positive".

5. ***Drug screening equipment shall be portable and sufficiently rugged to withstand generally recognized roadside usage, including storage and transport in police vehicles and operation in both indoor and outdoor environments at all hours.***

Manufacturers shall provide relevant documentation certifying as to this standard. The testing laboratory shall note any issues with portability, operability, and/or ruggedness observed during the evaluation process and shall make note whenever an error message occurs and the circumstances surrounding that event.

6. ***Drug screening equipment shall be capable of being operated at an ambient temperature range of at least 5°C to 35°C.***

   Manufacturers shall provide documentation detailing the usability of the drug screening equipment under the above-noted temperature range and under the manufacturer's stated operating ambient temperature range (if different). Manufacturers shall provide documentation detailing the effects of using oral fluid collection systems and readers outside of this range or manufacturer's range (if different).

7. ***Manufacturers shall state any known environmental conditions that are necessary for the proper operation of drug screening equipment.***

   Manufacturers shall provide documentation detailing the effects of using drug screening equipment outside of any noted environmental conditions.

8. ***Oral fluid collection systems shall be capable of being stored at an ambient temperature range of 5°C to 30°C, at a minimum. Oral fluid collection systems shall clearly and permanently indicate if they have been exposed to environmental conditions outside of any manufacturer-stated critical storage and/or transport ranges which would affect the reliability of the analysis.***

   Manufacturers shall provide documentation detailing the usability of oral fluid collection systems under the above-noted temperature range and under the manufacturer's stated storage ambient temperature range (if different). Manufacturers shall provide documentation detailing the testing performed to confirm that oral fluid collection systems clearly and permanently indicate if they have been exposed to environmental conditions outside of any manufacturer-stated storage and/or transport ranges. Manufacturers shall provide documentation detailing the effects of using oral fluid collection systems that have been stored outside of these ranges.

9. ***Drug screening equipment shall comply with generally recognized safety requirements. No part shall pose a health and safety risk to the operator and/or subject during routine use. Drug screening equipment shall not pose a hygiene issue to the operator and/or subject; any oral fluid collection systems used shall be provided by the manufacturer new, individually wrapped, for single use. Drug screening equipment shall be designed such that operators shall not come***

into direct contact with oral fluid from test subjects. No part of oral fluid collection systems may become detached in the mouth, leak, injure the mouth, or be used as a weapon.

Manufacturers shall submit documentation detailing the safety of the oral fluid collection systems. Oral fluid collection systems shall be supplied complete with Health and Safety instructions and advice for the disposal of waste. Throughout the evaluation procedures, the testing laboratory shall monitor for any potential hygiene issues, confirm that oral fluid collection systems provided are new, individually wrapped, for single use, and identify any actual or potential health and safety issues for the operator and/or subject.

Oral fluid shall be collected from 20 individuals using manufacturer-provided oral fluid collection systems. The testing laboratory shall monitor the oral fluid collection process for any actual or potential health and safety and/or hygiene issues. The ability and time for these test subjects to provide required volumes of oral fluid shall also be monitored as part of evaluation procedure #27.

10. ***All manuals, instructions for use, and results shall be available in both official languages (English and French).***

    The testing laboratory shall verify that all submitted manuals and instructions for use are in both English and French, and that the drug screening equipment submitted by manufacturers is capable of producing printed results and unit display results in both English and French. The DDC reserves the right to verify, by an external service, the translation of all manuals, instructions for use, and analytical results.

11. ***Drug screening equipment shall be compliant with Canada's 110 V based electrical system.***

    Manufacturers shall submit proof that any electrical equipment has been approved by an electrical safety certification body recognized in Canada.

12. ***Battery operated drug screening equipment shall be equipped with a low battery indicator.***

    This standard shall be confirmed by visual inspection and/or review of the information provided by the manufacturer.

13. ***Drug screening equipment shall not be adversely affected by radio frequency interference (RFI).***

    The manufacturer shall submit documentation which demonstrates that the drug screening equipment is not adversely affected by RFI.

14. ***Drug screening equipment analytical results shall not be impacted by the use of cosmetics, recent smoking, and/or food or beverage consumption by subjects.***

    Manufacturers shall submit documentation of all testing performed to determine the effect, if any, of common versions of, or ingredients contained within the above-noted substances. If effects are noted, manufacturers shall indicate appropriate mitigation strategies to ensure that results are not impacted, and the scientific rationale for these strategies. The DDC reserves the right to perform additional testing in this area.

15. ***Drug screening equipment shall use Metric System units.***

    This standard shall be evaluated as part of the review of all manuals, instructions for use, results, and operations conducted during the drug screening equipment evaluation.

16. ***Drug screening equipment shall clearly indicate when equipment errors have occurred.***

    This standard shall be evaluated as part of all operations conducted during the drug screening equipment evaluation. The testing laboratory shall review manufacturer instructions for clarity of listed error messages and any associated directions for remedial actions.

17. ***Drug screening equipment shall generate a printed record of analytical results. Results shall be binary and not require interpretation.***

    This standard shall be evaluated as part of the review of analytical results generated during the drug screening equipment evaluation.

18. ***Printed analytical results shall contain the following information at a minimum:***
    a. ***Identification of the drug screening equipment, including serial number;***
    b. ***Software version number;***
    c. ***Date and time of test;***
    d. ***Unique test identifier;***
    e. ***Results of the analysis for each of the specific drugs of interest;***
    f. ***Name of operator; and***
    g. ***Results of drug screening equipment self-check.***

    This standard shall be evaluated as part of the review of analytical results generated during the drug screening equipment evaluation.

19. ***The results of each subject test shall be retained in readable or printable form until the time a new subject test is initiated or until the drug screening equipment is turned off.***

This standard shall be evaluated as part of the review of analytical results generated during the drug screening equipment evaluation.

20. ***If drug screening equipment is capable of storing test results in its memory, it shall:***
    a. ***Have the capability to retain at least 200 uniquely identified test results;***
    b. ***Have the capability to retain quality control cartridge analytical results;***
    c. ***Notify the operator when the equipment memory is approaching capacity;***
    d. ***Provide this notification when there is less than 20 memory storage positions available;***
    e. ***Ensure that test results stored in memory shall not differ from that recorded and displayed at the time of testing;***
    f. ***Ensure that test results shall be protected from accidental or deliberate alteration;***
    g. ***Have the capability to detect and report corrupted data; and***
    h. ***Ensure that access to stored data is password-protected.***

The manufacturer shall provide details of the quality assurance procedures followed during the validation and verification of the software used to ensure the above-noted capabilities.

21. ***If drug screening equipment is capable of storing analytical test results in its memory, it shall:***
    a. ***Have the capability for stored test results to be downloaded and stored within an appropriate external database/records storage system; and***
    b. ***Ensure that the contents of any such downloaded data shall not differ from that displayed at the time of testing.***

After data has been downloaded, the drug screening equipment memory shall be cleared and be re-usable. Access to download data and to clear drug screening equipment memory shall be password-protected. Any data link between the drug screening equipment and external databases/records storage systems shall be limited to the transfer of stored test results from the drug screening equipment to the external system.

The manufacturer shall provide details of the quality assurance procedures followed during the validation and verification of the software used to ensure the above-noted capabilities.

22. The subject test procedure shall include at a minimum:

- ***a. A reader self-check;***
- ***b. A check to ensure that the oral fluid collection system is within its expiry date and that the reader has been serviced within the last 12 months;***
- ***c. A subject test; and***
- ***d. A check to ensure that the subject test has run correctly.***

The operator shall not be able to manually override expiry dates or dates of service entered into drug screening equipment.

Manufacturers shall supply documentation detailing all checks performed by the reader, including how these checks are performed and their purpose. Analytical results obtained during the evaluation shall be monitored to ensure that the above-noted check results are included, and that check results are consistent with any errors observed. Monitoring shall be performed of analytical results to confirm that the oral fluid collection system is within its expiry date and that the reader has been serviced within the previous 12 months. The testing laboratory shall test the drug screening equipment to confirm that expiry and service dates cannot be overridden during operation. The testing laboratory shall alter dates to beyond the expiry dates of oral fluid collection systems and to beyond 12 months since the last reader service to confirm that the reader will indicate these conditions during its checks.

23. Readers shall be ready for first use within 10 minutes of being switched on. Any reader with a "stand-by position" shall be ready for use 1 minute after switching from this position. The reader shall not be usable before it is ready.

Ten (10) separate tests shall be conducted in which the reader is monitored to ensure that it is ready for use within 10 minutes of being switched on. During each of these periods between the reader being switched on and being ready for use, it shall be tested at least twice to ensure that sample testing cannot be performed.

For readers with a "stand-by position", a minimum of 10 separate tests shall be conducted in which the reader is monitored to ensure that it is ready for use within 1 minute after switching from this position. During each of these periods between the reader being switched from "stand-by position" to being ready for use, the reader shall be tested at least once to ensure that sample testing cannot be performed.

24. Readers shall be ready for use within 5 minutes of completion of the previous test.

Ten (10) successive tests less than 5 minutes apart shall be conducted as part of the evaluation.

25. ***Drug screening equipment shall indicate, within 10 minutes from sample insertion into the reader, whether a subject's oral fluid is positive or negative for each of the individual specific drugs of interest.***

    Tests performed during the evaluation shall be monitored to ensure that either analytical results or an error message are generated within 10 minutes from sample insertion into the reader. Tests performed during the evaluation shall be monitored to ensure that results clearly indicate whether the oral fluid sample tested is positive or negative for each of the specific drugs of interest.

26. ***Drug screening equipment shall only indicate an analytical result when the sample analysis has been successfully completed. Otherwise it shall indicate an error message within 10 minutes from sample insertion into the reader.***

    Tests performed during the evaluation shall be monitored to ensure that analytical results are only indicated when the sample analysis has been successfully completed. Tests performed during the evaluation shall be monitored to ensure that either analytical results or an error message are generated within 10 minutes from sample insertion into the reader.

27. ***Oral fluid collection systems shall reliably collect a sufficient volume of oral fluid from subjects for successful analysis by the drug screening equipment. They shall clearly and readily indicate to the operator when the required volume has been collected. The volume of oral fluid required to be collected shall be reasonably capable of being provided by subjects within 4 minutes of start of collection.***

    Manufacturers shall submit documentation detailing the reliability (i.e., within 10% of the target) of the oral fluid volume collected, and at which the operator is notified of sufficient volume. Oral fluid collection systems used during the evaluation shall be monitored to determine:

    a. If they clearly indicate when sufficient oral fluid has been collected;
    b. If so, this was sufficient for proper analysis; and
    c. All subjects were capable of providing the required volume of oral fluid within 4 minutes of start of collection (see evaluation procedure #9).

28. ***Once analysis has been completed, oral fluid collection systems shall not be capable of being re-analyzed.***

    Manufacturers shall submit documentation of the mechanisms which prevent re-analysis of oral fluid collection systems. The testing laboratory shall attempt to re-analyze oral fluid collection systems that were previously successfully analyzed.

29. ***Oral fluid collection systems shall not contain any additive which can stimulate oral fluid production.***

    Manufacturers shall submit documentation that their oral fluid collection systems do not contain any additives which can stimulate oral fluid production.

30. ***Oral fluid collection systems shall be suitable for use for at least 12 months from the date of manufacture.***

    Manufacturers shall provide data on the long term stability of their oral fluid collection systems indicating that it meets or exceeds the above-stated period between manufacture and expiration.

31. ***Each individual oral fluid collection system package shall clearly indicate the following:***
    a. ***The name of the manufacturer;***
    b. ***Specific identification of the appropriate reader to be used;***
    c. ***The target drugs included in the test panel of the oral fluid collection system;***
    d. ***The expiry date of the oral fluid collection system;***
    e. ***The manufacturing lot number; and***
    f. ***The ambient temperature range in which the oral fluid collection system may be stored and/or used, as applicable.***

    All oral fluid collection systems submitted for the purposes of equipment evaluation shall be checked to ensure that the above-noted requirements are clearly indicated on their individual packages, and that their expiration dates have not passed.

32. ***Readers shall have the capability of analyzing both positive and negative quality control (QC) cartridges. They shall be capable of generating a printed record of the results of these QC cartridge analyses. This record shall contain, at a minimum:***
    a. ***Specific identification of the reader, including serial number;***
    b. ***Software version number;***
    c. ***Date and time of QC check;***
    d. ***Expiry date of QC cartridge, if applicable;***
    e. ***Results of the QC check for both positive and negative QC cartridges; and***
    f. ***Name of operator.***

    If the QC cartridge analyses do not provide positive results for positive control cartridges and negative results for negative control cartridges, the reader shall not perform any subject testing until it has been serviced. If QC cartridge analyses have not been carried out on the reader for

more than 15 days, it shall not perform any further subject testing until such QC cartridge analyses have been completed.

A minimum of 10 separate analyses of each of the positive and negative QC cartridges provided by the manufacturer shall be tested. To meet this standard, all positive and negative control cartridges shall provide proper results on the reader. The testing laboratory shall check that the reader does not perform any further subject testing after more than 15 days without QC cartridge analyses being completed.

33. ***The calibration of the reader shall remain stable for a period of at least 12 months from last service. Readers shall be provided by the manufacturer with a certificate of calibration from a calibration facility authorized by the manufacturer.***

    Manufacturers shall provide data on their long term calibration stability indicating that it meets or exceeds the period of at least 12 months from date of last reader service. The testing laboratory shall confirm that readers are provided with a certificate of calibration from a manufacturer-authorized calibration facility.

34. ***Access to repair/calibrate/service readers shall be restricted to the manufacturer and their authorized agents and appropriate quality assurance measures shall be followed during these procedures.***

    The manufacturer shall provide details of the quality assurance measures followed during the repair/calibration/servicing of readers. Manufacturers shall provide a current list of their authorized agents to repair/calibrate/service readers.

Appendix A

Security Access Levels for Drug Screening Equipment

Access to the functions of drug screening equipment shall be password protected. The security access levels as follows shall reflect:

Operator level access: Access restricted to routine operation of the drug screening equipment, including:

- Performing subject tests;
- Performing negative and positive QC cartridge tests;
- Printing results of latest test results; and
- Printing results of latest negative and positive QC cartridge tests.

Supervisor level access: Access includes routine operation of the drug screening equipment, as well as data control and limited repair functions, including:

- The above-noted operator level access functions;
- Access to any tests stored in memory;
- Printing results of any tests stored in memory;
- Downloading test results to an appropriate external database/records storage system and to subsequently clear downloaded test results from the drug screening equipment memory;
- Granting access to new operators and supervisors; and
- Changing dates and/or times.

Repair/calibrate/service staff access: Access includes operation of the drug screening equipment, data control, repair, calibration and service functions, including:

- The above-noted operator level access functions;
- The above-noted supervisor level access functions; and
- Access to perform reader repairs, calibration, service, and carry out any associated performance checks.

NOTE: any repair/calibration/service staff access to in-field subject test results shall be restricted to the purposes of the repair, calibration, and service of the drug screening equipment and/or to ensure proper data control.

Manufacturer access: access includes manufacture and operation of the drug screening equipment, data control, repair, calibration, and service functions, including:

- The above-noted operator level, supervisor level and repair/calibration/service staff level access; and

- Access to perform manufacturing-related functions.

NOTE: any manufacturer access to in-field subject test results shall be restricted to the purposes of the repair, calibration, and service of the drug screening equipment, to ensure proper data control, and/or for manufacturing-related functions.

Appendix B

Formulation of Synthetic Oral Fluid Matrix

Unless otherwise stated, all test solutions used for drug screening equipment evaluations will use the following synthetic oral fluid matrix which employs distilled water as the solvent. A small amount (< 0.1%) of surfactant may be added to the test solutions to improve solution stability. The composition of the synthetic oral fluid shall be as follows:

Component	**Concentration (mg/L)**
Potassium chloride	1360
Bovine mucin (from sub-maxillary glands)	1300
Potassium hydrogen phosphate	950
Sodium chloride	860
Sodium azide	500
Sodium hydrogen carbonate	440
Potassium thiocyanate	250
Calcium chloride	210

Drug Screening Equipment Evaluation Sequelae

The DDC reserves the right to, upon review of the evaluation data and reports from the testing laboratory, permit the manufacturer to revise specific components of their drug screening equipment and to re-submit for evaluation. In such instances, the DDC will determine the extent of re-evaluation required and indicate that to the manufacturer.

The DDC also reserves the right to, upon review of the evaluation data and reports from the testing laboratory, consider recommending the drug screening equipment for approval using a subset of the originally-submitted target compounds (e.g., successful for THC analysis, but not for cocaine or methamphetamine). In such instances, the manufacturer will be required to remove the testing capabilities for those target compounds which were not successful, and to re-submit for evaluation of their revised drug screening equipment. In such instances, the DDC will determine the extent of re-evaluation required.

On successful completion of the evaluation, as determined by the DDC, the Chair of the DDC (or designate) shall forward the specific drug screening equipment name to the Attorney General of Canada with a recommendation that the equipment be approved for use. For the purposes of this recommendation, unless specifically advised by the DDC, the manufacturers shall:

1. Not change the drug screening equipment in any way;
2. Not advertise the drug screening equipment as being approved for any other use;
3. Ensure that the name (as specified in the recommendation) and serial number of each drug screening equipment unit is clearly identified by an indelible marking;
4. Ensure that the serial number is unique to each unit;
5. Label any software or firmware with a version number;
6. Ensure that any update to the operating instructions is approved by the DDC before being distributed. Once approved, updates shall be sent by the manufacturer to all services that have purchased the drug screening equipment;
7. Ensure that manufacturer-authorized repair/calibration/service facilities are available. Manufacturers shall provide current lists of these facilities;
8. Ensure that repair/calibration/service facility staff are properly trained and provide detailed records of any such services performed on drug screening equipment;
9. Ensure that each new unit is provided with a certificate of calibration from a manufacturer-authorized calibration facility;
10. Ensure that QC cartridges which are currently within their expiration dates are available to services;
11. Ensure that any authorized manufacturing and/or repair/calibration/service facilities shall be suitably accredited or certified and open to inspection by the DDC (or designate);

12. Ensure that all versions of recommended drug screening equipment software and/or firmware are available upon request by the DDC;
13. Be available to answer questions from the DDC as to technical aspects of their drug screening equipment, including software source code and circuit diagrams;
14. If required, make provision for expert witnesses for court cases with respect to the theory, operation and performance of the drug screening equipment;
15. If required, assist with police and government forensic laboratory training with respect to theory, operation and performance of the drug screening equipment; and
16. Submit to the DDC (or designate) 50 oral fluid collection systems from each new batch/lot produced for use in Canada. The DDC reserves the right to examine these oral fluid collection systems to determine their continued appropriateness for use.

Failure to adhere to the above-noted criteria may result in the DDC recommending the drug screening equipment be de-listed. The DDC shall undertake to keep all proprietary information provided by manufacturers confidential. The DDC reserves the right to periodically update recommended drug screening equipment standards and associated evaluation procedures. Additional specific drugs of interest may be added to these standards by the DDC without affecting the approval status of existing drug screening equipment.