Canadian Society of Forensic Science Drugs and Driving Committee (DDC)
Drug Screening Equipment – Oral Fluid Standards and Evaluation Procedures
Appendix D Revision: 001, Effective: July 1, 2025

Appendix D: Drug Screening Equipment Modifications

All drug screening equipment used in Canada, as defined in section 320.11 of the *Criminal Code,* is listed in the *Approved Drug Screening Equipment Order*. This equipment has been tested according to the standards described by the Canadian Society of Forensic Science, Drugs and Driving Committee (DDC), Drug Screening Equipment - Oral Fluids Standards and Evaluation Procedures. However, a manufacturer may decide to upgrade or modify their equipment. When this occurs, the manufacturer must notify the Department of Justice (DOJ) and advise them of any proposed changes. This information will be forwarded to members of the DDC for consideration and to determine if further equipment evaluation is required prior to implementation. The DDC will deem the proposed modification(s) as Category 1, 2 or 3, as described below:

Category 1: Swabs and Test Kits

This category involves changes associated with the Approved Drug Screening Equipment swabs and/or testing kits, where the modification may influence the analytical performance of the equipment including sensitivity and or specificity to any of the targeted drugs. An example of a Category 1 modification would be if the manufacturer changes the antibody in the test kit immunoassay.

Category 1 modifications require a re-evaluation using some, or all, of the procedures set out in the Oral Fluids Standards and Evaluation Procedures. The DDC will determine which standards to evaluate and will advise the manufacturer to provide the relevant equipment.

Category 2: Housing and Equipment

This category involves changes to the Approved Drug Screening Equipment analyser, where the modification may alter sample delivery, sample processing or results reporting. This may include components such as the collection device, the unit's housing and any electrical components including software/firmware modifications. An example of a Category 2 modification would be if the manufacturer decided to change a component of the optical system within the analyser.

Category 2 modifications may require a re-evaluation using some, or all, of the procedures set out in the Oral Fluids Standards and Evaluation Procedures. The DDC may decide to escalate to a Category 1 modification based on the findings.

Category 3: Aesthetics and Usability

This category involves minor changes to the Approved Drug Screening Equipment to either change the aesthetic look of the unit and/or components. It may also involve making minor modifications to improve operation of the equipment. This may include changing the information on equipment packaging. This category of modification should not impact the analytical performance of the equipment.

Category 3 modifications will be carefully considered by the DDC and documented. The DDC may decide to escalate to Category 1 or Category 2 modification, based on the findings.

General Policy and Procedures

1. Manufacturers will submit a formal request to the DOJ for modification evaluation, along with information including the justification for the modification, information to support that the modification does not affect performance, technical specifications and any additional information that will assist the DDC.

2. The DDC will determine the type of modification and determine if and what standards of the Drug Screening Equipment - Oral Fluid Standards and Evaluation Procedures will need to be examined. The DDC will notify the manufacturer of the outcome of this determination.

3. Manufacturers will provide the DDC with the appropriate equipment, free of charge, to enable a proper evaluation and will also provide the DDC with appropriate upgrades to any exemplar equipment to ensure the DDC has continued access to functional equipment.

4. Once the DDC has completed any re-evaluation and determined that the modification has not changed the performance of the Approved Drug Screening Equipment, the Chair of the DDC will advise the DOJ, and the equipment will retain its approved status. There is no requirement for the modified equipment to be re-designated, unless the name of the equipment has changed.

5. If the equipment fails the evaluation, the DDC Chair will contact the DOJ and the manufacturer to advise them of the findings. The manufacturer will be given the opportunity to address any deficiencies. If the deficiencies cannot be rectified, the DDC may make a recommendation to the DOJ to remove the device from the Approved Drug Screening Equipment Order (SOR/2018-179)