

Equipment Amendment Review Synopsis – Modification of SoToxa™ Test Kit (2025-07-01)

The SoToxa™ Mobile Test System, an Abbott SoToxa™ Test Cartridge and an Abbott SoToxa™ Oral Fluid Collection Device, when used together, are *Approved Drug Screening Equipment* as described in 320.11 of the *Criminal Code*. The Drugs and Driving Committee (DDC) has reviewed the proposed modification of the SoToxa™ Test Kit product code TOX417. A SoToxa™ Test Kit contains both the Test Cartridge and the Oral Fluid Collection Device. A summary of the modification is included below:

- Changes to the anti-body source used to manufacture the SoToxa™ Test Cartridge with a corresponding change in storage temperature of 15 to 25 degrees Celsius.
- The SoToxa™ Mobile Test System and the SoToxa™ Oral Fluid Collection Device remain unchanged

Due to the extent of the change, the DDC determined that the SoToxa™ Mobile Test System, the Test Cartridge and the Oral Fluid Collection Device would require evaluation to ensure that it continued to meet standards 2 to 4 of the Drug Screening Equipment – Oral Fluid Standard and Evaluation Procedures for tetrahydrocannabinol (THC) only. It was determined that changes to the equipment do not impact the ability of the equipment to meet all the remaining standards.

At the conclusion of the evaluation, the DDC has determined that the modification to the SoToxa™ Test Cartridge within the Test Kit meets all the requirements as set out in the Drug Screening Equipment – Oral Fluid Standards. The DDC recommends that the SoToxa™ Mobile Test System, an Abbott SoToxa™ Test Cartridge and an Abbott SoToxa™ Oral Fluid Collection Device, when used together, continue to be approved for the purposes of section 320.11 of the *Criminal Code* as equipment that is designed to ascertain the presence of a drug in a person's body.

The DDC has additionally determined:

- The update to the SoToxa™ Test Cartridge does not alter other functionality of this equipment.
- That new lots of TOX417 with the modified Test Cartridge do not invalidate any older lots of the Test Cartridge.

Users are reminded to follow the manufacturer's instructions for use and storage of the Sotoxa™ Mobile Test System and Test Kits.