Forensic Science Regulator

Regulator's Notification: No. 06-2024 reissue

Issue

This notification was initially published in November 2024. This updated version clarifies the Regulator's conclusion of the quality failure in relation to compliance to the Code.

The use of certified reference materials (CRMs) in the undertaking of forensic science activity (FSA) of "Toxicology: analysis for drugs in relation to s5A of the Road Traffic Act 1988" (FSA – DTN 102).

Background

The analysis for drugs in blood samples in relation to s5A of the Road Traffic Act 1988 is a FSA that is subject to the Code. Key Forensic Services reported to the Regulator that they had made a procedural error in the use of CRMs in the analysis of tetrahydrocannabinol (THC). The Key Forensic Services method required different manufacturer lot numbers of CRM to be used to prepare calibrants and internal quality control (QC) samples. Over the period 25th June to 27th September 2024 the same batch of CRMs was used in error. Key Forensic Services conducted an internal investigation and found that the QC stock used was made accurately and was stable over the period of use and concluded that all results can be considered to be accurate within the Forensic Science Regulator's Expanded Uncertainty (FSREU) threshold for THC i.e. 30%.

Actions and Outcomes

The Regulator commissioned an independent review to assess the significance of the procedural error.

The independent review concluded that the procedural error did not invalidate any of the case results reported over the period in question. This is partly due to procedures in place at Key Forensic Services, including the use of CRMs supplied by ISO 17034 accredited suppliers and the overlapping period between changing calibrants and QCs. The review also found that the unaccounted for variables associated with use of the same CRM for preparation of calibrants and QCs would not be expected to have any significant impact on the measured results and was within the FSREU. The review found Key Forensic Services to be compliant with the requirements of the Code, had identified the root cause and taken appropriate remedial action.

The Regulator's Code version 1 did not directly make stipulations around the use of CRMs in s5A testing, however it did require accreditation to ISO/IEC 17025 which at the time required adherence to Lab 51 as part of UKAS' accreditation process. Lab 51 set the requirement for CRMs from separate sources to be used where possible. Whilst the Regulator did not set this requirement in the Code, he does accept that there was an inherent and indirect best practice to do so. As such, Key Forensic Services was found to be compliant with regulatory requirements in the Regulator's Code version 1, and the scientific review clarified the residual risk as low.

The Regulator's Code version 2 has subsequently been updated to include the

following requirement for s5A drugs driving analysis: “For any part of the analysis employing a chromatographic method the forensic unit shall follow these requirements: Certified reference materials (CRMs) from different manufacturers shall be used to prepare calibrants and QCs for each analyte, but if this is not possible then CRMs with different lot numbers from the same manufacturer is a suitable alternative option.” Lab 51 has also been disapplied to the accreditation process of DTN-102.

Dr Marc Bailey **December 2025**
Forensic Science Regulator