

PROJECT REVIEW

“Production of Pure Substance CRMs for the Detection of Doping with Testosterone Precursors and 19 norsteroids”

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The aim of the project is to produce Certified Reference Materials (CRM5) of marker metabolites for testosterone, testosterone precursors and 19-norsteroids. These materials are needed by laboratories undertaking testing and research in this area. Their availability will contribute to improving the quality assurance procedures, the intercomparability and the assessment of the measurement uncertainty in such analyses, and to fundamental research into the qualitative and quantitative detection of abuse of these compounds.

Project Output:

Ten Certified Reference Materials, with appropriate analysis certificates, for laboratories testing for doping involving androstendione, DHEA, testosterone or 19-norsteroids. The aim will be the preparation of sufficient material for the anticipated worldwide requirements for five years.

Background & Discussion

The availability of the appropriate certified reference materials (CRM5) is a fundamental necessity for harmonizing methodology for the detection of anabolic steroid abuse. It is a condition of accreditation to ISO Guide 17025 that testing laboratories use the appropriate reference materials. The availability of CRMs produced under a rigorous quality assurance protocol is thus a key requirement for improving the confidence in results obtained by worldwide programmes of doping analysis and detection. CRMs are necessary as analytical benchmarks for method development and validation, for verification of the application of standardised procedures, for establishing the intercomparability and traceability of measurements, and for assessment of the measurement uncertainty associated with test results. They can assist in the evaluation of the technical performance of a laboratory and in ensuring the comparability of and confidence in analytical measurements obtained in different locations.

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Results

The objective of the project is the preparation, certification and provision for WADA-accredited laboratories of pure substance reference materials for use in detecting doping with precursors ("prohormones") for testosterone and for 19-nor steroids.

The following activities, in line with the approved project plan, have been undertaken:

- consultation with IOC/WADA accredited doping laboratories.
- development of a target CRM list for production.
- external tendering for candidate material preparation.
- production by the CRM team of four candidate CRMs (19-norandrosterone sulfate, 19-noretiocholanolone sulfate, 3 α -hydroxy-5 α -androst-1-en-17-one, 5 α -androst-1-ene-3,17-dione).
- production through sub-contracting of four candidate CRMs (7-keto DHEA, 16 β -hydroxy DHEA, 4 β -hydroxy DHEA and 16 α -hydroxy androsterone).
- production through sub-contracting of five additional candidate CRMs (7 α -hydroxy DHEA, 7 β -hydroxy DHEA, 6 β -hydroxyandrosterone, 6 β -hydroxyetiocholanolone, 3 α -hydroxy-4-estren-17-one).
- certification by NMI of thirteen materials (6 β -hydroxyandrosterone, 6 β -hydroxyetiocholanolone, 7-keto DHEA, 7 α -hydroxy DHEA, 7 β -hydroxy DHEA, 4 β -hydroxy DHEA, 16 β -hydroxy DHEA 16 α -hydroxy androsterone, 19-norandrosterone sulfate, 3 α -hydroxy-5 α -androst-1-ene-17-one, 5 α -androst-1-en-3,17-dione, 3 α -hydroxy-4-estren-17-one and 19-noretiocholanolone sulfate) for issue to doping control laboratories as NMI CRMs.
- review and approval of all thirteen CRMs by an external panel of experts.