# UKAS ANDROLOGY ACCREDITATION

**Dave Sanders**, **John Ringrow** and **Al Bryant** from UKAS give an update on the examination and processing of human semen.

In 2021, the World Health Organization published the 6th Edition of the *WHO laboratory manual for the examination and processing of human semen*. For many organisations accredited by the United Kingdom Accreditation Service (UKAS), this is the go-to reference document for diagnostic semen analysis. This document is referenced on UKAS schedules of accreditation as the methodology applied by laboratories providing accredited fertility analysis services in the UK.

UKAS is the sole national accreditation body for the UK and is recognised by government to assess, against nationally and internationally agreed standards, organisations that provide conformity assessment services, such as certification, testing, inspection, calibration and verification.

Accreditation builds public confidence in standards and quality initiatives. Assessment and accreditation by UKAS promotes the importance of quality performance requirements and verifies that they are met. This delivers an independent, impartial confirmation of technical competence.

The wide range of sectors accredited by UKAS reflects the demand from departments and policymakers across all areas of government and the public sector. Working with UKAS, they gain a trusted and experienced partner and access to an internationally recognised and well-established accreditation service.

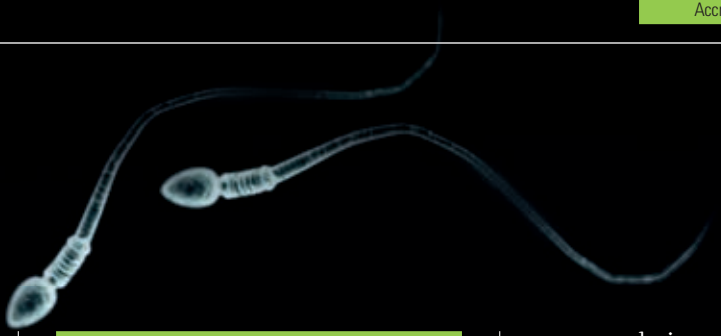
Throughout 2022, UKAS has been establishing the transition process for accredited laboratories, from WHO 2010 to WHO 2021. To manage this efficiently, and to ensure that there is not any perceived commercial advantage by being the first to transition, the transitions will take place independent of each laboratory's standard annual assessment. All laboratories will be assessed within a two-month period and all schedules of accreditation will be published on the same date (assuming any findings raised during the assessment have been cleared).

## Schedule of accreditation

The schedule of accreditation is a critical document, as it defines the measurement capabilities, ranges and boundaries of the activities for which the organisation holds accreditation. Each accredited organisation's schedule is published on the UKAS website and is publicly available to view on the UKAS website. Whilst most andrology laboratories are accredited to ISO 15189:2012, there are a small number that are accredited to ISO 17025:2017. Regardless of the accreditation standard, the transition process will remain the same.

All currently accredited laboratories will shortly receive communication from UKAS confirming the transition process.

Laboratories need to perform a gap



analysis to identify the differences between the 2010 and 2021 laboratory manuals and will need to implement appropriate changes to laboratory documentation and practice.

To transition, UKAS will require all laboratories to submit requested documentation to UKAS in January 2023. During March and April 2023, the submitted documentation will be assessed by UKAS, to ensure that the laboratory's own transition activities demonstrate conformance to the requirements of the relevant ISO standard and to the new WHO 2021 laboratory manual. Subject to a positive recommendation, and clearance of any mandatory findings raised, laboratories will transition to accreditation to the 2021 laboratory manual, and the schedules of accreditation will be updated to reflect this.

## Key areas of change

To transition UKAS accreditation to the 2021 laboratory manual, laboratories will need to submit to UKAS evidence of actions taken to address the changes from the 2010 manual. UKAS has identified some key areas of change (see box, right).

UKAS has produced a gap analysis template for laboratories to complete and submit their documentation, linking the evidence to the relevant clause within ISO 15189:2012 and section of the WHO 2021 manual. This template shall be provided to all accredited laboratories, and enables laboratories to embed the documentation that is relevant to each specific area. The gap analysis will also be available on the UKAS website in due course.

Laboratories will be asked to provide evidence covering at least the following requirements:

- Training and competence
- Information for users
- Pre-examination processes
- Selection, verification and validation
- Reporting of results
- Quality assurance.

IMAGES: SCIENCE PHOTO LIBRARY

## KEY AREAS OF CHANGE

**Sample collection:** More detail has been given regarding sample collection, transportation and pre-examination.

**Examination processes:** Additional detail is included in the 2021 manual. Motility is now to be assessed as four grades; many experienced andrologists will remember this from earlier versions of WHO. The need for replicate dilutions or assessments of slides has been updated. This is reliant on effective sample mixing processes to attempt to achieve homogeneity in the sample. For morphology, in addition to assessing the percentage "ideal" sperm, there is also a requirement to determine the prevalence of the individual defects.

**Reporting:** Decision limits are now given. Whilst similar to the previous reference limits, there have been some changes.

Only documents that provide evidence directly relating to the area of the standard listed in the gap analysis should be submitted. When submitting evidence, the laboratory shall ensure that the relevant sections of any documents are referenced in the gap analysis (e.g. "see paragraph 4.3"). If large documents are submitted without guidance, there is a risk that the key evidence points could be missed, resulting in a non-conformance being raised.

Where non-conformance is identified, UKAS shall raise an improvement action, as per all UKAS assessments. Where findings are raised, there will be a four-week period for the laboratories to implement any required actions, and to submit evidence for UKAS to review. An assessment report (including a recommendation on the transition) shall be issued following the assessment.

## Practical challenges

It is UKAS's experience that accredited laboratories have a good understanding of the accreditation process and employ knowledgeable and competent staff. UKAS acknowledges that there are some practical challenges associated with implementing the requirements of the updated WHO laboratory manual, but remains confident that accredited laboratories will understand and implement all required changes. We advise all affected laboratories to use this time (prior to the document submission due date) to prepare; familiarise technical and management staff with the WHO 2021 laboratory manual and identify and implement necessary changes.

Any questions about the transition process are to be directed to the laboratory's UKAS Assessment Manager in the first instance. Unaccredited laboratories interested in finding out more about accreditation can find information on the UKAS website (ukas.com) or contact info@ukas.com. BMS

**Dave Sanders** is an Assessment Manager, **John Ringrow** is a Senior Assessment Manager and **Al Bryant** is a Healthcare Accreditation Specialist. All are based at UKAS.