

Technical Bulletin: Andrology transition - WHO 2021 - update

17 May 2023

The majority of UKAS transition assessments to the 6th edition of the WHO laboratory manual for the examination and processing of human semen have now taken place, with most laboratories receiving a positive recommendation to transition accreditation to the requirements of the new WHO laboratory manual when the mandatory findings raised have been resolved.

Due to unforeseen resourcing issues, a small number of transition assessments were rescheduled. UKAS is grateful to those customers who were affected and accepted a revised assessment date.

A number of themes have been identified in findings raised - the most common theme is a lack of documentary evidence provided to UKAS to demonstrate the requirements of the updated WHO laboratory manual had been implemented, including evidence of method verification, staff training and competency assessment.

As there is now a significant amount of work required by laboratories and UKAS to provide and review evidence to close the mandatory findings, and acknowledging the resource required to complete this, UKAS has extended the date on which schedules of accreditation will be updated to reference the 6th edition of the WHO laboratory manual from 03 July 2023 to **29 September 2023**.

Customers shall continue to submit evidence on or before the deadlines set by UKAS; any delays in evidence submission risks the findings not being cleared by 29 September 2023.

All laboratories that have cleared all mandatory findings on or before 29 September 2023 shall have their schedule of accreditation updated to reference the 6th edition of the WHO laboratory manual with 29 September 2023 as the date of issue.

Laboratories that have not cleared the mandatory findings on or before 29 September 2023 shall have their schedule of accreditation updated to state "5th edition of the WHO laboratory manual WITHDRAWN". These laboratories shall continue to work towards closing their mandatory findings and transitioning to the 6th edition of the WHO laboratory manual. If mandatory findings are not closed by 31 December 2023, accreditation to ISO 15189:2012 will be withdrawn for the andrology scope by 05 January 2024.

If you have any queries regarding the transition process, please contact Louise Davison, louise.davison@ukas.com, and cc your Assessment Manager.