

Technical Bulletin: Andrology Transition - WHO 2021

19 January 2023

The updated version (edition 6) of the WHO laboratory manual for the examination and processing of human semen was published in 2021. UKAS customers accredited for examination and processing of semen for fertility assessment are assessed against the requirements of ISO 15189:2012 or 17025:2017 and the requirements of the WHO laboratory manual, with reference to the manual included on the schedule of accreditation.

This bulletin is to inform you of the transition process for accreditation to the 2021 edition of the laboratory manual (WHO 2021) and was sent to all accredited andrology customers on 01/11/2022.

All accredited customers shall undergo a desktop assessment in March / April 2023, to assess the satisfactory implementation of the changes resulting from this new edition of the WHO laboratory manual. This assessment will be charged as per the 2022/23 UKAS Standard Terms of Business and shall require 1.5 days office effort.

The assessment shall be undertaken via a review of pre-submitted documents/records, utilising the transition template/gap analysis document provided by UKAS and completed in full by each laboratory, as a desktop assessment. No input will be required from the customer on the day of assessment, and UKAS will not request or accept any additional evidence on the day of the assessment.

Following the assessment, an Assessment Report shall be issued by UKAS using the initial gap analysis document submitted with the requested documentation; assessment conclusions / summary and recommendation on transition shall be added to the gap analysis template by the UKAS assessment team, and the report shall include comments regarding areas of conformity and non-conformance. An Improvement Action Report (IAR) will be provided if any mandatory or recommended findings are raised. The Assessment Report/Recommendation and IAR will be provided to each customer via email; if customers have any queries regarding the findings raised there will be an opportunity to discuss these with a UKAS senior assessment manager (details will be provided with the issued report(s)).

Standard UKAS processes will be followed, requiring submission of evidence relating to mandatory findings within one month, followed by UKAS review of submitted evidence and request for further evidence if required. When all mandatory findings are closed, confirmation of this shall be sent by email.

All laboratories that have no findings raised or have cleared all mandatory findings on or before 30/06/2023 shall have the schedule of accreditation updated to reference the 6th edition of the WHO laboratory manual on 03/07/2023 (first working day of July).

Next steps

In order for UKAS to complete this project efficiently, please complete the linked [gap analysis](#) and return it to medlabscustomerservice@ukas.com on or before **31/01/2023**, with the email subject line:

Andrology WHO 2021 transition gap analysis, Customer number XXXX, Customer name XXXXX

Failure to return the completed gap analysis and any supporting documentation by 31/01/2023 may put your accreditation at risk.

UKAS will acknowledge receipt of your email within 1 working day; if you don't receive acknowledgement then please contact medlabscustomerservice@ukas.com.

UKAS will deliver a **single opening meeting** for this transition project to all customers on **17 February 2023 at 10:30am**. The Microsoft Teams link for this meeting is shown below:

https://teams.microsoft.com/l/meetup-join/19%3ameeting_MDA0OGNkMzltNTMzYi00MmVILWFmNTMtYzA1M2Q3MmU4NGYy%40thread.v2/0?context=%7b%22Tid%22%3a%22e08d0ae4-f281-4b19-957d-e96406dd81fd%22%2c%22Oid%22%3a%22f93a78f-6bf1-4e87-b754-9a0a28dc2913%22%7d

Meeting ID: 357 466 984 790

Passcode: cZUpRs

[Link to recording of the opening meeting](#)

UKAS will schedule the assessment dates to take place in March/April 2023. You will receive confirmation of the date of your desktop assessment in due course.

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