

Technical Bulletin: Publication of ISO 15189:2022

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ISO 15189:2022 *Medical Laboratories – Requirements for quality and competence* was published on 6th December 2022*. The International Laboratory Accreditation Cooperation (ILAC) has agreed that there shall be a three-year transition period; by the end of this period providers accredited to ISO 15189:2012 worldwide must have been assessed and accredited to ISO 15189:2022.

Key updates to the standard include a greater focus on clinical risk and the impact of services on patients, incorporation of the requirements of ISO 22870:2016 Point-of-care testing (POCT) - Requirements for quality and competence, and a structural reorganisation to bring the standard in line with ISO 17000-series standards (the “parent” standards of ISO 15189).

As the updated ISO 15189:2022 standard incorporates the requirements of ISO 22870:2016, accredited POCT providers will only be assessed against the requirements of ISO 15189:2022 in future, and ISO 22870:2016 will be made obsolete in due course.

More detail will follow, in the next few weeks, of detailed UKAS guidance for transition of customers currently accredited under ISO 15189:2012 and the impact of the new standard on applicant customers.

UKAS has worked with The Institute of Biomedical Science (IBMS), Royal College of Pathologists (RCPATH) and the Association for Clinical Biochemistry & Laboratory Medicine (ACB) to produce a Position Statement, available [here](#).

***Note:** ISO 15189:2022 is available direct from [ISO](#) (International Organization for Standardization). It will be available from [BS Online \(BSOL\)](#) in due course.