



الاعتماد السعودي
Saudi Accreditation

SAAC transition plan for ISO15189:2022

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Referring to the decision of the ILAC GA 26.08: “As the revised version of ISO 15189 is scheduled for publication in 2022 or early 2023, the General Assembly endorses the recommendation of the AIC that a transition period of 3 years from the date of publication be adopted. Noting that the requirements for Point of Care Testing (POCT) contained in ISO 22870:2016 have been incorporated into the revised ISO 15189, ISO 22870:2016 in conjunction with ISO15189:2012 will still be recognized as a Level 4 standard for POCT for the duration of the transition period. At the end of the transition period, accreditation of a medical laboratory to ISO 15189:2012 and accreditation of POCT to ISO 22870:2016 in conjunction with ISO15189:2012 will not be recognized under the ILAC Arrangement”. And following the publication of the international standards 15189:2022 “Medical laboratories — Requirements for quality and competence” on 6th December 2022, replacing the Standard ISO 15189:2012. SAAC inform its accredited medical laboratory that the transition period for the implementation of the new version of the standard ISO15189:022 will end by 6th December 2025

SAAC will accept new laboratory request for accreditation to ISO 15189:2022 from July 2023

Assessment according the new version of ISO15189:2022 standard will be optional for any accredited medical testing laboratory whose assessment is scheduled before December 2024. After this date all SAAC' assessment (new request of accreditation, renewal) will be according the new standard ISO15189:2022.

All accredited medical testing laboratories according the standard IS15189:2012 shall implement a gap analysis and transition plan by 60 days before the SAAC assessment (renewal)

The transition assessments will take place with the scheduled periodic assessment (surveillance or renewal). If there is a need of an additional assessment time will be required to ensure that all clauses of the new standard are covered at the assessment it should be so that the period of validity of SAAC certificate of accreditation does not exceed December 2025.

If the laboratory has not successfully completed their transition to ISO 15189:2022 before 6th December 2025, then the existing accreditation for ISO 15189:2012 will be withdrawn on this date. Laboratories that have not transitioned to the 2022 version by this date will no longer be able to claim accreditation for their laboratory activities.

Accredited Point of Care Testing (POCT)

The requirements for Point of Care Testing (POCT) contained in ISO 22870:2016 have been incorporated into the revised ISO 15189:2022, and ISO 22870:2016 has been withdrawn. For the duration of the transition period ISO 22870:2016 in conjunction with ISO15189:2012 will still be recognized as a Level 4 standard for POCT. At the end of the transition period, the accreditation of POCT to ISO 22870:2016 in conjunction with ISO15189:2012 will not be recognized. POCT systems will be assessed against ISO 15189:2022 as part of the laboratory transition assessment.

If you have any further queries, please contact your SAAC laboratory accreditation general manager

Disclaimers

In order to facilitate a smooth transition to the new standard, SAAC kindly requests accredited medical test laboratories to implement their transition action plan before the end of December 2023. The transition plan will be assessed by SAAC Team during the scheduled next evaluation. At least the plan should include:

- Management System Changes identified within the laboratories.
- Details of specific actions planned to implement necessary changes.
- The timeframe for completion of such actions.
- The persons responsible for the actions.
- Process in place to monitor progress and completion of the actions.
- Staff training on ISO 15189:2022
- Confirmation on the option (see table below).

SAAC Transition PLAN

1	July 2023	New applications to ISO 15189:2022	Applications for accreditation to the new standard will be accepted from July 2023
2	From July 2023 to December 2024	Existing accreditations to ISO 15189:2012	<ul style="list-style-type: none"> Your 2023 -assessment will be to ISO 15189:2012 POCT systems will be assessed to ISO 22870:2016
3	From July to December 2025	Existing accreditations to ISO 15189:2012	<ul style="list-style-type: none"> Gap analysis and transition plan to be implemented 60 days before the scheduled assessment (renewal)
4	Existing accreditations to ISO 15189:2012 If your assessment visit are after December 2024		<ul style="list-style-type: none"> SAAC Assessment will be according ISO 15189:2022 (mandatory) POCT systems will be also be assessed to ISO 15189:2022
5	Existing accreditations to ISO 15189:2012 who apply for extension to scope to include POCT		<ul style="list-style-type: none"> If you apply for an extension to scope to include POCT you will be assessed as above, depending on the version of ISO 15189 the rest of your laboratory is accredited to
6	Existing accreditations to ISO 15189:2012 who apply for extension to scope for new disciplines		<ul style="list-style-type: none"> If you apply for an extension to scope to include new tests, you will be assessed against whichever version of ISO 15189 the rest of your laboratory is accredited to



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Thank you