

# PJLA Update Notification

## **Update Notification # 64**

**Update Notification Release Date:** 12/6/2023

**Form/Procedure/Policy:** ISO 15189 Medical Laboratory Standard Transition Requirements

## **Attention Applicant/Accredited Medical Laboratories**

ISO 15189:2012 has now transitioned to the ISO 15189:2022 version. A 3-year transition period has been granted by ILAC to all accreditation bodies to complete transition assessments and update scopes of accreditation by December 31, 2025. This new standard also incorporates Point of Care Testing (POCT) previously contained in ISO 22870:2016. Due to this incorporation, scopes of accreditation reflecting the new 15189 standard will no longer specify ISO 22780:2016.

In order to meet this transition requirement, all labs must undergo a transition assessment by no later than August 31, 2025, regardless of assessment schedule. These assessments may be conducted with routine assessments (i.e. surveillance, reassessment) or as a separate assessment.

New applicants can apply to either version of the standard until August 31, 2024. After this date, the ISO15189:2012 version will only be offered to applicants. If new applicants choose to become accredited to the 2012 version of the standard, they will be expected to follow the above transition requirements.

Thank you!