

PJLA Update Notification

Update Notification # 95

Update Notification Release Date: 10/23/25

Form/Procedure/Policy: ASCA Program Requirement Update: Certificates & Scopes of Accreditation; LF-64a ASCA

Attention All Applicant and Accredited Organizations:

At the request of the U.S. FDA ASCA Program, Accreditation Bodies (ABs) can no longer identify ASCA-accredited tests on scopes of accreditation. Accordingly, PJLA is implementing the following changes, effective 10/31/25.

What is changing

1. Removal of ASCA test listings from scopes, as assessments occur.
 - Individual identification of ASCA items will no longer appear on your scope of accreditation.
2. Removal of ASCA references from certificates, as assessments occur.
 - There will no longer be a reference to ASCA on your accreditation certificate.
3. Addition of FDA-approved footnote on scopes
 - A general footnote will be added beneath the scope table stating:

“This laboratory has been assessed under the FDA ASCA program. Participation in the FDA ASCA program with a list of specific tests can be confirmed by visiting their website <https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfStandards/asca-accredited-testing-laboratories.cfm>.”

Required actions for your laboratory for the next assessment

1. Review the LF-64 (Scope of Table input) with the assessor
 - This is a complete and current list of all methods/activities to be assessed for your standard scope.
2. As assessments are scheduled or as new scopes are being issued after the above date, you will be required to submit a new LF-64a ASCA form
 - Complete the LF-64a ASCA form. This internal tracking document will be used by PJLA assessors and your laboratory during the assessment process to manage ASCA participation details.
 - Note: LF-64a ASCA is **not** published with your scope or certificate; it is for assessment planning and records only.

Timing and transition

- The changes will occur as your scheduled assessment occurs.
- During the transition, existing published scopes will be revised to remove ASCA test listings and add the FDA-approved footnote verbatim.

What you will see on your scope

- Under the scope table, the exact footnote below will appear (verbatim, unchanged):

“This laboratory has been assessed under the FDA ASCA program. Participation in the FDA ASCA program with a list of specific tests can be confirmed by visiting their website <https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfStandards/asca-accredited-testing-laboratories.cfm>.”

Questions

If you have questions about completing LF-64 or LF-64a ASCA, or about how these changes affect your scope or certificate, please contact PJLA.

We appreciate your prompt cooperation as we align with FDA ASCA Program requirements.

-PJLA Management