PJLA Update Notification

Update Notification # 69
Update Notification Release Date: February 21, 2024
Form/Procedure/Policy: SOP-1 Accreditation Procedure ASAC Rev 1.1, LF-56-17025-2k17-Working Document ASCA Biocompatibility-Rev 1.1, and LF-56 2K-17-ASCA-Bio-GLP Supplemental Checklist-Rev 1.1

Attention Applicant/Accredited Organizations

SOP-1 Accreditation Procedure ASAC Rev 1.1:

- Update to section 7.2: Assessors shall review the CAB's policies and procedures to ensure they support ASCA program specifications and do not simply duplicate language as it appears in the ASCA program specifications.
- Update to section 9.1 Test methods will reference the year as indicated in the ASCA database and include the FDA unique ID number.
- Update to section 9.1 within 6 months of receiving accreditation by PJLA. Failure to submit an application within this timeline will result in the removal of ASCA accreditation.
- Update to section 12.1 If the FDA notifies PJLA of any issues with a CAB's application that resulted in a rejection of the application or a particular test method, SOP-9 complaint procedure or SOP-11 suspension, reduction of scope, withdrawal procedure will be utilized. This may require PJLA to remove test methods or the entire accreditation until an investigation is completed either through on-site assessment or documentation review.
- Update to section 13.0 CABs that do not seek final approval by the FDA are prohibited from claiming ASCA accreditation.

LF-56-17025-2k17-Working Document ASCA Biocompatibility-Rev 1.1, and LF-56 2K-17-ASCA-Bio-GLP Supplemental Checklist-Rev 1.1:
No changes to the requirements of the FDA ASCA program. Both checklists have been updated to include questions on existing requirements to ensure (CAB) compliance

Organizations can find a copy of this revised form on our website at www.pjlabs.com/resources/pjla-documents.

Thank you!