

Application for ASCA Accreditation

A complete application from a testing laboratory seeking *ASCA Accreditation* includes the following components. If a testing laboratory application will be for multiple testing sites, documentation should be clear with respect to the site to which it applies.

A. Administrative Information

- Organization name and address
- Designated point of contact: first and last name, title, phone number, and email address
- Alternate designated point of contact: first and last name, title, phone number, and email address

B. Scope of ASCA Accreditation

Indication of the requested scope of *ASCA Accreditation* from the list of FDA-recognized consensus standards and test methods in the ASCA Pilot (more than one standard and test method may be chosen).

C. Information in Support of Competence

Information demonstrating ability to participate in the ASCA Pilot.

- Proof of testing laboratory accreditation that shows:
 - The accreditation is from an ASCA-recognized accreditation body.
 - The scope of *ASCA Recognition* for the accreditation body includes the scope for which they accredited the testing laboratory.
 - The scope of accreditation provided by the ASCA-recognized accreditation body to the testing laboratory matches the testing laboratory's requested scope of *ASCA Accreditation*.
- A copy of the Index of SOPs and any relevant ASCA test-related documents (e.g., SOPs, work instructions, master protocols, test-specific protocols, data collection worksheets, training information) applicable to any biological evaluation of medical device standards and test methods if included in the requested scope of *ASCA Accreditation*.

D. Signed Agreement

Confirmation that the testing laboratory has read, understood, and agrees to adhere to all of the following for its ASCA Pilot-related activities:

- Conduct testing in accordance with ISO/IEC 17025, and the relevant ASCA program specifications.
- Abide by the ASCA program specifications to achieve and maintain status as an ASCA-accredited testing laboratory.

- Provide all ASCA Pilot documentation to FDA upon request.
- Allow FDA to conduct audits upon request; audits may include observations of testing activities and documentation review.
- Establish and maintain appropriate communication with FDA. A testing laboratory should not hesitate to contact FDA regarding the ASCA Pilot. FDA expects that appropriate communication includes the following at a minimum:
 - Notification to FDA within five calendar days via email of any changes that may impact the testing laboratory's participation.
 - Attendance at regularly scheduled teleconferences with FDA as requested. Regular interactions between testing laboratories and FDA will provide the opportunity for discussions about ASCA implementation issues, e.g., training needs, possible improvements and other program-related topics. FDA plans to hold these teleconferences with testing labs as a group, not with individual laboratories.
 - Provision of annual reports of complaint handling to FDA.
- Commit that all relevant FDA training will be completed by appropriate individuals prior to conducting testing under the ASCA Pilot.
- Ensure that proprietary information is protected per client agreements.
- Acknowledge that FDA maintains complete discretion regarding granting *ASCA Accreditation* in the ASCA Pilot. FDA may suspend or withdraw *ASCA Accreditation* at any time.
- Confirm, to the best of your knowledge, all information submitted to FDA is truthful and accurate and that no material fact has been omitted.