NAMSA®

FDA ASCA ACCREDITATION FAQ

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FAQ

NAMSA FDA ASCA Accreditation

• What is ASCA?

ASCA stands for Accreditation Scheme for Conformity Assessment. ASCA is a pilot program launched by the U.S. Food and Drug Administration (FDA) intended for qualified accreditation bodies to accredit testing laboratories to perform premarket testing for medical device companies.

• How did NAMSA receive this accreditation?

NAMSA has been involved for a few years with the FDA on the development of this program, specific to biocompatibility laboratories. In 2020, the FDA launched the pilot qualification efforts and NAMSA completed all steps required by the FDA, including a successful audit by an accredited body and a successful application to the FDA. NAMSA was notified by public announcement by the FDA of their accreditation status on July 22, 2021. (link here to the FDA published list)

• How do manufacturers benefit from working with an ASCA lab?

The ASCA program was developed by the FDA to "increase consistency and predictability in the FDA's approach to assessing conformance with FDA-recognized consensus standards and test methods eligible for inclusion in the ASCA Pilot in medical device premarket reviews." [1]. As such, some of the benefits manufacturers receive when working with an ASCA laboratory include pre-approved standard test methods, a summary report for submission to the FDA (much shorter and concise than a standard GLP report), possible decreased submission review time, expected fewer or no FDA deficiency questions on ASCA test methods and a decreased burden on FDA reviewers regarding ASCA test methods.

• Is ASCA testing performed utilizing GLP?

Yes, all ASCA tests are performed with GLP as they are meant for submission to the FDA. Sponsors will receive full GLP reports as well as ASCA summary reports.

• What report do I submit to the FDA for ASCA testing?

For all qualified ASCA test methods, a NAMSA Study Director will provide Sponsors an ASCA summary report. Then, the Sponsor should simply provide that summary report along with a Declaration of Conformance, completed by the manufacturer [1], to the FDA. It will no longer be necessary to submit the complete GLP report for these ASCA test methods.

• Will ASCA testing take longer than normal GLP testing?

At NAMSA, our goal is to keep ASCA testing turnaround times (TAT) as close as possible to non-ASCA GLP testing. Currenlty, ASCA testing has about 14 more days added due to NAMSA's test volume, not to mention that the requirements for ASCA qualified Study Directors and lab personnel are very strict. These restrictions limit the number of NAMSA Study Directors and lab personnel certified to perform ASCA testing.

• Can I do ASCA testing STAT at NAMSA?

At this time, ASCA testing is not available for STAT. If Sponsors need testing quickly, we recommend doing standard GLP STAT testing and not ASCA.

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FAQ

• Are there specific test codes used for NAMSA's ASCA testing?

Yes, NAMSA has developed special test codes to keep ASCA testing clearly identified in throughout our laboratories. They are available by requesting a quote from NAMSA.

• If I have custom test codes and methods set up at NAMSA, are these eligible for ASCA?

No custom test codes or test methods are eligible. To receive the ASCA testing summary report, all testing must be performed by our ASCA approved test methods.

• What tests are eligible for ASCA?

The FDA only offers the accreditation for specific tests and test methods outlined in their Pilot Study. NAMSA has accreditation for all eligible testing as identified by the FDA for ASCA certification.

TEST CODE	Test DESCRIPTION
V0607-100-ASCA	ASCA ASTM Hemolysis Study - Extract and Direct Contact Method
TI262-800-ASCA	ASCA ISO Skin Irritation Study - Extract
TI262-809-ASCA	ASCA ISO Skin Irritation Study
V0639-000-ASCA	ASCA SC5b-9 Complement Activation Assay
V0639-001-ASCA	ASCA SC5b-9 Complement Activation Assay with Sponsor Provided Control
V0014-130-ASCA	ASCA Cytotoxicity Study Using the ISO Elution Method - Extract
TI251-800-ASCA	ASCA ISO Intracutaneous Irritation Study - Extract
TI251-805-ASCA	ASCA ISO Intracutaneous Irritation Study - Extract Retest
TI260-300-ASCA	ASCA ISO Closed Patch Sensitization Study
TI260-302-ASCA	ASCA ISO Closed Patch Sensitization Study - Rechallenge
TI261-300-ASCA	ASCA ISO Maximization Sensitization Study - Extract
TI261-302-ASCA	ASCA ISO Maximization Sensitization Study - Extract Rechallenge
T0625-500-ASCA	ASCA ISO Acute Systemic Toxicity Study - Extract
T0625-505-ASCA	ASCA ISO Acute Systemic Toxicity Study - Extract Retest
TU010-807-ASCA	ASCA USP Pyrogen Study - Material Mediated
TU010-808-ASCA	ASCA USP Pyrogen Study - Material Mediated with Continuation
TU010-827-ASCA	ASCA USP Pyrogen Study - Material Mediated - Naive Rabbits
TU010-828-ASCA	ASCA USP Pyrogen Study - Material Mediated with Continuation - Naïve Rabbits
ASCA-SUMMARY REPORT	ASCA summary test report for biocompatibility testing

• Are all medical devices eligible to undergo ASCA testing?

Not all materials in medical devices are eligible for ASCA per the FDA accreditation. The following materials are not eligible:

o Absorbable and In situ polymerizing devices

o Liquid devices

o Creams

o Gels

o Hydrogels

o Devices containing nanomaterials

• How do I get a quote for ASCA testing at NAMSA?

Sponsors can receive a quote for ASCA testing by contacting their Business Development Executive or by completing the form found here: http://www2.namsa.com/ascaaccredited

• Is there information on the FDA website regarding ASCA?

Complete information can be found on the FDA's PilotPprogram at this link: https://www.fda.gov/medical-devices/standards-and-conformity-assessment-program/accreditation-scheme-conformity-assessment-asca

• How do I know if my product is eligible for ASCA testing?

Guidance can be found on the FDA page above; Sponsors should confirm materials are not excluded from the list above. Please contact a NAMSA Business Development Executive or complete this form to have a NAMSA professional reach out to directly: http://www2.namsa.com/ascaaccredited

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About NAMSA

Helping medical device Sponsors improve healthcare since 1967, NAMSA is the only 100% medical device-focused, full continuum Contract Research Organization (CRO) in the world. Driven by our global regulatory expertise and in-depth therapeutic knowledge, NAMSA is dedicated to accelerating medical device product development, offering only the most proven solutions to move clients' products through the development lifecycle efficiently and cost-effectively. From medical device testing; regulatory, reimbursement and quality consulting; and clinical research services, we are the industry's premier, trusted partner for successful development and commercialization outcomes.

References

1. FDA published list: https://www.fda.gov/medical-devices/standards-and-conformity-assessment-program/asca-accredited-testing-laboratories
2. NAMSA ASCA Accreditation Information: http://www2.namsa.com/ascaaccredited
3. FDA Pilot program: https://www.fda.gov/medical-devices/standards-and-conformity-assessment-program/accreditation-scheme-conformity-assessment-asca

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