

Mockups for a Testing Lab's CCP-ASCA webform



Apply for ASCA Accreditation



Basic info

Laboratory info

Testing laboratory name

Acronym for testing laboratory (optional)

Address line 1

Address line 2 (optional)

City

State (US)

ZIP/Postal code

Country

Province/region (optional)

Business phone number

Website URL (optional)

Point(s) of contact

Primary Point of Contact

First Name

Last name

Title (optional)

Phone number

Email address

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Apply for ASCA Accreditation

Basic information **Scope of accreditation** Files and documents Review & send to FDA

Scope of accreditation

Accreditation body

ANSI National Accreditation Board (ANAB) ▾

Consensus standards

<input type="checkbox"/>	Standard developing organization	Standard designation number	ASCA category	Title of standard
<input type="checkbox"/>	ISO	10993-5 Third edition 2009-06-01	Biocompatibility	Biological evaluation of medical devices - Part 5: Tests for in vitro cytotoxicity
<input type="checkbox"/>	IEC	60601-2-10 Edition 2.1 2016-04	Basic safety and essential performance	Medical electrical equipment - Part 2-10: Particular requirements for the basic safety and essential performance of nerve and muscle stimulators
<input type="checkbox"/>	IEC	60601-2-18: Edition 3.0 2009-08	Basic safety and essential performance	Medical electrical equipment - Part 2-18: Particular requirements for the basic safety and essential performance of endoscopic equipment
<input type="checkbox"/>	ASTM	F756-17	Biocompatibility	Standard Practice for Assessment of Hemolytic Properties of Materials
<input type="checkbox"/>	IEC	60601-2-10 Edition 2.1 2016-04	Basic safety and essential performance	Medical electrical equipment - Part 2-10: Particular requirements for the basic safety and essential performance of nerve and muscle stimulators
<input type="checkbox"/>	IEC	60601-2-18: Edition 3.0 2009-08	Basic safety and essential performance	Medical electrical equipment - Part 2-18: Particular requirements for the basic safety and essential performance of endoscopic equipment
<input type="checkbox"/>	ASTM	F756-17	Biocompatibility	Standard Practice for Assessment of Hemolytic Properties of Materials

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Files and documents

Information demonstrating ability to participate in the ASCA pilot (i.e., supporting document[s] demonstrating competency)

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Basic Information

Laboratory details

ABC Testing Laboratory, Inc.
Acronym: ABC

123 Main Street
Fresno, California 12345
United States

+1-234-432-4224
<https://www.abctestinglab.com>

Point(s) of contact

Anthony Fauci
Test Manager
+1-222-222-2222
aaron.rodgers@abctestinglab.com

Eric Lucci
Tester
+1-222-222-2222
eric.lucci@abctestinglab.com

Scope of accreditation

AL2A

ISO	10993-5 Third edition 2009-06-01	Biocompatibility	Biological evaluation of medical devices - Part 5: Tests for in vitro cytotoxicity
IEC	60601-2-10 Edition 2.1 2016-04	Basic safety and essential performance	Medical electrical equipment - Part 2-10: Particular requirements for the basic safety and essential performance of nerve and muscle stimulators
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ASTM	F756-17	Biocompatibility	Standard Practice for Assessment of Hemolytic Properties of Materials

Files and documents

Letter(s) from one or more accreditation bodies stating your prequalifications:

PrequalLetterfromAB.pdf

Additional supporting document(s) demonstrating competency:

Medtronics_nonIVD_Syringe.pdf

By submitting, you are agreeing with the terms of participation described in [Section D of Appendix B of the ASCA Pilot program guidance document](#).

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Mockups for an Accreditation Body's CCP-ASCA webform



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Basic info

Accreditation body

Accreditation body name

Acronym for accreditation body (optional)

Address line 1

Address line 2 (optional)

City

State (US)

ZIP/Postal code

Business phone number

Website URL (optional)

Point(s) of contact

Primary Point of Contact

First Name

Last name

Title (optional)

Phone number

Email address

[Add more](#)



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Scope of accreditation

Select all that apply

<input type="checkbox"/>	Standard developing organization	Standard designation number	ASCA category	Title of standard
<input type="checkbox"/>	ISO	10993-5 Third edition 2009-06-01	Biocompatibility	Biological evaluation of medical devices - Part 5: Tests for in vitro cytotoxicity
<input type="checkbox"/>	IEC	60601-2-10 Edition 2.1 2016-04	Basic safety and essential performance	Medical electrical equipment - Part 2-10: Particular requirements for the basic safety and essential performance of nerve and muscle stimulators
<input type="checkbox"/>	IEC	60601-2-18: Edition 3.0 2009-08	Basic safety and essential performance	Medical electrical equipment - Part 2-18: Particular requirements for the basic safety and essential performance of endoscopic equipment
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Files and documents

Supporting document(s) demonstrating ability to participate in the ASCA pilot (i.e., information in support of competence):

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Basic Information

Accreditation body details

New Accreditation Body, Inc.
Acronym: NAB

123 Main Street
Fresno, California 12345
United States

+1-234-432-4224
https://www.NAB.com

Point(s) of contact

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marie.curie@NAB.com

Nels Anderson

Tester
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nels.anderson@NAB.com

Scope of accreditation

ISO	10993-5 Third edition 2009-06-01	Biocompatibility	Biological evaluation of medical devices - Part 5: Tests for in vitro cytotoxicity
IEC	60601-2-10 Edition 2.1 2016-04	Basic safety and essential performance	Medical electrical equipment - Part 2-10: Particular requirements for the basic safety and essential performance of nerve and muscle stimulators
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ASTM	F756-17	Biocompatibility	Standard Practice for Assessment of Hemolytic Properties of Materials

Files and documents

Supporting document(s) demonstrating competency:

- Competency.pdf
- Additional_Data_here.xls

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