

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

[Add more](#)



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

Remove

[Add another accreditation body](#)

Cancel

Next



Apply for ASCA Accreditation



Files and documents

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

📎 Drag & drop your document(s) here, or [browse](#) for it

Back

Next



Apply for ASCA Accreditation



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
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
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](#).

[Back](#)

[Submit](#)

Mockups for an Accreditation Body's CCP-ASCA webform



Apply for ASCA Recognition



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](#)



Apply for ASCA Recognition

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

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
<input type="checkbox"/>	ASTM	F756-17	Biocompatibility	Standard Practice for Assessment of Hemolytic Properties of Materials
<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

Back

Next



Apply for ASCA Recognition



Files and documents

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

Drag & drop your supporting documents here, or [browse](#) for it

[Back](#)

[Next](#)



Apply for ASCA Recognition



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

Marie Curie

Test Manager
+1-222-222-2222
marie.curie@NAB.com

Nels Anderson

Tester
+1-222-222-2222
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
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
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

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

[Back](#)

[Submit](#)