ASCA-Accredited Testing Laboratories

This page lists ASCA-accredited testing laboratories and their respective scopes of accreditation.

Notes:

- Testing laboratories who wish to participate in ASCA should demonstrate that they have been accredited by an ASCA-recognized accreditation body to the currently FDA-recognized versions of the standards and test methods included in ASCA. Please check the Recognized Consensus Standards database for the currently recognized versions.
- Some FDA-recognized consensus standards included in ASCA have an identical U.S. adoption (for example, IEC 60601-2-47, ANSI/AAMI/IEC 60601-2-47). If a testing laboratory has an international (e.g., IEC, ISO) version of a standard in their scope of ASCA Accreditation, any identical US adoption associated with the FDA Recognition number is also considered included in the testing laboratory's scope. For example, if IEC 60601-2-47 with FDA Recognition number 3-155 is listed in a testing laboratory's scope of ASCA Accreditation, testing to the associated ANSI AAMI IEC version is also acceptable even if it is not explicitly listed in the testing lab's scope.
- Some FDA-recognized international consensus standards (e.g., IEC, ISO) included in ASCA are recognized specifically with U.S. national differences applied (e.g., IEC 60601-1, IEC 61010-1). When U.S. national differences are applied to the international versions, they are considered equivalent to the corresponding U.S. adoptions of those standards (e.g., ANSI AAMI ES60601-1, ANSI UL 61010-1). For testing laboratories listed below with such standards in their scope, both the US adoptions and the international versions of the standards are considered as part of their scope of *ASCA Accreditation*.
- Labs listed below with a status of "FDA Initiated Withdrawal" have had their ASCA Accreditation withdrawn as a result of failing to meet the requirements of the ASCA Program as detailed in Section 514(d) of the FD&C Act and the relevant ASCA guidance documents. For some labs listed with a status of "FDA Initiated Withdrawal," the FDA has identified data integrity concerns with testing conducted by the testing laboratory and submitted to the agency in premarket submissions.
- Labs listed below with a status of "Voluntarily Withdrawn" have requested that their ASCA Accreditation be withdrawn voluntarily. This is often due to business decisions (e.g. closing of or moving the laboratory location, limited laboratory services, etc.).

Learn more...[6]

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Test Lab: Element Materials Technology Warwick Ltd ¿ Hull [TL-167]
Accreditation Status: Accreditation Granted - Start Date: 10/03/2025
Accreditation Body Organization Name: A2LA
Test Lab Primary Contact: Neil Roche, neil.roche@element.com, Unit E, South Orbital Trading Park Hedon Road Hull, East Yorkshire GB HU9 1NJ

Scope of ASCA Accreditation

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Status	Status Date	Category	Biocompatibility Test Method	Recognition Number	Standards Development Organization	Standard Designation Number and Date	Title	Exclusions
Accreditation Granted	10/03/2025	Basic safety and essential performance		19-36	IEC	60601-1-2 Edition 4.1 2020-09 CONSOLIDATED VERSION	Medical electrical equipment - Part 1-2: General requirements for basic safety and essential performance - Collateral Standard: Electromagnetic disturbances - Requirements and tests[23]	
Accreditation Granted	10/03/2025	Basic safety and essential performance		19-38	IEC	60601-1-11 Edition 2.1 2020-07 CONSOLIDATED VERSION	Medical electrical equipment - Part 1-11: General requirements for basic safety and essential performance - Collateral Standard: Requirements for medical electrical equipment and medical electrical systems used in the home healthcare environment[24]	
Accreditation Granted	10/03/2025	Basic safety and essential performance		19-39	IEC	60601-1-12 Edition 1.1 2020-07 CONSOLIDATED VERSION	Medical electrical equipment - Part 1-12: General requirements for basic safety and essential performance - Collateral Standard: Requirements for medical electrical equipment and medical electrical systems intended for use in the emergency medical services environment[25]	
Accreditation Granted	10/03/2025	Basic safety and essential performance		19-46	ANSI, AAMI	ES60601-1:2005/(R)2012 & A1:2012, C1:2009/(R)2012 & A2:2010/(R)2012 (Cons. Text) [Incl. AMD2:2021]	Medical electrical equipment - Part 1: General requirements for basic safety and essential performance (IEC 60601-1:2005, MOD) [Including Amendment 2 (2021)][26]	
Accreditation Granted	10/03/2025	Basic safety and essential performance		19-49	IEC	60601-1 Edition 3.2 2020-08 CONSOLIDATED VERSION	Medical electrical equipment - Part 1: General requirements for basic safety and essential performance - Note: This standard is recognized with relevant US national differences applied, see references #1 and #2 in the Relevant FDA Guidance and/or Supportive Publication section below.[27]	
Accreditation Granted	10/03/2025	Basic safety and essential performance		5-131	IEC	60601-1-8 Edition 2.2 2020-07 CONSOLIDATED VERSION	Medical electrical equipment - Part 1-8: General requirements for basic safety and essential performance - Collateral Standard: General requirements, tests and guidance for alarm systems in medical electrical equipment and medical electrical systems[28]	
Accreditation Granted	10/03/2025	Basic safety and essential performance		5-132	IEC	60601-1-6 Edition 3.2 2020-07 CONSOLIDATED VERSION	Medical electrical equipment - Part 1-6: General requirements for basic safety and essential performance - Collateral standard: Usability[29]	

Scope History

Action Type	ASCA Status	Effective Start Date	Biocompatibility Test Method	Recognition Number	Designation Number	Exclusions

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