

Certificate US20/819944041

The management system of

Scantibodies Laboratory, Inc.



9336 Abraham Way, Santee, CA, 92071, United States Of America

has been assessed and certified as meeting the requirements of

ISO 13485:2016

EN ISO 13485:2016

For the following activities

Manufacture and distribution of serum, controls, antibodies, in vitro diagnostic reagents and kits.

Manufacture and distribution of blood products for therapeutic, research and in-vitro diagnostics.

Contract manufacture of serum, controls, antibodies, in vitro diagnostic reagents and kits.

This certificate is valid from 06 June 2024 until 27 August 2026 and remains valid subject to satisfactory surveillance audits.

Issue 7. Certified since 27 August 2020

Certified activities performed by additional sites are listed on subsequent pages.

Authorised by

Jonathan Hall
Global Head - Certification
Services

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Scantibodies Laboratory, Inc.



ISO 13485:2016

EN ISO 13485:2016

Issue 7

Sites

Scantibodies Laboratory, Inc.
9336 Abraham Way, Santee, CA, 92071, United States Of America
Headquarters address. Manufacture of standards and controls.

Scantibodies Laboratory, Inc. (Building 2)
9236 Abraham Way, Santee, CA, 92071, United States Of America
Manufacture of standards and controls.

Scantibodies Laboratory, Inc. (Building 3)
9216 Abraham Way, Santee, CA, 92071, United States Of America
Manufacture of products in the scope of certification.

Scantibodies Laboratory, Inc. (Building 4)
9343 Wheatlands Rd, Santee, CA, 92071, United States Of America
Warehouse and distribution of products in the scope of certification.

Scantibodies Laboratory, Inc. (Building 5)
10946 N. Woodside Ave., Santee, CA, 92071, United States Of America
Purchasing and Human Resources in support of manufacture, warehouse and distribution of products in the scope of certification.

Scantibodies Laboratory, Inc. (Ramona Ranch)
2365 San Vicente Road, Ramona, CA, 92065, United States Of America
Manufacture of antibodies.

Scantibodies Laboratory, Inc. (Otay A)
2311 Marconi Court , San Diego, CA, 92154, United States Of America
Warehouse and distribution of products in the scope of certification.

Scantibodies Laboratory, Inc. (Otay B)
1658 Gales Blvd., San Diego, CA, 92154, United States Of America
Warehouse and distribution of products in the scope of certification.



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Certificate US20/819944041, continued

Scantibodies Laboratory, Inc.

SGS

ISO 13485:2016

EN ISO 13485:2016

Issue 7

Sites

Scantibodies Laboratory, Inc. (Otay C)
8005 Saint Andrews Ave., San Diego, CA, 92154, United States Of America
Warehouse and distribution of products in the scope of certification.

Laboratorios Scantibodies, S.A. de C.V. (Building A)
Calle Los Viñedos No. 4100, Parque Industrial El Bajío (Building A), Tecate, Baja California, 21430, Mexico
Manufacture of products in the scope of certification.

Laboratorios Scantibodies, S.A. de C.V. (Building B)
Calle Del Bajío No.5000, Parque Industrial El Bajío (Building B), Tecate, Baja California, 21430, Mexico
Manufacture of products in the scope of certification and warehouse.

Laboratorios Scantibodies, S.A. de C.V. (Esperanza facility)
Calle Maquiladoras No. 36, Entre Canon Del Padre Y Melchor Muzquiz, Ciudad Industrial, Tijuana Baja California,
22444, Mexico
Warehouse and distribution of products in the scope of certification.



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