

DRLM Home (mainMenu.htm)

▼ Facility
▼ Products Listing

### Annual Registration Successful

Facility: LABORATORIOS SCANTIBODIES S.A. DE C.V., TECATE, Baja California, MEXICO

You have successfully updated your registration and listing information for 2022.

Your registration will be valid through Dec 31, 2022.

Be sure to print this page for your records.

The next registration renewal period is October 1 - December 31, 2022.

**Registering your facility and listing devices does not, in any way, constitute FDA approval of your facility or devices.**

You may contact the FDA with any questions at [reglist@cdrh.fda.gov](mailto:reglist@cdrh.fda.gov).

**The Owner/Operator Number for this Registration is: 2020808.**

**Facility Information**

**Registration Number:** 3002792284  
**Initial Importer:** N  
**Facility Name:** LABORATORIOS SCANTIBODIES S.A. DE C.V.  
**Legal Name:**  
**Address:** Calle Los Vinedos #4100, Parque Industrial El Bajio CP 21430  
 TECATE, Baja California, --, MEXICO  
**DUNS Number:**  
**Foreign Trade Zone:** N  
**Facility URL:**  
**Other Business Trade Name(s):**  
**Establishment located on a campus:**

**Owner/Operator Information**

**Owner/Operator Number:** 2020808  
**Contact Name:** Julio C Padilla Gil  
**Company:** SCANTIBODIES LABORATORY INC.  
**Address:** 9336 Abraham Way , --  
 Santee, CALIFORNIA, 92071, UNITED STATES  
**Telephone:** 001 - 619 - 2589300 - 5203  
**Fax:** 001 - 619 - 2589366  
**E-mail:** julio.padilla@scantibodies.com  
**DUNS Number:** 087577680

**Official Correspondent Information**

**Contact Name:** Mazzie Pagan  
**Company:** SLI-Regulatory Affairs  
**Address:** 9336 ABRAHAM WAY  
 Santee, CALIFORNIA, 92071, UNITED STATES  
**Telephone:** 001 - 619 - 2589300 - 5284  
**Fax:** 001 - 619 - 2583974  
**E-mail:** mazzie.pagan@scantibodies.com  
**DUNS Number:**

**United States Agent Information**

**Contact First Name:** Julio  
**Contact Last Name:** Padilla  
**Contact Title:** Mr  
**Business Name:** Scantibodies Laboratory, Inc.  
**Address:** 9336 Abraham Way  
 Santee, California, 92071, UNITED STATES  
**Phone:** 619 - 2589300 -5203  
**Fax:**  
**DUNS Number:** 139242874  
**E-mail:** julio.padilla@scantibodies.com

**Device Listings**

Listing Number	Premarket Submission Number/Type	Product Code(s)	Device Name(s)	Activities	Importers
D426558	Enforcement Discretion	QKP	Coronavirus antigen detection test system.	Repackager/Relabeler Contract Manufacturer Manufacturer	SCANTIBODIES LABORATORY, INC.

D216611	K991747	LYR	Helicobacter pylori	Repackager/Relabeler Manufacturer Contract Manufacturer	SCANTIBODIES LABORATORY, INC.
D216610	K934484	GTZ	ANTISERA, ALL GROUPS, STREPTOCOCCUS SPP.	Manufacturer Contract Manufacturer Repackager/Relabeler	SCANTIBODIES LABORATORY, INC.
D216613	K020799	JHI	Visual, pregnancy hCG, prescription use	Manufacturer Contract Manufacturer Repackager/Relabeler	SCANTIBODIES LABORATORY, INC.
D216612	K011097	GTY	ANTIGENS, ALL GROUPS, STREPTOCOCCUS SPP.	Manufacturer Contract Manufacturer Repackager/Relabeler	SCANTIBODIES LABORATORY, INC.
D216716	K112177	KHO	FLUOROMETER, FOR CLINICAL USE	Repackager/Relabeler Manufacturer	SCANTIBODIES LABORATORY, INC.
		PSZ	Devices detecting influenza A, B, and C virus antigens	Contract Manufacturer	
D216718	K131166	JHI	Visual, pregnancy hCG, prescription use	Repackager/Relabeler Manufacturer Contract Manufacturer	SCANTIBODIES LABORATORY, INC.
D216717	K101918	GQG	ANTIGEN, CF (INCLUDING CF CONTROLS), RESPIRATORY SYNCYTIAL VIRUS	Contract Manufacturer Repackager/Relabeler Manufacturer	SCANTIBODIES LABORATORY, INC.
D216719	K123793	KHO	FLUOROMETER, FOR CLINICAL USE	Repackager/Relabeler Manufacturer	SCANTIBODIES LABORATORY, INC.
		GTY	ANTIGENS, ALL GROUPS, STREPTOCOCCUS SPP.	Contract Manufacturer	
D216710	K102175	JHI	Visual, pregnancy hCG, prescription use	Manufacturer Repackager/Relabeler Contract Manufacturer	SCANTIBODIES LABORATORY, INC.
D216711	K902510	KTN	System, test, infectious mononucleosis	Manufacturer Contract Manufacturer Repackager/Relabeler	SCANTIBODIES LABORATORY, INC.
D216714	K070747	GQG	ANTIGEN, CF (INCLUDING CF CONTROLS), RESPIRATORY SYNCYTIAL VIRUS	Manufacturer Repackager/Relabeler Contract Manufacturer	SCANTIBODIES LABORATORY, INC.
D216713	K955108	GTZ	ANTISERA, ALL GROUPS, STREPTOCOCCUS SPP.	Manufacturer Contract Manufacturer Repackager/Relabeler	SCANTIBODIES LABORATORY, INC.
D216608	K021423	KHE	REAGENT, OCCULT BLOOD	Manufacturer Contract Manufacturer Repackager/Relabeler	SCANTIBODIES LABORATORY, INC.
D216607	K053146	PSZ	Devices detecting influenza A, B, and C virus antigens	Repackager/Relabeler Contract Manufacturer Manufacturer	SCANTIBODIES LABORATORY, INC.
D216609	K973858	JHI	Visual, pregnancy hCG, prescription use	Manufacturer Contract Manufacturer Repackager/Relabeler	SCANTIBODIES LABORATORY, INC.
D216720	K130398	GQG	ANTIGEN, CF (INCLUDING CF CONTROLS), RESPIRATORY SYNCYTIAL VIRUS	Contract Manufacturer Manufacturer Repackager/Relabeler	SCANTIBODIES LABORATORY, INC.
D426996	Enforcement Discretion	QMN	COVID-19 Multi-Analyte Antigen Device	Contract Manufacturer Manufacturer Repackager/Relabeler	SCANTIBODIES LABORATORY, INC.
D244734	K141775	GTY	ANTIGENS, ALL GROUPS, STREPTOCOCCUS SPP.	Repackager/Relabeler Contract Manufacturer Manufacturer	SCANTIBODIES LABORATORY, INC.
D216705	K912868	GTZ	ANTISERA, ALL GROUPS, STREPTOCOCCUS SPP.	Repackager/Relabeler Manufacturer Contract Manufacturer	SCANTIBODIES LABORATORY, INC.
D216704	K945080	GTY	ANTIGENS, ALL GROUPS, STREPTOCOCCUS SPP.	Manufacturer Repackager/Relabeler Contract Manufacturer	SCANTIBODIES LABORATORY, INC.
D216707	K946276	LJC	ENZYME LINKED IMMUNOABSORBENT ASSAY, (CHLAMYDIAE GROUP)	Contract Manufacturer Repackager/Relabeler Manufacturer	SCANTIBODIES LABORATORY, INC.

Confirmation Page

D432888	K163713	LSR	REAGENT, BORRELIA SEROLOGICAL REAGENT	Contract Manufacturer	SCANTIBODIES LABORATORY, INC.
D216708	K020801	JHI	Visual, pregnancy hCG, prescription use	Manufacturer Contract Manufacturer Repackager/Relabeler	SCANTIBODIES LABORATORY, INC.
D432886	K173496	LSR	REAGENT, BORRELIA SEROLOGICAL REAGENT	Contract Manufacturer	SCANTIBODIES LABORATORY, INC.
D216701	K931761	JJX	Single (specified) analyte controls (assayed and unassayed)	Contract Manufacturer Repackager/Relabeler Manufacturer	SCANTIBODIES LABORATORY, INC.
D216703	K991633	PSZ	Devices detecting influenza A, B, and C virus antigens	Manufacturer Repackager/Relabeler Contract Manufacturer	SCANTIBODIES LABORATORY, INC.
D216702	K974108	JJX	Single (specified) analyte controls (assayed and unassayed)	Contract Manufacturer Repackager/Relabeler Manufacturer	SCANTIBODIES LABORATORY, INC.
D447201	Enforcement Discretion	QJR	Reagents, 2019-novel coronavirus nucleic acid	Repackager/Relabeler Manufacturer Contract Manufacturer	SCANTIBODIES LABORATORY, INC.
D432852	510(k) exempt	JRC	MICRO PIPETTE	Manufacturer	SCANTIBODIES LABORATORY, INC.
D037499	K030258	LCX	KIT, TEST, PREGNANCY, HCG, OVER THE COUNTER	Contract Manufacturer Manufacturer	SCANTIBODIES LABORATORY, INC.

Date of Initial Registration: 2002-08-08 14:13:03.0