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## 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 2023.

Your registration will be valid through Dec 31, 2023.

Be sure to print this page for your records.

The next registration renewal period is October 1 - December 31, 2023.

***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:**

**Mario Coronado**

**Company:**

**SCANTIBODIES LABORATORY INC.**

**Address:** 9336 Abraham Way  
Santee, CALIFORNIA, 92071, UNITED STATES

**Telephone:**  
1 - 619 - 2589300 - 5620

**Fax:**  
1 - 619 - 2583974

**E-mail:** mario.coronado@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	Premarket Submission 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 Contract Manufacturer	SCANTIBODIES LABORATORY, INC.
			PSZ	Devices detecting influenza A, B, and C virus antigens		
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	

			GTY	ANTIGENS, ALL GROUPS, STREPTOCOCCUS SPP.	Contract Manufacturer	SCANTIBODIES LABORATORY, INC.
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.

D465957	Enforcement Discretion		LQP	CAMPYLOBACTER SPP.	Repackager/Relabeler Contract Manufacturer	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.
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.
D459932	Enforcement Discretion		QKO	Reagent, coronavirus serological	Repackager/Relabeler Contract Manufacturer Manufacturer	SCANTIBODIES LABORATORY, INC.
D432852		510(k) exempt	JRC	MICRO PIPETTE	Manufacturer	SCANTIBODIES LABORATORY, INC.
D462917	Enforcement Discretion		PSZ	Devices detecting influenza A, B, and C virus antigens	Contract Manufacturer Repackager/Relabeler	
D460580	Enforcement Discretion		LLH	REAGENTS, CLOSTRIDIUM DIFFICILE TOXIN	Repackager/Relabeler Manufacturer Contract 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**

