

12/12/2018

FDA | U.S. Food and Drug Administration



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 2019.

Your registration will be valid through Dec 31, 2019.

Be sure to print this page for your records.

The next registration renewal period is October 1 - December 31, 2019.

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.

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.
Address:	Calle Los Vinedos #4100, Parque Industrial El Bajio CP 21430 TECATE, Baja California, --, MEXICO
Foreign Trade Zone:	N

Owner/Operator Information

Owner/Operator Number: 2020808
Contact Name: Julio C Padilla Gil
Company: SCANTIBODIES LABORATORY INC.
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DUNS Number: 087577680

Official Correspondent Information

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United States Agent Information

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Fax: 757 -2240179
DUNS Number: 139242874
E-mail: david.lennarz@registrarcorp.com

Device Listings

Listing Number	Premarket Submission Number/Type	Product Code(s)	Device Name(s)	Activities	Importers
D216716	K112177	KHO	FLUOROMETER, FOR CLINICAL USE	Repackager/Relabeler	SCANTIBODIES LABORATORY, INC.
		PSZ	Devices detecting influenza A, B, and C virus antigens		
D216718	K131166	JHI	Visual, pregnancy hCG, prescription use	Repackager/Relabeler	SCANTIBODIES LABORATORY, INC.
D216717	K101918	GQG	ANTIGEN, CF (INCLUDING CF CONTROLS), RESPIRATORY SYNCYTIAL VIRUS	Repackager/Relabeler	SCANTIBODIES LABORATORY, INC.
D216719	K123793	KHO	FLUOROMETER, FOR CLINICAL USE	Repackager/Relabeler	SCANTIBODIES LABORATORY, INC.
		GTY	ANTIGENS, ALL GROUPS, STREPTOCOCCUS SPP.		
D216710	K102175	JHI	Visual, pregnancy hCG, prescription use	Repackager/Relabeler	SCANTIBODIES LABORATORY, INC.
D216611	K991747	LYR	Helicobacter pylori	Repackager/Relabeler	SCANTIBODIES LABORATORY, INC.
D216610	K934484	GTZ	ANTISERA, ALL GROUPS, STREPTOCOCCUS SPP.	Repackager/Relabeler	SCANTIBODIES LABORATORY, INC.
D216613	K020799	JHI	Visual, pregnancy hCG, prescription use	Repackager/Relabeler	SCANTIBODIES LABORATORY, INC.
D216711	K902510	KTN	SYSTEM, TEST, INFECTIOUS MONONUCLEOSIS	Repackager/Relabeler	SCANTIBODIES LABORATORY, INC.
D216612	K011097	GTY	ANTIGENS, ALL GROUPS, STREPTOCOCCUS SPP.	Repackager/Relabeler	SCANTIBODIES LABORATORY, INC.
D216714	K070747	GQG	ANTIGEN, CF (INCLUDING CF CONTROLS), RESPIRATORY SYNCYTIAL VIRUS	Repackager/Relabeler	SCANTIBODIES LABORATORY, INC.

D216713	K955108	GTZ	ANTISERA, ALL GROUPS, STREPTOCOCCUS SPP.	Repackager/Relabeler	SCANTIBODIES LABORATORY, INC.
D244734	K141775	GTY	ANTIGENS, ALL GROUPS, STREPTOCOCCUS SPP.	Repackager/Relabeler	SCANTIBODIES LABORATORY, INC.
D216705	K912868	GTZ	ANTISERA, ALL GROUPS, STREPTOCOCCUS SPP.	Repackager/Relabeler	SCANTIBODIES LABORATORY, INC.
D216704	K945080	GTY	ANTIGENS, ALL GROUPS, STREPTOCOCCUS SPP.	Repackager/Relabeler	SCANTIBODIES LABORATORY, INC.
D216608	K021423	KHE	REAGENT, OCCULT BLOOD	Repackager/Relabeler	SCANTIBODIES LABORATORY, INC.
D216707	K946276	LJC	ENZYME LINKED IMMUNOABSORBENT ASSAY, (CHLAMYDIAE GROUP)	Repackager/Relabeler	SCANTIBODIES LABORATORY, INC.
D216607	K053146	PSZ	Devices detecting influenza A, B, and C virus antigens	Repackager/Relabeler	SCANTIBODIES LABORATORY, INC.
D216708	K020801	JHI	Visual, pregnancy hCG, prescription use	Repackager/Relabeler	SCANTIBODIES LABORATORY, INC.
D216609	K973858	JHI	Visual, pregnancy hCG, prescription use	Repackager/Relabeler	SCANTIBODIES LABORATORY, INC.
D216720	K130398	GQG	ANTIGEN, CF (INCLUDING CF CONTROLS), RESPIRATORY SYNCYTIAL VIRUS	Repackager/Relabeler	SCANTIBODIES LABORATORY, INC.
D216701	K931761	JJX	Single (specified) analyte controls (assayed and unassayed)	Repackager/Relabeler	SCANTIBODIES LABORATORY, INC.
D216703	K991633	PSZ	Devices detecting influenza A, B, and C virus antigens	Repackager/Relabeler	SCANTIBODIES LABORATORY, INC.
D216702	K974108	JJX	Single (specified) analyte controls (assayed and unassayed)	Repackager/Relabeler	SCANTIBODIES LABORATORY, INC.
D037499	K030258	LCX	KIT, TEST, PREGNANCY, HCG, OVER THE COUNTER	Contract Manufacturer	SCANTIBODIES LABORATORY, INC.

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