

10/14/2019

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 2020.

Your registration will be valid through Dec 31, 2020.

Be sure to print this page for your records.

The next registration renewal period is October 1 - December 31, 2020.

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

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|-----------------------------|---|
| 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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E-mail: julio.padilla@scantibodies.com
DUNS Number: 087577680

Official Correspondent Information

Contact Name: David Lennarz
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E-mail: david.lennarz@registrarcorp.com
DUNS Number: 139242874

United States Agent Information

Contact Name: David Lennarz
Contact Title: Mr
Business Name: Registrar Corp
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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 |
|----------------|----------------------------------|-----------------|---|---|-------------------------------|
| 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. |
| 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. |
| D216708 | K020801 | JHI | Visual, pregnancy hCG, prescription use | Manufacturer Contract Manufacturer Repackager/Relabeler | 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. |

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| 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 Contract Manufacturer | SCANTIBODIES LABORATORY, INC. |
| | | GTY | ANTIGENS, ALL GROUPS, STREPTOCOCCUS SPP. | | |
| 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. |
| D037499 | K030258 | LCX | KIT, TEST, PREGNANCY, HCG, OVER THE COUNTER | Contract Manufacturer Manufacturer | SCANTIBODIES LABORATORY, INC. |