Luminex

Luminex Corporation
Licensed Technology Group (LTG)
Quality and Capabilities Self-Assessment

Luminex and Diasorin Molecular are dedicated to improving the health of patients globally by maintaining leadership in the design and manufacture of biological test solutions. Our priority is the delivery of reliable and effective products that provide timely results for our customers and partners. We continually improve in order to provide innovative solutions to enhance customer satisfaction and the quality of life for our patients.

We envision a Luminex solution in every lab around the world seeking to obtain timely and confident answers. We aim to lead with transformative solutions that uniquely accelerate reliable answers while reducing the overall cost of advancing health.

We developed this self-assessment in an effort to answer your questions about our business and capabilities. If you have further questions about our capabilities, please contact our customer service teams.

SECTION 1 – COMPANY HISTORY

Luminex Corporation is an American biotechnology company founded in 1995 and headquartered in Austin, Texas, specializing in the development, manufacturing, and commercialization of proprietary biological testing technologies for multiplex analysis of proteins, nucleic acids, and other biomolecules. Its flagship innovation, the xMAP® Technology, utilizes color-coded microspheres to enable high-throughput, simultaneous detection of up to 500 analytes in a single reaction, revolutionizing applications in diagnostics, research, and drug development. In Julyl 2021, Luminex was acquired by the Italian diagnostics firm DiaSorin S.p.A., allowing its multiplexing platforms to integrate with Diasorin's global portfolio of molecular and immunodiagnostic solutions while continuing operations under the Luminex brand.

SECTION 2 – SUPPLIER INFORMATION - GENERAL INFORMATION

Site or Facility Name	Luminex Corporation – Austin Facility
Type of Entity	Subsidiary
Parent Company	Diasorin Inc.
Address	12212 Technology Blvd., Austin, Texas
State of Incorporation	Delaware
Ownership	Private
Phone	1-512-219-0820
Website	https://us.diasorin.com/en/luminex
Operations Overview	Design, development, manufacturing, distribution, and service of microsphere-based and PCR-based systems used in detection, diagnosis and/or management of nucleic acid related applications.

SECTION 2 – SUPPLIER INFORMATION - GENERAL INFORMATION (CONT)	
Years in business	Founded in 1995
Footprint	220,567 sq ft
Hours of operations	Mon – Fri standard day shift (8:30 a.m. – 5:00 p.m.)
Number of employees	501 – 1,000 employees
Number of employees in quality unit	10-15
Compliance profile	ISO 13485, MDSAP, FDA registration # 1650733
NAICS Code	325413, 334516
DUNS Number	96-547-6641
Business Classification	Biotechnology, Medical Devices, and Life Sciences
Remit Address (For Payments):	PO BOX 844222 Dallas, TX 75284-4222
Remit email address	support@luminexcorp.com
PO email address	orders@luminexcorp.com
General email	support@luminexcorp.com
Fax	1-512-219-0544
Geographic Locations Served	Worldwide

SECTION 3 – SUPPLIER QUESTIONNAIRE - OPERATIONAL POLICIES	
Does the site utilize the following written policies, programs, or procedures?	
1. Quality manual	Yes
2. Disaster recovery plan (Business Continuity Plan)	Yes
3. Environmental, health, and safety	Yes
4. Pest management	Yes
5. Record retention	Yes
6. Legal and contractual commitments	Standard warranty terms can be found on our website (https://us.diasorin.com/en/service-support/service-contracts). Additional legal contractual commitments are negotiated under Quality and Supplier Agreements.

SECTION 3 – SUPPLIER QUESTIONNAIRE - QUALITY SYSTEM	
Does the site utilize the following written policies, programs, or procedures?	
7. Does management review systems and operations at least once per year?	Yes
8. Do you have standard operating procedures, work instructions, and policies?	Yes. Employees have access to relevant documents at their point of use.
9. Is there a system for document control (including documented records of change)?	Yes
10. Do you notify customers of changes to specification of the products, services, or in the parameters of your manufacturing process that may affect performance, quality or reliability?	Yes, in accordance with established quality agreements.
11. Do you have policies and procedures in place that ensure the protection of your customer's confidential information?	Yes
12. Do you have procedures for controlling quality-related records (completed documents regarding product or services)?	Yes
13. Do you have a backup system for electronic quality-related records?	Yes
14. Do you train and/or certify employees prior to performing a procedure or task?	Yes, and training records are maintained.
15. Does your company perform internal audits?	Yes
16. Do you have a system for design control?	Yes
17. Is there a documented procedure in place to ensure customer requirements are being met?	Yes

SECTION 3 – SUPPLIER QUESTIONNAIRE - MATERIAL HANDLING / STORAGE / DISTRIBUTION	
18. Do you have a formal supplier evaluation process?	Yes, suppliers are evaluated and monitored, and a list of approved suppliers is maintained.
19. Do you have a system in place for handling and storing materials according to manufacturer's specifications?	Yes
20. Do you have a system for the control of customer-supplied material?	Yes
21. Do you have a system for product identification and traceability?	Yes. Traceability is maintained from raw material receiving through final product distribution.
22. Is there a system in place for controlling product with a defined shelf-life?	Yes

SECTION 3 – SUPPLIER QUESTIONNAIRE - PRODUCTION CONTROL	
23. Do you have Quality Control (QC) requirements for each product?	Yes. Only products that have met specifications are released for distribution.
24. Do you have a system in place for handling and storing materials according to manufacturer's specifications?	Yes
25. Do you perform incoming inspection on raw materials?	Yes
26. Do you have a system for product identification and traceability?	Yes. Traceability is maintained from raw material receiving through final product distribution.
27. Do you perform in-process inspection of intermediate components and products?	Yes, as applicable to ensure products are manufactured to specifications.
28. Do you perform final inspection of products prior to release?	Yes
29. Do you have segregated areas for quarantined/rejected goods (MRB)?	Yes
30. Do you have a documented process to perform rework or reprocessing orders?	Yes

SECTION 3 – SUPPLIER QUESTIONNAIRE - MEASUREMENT, ANALYSIS AND IMPROVEMENT	
31. Do you have a system to control non-conforming materials and products?	Yes
32. Do you notify customers when non-conforming material or product is shipped?	Yes
33. Do you have a customer complaint investigation system?	Yes
34. Do you have a corrective and preventive action program?	Yes
35. Do you have a system in place for recalls and field actions?	Yes
36. Do you have a system in place to qualify equipment?	Yes. Qualifications records are maintained.
37. Do you have a system in place for equipment calibration?	Yes. Calibration standards are traceable. Calibration records are maintained.
38. Do you have a system in place for preventive maintenance of equipment?	Yes
39. Do you have a system to control out of se vice equipment?	Yes

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