



## Supplier Common Questions and Answers

### SECTION 1 - SUPPLIER INFORMATION GENERAL INFORMATION

<b>Site or Facility Name</b>	Luminex Corporation – Austin Facility
<b>Parent Company</b>	DiaSorin Inc.
<b>Address</b>	12212 Technology Blvd., Austin, Texas
<b>Phone</b>	1-512-219-0820
<b>Website</b>	<a href="https://us.diasorin.com/en/luminex">https://us.diasorin.com/en/luminex</a>
<b>Operations Overview</b>	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.
<b>Years in business</b>	Founded in 1995
<b>Footprint</b>	220,567 sq ft
<b>Hours of operations</b>	Mon – Fri standard day shift
<b>Number of employees</b>	501 – 1,000 employees
<b>Number of employees in quality unit</b>	10
<b>Compliance profile</b>	ISO 13485, MDSAP, FDA registration # 1650733

### SECTION 2 - SUPPLIER QUESTIONNAIRE OPERATIONAL POLICIES

*Does the site utilize the following written policies, programs, or procedures?*

<b>1. Quality manual</b>	Yes
<b>2. Disaster recovery plan</b>	Yes
<b>3. Environmental, health, and safety</b>	Yes
<b>4. Pest management</b>	Yes
<b>5. Record retention</b>	Yes

## SECTION 2 – SUPPLIER QUESTIONNAIRE OPERATIONAL POLICIES (CONT.)

*Does the site utilize the following written policies, programs, or procedures?*

- |  |   |
|--|---|
| <b>6. Does management review systems and operations at least once per year?</b>  | Yes   |
| <b>7. Do you have standard operating procedures, work instructions, and policies?</b>  | Yes. Employees have access to relevant documents at their point of use. |
| <b>8. Is there a system for document control (including documented records of change)?</b>   | Yes   |
| <b>9. 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?</b> | Yes, in accordance with established quality agreements.                 |
| <b>10. Do you have policies and procedures in place that ensure the protection of your customer's confidential information?</b>  | Yes   |
| <b>11. Do you have procedures for controlling quality-related records (completed documents regarding product or services)?</b>   | Yes   |
| <b>12. Do you have a backup system for electronic quality-related records?</b>   | Yes   |
| <b>13. Do you train and/or certify employees prior to performing a procedure or task?</b>  | Yes, and training records are maintained.                               |
| <b>14. Does your company perform internal audits?</b>  | Yes   |
| <b>15. Do you have a system for design control?</b>  | Yes   |
| <b>16. Is there a documented procedure in place to ensure customer requirements are being met?</b>   | Yes   |

## MATERIAL HANDLING / STORAGE / DISTRIBUTION

- |   |   |
|---|---|
| <b>17. Do you have a formal supplier evaluation process?</b>  | Yes, suppliers are evaluated and monitored, and a list of approved suppliers is maintained.     |
| <b>18. Do you have a system in place for handling and storing materials according to manufacturer's specifications?</b> | Yes   |
| <b>19. Do you have a system for the control of customer-supplied material?</b>  | Yes   |
| <b>20. Do you have a system for product identification and traceability?</b>  | Yes. Traceability is maintained from raw material receiving through final product distribution. |
| <b>21. Is there a system in place for controlling product with a defined shelf-life?</b>                                | Yes   |

## PRODUCTION CONTROL

<b>22. Do you have Quality Control (QC) requirements for each product?</b>	Yes. Only products that have met specifications are released for distribution.
<b>23. Do you have a system in place for handling and storing materials according to manufacturer's specifications?</b>	Yes
<b>24. Do you perform incoming inspection on raw materials?</b>	Yes
<b>25. Do you have a system for product identification and traceability?</b>	Yes. Traceability is maintained from raw material receiving through final product distribution.
<b>26. Do you perform in-process inspection of intermediate components and products?</b>	Yes, as applicable to ensure products are manufactured to specifications.
<b>27. Do you perform final inspection of products prior to release?</b>	Yes
<b>28. Do you have segregated areas for quarantined/rejected goods (MRB)?</b>	Yes
<b>29. Do you have a documented process to perform rework or reprocessing orders?</b>	Yes

## MEASUREMENT, ANALYSIS AND IMPROVEMENT

<b>30. Do you have a system to control non-conforming materials and products?</b>	Yes
<b>31. Do you notify customers when non-conforming material or product is shipped?</b>	Yes
<b>32. Do you have a customer complaint investigation system?</b>	Yes
<b>33. Do you have a corrective and preventive action program?</b>	Yes
<b>34. Do you have a system in place for recalls and field actions?</b>	Yes
<b>35. Do you have a system in place to qualify equipment?</b>	Yes. Qualifications records are maintained.
<b>36. Do you have a system in place for equipment calibration?</b>	Yes. Calibration standards are traceable. Calibration records are maintained.
<b>37. Do you have a system in place for preventive maintenance of equipment?</b>	Yes
<b>38. Do you have a system to control out of service equipment?</b>	Yes

**Luminex** [qualityLTG@luminexcorp.com](mailto:qualityLTG@luminexcorp.com)

Austin, TX  
p: +1 (512) 381 4397  
w: diasorin.com

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