## Technical Specification of HPLC system

| S.N. | Purchaser's Requirement | Bidder's Compliance Sheet | | |
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| | | Compliance Yes/No | Deviation(if any) | Corresponding page no. of data sheet/catalogue on support of specification |
| | **Bidder Name:** | | | |
| | **Manufacturer:** | | | |
| | **Brand:** | | | |
| | **Type/Model:** | | | |
| | **Country of Origin:** | | | |
| 1 | **Description of function** | | | |
| 1.1 | Fully automated HPLC system dedicated to testing and screening of Thalassemia and Hemoglobinopathy. | | | |
| 2 | **Operational Requirements** | | | |
| 2.1 | Fully automated, latest bench-top HPLC analyzer to screen and quantitate hemoglobin's HbA1c, HbA2, HbF and detect abnormal hemoglobin's like HbS, HbD, HbE etc. | | | |
| 3 | **System Configuration** | | | |
| 3.1 | Fully Automatic HPLC analyzer, complete unit with complete accessories, reagents. | | | |
| 4 | **Technical Specification** | | | |
| 4.1 | System shall be of latest technology for testing and screening of Thalassemia and Hemoglobinopathy. | | | |
| 4.2 | Sample Volume: Approximately 2 ml of whole blood. | | | |
| 4.3 | System should have throughput of minimum 8 samples per hour for hemoglobinopathy and minimum of 16 samples per hour for HbA1c. | | | |
| 4.4 | System should have complete ready to use kit in one set. (Buffers, columns, primers, calibrators etc.) | | | |
| 4.5 | System should have dual program mode to perform either HbA1c or B-Thalassemia without changing any reagents or columns. | | | |
| 4.6 | Flexibility to use different sample containers like primary tubes with different sizes, sample cups for easy processing. | | | |
| 4.7 | System should have inbuilt color touch screen. | | | |
| 4.8 | System should have inbuilt graphic thermal printer. | | | |
| 4.9 | Result storage: minimum 2000 result storage system with | | | |



NEC No: 442 Biomedical "A"

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| | graphs. | | | |
| 4.10 | With bar code reader. | | | |
| 4.11 | Should have inbuilt system check facility for all parameters (cartridge, buffer, reagent, waste etc.) before the sample analysis. | | | |
| **5** | **Accessories, Spares and Consumables** | | | |
| 5.1 | Accessories: | | | |
| | Shall provide sufficient kits of each parameter as a start-up kit complete with reagents, controls, calibrators, accessories, etc. free of cost. | | | |
| 5.2 | All standard accessories, consumables and parts required to operate the equipment, including all standard tools and cleaning and lubrication materials, to be included in the offer. Bidders must specify the quantity of every item included in their offer (including items not specified above). | | | |
| **6** | **Operating Environment** | | | |
| 6.1 | The product offered shall be designed to be stored and to operate normally under the conditions of the purchaser's country. The conditions include power supply, climate, temperature, Humidity etc. | | | |
| 6.2 | Power supply: 220-240 VAC, 50Hz fitted with appropriate plug. The power cable must be at least 3 meter in length. | | | |
| **7** | **Standards and safety Requirements.** | | | |
| 7.1 | Must submit ISO 13485:2003/AC: 2007 for medical devices. | | | |
| 7.2 | System should be FDA approved. | | | |
| 7.3 | System should be NGSP (National Glycohemoglobin Standardization Program) certified. | | | |
| **8** | **User Training** | | | |
| 8.1 | Must provide user training (including how to use and maintain the equipment). | | | |
| **9** | **Warranty** | | | |
| 9.1 | Comprehensive warranty for 1 year after acceptance. | | | |
| **10** | **Maintenance Service during Warranty period** | | | |
| 10.1 | During warranty period, bidder must ensure preventive/corrective maintenance whenever required. | | | |
| **11** | **Installation and Commissioning** | | | |
| 11.1 | The bidder must arrange for the equipment to be installed and commissioned by certified or qualified personnel; any prerequisites for installation to be communicated to the purchaser in advance, in detail. | | | |



NEC No: 442 Biomedical "A"

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| **12** | **Documentation** | | | |
| 12.1 | User (operation) manual in English. | | | |
| 12.2 | Service (Technical/maintenance) manual in English. | | | |
| 12.3 | List of reagents, important spare parts and accessories with their part numbers and costing. | | | |
| 12.4 | Certificate of calibration and inspection from factory. | | | |
| 12.5 | List of hospitals or places in Nepal where similar system are being used. | | | |
| | Bidder must completely fill the Technical Specification form (TSF). Only Yes/no/all complies should not be written. Page number in the catalogue of all the required parameters must be clearly mentioned and highlighted. Failure in doing so may lead to rejection of bid from technical committee. | | | |

NEI No: 441 Biomedical "X"