HLL LIFECARE LIMITED
(A Government of India Enterprise)
Plot No. 71, Sector-7, IMT -122051
District - Gurugram, Haryana state
Phone: (0124) 4030949
website: www.lifecarehll.com

EXPRESSION OF INTEREST
No. HLL: MFG:SOURCE:EOI:CM:LL:01:2019-20 DT.16.10.2019

TENDER DOCUMENT

FOR

"EMPANELMENT OF MANUFACTUERER(S) FOR MANUFACTURE & SUPPLY OF IN VITRO DIAGNOSTIC KITS ON CONTRACT MANUFACTURING/UNDER LOAN LICENSE"

Last date and time for Receipt of Bid	: **11.11.2019 up to 11:00 Hrs.**
Date and time of opening of Bid	: **11.11.2019 at 12:00 Hrs.**

TABLE OF CONTENTS

Titles	Page no.
1. Notice Inviting Expression of Interest	3
2. Bid Data Sheet & Background Note	5
3. Eligibility Criteria	6
4. Scope of work & General Instructions To The Bidders	7
5. Specific Terms & Conditions of Contract	12
Format -1 : Self Declaration	13
Annexure -1: Technical specifications	14
Annexure -2: Price Bid Format	16

EXPRESSION OF INTEREST
No. HLL: MFG:SOURCE:EOI:CM:LL:01:2019-20 DT.16.10.2019

1. NOTICE INVITING EXPRESSION OF INTEREST

HLL Lifecare Limited (Formerly Hindustan Latex Limited) (HLL) is a "Mini Ratna" PSU under the Ministry of Health & Family Welfare, Govt. of India involved in the promotion of Health care Products through its marketing division. HLL invites Expression of Interest from interested Pharma. / Diagnostic Manufacturers TO MANUFACTURE & SUPPLY IN- VITRO DIAGNOSTIC KITS - SICKLE CELL SOLUBILITY KIT, THALASSEMIA SOLUBILITY KIT, SALT IODINE TESTING KIT ON CONTRACT MANUFACTURING / UNDER LOAN LICENCE MANUFCATURING. Its contents etc are given in this Bid document.

The scope of work under the present Expression of Interest covers the following:

1. Manufacture & Supply (on door delivery basis) of diagnostic kits - Sickle cell solubility Kit, Thalassemia cell solubility Kit and Salt Iodine Testing kit for field screening ON CONTRACT MANUFACTURING / UNDER LOAN LICENSE.

2. Liaison for institutional sales of In vitro diagnostic kits, collection of I notes / CRC and payment collections

3. Ensure strict compliance to all statutory regulations with furnishing of a "Certificate of Analysis" confirming to Drugs & Cosmetics Act, 1940 and Rules, 1945 & Medical Devices Rule, 2017 for each batch of products manufactured from the facility.

4. Follow current Good Manufacturing practices throughout the manufacturing process.

5. Ensuring Production of quality products at all stages and at all time.

6. Maintenance of Batch manufacturing records and other relevant records as per the requirement of Drugs & Cosmetic Act, 1940 and the rules there of.

The details of item, item specifications and terms & conditions etc. are given in Tender documents. The same can be had from our Office on any working day between 11:00 AM to 3:30 PM by paying Rs 5000/- by Cash / D.D. (inclusive of GST) drawn in favour of HLL Lifecare Limited, payable at State Bank of India, Nipani - 591 237, Dist Belagavi, Karanataka. Also, Tender documents can also be downloaded from our website **www.lifecarehll.com or** Govt. Procurement Portal **eprocure.gov.in.** However, the cost of **Tender documents i.e. Rs. 5000 /- by D.D. shall be given along with the Technical Bid.**

Price of bidding document (non-refundable)	**Rs. 5000.00**
Sale of tender document (between 10.30 to 15.00 hrs)	**17.10.2019 to 09.11.2019**
Pre bid meeting (IST) at Manesar, Gurgaon	**22.10.2019 at 11:00 Hrs.**
Last date and time (IST) for receipt of bids	**11.11.2019 up to 11:00 Hrs.**
Date & Time (IST) of opening of Technical bids	**11.11.2019 at 12:00 Hrs.**

We request you to submit your sealed bid (Technical and Financial bid) for the Empanelment of Manufacturer(s) to manufacture & supply of In Vitro diagnostic kits on Contract Manufacturing/Under Loan License.

In case you need any further information, please feel free to contact the undersigned through email pngupta@lifecarehll.com or through Phone 9999305085.

Unit Chief, HLL MFG

2. BID DATA SHEET & BACKGROUND NOTE

Address for Submission of Bids	**Unit Chief,** **HLL Lifecare Limited** **(A Govt. of India Enterprise)** **Plot No. 71, Sector-7, IMT, Manesar 122051** **Dist. Gurugram, Haryana state** **Tel: (0124) 4030949**
Bid validity	90 days from the date of bid opening
No. Of copies	No. of copies: 1 original
Dead line for submission of Bid	**11.11.2019 up to 11:00 Hrs.**
Date of opening of Bid	**11.11.2019 at 12:00 Hrs.**

BACKGROUND NOTE

Company Background

HLL Lifecare Limited (formerly Hindustan Latex Limited) (HLL) is a Mini Ratna (Category-1 PSE) company under the Ministry of Health and Family Welfare. Our Corporate head office is at Thiruvananthapuram, Kerala. We have seven production units – two in Thiruvananthapuram, one each at Kakkanad, Irapuram in Kerala and one each at Kanagala, Belagavi, Karnataka & Indore M.P., and Manesar, Haryana. Procurement & Consultancy Office at Noida, Manufacturing facility at CSEZ and Marketing Offices around the Country. We have Five subsidiaries viz., HLL Biotech Ltd., Goa Antibiotics Ltd., HLL Infra Tech Services Ltd., Lifespring Hospitals (P) Ltd., and HLL Management Academy.

HLL has developed an impressive production infrastructure for a range of Contraceptives and Health Care Products. We are also planning to venture into new and challenging frontiers in the area of Health Care such as Vaccines, R&D, Hospitals and Pharmaceuticals. The total employee strength of HLL is around 5000.

3. ELIGIBILITY CRITERIA FOR BIDDERS

a. The bidder shall be manufacturer of Sickle cell solubility kit, Thalassemia solubility kit, Salt Iodine detecting kit in regulatory compliant facility and spare capacity to manufacture and supply 2 - 5 lakh kits / annum of each kit to HLL. The Manufacturers / Bidder should have manufacturing and marketing experience of tendered items of minimum 2 years and the same shall be supported by documentary evidence.

b) The manufacturer should have annual sales turnover of minimum Rs 1.0 Crore during any one of the last three financial years i.e. 2016-17, 2017-18 and 2018-19. Annual Report / Certificate from Chartered Accountant shall be enclosed.

c) The tenderer should have Non-Conviction Certificate for last 1 year (Self attested copy should be enclosed).

d) Copy of Site Master File must be enclosed.

e) A Demand Draft /Bank Guarantee for Rs 1,00,000/- towards Earnest Money Deposit, drawn in favour of "HLL Lifecare Ltd." and payable at SBI, Nipani, Dist Belagavi, Karanataka shall be enclosed.

f). A Demand Draft for Rs 5,000/- towards cost of Tender Form, drawn in favour of "HLL Lifecare Ltd." and payable at SBI, Nipani, Dist Belagavi, Karanataka shall be enclosed.

g) A self-declaration to enter into an agreement as stipulated in the tender document in case of contract manufacturing / Under Loan License manufacturing within 10 days from the date of issue of order needs to be enclosed with Technical Bid.

h) Manufacturer shall submit Self Declaration that the company is not black listed by any state Govt. or Govt. of India in the prescribed format provided as Format -1.

4. SCOPE OF WORK & GENERAL INSTRUCTIONS TO BIDDERS

General Scope

1. Manufacture & Supply (on door delivery basis) of diagnostic kits - Sickle cell solubility Kit, Thalassemia cell solubility Kit and Salt Iodine Testing kit on Contract Manufacturing / Under Loan License.

2. Liaison for institutional sales of In vitro diagnostic kits, collection of I notes / CRC and payment collections

3. Ensure strict compliance to all statutory regulations with furnishing of a "Certificate of Analysis" confirming to Drugs & Cosmetics Act, 1940 and Rules, 1945 & Medical Devices Rule, 2017 for each batch of products manufactured from the facility.

4. Follow current Good Manufacturing practices throughout the manufacturing process.

5. Ensuring Production of quality products at all stages and at all time.

6. Maintenance of Batch manufacturing records and other relevant records as per the requirement of Drugs & Cosmetic Act,1940 and the rules there of .

GENERAL INSTRUCTIONS TO BIDDERS

1. Ethical Standard

1.1 Bidders are expected to observe the highest standard of ethics during the procurement and execution of this Contract. In pursuit of this policy, HLL will reject a proposal for award if it determines that the Bidder being considered for award has engaged in corrupt or fraudulent practices in competing for the Contract

For the purposes of this provision, the terms set forth below are defined as follows:

(i) Corrupt practice: means the offering, giving, receiving, or soliciting of anything of value to influence the action in the procurement process or in Contract execution; and

(ii) Fraudulent practice: means a misrepresentation of facts in order to influence procurement process including collusive practices designed to establish bid prices at artificial, non-competitive levels to deprive HLL of the benefits of competition;

2. Cost of Bidding

The Bidder shall bear all costs associated with the preparation and submission of its bid, and the Purchaser will in no case be responsible or liable for those costs.

3. Clarification of Bidding Documents

a) A prospective Bidder requiring any clarification of the Bidding Documents may notify the Purchaser in writing, or by e mail at the purchasers mailing address indicated in the Invitation for Bids. The Purchaser will respond in writing to any request for clarification of Bidding Documents, which it receives not later than 5 days prior to the deadline for submission of Bids prescribed by the Purchaser.

b) During the bid evaluation, the Purchaser may, at its discretion, ask the Bidder for a clarification of its bid. The request for clarification and the response shall be in writing, and no change in the price or substance of the bid shall be sought, offered, or permitted.

4. Amendment of bidding documents

a) At any time prior to the deadline for submission of bids, the Purchaser may, for any reason, modify the Bidding Documents by amendment in company website only.

b) The amendment will be notified in writing or e-mail to all prospective Bidders, which have received the Bidding Documents and will be binding on them.

Preparation of Bids

5. Language of Bid

All correspondence and documents related to the bid shall be in English.

6. Documents Accompanying the Bid

The Response to mandatory requirements shall consist of:

a. A forwarding letter indicating the submission of sealed Technical Bid. An authorized person holding the Power of Attorney should sign the letter.

b. Power of Attorney in original and/or duly notarized.

c. Signed copy of Tender Document (all pages to be signed & stamped)

d. Organization structure of the Bidder & escalation mechanism.

e. Copy of the Manufacturing License from competent authority, if applicable.

f. Copies of executed any orders, if available.

7. For all the parts of the Bid, the Bidder shall prepare one original bid as per Bid Data Sheet (BDS). The Bid consisting of the complete set of documents shall be signed by the Bidder or a person duly authorized to bind the Bidder to the Contract. All pages of the bid shall be numbered except for un-amended printed literature, which shall be initialed by the person signing the bid.

8. The bid shall contain no interlineations, erasures, or overwriting, except to correct errors made by the Bidder, in which case the person or persons signing the bid shall initial such corrections.

9. Period of Validity.

Empanelment shall remain valid up to 3 years from the date of signing the agreement; further renewal shall be made upon mutual agreement at agreed terms.

Submission of Bids

10. Sealing and Marking of Bids

The Bidder shall prepare and seal technical bid and price bid in two separate envelopes with requisite documents super scribing the envelopes as No. HLL: MFG: SOURCE: EOI:CM:LL:01:2019-20 Dt.16.10.2019 "Technical Bid" and "Price Bid" respectively. Further, both the envelops shall be kept in outer envelop super scribing the envelope as EOI No. HLL: MFG: SOURCE: EOI:01:2019-20 DT.16.10.2019 "Bid for Empanelment of Manufacturer to Manufacture & Supply of In Vitro Diagnostic Kits ON CONTRACT MANUFACTURING/ UNDER LOAN LICENSE"

i) The envelope shall be addressed to HLL at the address given in the bid data sheet and

ii) Bear the Contract name, the Invitation for Bids title and number, and the statement DO NOT OPEN BEFORE 11.11.2019 (Mention the date of opening of the bid as given in the tender documents).

iii) EMD & Bid Document fee shall be provided along with the technical bid without fail so proof of EMD and Bid document fee submissions are available with technical bid.

iv) If the outer envelope is not sealed and marked as required HLL will assume no responsibility for the bids misplacement or premature opening.

11. Deadline for Submission of Bids

Bids must be received by HLL at the address specified in the bid not later than the time and date stated in the bid. HLL may, at its discretion, extend this deadline for submission of bids in which case all rights and obligations of HLL and Bidder thereafter be subject to the deadline as extended.

12. Late Bids

Any bid received by HLL after the bid submission deadline prescribed by HLL in the bid, will be rejected and returned unopened to the Bidder.

13. Modification and Withdrawal of Bids

Bids once submitted should not be modified. However in exceptional cases where modification is inevitable, the following procedure for the same should be adopted.

13.1 Modification will be permitted only if a written notice of the same is received by HLL prior to the deadline prescribed for bid submission.

13.2 The Bidder's modifications shall be prepared, sealed, marked, and dispatched as follows

(a) The Bidders shall provide copy of any modification(s) to its bid, clearly identified as such, marked BID MODIFICATIONS ORIGINAL The envelope shall be sealed in which shall be duly marked BID.

13.3 A Bidder wishing to withdraw its bid shall notify HLL in writing prior to the deadline prescribed for bid submission. The withdrawal notice shall be addressed to HLL

at the address named in the bid data sheet and bear the Contract name, and the words BID WITHDRAWAL NOTICE. Bid withdrawal notices received after the bid submission deadline will be ignored and the submitted bid will be deemed to be a validly submitted bid.

13.4 No bid may be withdrawn in the interval between the bid submission deadline and the expiration of the bid validity period specified.

14. In the event of the date specified for bid receipt and opening being declared as a closed holiday for purchaser's office, the due date for submission of bids and opening of bids will be the following working day at the appointed times.

15. The purchaser may, at its discretion, extend this deadline for submission of bids by amending the Bid Documents or any other reasons, in which case all rights and obligations of the Purchaser and Bidder previously subject to the deadline will thereafter be subject to the deadline as extended, in our website.

Purchaser will not be held responsible for the postal delay, if any, in the delivery of the bidding document or the non-receipt of the same. Bids sent by e mail Telex/Fax/Telegraph will not be accepted.

The company reserves the right to club or split the items of works, change the qualifying criteria at their discretion and to reject the bid or cancel the tender without assigning any reason thereof.

Bid Opening and Evaluation

16. Opening of Bids by HLL

Bids received before the dead line of the submission of the bid will be opened on the date and time of opening mentioned in the Bid Data Sheet (BDS).

Bidders wishing to be present at the time of such opening may send their duly authorized representative.

17. Preliminary Examination of Bids

17.1 HLL will examine the bids to determine whether they are complete, whether any computational errors have been made, whether required securities have been furnished, whether the documents have been properly signed, and whether the bids are generally in order.

17.2 HLL may waive any minor nonconformity, or irregularity in a bid that does not constitute a material deviation, provided such waiver does not prejudice or affect the relative ranking of any Bidder.

17.3 HLL may inspect manufacturing facility for verifying manufacturing feasibility, spare capacity offered and information, documents shared against the tender enquiry. The bidders shall extend support during inspection and to provide requisite information, documents.

18. Clarifications on Bids

During the bid evaluation, HLL may, at its discretion, ask the Bidder for a clarification of its bid. The request for clarification and the response shall be in

writing, and no change in the price or substance of the bid shall be sought, offered, or permitted.

19. Contacting HLL

19.1 From the time of bid opening to the time of Contract award, if any Bidder wishes to contact HLL on any matter related to the bid, he shall do so in writing.

19.2 If a Bidder tries to influence HLL directly or otherwise, interfere in the bid evaluation process and the Contract award decision, his bid will be rejected.

20. HLL's Right to Accept or reject any or all Bids

20.1 HLL reserves the right to accept or reject any bid or to annul the bidding process and reject all bids at any time prior to Contract award, without assigning any reason thereof.

20.2 HLL reserves the right to inspect the manufacturing premises, if so warranted before empanelment and any time during the contract period

21. Notification of Award

Prior to the expiration of the period of bid validity, HLL will notify the successful Bidder in writing that its bid has been accepted.

22. Signing of Contract

22.1 At the same time as HLL notifies the successful Bidder that its bid has been accepted, HLL will send the Bidder the Contract Form provided in the Bidding Documents, incorporating all agreements between the parties.

22.2 Not more than ten (10) days following receipt of the Contract Form, the successful Bidder shall prepare the contract agreement on a Non Judicial stamp paper of RS 100/-, sign, date and return it to HLL.

In case, the successful bidder does not do so, HLL in its discretion may cancel the bid of the successful bidder and may accept the bid of the next higher bidder and the successful bidder also be liable to pay damages to HLL.

5. SPECIFIC TERMS & CONDITIONS OF CONTRACTS

1. The manufacturer shall not, at any time, assign, sub-let or make over the contract or the benefit thereof or any part thereof to any person or person what so ever.
2. The manufacturer must submit Batch wise Test Analysis report of In Vitro diagnostic Kits from NABL certified laboratories only in original along with each consignment.
3. The manufacturer shall submit batch wise samples of In Vitro diagnostic kits supplied to the undersigned before the commencement of supply.
4. The In Vitro diagnostic kits shall be supplied in the package specified in Compliance of D&C Act requirements and the package shall carry the logograms specified.
5. No advance payment towards costs of In Vitro Diagnostic kits etc. shall be made to the supplier. The payment against part supply will not be entertained.
6. On completion of supplies of ordered quantities, bills/Invoices should be raised in triplicate in the name of HLL Lifecare Limited.
7. If any time a particular product is found damaged or the packaging has deteriorated or the test reports has failed then the supplier has to replace the whole quantity of item at his own cost within 30 days.

8. Terms of Payment: will be decided at the time of signing of agreement.

9. Delivery Schedule: The quantity to be delivered will be intimated as per the schedule given from time to time FOR various consignees of various states.

6. Taxes and Duties: The Bidder shall bear and pay all taxes, duties, levies, and charges assessed on the bidder by all municipal, state, or national government authorities, in connection with the Goods and Services supplied under the Contract. Income Tax and Other Taxes as applicable at the time of execution of job or any other government-imposed liabilities would be deducted from each bill submitted by the bidder.

FORMAT-1

SELF-DECLARATION
(by established manufacturer)

To,

Unit Chief,

HLL Lifecare Limited

Plot No. 71, Sector-7, IMT, Manesar- 122051
Dist .: Gurugram

Dear Sir,

This is to certify that our Company has not been Black Listed either by any State Government or Government of India in connection with Manufacturing or Sourcing, Packaging & Distribution of In Vitro Diagnostic Kits & other related medical products manufactured by us.

Date:
Place:

Signature:

Name:
Designation:

Common Seal:

ANNEXURE-1: Technical Specifications

A. Technical Specifications

Specification for the kit for screening of sickle cell hemoglobin through solubility test Kits

- Kits should be capable of identify sickle hemoglobin (HbS) through turbidity.
- Kits should contain solubility buffer, Reducing agent (Powder), clear disposable tubes, isopropanol swab, lancet, and dropper and any other accessories required for field screening – Micro pipette, Reading Stand, disposable tips for pipette etc.
- Kits should be stable at room temperature and easy to transport. Kits would have negative and positive control.
- Preferable pack size: 50 test/kit

Specification for the kit for screening of Thalassemia trait through NESTROFT test Kits

- Kit should be capable of identifying beta Thalassemia trait turbidity method.
- Kits should contain buffer, clear disposable test tubes, isopropanol swab, lancet, and dropper and any other requisite accessories required for field screening Micro pipette, Reading Stand, disposable tips for pipette etc.
- Kits should be stable at room temperature and easy to transport. Kits would have negative and positive control.
- Preferable pack size: 50 test/kit

Specifications for Salt testing Kits:-

1. The salt testing kit should be ready in use, liquid form. Each salt testing kit should have 20 ml testing solution or testing capacity of 75-100samples. Supply should be in plastic screwed cap vial and able to dispense one drop at the time for use at community level. It can be stored at ambient temp and relative humidity (20-90% +/- 10%) in any part of the country.
2. The kit should be able to differentiate (a) Salt with nil iodine (b) Salt with inadequate iodine in the range of 05 to less than 15 ppm. (c) Salt with adequate level of iodine 15ppm and above
3. The kit should be able to detect iodine level in salt from various sources and characteristics e.g. salts that are alkaline/acidic in nature and with varying sodium chloride content in the country.
4. The test kit should have been evaluated and validated by at least one International agencies WHO, UNICEF ,MI and or National Level Laboratories such as National Institute of Nutrition, Hyderabad, National Centre for Disease Control, Delhi : All India Institute of Hygiene & Public Health, Kolkata: Central Food Tech Research Inst., Mysore: ICMR & Council of Scientific and Industrial research Laboratories. The validation should include tests for quality, packaging, ready to use testing (drop by drop), stability at various places, shelf life under sealed condition as well as open condition, as all parameters are interlinked. The testing laboratory should submit a detailed report about all test parameters including how they vary under different field conditions.
5. The offered Manufacturers/Bidder should have manufacturing and marketing experience minimum 2 years and should be supported by documentary evidence.
6. The shelf life of the Salt Testing kit should be at least one year and when the vial is opened it should not be less than 4-6 months.

7. Pack size: Each salt testing kit should be independently packed and not more than 10 kits in a bigger package, for the purpose of ease of transportation/distribution.
8. Bidders are required to submit documentary proof in support of above quoted specifications and requirements along with the bids.
9. Bidders are also required to submit kit samples as per technical specification of salt testing kit

B. Common Salient Features of above test kits suitable for field screening:

1. Test should be sensitivity to perform field test. Kits should have sensitivity and specificity as per standards.
2. Kit can be stored at 45 deg.
3. Test can be carried out at RT (at 45 deg.)
4. Test can be performed without help of electrically operated equipments eg. Centrifuge machine
5. Test should not required sophisticated instrument to interpret the results.
6. It should not require much technical expertise to differentiate between disease cells & normal individuals cells
7. Company must mention about conditions leading to false positive or false negative results
8. Shelf life: the reagents in the solubility test kit have shelf life of one (1) year. Shall be submitted stability data in support of product shelf life.

Annexure- 2

PRICE BID FORMAT (EOI No. HLL: MFG: SOURCE: EOI: 01:2019-20 DT.16.10.2019) :

The below mentioned format should be used for submission of financial bid by bidders:

FORMAT FOR SUBMISSION OF FINANCIAL BID

Percentage of Profit Share offered to HLL as a % of turnover	

Note:

- Pl refer Annexure -1 for product details, product packaging and technical specifications and EOI document for the scope of work

- Kit contents, packaging and accessories in technical specifications are indicative and shall meet specific requirements of Govt. orders