



क्षेत्रीय आयुर्वेद चयापचय विकार अनुसंधान संस्थान
(सी. सी. आर. ए. एस, आयुष मंत्रालय, भारत सरकार),
सरकारी केंद्रीय औषधागार, अशोक स्तंभ जयनगर बेंगलूरु 560011
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F. No. 6-51/2015/NADRI/BNG/IMR/AYUSH DDM/07

Date: 03-04-2018

INVITING TENDERS

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1. NOTICE INVITING TENDERS

- i. Regional Ayurveda Research Institute for Metabolic Disorders (RARIMD) (Central Council for Research in Ayurvedic Sciences Ministry of AYUSH, New Delhi) Govt. Central Pharmacy Annexe, Ashoka Pillar, Jayanagar Bengaluru 560011, on behalf collaborating Institutes/Centres for AYUSH D projects, invites sealed quotations in **two bid system** (Technical bid and financial bid) from NABL accredited reputed, eligible and qualified laboratories for conducting the specified laboratory investigations for two collaborative clinical research projects mentioned in the tender document.

Name of the activity	Centres	Earnest Money Deposit	Tender fee	Proposed Dates and time
Outsourcing of Laboratory investigations for two clinical projects on AYUSH D in Prediabetes and Type 2 Diabetes Mellitus from NABL	1. All India Institute of Medical Sciences, Ansari Nagar East, New Delhi, 110029. 2. RA Poddar Ayurvedic Medical College, Dr. Annie Besant Road, Worli, Mumbai - 400 018. 3. Rajiv Gandhi Government Post-Graduate Ayurvedic College Paprola Panchrukhi Road, Paprola, Distt-Kangra (HP) 176125. 4. Regional Ayurveda Research	1,50,000 (One lakh Fifty Thousand only).	1000/- (non refundable)	<ul style="list-style-type: none">• Tender start date: 04.04.2018• Tender Closing date: 26.04.2018 upto 5 pm• Pre bid meeting date venue and time: 16.04.2018 at RARIMD Govt. Central Pharmacy annexe, Ashoka Pillar, Jayanagar

accredited laboratories for centres mentioned.	Institute For Metabolic Disorders, Ashoka Pillar, Jayanagar, Bangalore 560011. 5. BMK Ayurved Mahavidyalaya (KLE Society's), Shahpur, Belgaum, Karnataka 590003.			Bengaluru 560011 at 11 am • Technical bids Tender Opening date: 27.04.2018 at 3.00 pm.
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- ii. Total work as specified in the tender document involves collection of body fluid samples (blood and urine) from the centers mentioned above table and **analyzed at a single NABL accredited lab (centralized sample processing only)** in the country.
- iii. The payment for the investigations will be made by the respective centre.
- iv. Tender documents containing detailed specifications can be had from the office of RARIMD, Ashoka Pillar, Jayanagar Bengaluru 560011 from 10.00 am to 4 pm till a day prior to closing date of receipt of bid indicated above by post/courier/in person. Each page of the document including terms and conditions should be signed by the tenderer. It is the responsibility of the tenderer to ensure that their bids whether sent by post or by courier or by person reaches Assistant Director In-charge, RARIMD, Ashoka Pillar, Jayanagar, Bengaluru 560011 within the stipulated date and time mentioned above. The bids reaching later that that will be summarily rejected.
- v. The bidders may download the tender documents directly from the website available at www.ccras.nic.in. They required to submit the tender cost fee of Rs. 1000/- by way of bank demand draft payable in favor of 'Regional Ayurveda Research Institute for Metabolic Disorders, Bengaluru'. The tender cost fee should not be mixed with EMD amount. The tenderers not following the above procedure will be summarily rejected.
- vi. The tender enquiry document is not transferable.
- vii. **Pre bid meeting** will be held on 16th April 2018 at RARIMD, GCP Annexe, Ashoka Pillar, Jayanagar, Bengaluru 560011. At 11 am.
- viii. In the event of any of the above mentioned dates being declared as a holiday/Closed day for RARIMD/CCRAS, The tenders will be received/opened on the next working day at the prescribed venue and time.
- ix. Any subsequent amendment/ Modification/ corrigendum will be uploaded on CCRAS website and shall not be published in the news papers.

Sd/-
Assistant Director In-charge
RARIMD, Bengaluru

Tender Document

2. Schedule of Requirements

2.1. Name of the Item: specification of rate contract of laboratory Investigations.

2.2. Subject: Outsourcing of laboratory Investigations for two clinical projects on AYUSH D

2.2.1. Project -1 A Randomized Placebo Controlled Prospective Phase II Clinical Study of an Ayurvedic Coded Drug AYUSH D on Glycemic Control in Prediabetic Subjects.

2.2.1.1.Objective1: To establish laboratory service for various investigations needed in the project at four places as mentioned below,

2.2.1.2. Areas to be covered: Tender is invited for providing laboratory for the investigations of the parameters at various levels as stated below:

- a) Sample Size: 264 (66 in each centre mentioned below) + 25 % screen failure and drop outs.
- b) Duration of the Study: 30 months
- c) Centers
 - i. All India Institute of Medical Sciences, Ansari Nagar East, New Delhi, 110029.
 - ii. RA Poddar Ayurvedic Medical College, Dr. Annie Besant Road, Worli, Mumbai - 400 018.
 - iii. BMK Ayurved Mahavidyalaya (KLE Society's), Shahpur, Belgaum, Karnataka 590003.
 - iv. Regional Ayurveda Research Institute For Metabolic Disorders, Ashoka Pillar, Jayanagar, Bangalore 560011.

2.2.1.3. Laboratory Investigations and Assessment Schedule [n = 264 (66 in each centre × 4)] for project 2

S N	Activity	Assessment Schedule							
		Screening /Baseline	FU -1 28 th Day	FU -2 56 th Day	FU -3 84 th Day	FU -4 112 th Day	FU -5 140 th Day	FU -6 168 th Day	FU -7 196 th Day
1	12 lead Electrocardiogram	✓							
2	HbA1c levels	✓			✓			✓	
3	Plasma Insulin	✓						✓	
4	Fasting blood glucose	✓	✓	✓	✓	✓	✓	✓	✓
5	Post-prandial blood glucose	✓	✓	✓	✓	✓	✓	✓	✓
6	Lipid profile (TC, HDL, LDL, VLDL and triglycerides)	✓			✓			✓	
7	<u>Liver Function tests</u> <ul style="list-style-type: none"> • Total protein • Albumin • Total bilirubin • Direct bilirubin • Albumin • Serum glutamic - pyruvic transaminase (SGPT/ALT) • Serum glutamic- oxaloacetic transaminase (SGOT/AST) • Alkaline phosphatase 	✓			✓			✓	
8	<u>Renal Function tests</u> <ul style="list-style-type: none"> • Blood Urea Nitrogen (BUN) • Serum Creatinine • Serum Uric Acid 	✓			✓			✓	
9	<u>Hemogram</u> <ul style="list-style-type: none"> • Hemoglobin • Red Blood Cell count (RBC) • White Blood Cell count (WBC) • Neutrophils • Lymphocytes • Monocytes • Basophils • Eosinophils • ESR • Platelet count 	✓			✓			✓	
10	Routine Urine analysis	✓			✓			✓	
11	Urine Microscopy	✓			✓			✓	
12	Urine Pregnancy Test	✓							

*The quote for ECG is liable to be cancelled based on the availability of facility at the above said centres.

2.2.2. Project -2: A Randomised Placebo Controlled Phase-II Clinical Study of an Ayurvedic Coded Drug AYUSH – D in the Management of Type 2-Diabetes Mellitus as add on Therapy to Metformin.

2.2.2.1. Objective 2: To establish laboratory service for various investigations needed in the project at four places as mentioned below.

2.2.2.2.Areas to be covered: Tender is invited for providing laboratory for the investigations of the parameters at various levels as stated below,

- a) Sample Size: 264 (66 in each centre mentioned below) + 25 % screen failure and drop outs.
- b) Duration of the Study: 30 months.
- c) Centers,
 - i. All India Institute of Medical Sciences, Ansari Nagar East, New Delhi, 110029.
 - ii. RA Poddar Ayurvedic Medical College, Dr. Annie Besant Road, Worli, Mumbai - 400 018.
 - iii. Rajiv Gandhi Government Post-Graduate Ayurvedic College Paprola Panchrukhi Road, Paprola, Distt- Kangra(HP) 176125.
 - iv. Regional Ayurveda Research Institute For Metabolic Disorders, Ashoka Pillar, Jayanagar, Bangalore 560011.

**2.2.2.3.Laboratory Investigations and Assessment Schedule [n = 264 (66
in each centre × 4)] for project 2**

S N	Activity	Assessment Schedule							
		Screening /Baseline	FU -1 28 th Day	FU -2 56 th Day	FU -3 84 th Day	FU -4 112 th Day	FU -5 140 th Day	FU -6 168 th Day	FU -7 196 th Day
1	12 lead Electrocardiogram	✓							
2	HbA1c levels	✓			✓			✓	
3	Plasma Insulin	✓						✓	
4	Fasting blood glucose	✓	✓	✓	✓	✓	✓	✓	✓
5	Post-prandial blood glucose	✓	✓	✓	✓	✓	✓	✓	✓
6	Lipid profile (TC, HDL, LDL, VLDL and triglycerides)	✓			✓			✓	
7	<u>Liver Function tests</u> <ul style="list-style-type: none"> • Total protein • Albumin • Total bilirubin • Direct bilirubin • Albumin • Serum glutamic-pyruvic transaminase (SGPT/ALT) • Serum glutamic- oxaloacetic transaminase (SGOT/AST) • Alkaline phosphatase 	✓			✓			✓	
8	<u>Renal Function tests</u> <ul style="list-style-type: none"> • Blood Urea Nitrogen (BUN) • Serum Creatinine • Serum Uric Acid 	✓			✓			✓	
9	Hemogram <ul style="list-style-type: none"> • Hemoglobin • Red Blood Cell count (RBC) • White Blood Cell count (WBC) • Neutrophils • Lymphocytes • Monocytes • Basophils • Eosinophils • ESR • Platelet count 	✓			✓			✓	
10	Routine Urine analysis	✓			✓			✓	
11	Urine Microscopy	✓			✓			✓	
12	Urine Pregnancy Test	✓							

*The quote for ECG is liable to be cancelled based on the availability of facility at the above said centres.

TOTAL SAMPLE SIZE (FOR BOTH PROJECTS IN ALL CENTERS): 528 (+ 25% screen failure)

2.2.Price Bid (Financial Bid)

1. This should be showed as per **Table 2**.
2. The quoted price should be inclusive of GST and GST should be stated separately
3. All pages of the Tender should be page numbered and indexed.
4. It is the responsibility of bidder to go through the TE document to ensure furnishing all required documents in addition to above, if any.
5. The authorized signatory of the bidder must sign the tender duly stamped at appropriate places and initial all the remaining pages of the tender.
6. A tender, who does not fulfil any of the above requirements and/or gives evasive Information/reply against any such requirement shall be liable to be rejected.
7. Tender sent by fax/telex/cable/electronically shall be ignored and not accepted at all.
8. The prices quoted by the bidder shall remain firm and fixed during the currency of the contract and not subject to variation on any account.

Note: The sentence “NOT TO BE OPENED” before _____ (*The bidder is to put the date & time of tender opening*), BID FOR ITEM & SCHEDULE NO. _____ (*The bidder is to put the “Brief Description of Goods” and the Schedule No. Of the Schedule of requirement where for the bid is being submitted*)” are to be written on these envelopes. The inner envelopes are then to be put in a bigger outer envelope, which will also be duly sealed, marked etc. as above. If the outer envelope is not sealed and marked properly as above, the purchaser will not assume any responsibility for its misplacement, premature opening, late opening etc. The bidder is to seal the original duly marking the same as “Original”, and writing the address of the purchaser and the tender reference number on the envelopes. Bidder shall seal ‘**Technical Bid**’ and ‘**Price Bid**’ separately and covers will be suitably super scribed. Both these sealed covers shall be put in a bigger cover and sealed. The price bid as per format enclosed of section VIII will be prepared individually for each item of a schedule and separate sealed envelope for each schedule shall be prepared. Accordingly, separate envelopes of Price Bids Schedule-wise should be submitted in a bigger enveloped & marked “PRICE BID

Note: Pre bid meeting will be held on 16th April 2018 at RARIMD, GCP Annexe, Ashoka Pillar, Jayanagar, Bengaluru 560011. At 11 am

4. Terms and Conditions

1. This will be a single tender comprising of investigations to be conducted for both the above mentioned projects (AYUSH D in Prediabetes and Type two Diabetes Mellitus at the centers mentioned above)
2. The quote encompassing collection logistics processing and report delivery should be uniform across all centers and should not vary.
3. All the required samples for the said investigations should be collected from the respective centers mentioned above and processed **at a single NABL accredited lab (centralized sample processing only)** in India. The logistics, collection and other costs should be covered in the tender cost.
4. Applicant should be NABL accredited laboratory renewed for the current year and applicable for all the investigations mentioned in the document. The agency shall submit the copy of accreditation certificate valid for current year.
5. The applicant should submit the trade license certificate
6. The applicant should submit the GST certificate
7. The applicant should submit the income tax returns for the past three years
8. Unit wise and frequency wise rates of each investigation and total cost of all investigations for the both projects should be quoted.
9. The particulars of investigation kits, reagents used (company's name) and reference ranges based on the kits should be stated separately and specifically in the tender.
10. The quotation should be inclusive of all taxes.
11. Ensure timely collection of sample from the study locations on call.
12. Any investigations not according to required methodology will be rejected.
13. During the period of contract, no increase in charges will be considered.
14. The Agency has no right to give, bargain, sell, assign or sublet or otherwise dispose of the contract or any part thereof, as well as to give or to let a third party take benefit or advantage of the present contract or any part thereof.
15. The service providers shall not divulge or disclose to any person, any details of the assigned work or project related information to maintain confidentiality.
16. Earnest Money Deposit: Each tender must be accompanied with earnest money deposit (EMD) of Rs. 1,50,000/- (Rupees one lakh fifty thousand only) in the form of Demand Draft or bank guarantee of any nationalized scheduled bank payable in favor of Regional Ayurveda Research Institute for Metabolic Disorders, Bengaluru. Tender without or inadequate EMD shall be summarily rejected. This will be returned

without interest in case of rejected tenders. The EMD and tender processing fee of 1000/- should be remitted in two separate Demand Drafts.

Earnest Money is required to protect the purchaser against the risk of the Bidder's conduct, which would warrant the forfeiture of the EMD. Earnest money of a bidder will be forfeited, if the bidder withdraws or amends its tender or impairs or derogates from the tender in any respect within the period of validity of its tender or if it comes to notice that the information/documents furnished in its tender is incorrect, false, misleading or forged without prejudice to other rights of the purchaser. The successful bidder's earnest money will be forfeited without prejudice to other rights of Purchaser if it fails to furnish the required performance security within the specified period.

The earnest money shall be valid for a period of one year from the date of opening of Technical bid. The EMD shall be valid for 1 year from Technical bid Tender opening date. Unsuccessful bidders' earnest money will be returned to them without any interest, after expiry of the tender validity period, but not later than thirty days after conclusion of the resultant contract. Successful bidder's earnest money will be returned without any interest, after receipt of performance security from that bidder.

17. Performance Security: The successful tenderer would furnish security equivalent to 5% of the total cost after adjustment of earnest money deposited in the shape of Bank Draft within ten days from the acceptance of his offer (only working days to be counted). If the successful tenderer has previously held any contract and furnished any security, the same would not be adjusted against this tender. No interest would be paid on the security. The Earnest Money Deposit of the successful tenderer shall be adjusted against the Security Deposit.
18. The agency will be ranked based on lowest rates for the services as also extent of meeting the other requirements on the establishment, experience, reputation and track record. The contract will be awarded to the successful bidder only after approval of the competent authority.
19. The quotations will be opened on 27th April 2018 at 3.00 pm at RARIMD, Ashoka Pillar, Jayanagar Bengaluru 560011 in the presence of authorized representatives of the agencies who wish to be present.
20. The quotation must be valid for minimum 90 days from the date of opening of quotations.
21. The contract is likely to commence from 15th May 2018 and would continue for a period of thirty months. No hike in the rates will be permissible during this period.

The period of the contract may be further extended if needed by RARIMD or may be curtailed/terminated before the contract period owing to break in the agreement.

22. The payment will be done through cheque as and when the bill is produced (monthly), after ensuring satisfactory work by the respective centers as mentioned above.
23. Any dispute/difference arising out of or relating to this agreement including interpretation of its terms will be resolved through joint discussions of the concerned parties. However, if disputes are not resolved by joint discussions, then the matter will be referred to arbitration as per the provisions of Arbitration Act, 1940 within the jurisdiction of Bengaluru.
24. A joint MoU will be signed with the approved tenderer before commencing the work.
25. The Officer In-charge of RARIMD reserves the right to cancel all bids without assigning any reason thereof.
26. Maximum number of patients to be recruited would be 66 per centre (264 subjects per project × 2 projects = 528), 25% enhanced subjects may be seen considering screen failure and 10% enhanced subjects may be enrolled considering premature drop outs.
27. The supplier shall not, without the purchaser's prior written consent, disclose the contract or any provision thereof including any specification, drawing, sample or any information furnished by or on behalf of the purchaser in connection therewith, to any person other than the person(s) employed by the supplier in the performance of the contract emanating from this Tender document. Further, any such disclosure to any such employed person shall be made in confidence and only so far as necessary for the purposes of such performance for this contract.
28. **Patent Rights:** The supplier shall, at all times, indemnify and keep indemnified the purchaser, free of cost, against all claims which may arise in respect of goods & services to be provided by the supplier under the contract for infringement of any intellectual property rights or any other right protected by patent, registration of designs or trademarks. In the event of any such claim in respect of alleged breach of patent, registered designs, trademarks etc. being made against the purchaser, the purchaser shall notify the supplier of the same and the supplier shall, at his own expenses take care of the same for settlement without any liability to the purchaser.

5. Form Templates

5.1.Undertaking/ Acceptance

To,
The Assistant Director Incharge
Regional Ayurveda Research Institute for Metabolic Disorders
(Central Council for Research in Ayurvedic Sciences, Ministry of AYUSH, Govt. of India)
Govt. Central Pharmacy Annexe,
Ashoka Pillar, Jayanagar,
Bangalore 560011
Ref. Your tender document No. _____ dated _____.

I/We, the undersigned hereby agree to all the terms and conditions, stipulated by the RARIMD - CCRAS, in this connection including delivery, payment terms, penalty etc. against above said tender document No. _____, dated _____. We now offer to carry out the laboratory investigations in our NABL accredited laboratory in centralized mode (i.e., collection of samples from all centres and processed at one NABL accreted centre) and deliver the reports in conformity with your above referred document and separate price bid have been enclosed.

If our tender is accepted, we undertake to perform the services as mentioned above, in accordance with the terms and conditions. We further confirm that, if our tender is accepted, we shall provide you with a performance security of required amount in an acceptable form.

We agree to keep our tender valid for acceptance as mentioned in the terms and conditions or for subsequently extended period, if any, agreed to by us. We also accordingly confirm to abide by this tender up to the aforesaid period and this tender may be accepted any time before the expiry of the aforesaid period. We further confirm that, until a formal contract is executed, this tender read with your written acceptance thereof within the aforesaid period shall constitute a binding contract between us.

We further understand that you are not bound to accept the lowest or any tender you may receive against your above-referred tender enquiry. We confirm that we fully agree to the terms and conditions specified in above mentioned TE document, including amendment/ corrigendum, delivery, penalty etc if any.

(Signature with date)

(Name and designation) Duly authorised to sign tender for and on behalf of the laboratory

5.2. Table 1- Technical bid Specifications

SN	Name of the Investigation	Methodology	Kits used	Reference range

Name _____

Business Address _____

Place: _____

Signature of Tenderer _____

Date: _____

Seal of the Tenderer _____

5.3. Table 2- Price bid Specifications

S N	Name of the Investigation	Price per sample	GST /tax	Price for Logistics	Total price	Total number of samples	Total Price for all samples	Total Price of Logistics for all samples	Total GST for all samples	Total price

Name _____

Business Address _____

Place: _____

Signature of Tenderer _____

Date: _____

Seal of the Tenderer _____