EOI No.ICMR/EoI/01-BMS /2023

Invitation for Expression of Interest (EoI)

For

Transfer of Technology for joint development and commercialization of a Multiplex 2-tube real-time RT-PCR assay for detection of enteric viruses (E*n*Viro-Qplex)

Indian Council of Medical Research
(Department of Health Research, GoI)
V. RamalingaswamiBhawan,
P.O. Box No. 4911, Ansari Nagar,
New Delhi - 110029, India

CONTENTS

Letter of Invitation

1. INVITATION OF EXPRESSION OF INTEREST

Indian Council of Medical Research, New Delhi, invites Expression of Interest (EoI) from the experienced manufactures/companies regarding 'Transfer of Technology fordevelopmentandcommercializationof"A multiplex 2-tube Real-timeRT-PCR assay for detection of enteric viruses (E*n*Viro-Qplex)" a novel diagnostic test, developed byICMR , which is useful in medical diagnostics for manufacturing/commercialization etc.

The EoIdocument containing the details of qualification criteria, submission details, brief objective &scope of work and evaluation criteria etc. can be downloaded from the ICMR website (https://www.icmr.gov.in)

Schedule for the Proponents is as under:

EoI Document Number	ICMR/EoI/01-BMS /2023
Date of Publication	Date: 09-06-2023
Last date of submission	Date: 08-07-2023

Note: The EoI may be submitted through registered post to the following address-

Dr. Nabendu S. Chatterjee,
Scientist G and Head,
V. RamalingaswamiBhawan,
P.O. Box No. 4911
Ansari Nagar, New Delhi - 110029, India

Shortlisted firm(s)/organization(s) shall only be contacted for the further process of finalization of agreement and technology transfer.

ICMR reserves the right to cancel this EoI and/ or invite afresh with or without amendments, without liability or any obligation for such EoI and without assigning any reason. Information provided at this stage is indicative and ICMR reserves the right to amend/add any further details in the EoI, as may be desired by the competent authority at ICMR and duly notified on its website.

2. Background

The Indian Council of Medical Research (ICMR), New Delhi, the apex body in India for the formulation, coordination and promotion of biomedical research, is one of the oldest medical

research bodies in the world. The ICMR has always attempted to address the growing demands of scientific advances in biomedical research on the one hand and the need of finding practical solutions to the health problems of the country, on the other.

ICMR-National Institute of Cholera and Enteric Diseases (ICMR-NICED), Kolkata,one of the constituent institutes of the Indian Council of Medical Research (ICMR), New Delhi, is a pioneer institute in research on diarrhoeal diseases. ICMR-NICED conducts research on acute diarrhoeal diseases of diverse etiologies as well as on typhoid fever, infective hepatitis and HIV/AIDS related epidemiological research and screening. TheInstitute conducts research on these diseases in both basic and applied aspects. NICED scientists have developed and patented many vaccine candidates against enteric pathogens. Diagnostic assays against enteric bacteria, parasites and viruses are being tested and validated. The Institute also trains health professionals for better management and prevention of diarrhoeal diseases and for rapid and correct diagnosis of the etiological agents.It is also a recognized center for validation of commercial kits by CDSCO. ICMR-NICED has developed and validated amultiplex Real time PCRassayfordetectionofenteric viruses (Rotavirus, Norovirus GI/GII and Adenovirus) named EnViro-Qplex which is ready for transfer of technology.

ICMR reserves all the Intellectual Property Rights and Commercialization rights of the said TECHNOLOGY. ICMR is lawfully entitled to enter into any form of **non-exclusive agreements** with experienced manufacturers through a defined agreement for manufacturing activities for the development of**"A multiplex 2-tube Real-time RT-PCR assay for detection of enteric viruses and the diagnostic kit encompassing the same (EnViro-Qplex)"**, hereinafter referred to as the **'Product'.**

3. Objective

To jointly develop and licensethe 'Technology" for a **Multiplex Real-time RT-PCR Assay** that iseffective/useful in**diagnosis of enteric viruses from human clinical samples** for manufacturing and marketing activities.

4. Broad Scope of Work

i. ICMR is willing totransfer the said technologyto the manufacturer on**an upfront license fee** and **Royalty**basis on fixed termcontract condition forundertaking R&D, validation, manufacturing and marketing of**the Product**.

ii. The firm(s)/organization(s) wouldbe granted rights to undertake R&D, validation, manufacture, sell, and commercialize the product **A multiplex2-tube real-time RT-PCR assay for detection of enteric viruses (EnViro-Qplex)**.

iii. The License Agreement following EoI is proposed to be executed on "**Non-Exclusive" basis** with single/multiple firms, due to the extensive demand of**the A multiplex 2-tube real-time RT-PCR assay for detection of enteric viruses (EnViro-Qplex).** (~~Technology~~/Product).

iv. ICMR-NICED Institutehas expertise in various techniques, methods and information relating to aforesaid technology which could be could be used for the production of**A multiplex 2-tube real-time RT-PCR assay for detection of enteric viruses (EnViro-Qplex**) and the kit thereafter.

ICMR-NICED Institute will provide expert guidance& technical support forthe production of**the Product** in all phases. Such technical oversight by ICMR-NICED would accelerate the development of the Product and its production.

v. The product developed is owned by ICMRwhich holds the IP,which shall mean patents, rights to inventions, copyright and related rights, moral rights, rights in designs, rights in trademarks, rights to preserve the confidentiality of information (including know-how and trade secrets) and any other intellectual property rights, in each case whether registered or unregistered and including all applications (or rights to apply for and be granted), divisional, continuations, continuations-in-part, reissues, renewals or extensions of, and rights to claim priority from, such rights and all similar or equivalent rights or forms of protection which subsist or will subsist now or in the future in any part of the world regarding subject matter disclosed in Licensed patents; and shall include without limitation, the Technology, Licensed Patents and Licensed Trademarks.

vi) The product developed by companies/manufacturers during development encompassing IP, shall be jointly owned by ICMR & the company /manufacturer.

5. Intellectual Property Rights

ICMR is the owner of the said TECHNOLOGY, including any underlying Intellectual Property(ies) and Commercialization rights. ICMR, legally possesses the rights and authority to retain full or part of the 'TECHNOLOGY' by itself or to assign at its discretion full or part of the TECHNOLOGY including any patent(s) or intellectual property rights(s) or the invention(s), and/or ICMR is lawfully entitled to enter into any form of non-exclusive license agreements with selected manufacturer(s) including transfer of the TECHNOLOGY through suitable agreement.

6. Revenue upon Technology Rights

Interested companies/manufacturerswith demonstrated capabilities in the area ofdiagnostic kit development andmanufacturingare invited to obtain the license for the 'Technology for the production of**A multiplex 2-tube real-time RT-PCR assay for detection of enteric viruses (E*n*Viro-Qplex)**which is effective/useful for the diagnosis of viral pathogens in patients with acute gastroenteritis.

The manufacturers/companies interested in obtaining the licensemay quote **licensing fee** and **Royalty** not less than **5% (five percent)** on **Net Sales** of theENDPRODUCT on half yearly basis as entered in the books of account maintained by the Company/Manufacturer, up to 31st March and up to 30th September respectively every year regularly and punctually and in any event not later than the last day of April and last day of October immediately following in every such year provided that the liability of the Company/Manufacturer to pay royalty shall accrue upon the commencement of the commercial sale of the Product **("Royalty")** manufactured at the plant, as per the terms of "**ICMR-Technology Transfer and Revenue Sharing Guidelines 2021"** and as per the amendments approved by the competent authority from time to time.

In the event of default in payment of royalty as above, **interest @ 12%** (twelve percent) per annum on the Royalty due shall be charged for the first six months. If default persists for more

than six months interest at similar rate will be charged on the accrued interest also from the due dates of payments till realization/recovery of such amounts by the ICMR. Taxes and levies, as made applicable by the Government, shall be charged at the time of payments made to ICMR over and above the payments that shall be applicable as per terms of specified license Agreement to be executed with selected companies.

"*NET SALES*" shall mean Revenue from sales of goods or services by all ICMR grantee/Licensees/Sub-licensee(s) based on net sales realization from operations, net of discounts and indirect taxes as defined by cost Accounting Standards-24 and certified by the Chartered Accountant".

7. Validity of License

This LICENSE shall be valid from the **EFFECTIVE DATE** and subject to covenants and conditions herein contained and shall remain in force for a period of twenty **(20) years** commencing from the accrual of LICENSEE's obligation to pay Royalty to LICENSOR, after the commercialization of the Product **(the "Term").** After the period of 20 years the LICENSE will be royalty free.

8. Details of documents to be furnished.

Proponents are requested to go through all pre-qualification requirements, scope of work for execution & requirements with respect to technical / financial capabilities for acceptance and submission of documents for verification by ICMR.
Documents to be furnished are:

i. Authorization Letter (Format – 1)
ii. Declaration - Expression of Interest (Format – 2)
iii. Undertaking with regard to Blacklisting (Format-3)
iv. Undertaking with regard to Laboratory facilities (Format – 4)
v. Undertaking with regard to Non-Litigation (Format – 5)
vi. Production Capacity Undertaking (Format-6)
vii. License fee and Royalty Offer (Format-7)
viii. EoI document with each page duly stamped and signed by the Authorized signatory.
ix. Supporting documents, as mentioned in Format-2
x. MSME Certificate (if applicable)
xi. Concept note on business plan
xii. Registration certificates of company/organization
xiii. Any other information which proponent may like to provide.

ICMR reserves the right to call for any clarifications confined in the broad scope, wherever such a clarification become necessary for proper judgment in evaluation.

9. Rejection Criteria

The application is liable to be rejected if:

- The proposal is not submitted as per the requirements indicated in the EoI.
- Not in the prescribed format.

- Not properly stamped and signed as per requirements.
- Received after the expiry of due date and time.
- All relevant supporting documents are not furnished with the Pre-Qualification criteria.
- The proposal shall be substantially responsive without any material deviation, failing which the proposal shall be summarily rejected.

10. Evaluation Methodology

Screening of EoIs shall be carried out as per Pre-Qualification criteria mentioned in the EoI document and based on verification of documents submitted. Only shortlisted proponents shall be contacted for discussion, finalization & execution of the License Agreement/Agreement.
The evaluation of the EoI shall be carried out in two distinct stages-
Stage 1: Technical stage where technical aspects will be evaluated.
Stage II: Financial Stage where eligible Stage I applicants will be evaluated on the basis of their quoted upfront fee and proposed royalty percentage.
The interested applicants are requested to apply in two separate envelopes Technical Bid (Annexure A) and Financial Bid (Annexure B) as per the Format given in the EoI Document. The envelope shall also bear the EoI reference number.

Mention on the top of the envelope, the following details:
1. CONFIDENTIAL – Technical Bid for Licensing of Technology (XXX)
2. CONFIDENTIAL – Financial Bid for Licensing of Technology (XXX)

Note: The Financial Bids of only those applicants shall be opened who qualify the Technical Bid.

11. Pre-Qualification Criteria (PQC)

The following will be the minimum Pre-Qualification Criteria (PQC). Responses not meeting the minimum PQC will be summarily rejected and will not be evaluated further:

Sl. No.	**Pre-Qualification Criteria**	**Supporting copy of documents required** (All documents must be self-attested by the authorized person of the proponent)
For Indian Manufacturers/ Companies		
1	The proponent shall be a legal entity, registered as Institution/Company/LLP/Society/ partnership firm/ proprietorshipfirm underrespective acts in India.	Registration of firm/organization/Company Incorporation Certificate from ROC/Partnership deed etc. whichever is applicable
2	The proponent must be registeredin India with taxation and other administrative authorities.	GST Registration or GST exemption certificate/ PAN Card
3	The proponent should have prior experience in R&D and manufacturing and must have marketed such products in three(3) immediate preceding years.	Research paper/Pamphlet / brochure of the product/DCGI License for existing product
4	The proponent has to be profitable	Certificate from the Chartered Accountant

	and should not have incurred overall loss in past three (3) years. (applicable on commercial firms/organizations only)	of the Organization/ Audited Balance sheets for last three financial years or Income Tax return.
5	The proponent should have good track record and notblack-listed by any Central /State Government / Public Sector Undertaking, Govt. of India, at least in three (3) immediate preceding Years. (applicable on commercial firms/organizations only)	Undertaking on the Letter Head ofthe Proponent duly signed & Stamped by Authorized Signatory (As per format – 3).
6	The proponent should have a registered office, manufacturing unit in India	Registration copies of both. Also should furnish DSIR certificate.
7	The proponent should have functional laboratory to carryout R&D for the product development	Undertaking on Proponent's Letter Head, duly signed and stamped by the Authorized Signatory (As per format – 4)
8	The proponent should not be involved in any major litigation that may have an impact of affecting or compromising the conditions required under this EoI and in theAgreement	Undertaking on Proponent's Letter Head, duly signed and stamped by the Authorized Signatory (As per format – 5)
9	GMP and ISO Certification (applicable on commercial firms/organizations only)	Registration copies of both
10	Capacity to produce at least……..(quanti ty) per week	Undertaking (As per format – 6)
11	Royalty offer	(As per format – 7)
12	Business Plan	A brief concept note on planning & execution, production, marketing etc. (not more than 5 pages)
For International Manufacturers/ Firms		
13	Shouldhave place of business in India and must be registered under relevant acts.	A copy of the Registration Certificate.
14	Global experience in handling similar projects	Copy of Global Client List / Purchase order.
15	Should be a reputed manufacturer or have established R& D facility in India with a valid license	Undertaking in this regard and copy of license/certifications

16	Turn over figure for the last three Financial years indicating sales in India.	Audited Balance sheets for last three financial years.
17	Average Net Profit for the last three years	Audited Profit and Loss statement duly signed by the chartered Accountant.

12. Disclaimer

i. ICMR shall not be responsible for any late receipt of applications for any reasons whatsoever.
ii. ICMR reserves the right to cancel the call forEoI without assigning any reasons thereof.
iii. ICMR may relax or waive any of the conditions stipulated in this document as deemed necessary in the best interest of the ICMR without assigning any reasons thereof.
iv. To include any other item in the Scope of work at any time after consultation with proponents or otherwise.
v. For International Clients:EoIand other necessary correspondences shall be submitted in English only.

13. Contacts

In case of any clarification required, please contact:

For Scientific issues-
(Dr. Shanta Dutta, Director, ICMR NICED)
Phone: +91-33-23633373; Email:director-niced@icmr.gov.in
(Dr. Mamta Chawla Sarkar, ICMR-NICED)
Phone: 9830660999 Email: chawlasarkar.m@icmr.gov.in

For Administrative issues
Dr. R. Lakshminarayanan, DDG (Admin), ICMR HQ, New Delhi
Email: -lakshminarayanan.r@icmr.gov.in

Format-1

Authorization Letter
(To be submitted on Agency's Letter Head)

To,

The Director General,
Indian Council of Medical Research,
Ansari Nagar, New Delhi.

Subject: Letter for Authorized Signatory
Ref: EoI No. ICMR/EoI/01-BMS /2023

Sir,

This has reference to your above-mentioned Expression of Interest (EoI) for Joint development and transfer of technology entitled "A multiplex 2-tube real-time RT-PCR assay for detection of enteric viruses (E*n*Viro-Qplex)".
Mr./Ms./Mrs./Dr…….is herebyauthorized to submit the EoI documents and participate in the processing on behalf of M/s……. (company Name) ……., who's signature is provided below.

(Specimen Signature of Representative)

Date:
Place:

Yours faithfully,

(Signature of the Authorized signatory)
Name:……..
Designation:……..
Seal:……..

Format-2

Expression of Interest
(To be submitted on Agency's Letter Head)

To,

The Director General,
Indian Council of Medical Research,
Ansari Nagar, New Delhi.

Subject: Submission of Expression of Interest (EoI) for joint development and transfer of technology entitled "Amultiplex 2-tube real-timeRT-PCRassayfordetectionofenteric viruses (E*n*Viro-Qplex)"

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Ref:ICMR/EoI/01-BMS /2023

Sir,

The undersigned having read and examined in detail all the EoI documents pertaining to your transfer of technology anddo hereby expresses the interest to undertake theresearch &development/ commercialization /manufacture/ sell of the product as mentioned in the EoI document. The details of the Company and contact person are given below:

Name of the Proponent	
Address	
Name, designation & address of the person (to whom all communications shall be made)	
Telephone No. (with STD code)	
Mobile No. of the contact person	
Email ID of the contact person	

The following documents are enclosed:

Sl. No.	Documents required	Type of document Attached	Page No.
1	Company Incorporation Certificate from ROC/Partnership deed etc.		
2	GST Registration orGST exemption certificate/ PAN Card.		
3	DCGI/CDSCO license for the existing products available in the market		
4	Certificate from the Chartered Accountant of the Organization/Audited Balance sheets for las three financial years,Income Tax return.		
5	Proof of a registered office and a manufacturing Unit inIndia. Including DSIR certificate		

6	GMP and ISO Certification. Registrationcopies ofboth		
7	Authorization Letter	As per format – 1	
8	Undertaking on theLetter Head of the Proponent duly signed& Stamped byAuthorized Signatory	As per format – 3	
9	Undertaking on Proponent's Letter Head, duly signed and stamped by the Authorized Signatory	As per format – 4	
10	Undertaking on Proponent's Letter Head, duly signed and stamped by the Authorized Signatory	As per format – 5	
11	Undertaking for declaring capacity to produce at least one lakh doses per week	As per format – 6	
12	Royalty Offer	As per format – 7	
13	MSME Certificate (if have any)		
14	Business Plan	A brief concept note on planning & execution, product development. Clinical trials/validation/regulatory affairs/ production, marketing etc. (not more than 5 pages)	

I/we hereby declare that my/our EoI is made in good faith and the information contained is true and correct to the best of my/our knowledge and belief.

Thanking you,

Yours faithfully,

(Signature of the Authorized signatory)
Name:
Designation:
Seal:
Place:

Format-3

Undertaking with regard to blacklisting
(To be submitted on Agency's Letter Head)

To,

The Director General,
Indian Council of Medical Research,
Ansari Nagar, New Delhi.

Subject: Undertaking regarding Blacklisting / Non-Debarment.
Ref:ICMR/EoI/01-BMS /2023

Sir,

It is hereby confirmed and declared that M/s……has not been blacklisted/debarredbyanyGovernmentDepartment/PublicSectorUndertaking/oranyotheragency forwhichworks/assignments/services have been executed / undertaken.

Yours faithfully,

(Signature of the Authorized signatory)
Name:
Designation:
Seal:
Place:

Format-4

Undertaking with regard tolaboratory facility
(To be submitted on Agency's Letter Head)

To,

The Director General,
Indian Council of Medical Research,
Ansari Nagar, New Delhi.

Subject: Undertaking regarding laboratory infrastructure.
Ref:ICMR/EoI/01-BMS /2023

Sir,

It is hereby confirmed and declared that M/s…..... do have adequate laboratory infrastructure (equipped laboratory facility) and experienced staff/skilled manpower to produce/manufacture the product "A multiplex 2-tube real-time RT-PCR assay for detection of enteric viruses (E*n*Viro-Qplex)".

Yours faithfully,

(Signature of the Authorized signatory)
Name:
Designation:
Seal:

Place:

Format-5

Undertaking with regard to Non-Litigation
(To be submitted on Agency's Letter Head)

To,

The Director General,
Indian Council of Medical Research,
Ansari Nagar, New Delhi.

Subject: Undertaking regarding Litigation.
Ref:ICMR/EoI/01-BMS /2023

Sir,

It is hereby confirmed and declared that M/s…..... and owner of the firm/board of directors, donot have any litigation / arbitration pending/under trial in court.

Yours faithfully,

(Signature of the Authorized signatory)
Name:
Designation:
Seal:
Place:

Format-6

Undertaking with regard to production capacity
(To be submitted on Agency's Letter Head)

To,

The Director General,
Indian Council of Medical Research,
Ansari Nagar, New Delhi.

Subject: Undertaking with regard to production capacity.
Ref:ICMR/EoI/01-BMS /2023

Sir,

It is hereby confirmed and declared that M/s…… doeshave the capacity in all mean (includinginfrastructure, fund, material, staff etc.) for manufacturing of "Amultiplex 2-tubereal-time RT-PCR assay for detection of enteric viruses (E*n*Viro-Qplex), a technology which is useful for the detection of enteric viruses in patients with acute gastroenteritis, min.0.5lakhper month

Yours faithfully,

(Signature of the Authorized signatory)
Name:
Designation:
Seal:
Place:

Format-7

Undertaking for Royalty
(To be submitted on Agency's Letter Head)

To,

The Director General,
Indian Council of Medical Research,
Ansari Nagar, New Delhi.

Subject: Undertaking for Royalty.
Ref:ICMR/EoI/01-BMS /2023

Sir,

It is hereby confirmed that M/s ……, agrees to pay a Royalty of **……. % (…….Percent)**to the ICMR to be calculated against the **Net Sales**donewith respect to the product marketed under this agreement.

(As per the terms of ICMR-Technology Transfer and Revenue Sharing Conditions, the **"NET SALES"** shall mean **revenue from sales of goods or services by all ICMR grantee/Licensees/Sub-licensee(s) based on net sales realization from operations, net of discounts and indirect taxes as defined by cost Accounting Standards-24 and certified by the Chartered Accountant)**

Yours faithfully,

(Signature of the Authorized signatory)
Name:
Designation:
Seal:
Place:

SCHEDULE – (A)

A multiplex 2-tubereal-timeRT-PCR assay for detection of enteric viruses (E*n*Viro-Qplex)

i. **About the Technology/Product/Process:**

Theproposed product can detectthree prevalent enteric viruses (Rotavirus, Norovirus, and Adenovirus) from the stool samples of patients with acute gastroenteritis attending hospitals/clinics and during viral gastroenteritis outbreaks in the community. It is a multiplex 2-tube real-time RT-PCR assay with ≈95% sensitivity and≈95% specificity. It circumvents the need to run three separate ELISA tests on each sample for testing of viral pathogens or casting of agarose gels for visualization of viral DNA as required in conventional RT-PCR assays.

ii. **Need and utility of invention:**

Diarrhoea is the 3rd leading cause of childhood mortality globally. Viruses (majorly Group A Rotavirus, Human Adenovirus species F, and Norovirus genogroup GI/GII) are accountable for >40% cases of childhood gastroenteritis. Viral etiology of acute gastroenteritis is often undetected and misdiagnosed as bacterial due to absence of commercially available affordable diagnostic assays. This leads to irrational use of antibiotics.The practicing pediatricians have recommended using such assay for childhood diarrhea for effective treatment. In most diagnostic labs in India, RV antigen ELISA test is available but other viruses are not tested. Available molecular assays for multiple enteric pathogens are cost prohibitive and need to be imported. As of date, no Indian company is manufacturing the molecular diagnostic kit for testing enteric viruses.Thus there is a need of a sensitive but cost effective and easy to use diagnostic assay for detection of enteric viruses.

iii. **Scope of Agreement:**

This agreement will enable the licensees to manufacture and market the product "A multiplex 2-tube real-time RT-PCR assay for detection of enteric viruses (E*n*Viro-Qplex)"and a kit for the same.

iv. **Role of ICMR**

ICMR NICED, shall hand over or provide Technology details and the methodology to the licensee or manufacturers selected through the EoI.

v. **Role of company**

a. The Company will undertake the scale-up as required, manufacturing and commercialization of the proposed product "Amultiplex 2-tube real-time RT-PCR assay for detection of enteric viruses (E*n*Viro-Qplex)".

b. The company will share the technical data with ICMR and participatein all discussions in a professional and mutually agreed-upon manner.

c. The company will allow authorized personnel/scientist/team of ICMR to visit the production facility as and when required, asenvisaged under this EOI and subsequent Agreement.

d. The company shall be responsible for obtaining all the regulatory approvals requiredfor commercialization.

vi. **Methodology/process:**

The technical details including methodology are main part of the technology transfer, which is duly covered under the intellectual property rights solely owned by ICMR, the same shall be shared only after finalization and execution of License Agreement.

vii. **Technology Readiness level**

The technology for real-time RT-PCR assay for detection of enteric viruses: Rotavirus, Norovirus GI and GII, Adenovirus and internal control: RNasePhas been developed and standardized at ICMR-NICED, Kolkata. The technology has been validated in house on clinical samples from hospitals in comparison to the standard commercial assays. Third party validation has been completed in three labs namely Enteric Diseases Division, Kasturba Medical College, Manipal Academy of Higher Education, Manipal,Division of Gastrointestinal sciences, Welcome trust Laboratory, CMC, Vellore and National Institute of Epidemiology, Chennai.Validation studies in third party labs determined ≈95% sensitivity and ≈ 95% specificity of this real-time assay. The technology is now ready for transfer for commercialization.

viii. **Unique Points of technology**

- This is first kind of kit developed in India that has the ability to detect multiple enteric viruses causing childhood gastroenteritis by Real Time PCR. Viral diarrhea accounts for

>40% cases of childhood gastroenteritis.

- This cost-effective assay to detect Rota, Adeno, and Norovirus type GI and GII is expected to prevent undesirable antibiotic usage due to proper identification of the etiology of gastroenteritis.
- The assay has Comparable sensitivity (≥95%) and specificity (>95%) to commercial real time RT-PCR assay.
- Facilitates detection of co-infections which might exacerbate disease severity compared to single virus infections.

ix) Third Party Validation

The assay has been independently validated by three external microbiology laboratories namely Enteric Diseases Division, Kasturba Medical College, Manipal Academy of Higher Education, Manipal, Division of Gastroenterology, Christian Medical College, Vellore and NIE, Chennai.

x. Envisaged Outcome:

Amultiplex real-time RT-PCR assay named **E*n*Viro-Qplex** for simultaneous detection of major enteric viruses causing childhood gastroenteritis from the human clinical samples. This is first kind of product developed in India that has the ability to detect multiple enteric viruses within 4 h. It confers the advantage of identifying co-infections in a single test.

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