Competitive Dialogue Tender Notice: 178/G/CD/2024/2025

Provision of Fully Automated Nucleic Acid Amplification Testing (NAT) for Pre-Transfusion Molecular Screening

I. INTRODUCTION

Rwanda Medical Supply (RMS) intends to procure **Fully Automated Nucleic Acid Amplification Testing (NAT) Equipment and reagents on a placement basis** for use in blood transfusion screening and infectious disease diagnostics. Due to potential variety of technical and commercial solutions available in the market, RMS will use the **competitive dialogue** procurement method for this tender.

II. PURPOSE OF THE COMPETITIVE DIALOGUE

Indeed, The end user and RMS are not currently in a position to explore technical solutions with they related financial arrangements available currently at the market. Therefore, we seek to engage in a structured dialogue with shortlisted suppliers to define the most suitable and feasible solutions. This process will help RMS:

- Explore and refine various technical configurations.
- Agree on the best commercial model for placement and reagent supply.
- Finalize legal and financial terms based on real-world capabilities.

III. SCOPE OF PROCUREMENT

RMS seeks suppliers who can:

- Provide **two (2)** fully automated NAT equipment on a **placement basis** (reagent rental model), fully installed and operational at no upfront cost to the facilities.
- Supply all necessary consumables and reagents during the entire contract period.
- Offer full maintenance and technical support, including spare parts, even after the warranty period.
- Ensure 24/7 equipment uptime and availability.
- Deliver comprehensive training for end-users on both clinical and technical aspects.
- Guarantee a reliable supply chain for continuous provision of reagents and consumables.

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IV. PROCUREMENT PROCEDURE

The competitive dialogue procedure will follow these key steps:

Phase I.

1. **This is the call for Initial Proposals**
   Interested bidders are invited to submit **initial technical proposals** in response to the high-level requirements described in the attached terms of reference. The documents required at this stage are listed in the next point (**Shortlisting of Bidders)**
2. **Shortlisting of Bidders**
   Bidders will be shortlisted based on evaluation of initial proposals by checking the following:
   a. Valid Company Registration Certificate in the country of origin or operation.
   b. A minimum of five (5) years of demonstrated experience in the supply, installation, and maintenance of medical diagnostic equipment on a placement/reagent rental basis.
   c. At least three (3) reference projects involving similar equipment placed in clinical or blood safety environments
   d. Technical Support Capacity-Evidence of an on-ground technical support team based in Rwanda or within the East African region. This should include (Number and qualifications of available biomedical engineers or technicians.
   e. Service response time commitments.
   f. Evidence of reliable access to the reagents and consumables required for continuous operation of the offered equipment.
   g. Technical documentation proving that the proposed NAT equipment is validated by one or more of the following: US FDA, CE-IVD, or related certification.
   h. Offers submitted directly by the original manufacturers of the proposed equipment will be given preferential consideration during the shortlisting
   i. Intermediaries, agents, or distributors may participate; however, their offers must include A valid manufacturer's authorization letter.

Phase II:

3. **Dialogue Phase**
   RMS will conduct structured dialogues with each of the shortlisted bidders. During this phase:
   - Technical specifications will be refined.
   - Confidentiality will be maintained for all bidder-specific information unless explicitly agreed otherwise.
   - Equal treatment of all bidders will be ensured.

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4. **Submission of Final Offers**
   After the dialogue phase concludes and specifications are finalized, RMS will invite **final offers** from all shortlisted suppliers.

5. **Evaluation and Contract Award**

   Final offers will be evaluated based on the established evaluation criteria. The contract will be awarded to the most economically advantageous offer. Some of evaluation criteria at the second stage may include: Quality and performance of the proposed NAT equipment; Technical specifications compliance; Robustness and reliability of the placement model; Cost-effectiveness and value-for-money; Supply chain reliability and logistics plan; Maintenance, support service quality, and response times; Past performance and references from similar projects.

V. SUBMISSION GUIDELINES

Interested suppliers are invited to submit **initial proposals** by 24/7/**2025.**

Submissions must be made electronically to our confidential email: tenders@rms.rw with the subject line: **"Tender for NAT Equipment Placement"**.

For questions and clarifications, please contact **rms.procurement@rms.rw** with a copy to **cgatsinzi@rms.rw , rumuhoza@rms.rw and jmurwanashyaka@rms.rw**

Done at Kigali on 24/6/**2025**

Dr. Loko Abraham
Chief Executive Officer

Terms of Reference (TOR)

The system must be fully automated with process control from samples pipetting to interpretation of final results with minimal end user interface for the whole period of testing procedure.

The system should be able to detect and discriminates the most critical viral targets nucleic acids(HIV1/2, HCV and HBV genotypes) in serum or plasma specimens from human donors in one.

Sample types: serum/plasma, living and cadaveric donor,

Minimum amount of sample required :1000-1100 µL (living donor) 300 µL (cadaveric donor) ,Sample processing volume 850 µL (living donor) 150 µL (cadaveric donor),

Pooling sizes: IDT; pools of 1, 6, 24, 96.

The system should support multiplexed nucleic acid testing feature for use in blood screening to be able to detect the viral targets either in single sample or in mini-pool samples. The system should be able to perform all steps from sample loading and processing and viral nucleic acid extraction to target amplification and detection automatically. Its principle should be based on either RT-PCR(Real Time PCR)or on TMA(Transcription Mediated amplification).

The system should have the following features and must provide documentary evidence that it can be achieved:

(a) Positive sample identification with barcode scanning,

(B) manually entered sample IDs possible

(C)Disposable filtered tips must be used to prevent any carryover and cross-contamination of samples

(D)Leaks, fibrin clots and bubbles during aspiration and dispense cycles and samples and reagents can be detected and documented

(E) True Level sensing or insufficient volume detection for samples and reagents can be detected and documented.

It should be ready to use reagents and stable either at room temperature or 2--8 to avoid any unnecessary delay or inconvenience.

The equipment should have a computer interface facility with the blood bank interface system to reduce any chance of error. The system must support single room operation and reagents should be ready to use and each kit should contain positive and negative controls, calibrators, internal and external controls and any other necessary chemical for the completion of the whole test procedure.

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The system should be validated proven in ratio to installation Qualification(IQ)Operational Qualification(OQ)and performance Qualification(PQ).

The thought of the system should range to 250 samples per 8 hour and atleast 400 in 12 hours including detection and discrimination, varieties are acceptable.

- The service provider will have to : install the equipment, and train end users.
- The system should be FDA, CE or Indian council validated.
- The system should be of the latest/ new version and different proposals are accepted.
- The proposal should include also maintenance fees. Catalogues/CD and quality compliance certificates and any other descriptive documents required.

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