

QUESTIONS FROM BIDDERS AND RESPONSES FROM NDOH FOR BID NDOH 02/2025-2026: APPOINTMENT OF A SERVICE PROVIDER FOR THE SUPPLY AND DELIVERY OF RAPID DIAGNOSTIC TESTS (RDT's) TO DEPARTMENT OF HEALTH FOR PERIOD OF THREE (3) YEARS

No	Question from bidder	Response from NDOH
1.	<p>We are in the process of submitting our application to your department and would like to kindly ask for clarification regarding the ICASA certification requirement.</p> <p>Could you please confirm which specific ICASA certificate is required as part of the application process?</p> <p>Your guidance will help us ensure that we submit the correct documentation.</p>	The Bid document has been revised in this regard replacing the ICASA requirement.
2.	<p>We have three queries concerning tender NDOH-02(2025/2026).</p> <ol style="list-style-type: none"> 1. What is the duration? The documents state both 2-years & 3-years. Which is correct? 2. The quantity is shown as 817,300 kits. Is this per annum or for 2-years or 3-years? 3. The bidders are asked to provide proof that they are ICASA certified. This must be a mistake as ICASA (Independent Communications Authority of South Africa) relates to the electronic communications, broadcasting & postal industries. It has no relevance for medical goods. 	The Bid document has been revised in this regard.
3.	<p>I wish to clarify the following regarding the above-mentioned tender (NDoH-02(2025/2026) advertised for RDT Malaria tests. The tender states that a company needs to prove that it is ICASA certified.</p> <p>Stage 1: Mandatory requirements</p>	The Bid document had been revised in this regard.

QUESTIONS FROM BIDDERS AND RESPONSES FROM NDOH FOR BID NDOH 02/2025-2026: APPOINTMENT OF A SERVICE PROVIDER FOR THE SUPPLY AND DELIVERY OF RAPID DIAGNOSTIC TESTS (RDT's) TO DEPARTMENT OF HEALTH FOR PERIOD OF THREE (3) YEARS

No	Question from bidder	Response from NDOH
	<ul style="list-style-type: none"> • Submit 1 box of minimum of 25 RDTs for Quality Assurance (QA) tests to the National Department of Health • Please attach certificate as proof that the company is ICASA certified. <p>Please confirm this, as ICASA is the Independent Communications Authority of South Africa - a regulatory body responsible for the telecommunications, broadcasting, and postal industries in South Africa? Should it not be SAHPRA certified - South African Health Products Regulatory Authority?</p> <p>Can you kindly also confirm whether the quantity of tests stated (817 300) is the quantity per year or for the full tender period (3 years).</p>	
4.	<p>We are currently reviewing the bid documentation for Tender No. NDoH-02 (2025/2026): Appointment of a Service Provider for the Supply and Delivery of Rapid Diagnostic Tests (RDTs) and would appreciate your kind assistance in clarifying the following points:</p> <p>1. ICASA Certification Requirement We noticed a reference to ICASA certification as part of the compliance requirements. As Malaria Rapid Diagnostic Tests are manual, non-electronic medical devices with no wireless or radio frequency-emitting components, could you kindly confirm whether this</p>	<p>The Bid document has been revised in this regard replacing the ICASA requirement.</p>

QUESTIONS FROM BIDDERS AND RESPONSES FROM NDOH FOR BID NDOH 02/2025-2026: APPOINTMENT OF A SERVICE PROVIDER FOR THE SUPPLY AND DELIVERY OF RAPID DIAGNOSTIC TESTS (RDT's) TO DEPARTMENT OF HEALTH FOR PERIOD OF THREE (3) YEARS

No	Question from bidder	Response from NDOH
	<p>requirement is applicable in this context, if so, please explain how, or if it may have been included in error?</p> <p>2. VAT Rate on pp.49 and pp.35 The VAT rate listed appears to be stated as 14% on pp.49, and 15% on pp.35, whereas the VAT rate at tender closing is 15.5%. Please clarify.</p> <p>3. Quantity Is the quantity of 817300 test kits an annual quantity or the total quantity over the tender period, i.e. 3 years?</p> <p>4. Training <i>"The supplier must train health care workers on how to use tests in the various provinces using RDT tests. Provincial training on using the RDT's is required on an annual basis for Doctors and Nurses at districts chosen by the provincial co-ordinators."</i> Please advise:</p> <ul style="list-style-type: none"> Is the training required once yearly for each (1) district that is chosen Approx. how many districts are chosen to be trained across the 9 provinces each year. For instance, there are a total of 52 districts in SA. 	

QUESTIONS FROM BIDDERS AND RESPONSES FROM NDOH FOR BID NDOH 02/2025-2026: APPOINTMENT OF A SERVICE PROVIDER FOR THE SUPPLY AND DELIVERY OF RAPID DIAGNOSTIC TESTS (RDT's) TO DEPARTMENT OF HEALTH FOR PERIOD OF THREE (3) YEARS

No	Question from bidder	Response from NDOH
5.	<p>May we please ask a question concerning this tender.</p> <p>It relates to point 13 of the product specification.</p> <p>“The test kit must be WHO pre-qualified as a Malaria RDT product”.</p> <p>If we make an offer of a malaria test kit, complying exactly with the specification, but not WHO pre-qualified, will our offer be automatically rejected.</p> <p>As you will be aware there are relatively few companies manufacturing malaria kits that are WHO pre-qualified. We are involved with test kits and would like to make a suitable offer but do not wish to waste your & our time, with an offer that will be rejected.</p> <p>Your response would be greatly appreciated.</p>	<p>"Thank you for your inquiry and interest in supplying malaria test kits.</p> <p>We appreciate your engagement and the effort to ensure your offer aligns with the required specifications.</p> <p>However, we must inform you that <i>offers for malaria test kits that are not WHO prequalified will unfortunately be automatically rejected.</i></p> <p>WHO prequalification is a mandatory requirement for several important reasons:</p> <ol style="list-style-type: none"> 1. Quality Assurance: WHO prequalification ensures that the product has met rigorous international standards for safety, efficacy, and quality through an independent and transparent evaluation process. 2. Programmatic Suitability: Prequalified tests are assessed not only for technical performance but also for their suitability in field conditions, including stability, ease of use, and compatibility with existing systems in malaria-endemic settings. 3. Global Health Standards: In alignment with national and global malaria strategies, including procurement regulations set by major donors and partners (e.g., the Global Fund, WHO, and other health authorities), only WHO-prequalified kits

QUESTIONS FROM BIDDERS AND RESPONSES FROM NDOH FOR BID NDOH 02/2025-2026: APPOINTMENT OF A SERVICE PROVIDER FOR THE SUPPLY AND DELIVERY OF RAPID DIAGNOSTIC TESTS (RDT's) TO DEPARTMENT OF HEALTH FOR PERIOD OF THREE (3) YEARS

No	Question from bidder	Response from NDOH
		<p>are eligible for public sector use in many countries, including ours.</p> <p>4. Risk Mitigation: Using non-prequalified kits introduces a significant risk of misdiagnosis, which could have serious public health consequences and undermine malaria control and elimination efforts.</p> <p>While we understand the limited number of prequalified suppliers poses a challenge, the requirement is in place to uphold the integrity, reliability, and safety of malaria diagnostics provided to communities.</p> <p>We hope this clarifies the criteria and encourages future consideration of WHO prequalification should you wish to pursue opportunities in this space."</p>