CENTRAL PROCUREMENT & SUPPLIES UNIT
MINISTRY FOR HEALTH
UB002, San Gwann Industrial Estate, San Gwann - SGN3000
Tel: (+356) 2540 4000 E-mail: info.cpsu@gov.mt

RfP Publication Reference: RfP 020-6093/20
File Referene: CPSU3536/20

Date: Wednesday, 14 October 2020

For the attention of all interested Economic Operators

Request for Participation (Negotiated)
for the supply of Point of Care Rapid Qualitative Tests for the Detection of SARS-CoV-2 Antigen in Human Nasopharynx

Clarifications No. 1

Reference is made to the Request for participation in caption.

Hereunder please find a set of clarifications which are construed to form an integral part of the RfP procurement document.

Clarification 1.1: Point A7 - if test kits are CE certified, why is a WHO recommendation obligatory too?

Answer 1.1: *RNA viruses tend to mutate frequently and since the said POCT in question are antigen based, any mutations in the viral envelope protein can lead to a high percentage of false negatives. Unfortunately, this interim process cannot allow for testing of other test kits not recommended by WHO due to the urgent circumstances not allowing for independent testing. However, we have asked our technical experts to consider it for the subsequent tender.*

Clarification 1.2: Point A10 – the standard for these test kits is to have one buffer per 10 tests, since being for healthcare professional use, this make sense considering only a 4 drops of buffer are required per test. For this reason, kindly consider one buffer per 10 test kits.

Answer 1.2: *These kits are to be used in various institutions like health centres, hospitals, schools, old people's homes etc. We cant afford having one buffer to cover 10 tests. This is not logistically acceptable since multiple testing has to be carried out and having one buffer per 10 kits will decrease testing time and also possibility of degredation of the buffer during handling by different operators doing the test.*

Clarification 1.3: Point 15 – qty 250 test kits are required by closing date, which is less than 4 days away. Kindly confirm samples which are packed with one buffer per 10 test kits will be accepted.

Answer 1.3: *Please refer to Answer 1.2 above.*

Clarification 1.4: In addition to the above, our suppliers informed us that as from October 2, 2020, there are only two WHO recommended rapid antigen tests available - one from Abbott and the other one from SD Biosensor.

https://www.who.int/diagnostics_laboratory/201002_eul_sars_cov2_product_list.pdf?ua=1

So basically only these 2 companies can participate and both will win something given it's a 60-40 shared tender unless the obligation to have WHO recommendation is withdrawn as requested below.

Thanks for considering our request below in an effort to provide more choice to CPSU and not have this tender limited to only 2 suppliers where both will win.

Answer 1.4: *Further to Answer 1.1, please note that as per information provided by the technical experts there are more than two WHO recommended rapid antigen tests available.*

Clarification 2.1: Please advise whether Schedule of participants, including the total value of the offer, will be published upon closing date.

Answer 2.1: *Yes, schedule of participants will be published, including the total value of the offer.*

Clarification 2.2: Kindly confirm whether in case of an award, each pack supplied needs to be 'DH'ed?

Answer 2.2: *Yes, in case of award each pack needs to be with DH markings.*

Clarification 2.3: In point 3.1 of the published RFP document it is stated that "The technical offer should include printed manufacturers' documentation (certifications, literature, etc) that the test kits being offered meet all the aspects and requirements stipulated in the specifications and conditions outlined in Section 1.2 of this document". Kindly advise whether a hard copy of the requested documents should be submitted together with the samples or else whether just a soft version with our electronic submission via e-mail on negotiation.cpsu@gov.mt would be acceptable?

Answer 2.3: *Kindly note that both a hard copy and a soft copy of the requested documents is to be submitted. A hard copy is to be submitted with the samples. A soft version of the documents is to be submitted as well with the electronic submission via email.*

Clarification 2.4: Are you going to publish a Technical Offer or each economic operator should prepare one of his own?

Answer 2.4: *Economic Operators participating in this RFP are to prepare their own technical offer based on the requirements of this RFP.*

Clarification 3.1: With reference to the specification that the test must be "recommended by the WHO", we feel that this is unreasonable since there are a number of companies with very high quality product fitting within the specifications of proven accuracy and precision with sensitivity and specificity of ≥ 90%, and with all the necessary certification in place. Kindly consider removing to allow highly reputable companies with high quality products to participate.

Answer 3.1: *Please refer to Answer 1.1 and Answer 1.4 above.*

Clarification 3.2: A one week deadline for the submission of samples is too tight especially considering the quantity requested. Kindly consider extending the deadline for submission of the bid, or at least extending the deadline for the submission of the samples, by 7-14 days.

Answer 3.2: *Kindly note that the deadline for submission of offers cannot be extended. Though we empathise, we are in a position nationally where we cannot extend.*

Clarification 3.3: "The test kit/cassette must be in a sealed pouch and must include ALL necessary items to perform test individually including but not limited to: a disposable sample pipette/dropper and diluents/buffers/reagents where necessary."- Since a swab needs to be performed by a healthcare professional we believe this individual wrapping requirement as regards to the diluent/buffer/reagent is unnecessary and limits competition for no valid reason. Kindly consider removing.

Answer 3.3: *This kit has to be individually wrapped to prevent contamination while swabbing and testing. It is imperative that the kit is individually wrapped to keep the kit in a good state for testing. Reagents/buffers/dropper and diluents and pipettes must be provided per kit since this will be more logistically viable during testing and reduces the testing time and prevention of degredation of reagents buffers while handling from multiple health care workers.*

Clarification 4: Kindly consider Extending Deadline for submission by one week.

Answer 4: *Please refer to Answer 3.2 above.*

Clarification 5: I have a question regarding the above call. You state in point A7 that the antigen rapid test should be WHO recommended, but to our knowledge, the only recommended tests are manufactured by Abbott Health and not available outside of the USA.

Our tests are 96/97% accurate and both MHRA approved and CE marked. Is this sufficient to meet your criteria before we send the required 250 tests for the Friday deadline?

Answer 5: *Please refer to Answer 1.1 and Answer 1.4 above.*

All other procurement documents, conditions and requirements, which are not superseded by this Clarification, remain in place.