Prebid-Clarifications (Date of pre-bid meeting 27-08-2020 14:00:00)

Bid No:- GEM/2020/B/754347 Dated: 24-08-2020

Item Name:- Real Time PCR (Polymerase Chain Reaction) Kits For Novel Coronavirus (SARS-CoV-2/COVID-19)

Sl.No.	Tender Specification (Clause No & Page No)	Name of Bidder	Representations Received from the bidders	Prebid Clarification
1	**Specificity-99% (Page Number 3 of Bid Document)**	Genes2Me	Our kit has been validated by ICMR where the specificity of 98.8% have been reported. Since it is multiplexed kit which have been made in India along with superior coverage of 3 SARS-COV2 specific genes (along with internal control) multiplexed in 1 tube assay having probes labelled with 4 different dyes, we request for relaxation so that we can participate in this bid. We would request for relaxation on this point so that we can participate in the bid.	All specificity values greater than or equal to 98.5 will be rounded off to 99 and will be considered as valid. Kits which were validated earlier and are not matching specificity value as per the current criteria may apply for re-validation of their kit through ICMR validation portal.
2	**Bid Specific Additional Terms and Conditions** **Point no 3 :** The bidder is required to upload, along with the bid, all relevant certificates such as BIS licence, type test certificate, approval certificates and other certificates as prescribed in the Product Specification given in the bid document. 4.Experience		We have manufacturing licence issued by DCGI, certificate of Validation from ICMR , CE-VD certificate, ISO13485, ISO 9001 and ISO 14001 certificates . **Kindly clear if BIS license and type test certificate is mandatory or not. Also kindly clarify that what is type test certificate and from this can be obtained.**	BIS license and type test certificate is not mandatory.
3	**Past Performace of 10%**		We are a registered Startup under startup India mission and Registered MSE organisation. Request you to please clarify if there is any exemption for startups and MSE organisations for the past performance of 10%.	Exemptiones will be given as per MSME and Startup guidelines issued by GOI.
4	Earnest Money Deposit (Page No. 01)	POCT Services	It shall be "The Bidders shall submit their EMDs' in proportion to their offered quantity". The EMD amount is quite high and also in your previous GeM Tenders and E-Tenders you have allowed EMDs in proportion of offered quantity.	Agreed.
5	Total Quanity- 50,00,000 (Page No. 01)		Clarification is required, whether a single bidder have to offer whole quantity or can quote quantity as per its eligibility as it was allowed in your previous Tenders.	Bid Splitting allowed as per Corrigendum 01 issued.
6	Experience Criteria (Clause No. 1 and Page No. 02)		It shall be "The bidder should have experience of supply of Medical Diagnostic Equipment's/Reagents/Kits during last 3 Years preceding the bid due date for a minimum of 100% of the estimated cost of offered quantity, for which bidder shall submit a CA certificate" as in your previous GeM Tenders and E-Tenders you have allowed experience of Diagnostic Equipment's/Reagents/Kits.	Allowed as per Corrigendum 01 issued.
7	Bid splitting not applied. (Page No. 02)		You have not allowed Bid Splitting, whereas in all your previous Tenders you have allowed Bid Splitting. Kindly clarify the same.	Bid Splitting allowed as per Corrigendum 01 issued.
8	The cumulative time temperature indicator technology shall be used on each kit and prequalified by WHO		1. Time temperature indicator is not the only way of ensuring temperature control There are various other methods that are cost effective and more accurate being employed by the manufacturers like data loggers, indicators etc. 2. Moreover in all previous bids this was not a mandatory specification Therefore, clarification required for current bid.	Each packaging unit with multiple kits should be shipped with one time temperature indicator.
9	Pack Size of the Kit:- 100 tests or reactions		Packsize may vary as per manufacturer specifications. Hence, it should be an open spec. Clarification sought in this regard.	As packaging size is not a golden parameter , the bidder can define their pack size. Minimum supply size of 1 lakh tests should be met, pack size may vary accordingly.

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10	Experience Criteria	Altona Diagnostics India Pvt Ltd	Manufacturing certificate of same or similar products should be accepted from the country of Origin and or group of companies or from the Headquarter. Similar documents like (Manufacturing certificates with required related contracts/orders should be accepted from group of companies/Country of origin.	Tender terms and condition shall prevail.
11	Past Performance		Past Performance should be accepted not only of same or similar products supplied in India (through authorised reseller) but also of group companies/country of origin.	Tender terms and condition shall prevail.
12	Bidder Turn Over Criteria		Turn over Criteria of group of companies/Country of Origin should be accepted too.	Tender terms and condition shall prevail.
13	Bid Requirements Point 17 - Past Performance - 10 %		Change required – Past Performance - NA Reason for Change: Many states have either not included or have removed the clause for past performance or the criteria of requirement of supply order given the current situation. As this pandemic has affected very large population of our country as well as state of Uttar Pradesh, the solution to this is also needed in mass and huge quantity. Hence it will be unfair to put the condition of past supply to these solutions, which are required in mass quantity and need to be supplied at affordable rates for the ailing millions across the country. To meet the demand and competitiveness, we would humbly request you to reconsider the Qualification criteria and remove this criterion of Past Performance, by putting this we will be obstructing the availability of above solutions to the ailing millions across the country and the	Tender terms and condition shall prevail.
14	Technical Specifications > Product Information Point 4 – Number of viral gene targets on which test is based – 2 or more		Change required: – Number of viral gene targets on which test is based – 1 or more.	Tender terms and condition shall prevail.
15	Point 7 - Target genes detection Multiplex detection in single tube should have at least 2 genes of the following: E/ORF/RdRP/N/S genes of SARS-CoV-2, along with human housekeeping gene or exogenous control as the internal control. Probe for each gene should have separate dye/ fluorophore so that the result for each gene can be read individually		Change required: - Multiplex detection in single tube should have at least 2 genes of the following: E/ORF/RdRP/N/S genes of SARS-CoV-2, along with human housekeeping gene or exogenous control as the internal control. Probe for each gene should have separate dye/fluorophore so that the result for each gene can be read individually/S gene of Sars Cov-2	Tender terms and condition shall prevail.
16	Point 15 - Reagent included in the kit Primer, Probe, enzymes, internal control, positive control and negative control		Change Required: - Primer, Probe, enzymes, internal control, positive control and negative control /**Reagents for Real time PCR**	Tender terms and condition shall prevail.

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17	Point 16 - Type of Fluorescent Probe used for the detection – RT-PCR Kit for detecting SARS-CoV-2 should use fluorescent probe based TaqMan chemistry with multiplex reactions in a single tube. Probes should have reporter dyes in the range of spectral separation to have compatibility with common RT-PCR machines available. Probe for each gene should have separate dye/ fluorophore so that the result for each gene can be read individually	Wrig Nanosystems Private Limited	Change required: - RT-PCR Kit for detecting SARS-CoV-2 should use fluorescent probe based TaqMan chemistry with multiplex reactions in a single tube. Probes should have reporter dyes in the range of spectral separation to have compatibility with common RT-PCR machines available. Probe for each gene should have separate dye/fluorophore so that the result for each gene can be read individually/Probe free chemistry used for detection	Tender terms and condition shall prevail.
18	Point 24 - Shelf life from the date of manufacture (in months)- 12, 18, 24 Or higher		Change Required: - Shelf life from the date of manufacture (in months)- **6, 12, 18, 24 Or higher** Reason for change: Currently the specification favors only the Taqman probe chemistry which is limited in production capacity, lot consistency is an issue and expensive. Probe free technology is a single step easy to use consistent in quality, technology approved by ICMR. This shall allow all ICMR approved products/manufacturers to participate in the tender. The assumption that probe-based kits have higher specificity is factually incorrect because SYBR Green based technology is being used for covid testing in other developed parts of the world too. The control reactions address any lack of specificity (if at all) for SYBR Green and probe-based methods, both. 1) WHO does not recommend any specific chemistry “such as Taqman probes” for RT-PCR (Annexure 2) 2) US FDA has already approved assays for SARS-CoV-2 diagnosis by using nucleic acid amplification tests that do not use a Taqman probe eg. (a) ID NOW COVID-19 (Abbott Diagnostics Inc.,) (B) CRISPRbased tests for SARS- CoV-2 (Cepheid Sherlock Biosciences) (Annexure 3) The kit should target the glycoprotein (S) gene for detection of Sars-CoV-2 as S gene does not mutate and gives the virus its spiked surface which makes the virus deadly. As the S gene does not mutate, the kit targeting S gene for detection of the virus shall give the most accurate results irrespective of virus mutations. 1) WHO recommendations: March 19, 2020: “In areas where COVID-19 virus is widely spread a simpler algorithm might be adopted in which, for example, screening by RT-PCR of a single discriminatory target is considered sufficient.” (Annexure 2) 2) Many US FDA approved kits target 1 gene for the diagnosis of SARS-CoV-2 eg. (A) IDNOW COVID- 19 (B) LYRA SARS-CoV-2 assay (C) Lab Corp COVID-19 RT-PCR test (D) Accula SARSCoV-2 test (E) Viracor SARS- CoV-2 assay (Annexure 3) 3) Published literature comparing commercial SARS-CoV-2 RT-PCR kits conclude that kits using	Tender terms and condition shall prevail.

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19			We would also like to draw your attention to the Order issued by the Govt of India regarding "Preference to Make in India dated 4th June 2020" (copy enclosed) which clearly ensures that no foreign manufactured product is allowed to participate in tenders below tender value of 200 Cr unless a written explanation of such a deviation from the Order is stated in writing by the procuring body and sent to the Standing Committee as appointed in the Order. The Order lays out rules to enable Indian manufactured products to be preferred in all circumstances and no relaxation shall be allowed for foreign products to let them participate in such tenders. Also, we would also like to draw your attention to the Order issued by the Govt of India regarding "Restriction on Public Procurement from Certain Countries Dated 23rd July 2020" (Copy enclosed) which states that any bidder from a country which shares a land border with India will be eligible to bid in any procurement whether goods , services or works only if the bidder is registered with the competent authority, specified in Annexure I. (Attached for your reference) List of countries to which LoC is extender: https://www.mea.gov.in/list-of-countries-loc-extended.htm	All the provisions of latest guidelines issued by Govt. In India is included in the bid.
20	CERTIFICATIONS & REPORTS Imported kits registered and licensed in India by DCGI & Indigenous manufactured kits licensed by the authority defined under Drugs and Cosmetics act 1940 and Medical Devices Rules, 2017 as amended till date	Vista Pharmacuiticals Ltd	For imported Kits, time should be allowed to approach DCGI for getting required permissions.	Tender terms and condition shall prevail.
21	UFDA		USFDA issues Letters to the Representative Offiice of the Manufacturer, which is generally situated in USA, whereas the manufacturing unit might be elsehwere in the World. We request you to consider such "Authorisation Letters" as part of the Manufacturer by taking general practices of USFDA into consideration.	Tender terms and condition shall prevail.

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22	Pg No. 2, Clause 15: Packing: Packing and Marking shall be strictly as per Technical Specifications and will be inspected in terms of provisions of specifications before clearing for dispatch. The Bar coding requirement shall also be properly understood and marked on the package as per the provision of the specification.	DSS Imagetech Pvt. Ltd.	Kindly specify the bar coding requirement so that it is properly understood and marked on package as per the provision of the specification.	Bar coding requirement, if any, shall be provided at the time of issue of purchase order.
23	Pg No. 4, Clause 27: Required Delivery Schedule: The delivery of the goods are to be made within 30 days of placement of notification of award. The delivery of the Goods shall be supplied to ICMR specified locations in New Delhi, Mumbai, Chennai, Kolkata. Each batch size should be a minimum One Lakh test for RT PCR Kit and the entire batch of One Lakhto be delivered at one depot rather than distributing amongst different depots. ICMR will inform to which depot the bidder has to deliver the kits.The supply line /schedule will be as per decision of ICMR/Buyer which will be indicated at the time of issuing the purchase order.		In order to maintain sanctity of batch production quality, we recommend smaller batch sizes. Is it acceptable if we provide one lakh test for RT PCR kits but in smaller batch sizes - 2 if acceptable? We will provide 50000 tests of one batch and 50000 tests of another batch to meet the requirement of one lakh.	Tender terms and condition shall prevail.
24	Pack Size of the Kit:- 100 tests or reactions	Bilcare Limited	Pack Size: 1 Kit contains 100 Tests or 200 Tests	As packaging size is not a golden parameter , the bidder can define their pack size. Minimum supply size of 1 lakh tests should be met, pack size may vary accordingly.
25	Pack Size of the Kit:- 100 tests or reactions	Meril Diagnostic Pvt Ltd.	We request you to amend the packsize to 96 tests instead of 100 as it is the widely used configuration for many instruments.	As packaging size is not a golden parameter , the bidder can define their pack size. Minimum supply size of 1 lakh tests should be met, pack size may vary accordingly.
26	Technical Specifications CERTIFICATIONS & REPORTS : Product Certifications/Approval	General Clarification		US-FDA approval OR Kit evaluated and validated by ICMR-NIV-Pune or any other designated ICMR validation institute is mandatory.
27	Technical Specifications	General Clarification		The bidder should submit catalogue/datasheet and ICMR/USFDA validation for the same make& model of kit as offered in GeM bid.