| Response To Pre-Bid Queries (Pre-Bid date: 11.05.2020) | | | | | |
|---|---|---|---|---|---|
| Tender Enquiry No.: HITES/PCD/ICMR/COVID-19/01/2020-21 dated: 08-05-2019 | | | | | |
| Item No. 1 Viral Transport Media (VTM) (2020_HLL_47913_1) | | | | | |
| **Sl. No** | **Tender Page & Para** | **TENDER SPECIFICATION** | **NAME OF THE FIRM** | **REPRESENTATION RECEIVED FROM THE FIRMS** | **COMMITTEE RECOMMENDATION** |
| 1 | Page 40, Para 1 | Two separately packed sterile synthetic fibre swabs (polyester, rayon, or Dacron) with plastic shafts or wire shaft (flexible Shaft). | M/s HORIBA India Pvt. Ltd. | Two Sterile Swabs: -<br>1) Polyester swab with Plastic shaft (PP ABS) for Oropharyngeal sampling<br>2) Sterile Nylon Synthetic Fiber Flexible swab with break point for Nasopharyngeal sample.<br><br>**Advantage:**<br>Nylon Swab is softer for taking sample, high bending, high Flexibility as compared to Polyester is low bending, low flexibility which is hard to collect nasal sample. | Suitable changes made in the technical specification |
| 2 | Page 40, Para 2 | 10-15 ml volume screw-cap, leak-proof self-standing tubes containing 2-3 ml viral transport medium (VTM) | M/s HORIBA India Pvt. Ltd. | 10ml double cap round bottom/screw cap leaked proof with 3ml media<br>Self-Standing/ Round Bottom.<br><br>**Advantage:**<br>3 ML advantage is that in case of resampling there will be no sample shortage.<br>Double Cap ensures single handed operation and avoid chances of cross contamination with respected to screw cap.<br>Nylon swab, VTM and Polyester swab all three should come in single sterile packs | Suitable changes made in the technical specification |
| 3 | | | M/s Micromaster Laboratories Pvt Ltd. | As per ICMR Criteria The VTM Tube Is Not self-standing It is Ok | Suitable changes made in the technical specification |

| | | | | | |
|---|---|---|---|---|---|
| 4 | | | M/s Global Lifescience | Since getting self standing tube from manufacturer companies are difficult, can we offer medium in 15 ml Centrifuge tube or 10 ml | Suitable changes made in the technical specification |
| 5 | | | M/s Trivitron Healthcare Pvt Ltd | 10-15 ml volume screwcap, leak-proof tubes containing 2-3 ml viral transport medium (VTM)"<br><br>**Justification:**<br>Non-self-standing tubes does not influence sample collection and thus it should be allowed | Suitable changes made in the technical specification |
| 6 | Page 40, Para 3 | Vial should have labeling stickers | **No queries** | | No queries |
| 7 | Page 40, Para 4 | VTM should contain protective antibiotics, antifungal agents to control microbial contamination and buffer to stabilize the pH. | **No queries** | | No queries |
| 8 | Page 40, Para 5 | The pH should be 7.3+ 0.3 and the osmolality in mOsm/Kg H20 500.00-600.00 | **No queries** | | Suitable changes made in the technical specification |
| 9 | Page 40, Para 6 | The medium should contain a cryoprotectant to preserve the viruses, if specimen are frozen for prolonged storage. | **No queries** | | No queries |
| 10 | Page 40, Para 7 | The medium should be stable at room temperature. | **No queries** | | No queries |
| 11 | Page 40, Para 8 | Should be European CE-IVD or US-FDA approved, if not should be validated and approved by any of the ICMR validation centres | **No queries** | | No queries |
| 12 | Page 40, Para 9 | Magnetic stands | **No queries** | | No queries |

| | | | | | |
|---|---|---|---|---|---|
| 13 | Page 40, Para 10 | Magnetic stand for RNA extraction with capacity of 12 tubes, 24 tubes, 36 tubes and/or 96 tubes. | M/s Genuine Biosystem Pvt Ltd | In tender schedule page no. 40, Technical specification of viral RNA and VTM has mentioned, but the magnetic stand is continued in VTM specications, It is applicable for Viral RNA kit, kindly clarify for the same. | Suitable changes made in the technical specification |
| 14 | | | M/s Agappe Diagnostics Ltd | Eligibility: Whether US-FDA is essential for all the three proposed items | Not item not specified |

| Response To Pre-Bid Queries (Pre-Bid date: 11.05.2020) | | | | | |
|---|---|---|---|---|---|
| Tender Enquiry No.: HITES/PCD/ICMR/COVID-19/01/2020-21 dated: 08-05-2019 | | | | | |
| Item No. 2 - RNA Extraction Kit (VTM) (2020_HLL_47913_2) | | | | | |
| **Sl. No** | **Tender Page & Para** | **TENDER SPECIFICATION** | **NAME OF THE FIRM** | **REPRESENTATION RECEIVED FROM THE FIRMS** | **COMMITTEE RECOMMENDATION** |
| 1 | Page 39, Para 1 | Kit should work with silica membrane column or magnetic bead-based technology allowing extraction of Viral RNA from Human Samples (Plasma, CSF, Urine, Other cell-free bodyextraction of Viral RNA from Human Samples (Plasma, CSF, Urine, Other cell-free body fluids and Cell-culture supernatants.) | M/s Dr. KPC Bioinnovations & Diagnostics | Ø eco' Viral RNA Isolation Kit manufactured by Dr. KPC Bioinnovations &<br>Diagnostics is a silica membrane column less isolation kit invented by Dr.<br>KPC Bioinnovations & Diagnostics.<br>Ø The kit neither use silica membrane column or magnetic bead-based<br>isolation technology.<br>Ø eco' RNA Isolation Kit is a centrifugation based isolation kit.<br>Ø No use of silica membrane column reduces a huge amount of plastic<br>waste generation.<br>Ø eco' RNA Isolation Kit can save 3500 kg plastic waste generation per million isolation compared to silica membrane column based isolation kit.<br>Ø The eco' Viral RNA Isolation Kit requires a heat block and a tabletop<br>centrifuge for isolation which is commonly available in all the pathological<br>lab/ diagnostic centres/ Virology lab.<br>Ø Kit protocol is such simplified, any technician can perform the isolation<br>without having any previous experience of RNA Isolation.<br>Ø Steps involved in isolation is the same with silica membrane column<br>based isolation.<br>Ø Carrier RNA is provided with the RNA isolation kit for better | No Change |

| | | | | | |
|---|---|---|---|---|---|
| 2 | Page 39, Para 2 | ▯ Should be able to process sample volume from 25 µl to 300 µl and elution volume from 30 to 100 µl. | **No queries** | | |
| 3 | Page 39, Para 3 | ▯ The kit should preferably use spiking with carrier RNA to enhance quantity of eluted viral RNA. | M/s Imperial Life Sciences | The kit should use spiking with carrier RNA to enhance quantity of eluted viral RNA (Optional; Applicable for kits based on silica membrane column technology)<br><br>**Reason:**<br>This point need to be removed as this feature of spiking with carrier RNA is available and applicable only for very few and limited kits that too based on silica membrane column technology | Suitable changes made in the technical specification |
| 4 | | | M/s Genes2ME | The kit based on silica membrane column technology should preferably use spiking with carrier RNA to enhance quantity of eluted viral RNA with Kits<br><br>**Reason for Amendment:** Spiking with carrier RNA is not available in most of the available Viral RNA extraction Kits in the market and only few Column based kits has this feature. So, this point can be removed from the tender specifications | |
| 5 | Page 39, Para 4 | ▯ Recovery of the Viral RNA should be more than equal to 85% | **No queries** | | |

| | | | | | |
|---|---|---|---|---|---|
| 6 | Page 39, Para 5 | □ Process of extraction may involve either centrifugation steps or magnetic stand based magnetic Bead separation. | GCC Biotech (India) Pvt Ltd | Ideally magnetic bead based process is technically/scientifically non-viable and should be removed.<br>If still considered – price/cost for both process should be evaluated separately as they are not comparable cost wise.<br><br>**Reason:**<br>Technically both the processes are un-comparable due to its technical application, and it is proven that yield of Nucleic acid from column based technique is much higher than Bead based technology and much user-friendly, time-saving with less time consuming and manual handling easier for expert and/ or new users.<br>If recommendation taken from scientist – they would reject magnetic based process due to various disadvantages.<br>We suggest either if both process are considered costing/price cannot be compared for both. | No Change |
| 7 | Page 39, Para 6 | □ Time per batch extraction should less than 60 minutes. | **No queries** | | |
| 8 | Page 39, Para 7 | □ The extraction kit should be compatible with manual and/or automated platforms | M/s Trivitron Healthcare Pvt Ltd | The extraction kit should be compatible with manual process<br><br>**Justification:**<br>Automated platforms are closed system for extraction kits. | No Change |

| | | | | | |
|---|---|---|---|---|---|
| | | | M/s Dr. KPC Bioinnovations & Diagnostics | Ø eco' Viral RNA Isolation Kit is a manually operated RNA Isolation Kit. It won't work with automated platforms.<br>Ø Although manually operated, any commonly available lab centrifuge can process a higher number of samples in less time using eco' Viral RNA Isolation Kit.<br>Ø eco' Viral RNA Isolation Kit can process better number in less time compared to silica membrane column based automated platform | No Change |
| 9 | Page 39, Para 8 | Should be European CE-IVD or US-FDA approved should submit certificates or should be validated by any of the ICMR validation centres | **No queries** | | |
| 10 | Page 66, Para (Part-I) | **Note:<br>- If the RNA Extraction Kit offered is Magnetic Bead Type, then 10 numbers of magnetic stands are to be supplied per lakh tests offered and the offered price should include the price of offered magnetic stand (Size of the offered Magnetic Stand shall be mentioned specifically in the offer). | M/s LifeLine Pharma | If the RNA Extraction Kit offered is Magnetic Bead Type, then 10 numbers of magnetic stands + 4 Thermoshakers are to be supplied per lakh tests offered and the offered price should include the price of offered magnetic stand (Size of the offered Magnetic Stand and Thermoshaker shall be mentioned specifically in the offer).<br>**Reason:**<br>Both Thernoshakers and Magnetic stand are must required with Magnetic based Extraction kits and must be provided along with the kit so that to make sure smooth functioning of the tests and at scale at all the centres | Suitable changes made in the technical specification |

| | | | | | |
|---|---|---|---|---|---|
| 11 | | | M/s Labindia Healthcare Pvt. Ltd. | The bidder should follow the recommendation of ICMR for use of thermoshaker and magnetic stands, for whichever type of RNA Extraction Kit offered is Magnetic Bead Type/column type. In case of Magnetic Bead type, then 10 numbers of magnetic stands and upto 4 thermoshakers are to be supplied per lakh tests free of cost. | |
| 12 | | | M/s Patel Enterprises | Both Thermo shakers and Magnetic stand may be required for good quality results. Therefore the bidder must provide magentic racks and Thermoshakers free of cost along with Magnetic based Extraction kits for seamless working of the tests at all the centers. The bidder should also be able to supply the required Thermoshakers and Magnetic stand | |
| 13 | | | M/s Alliance Transfusion Pvt. Ltd. | It can be modified as: The bidder should supply the necessary equipments such as such magnetic racks, thermal heating blocks with vibrations, as recommended by any evaluating body of repute such as ICMR. The bidders should supply 10 magnetic racks and 3-4 thermal heating blocks with vibrations free of cost per 1 lakh extraction kits to ensure smooth functioning of the lab. | |
| 14 | | | M/s Agappe Diagnostics Ltd | Eligibility: Whether US-FDA is essential for all the three proposed items | No Change |

| Response To Pre-Bid Queries (Pre-Bid date: 11.05.2020) | | | | | |
|---|---|---|---|---|---|
| Tender Enquiry No.: HITES/PCD/ICMR/COVID-19/01/2020-21 dated: 08-05-2019 | | | | | |
| Item No. 3 - Combo RT-PCR COVID-19 Tests (2020_HLL_47913_2) | | | | | |
| **Sl. No** | **Tender Page & Para** | **TENDER SPECIFICATION** | **NAME OF THE FIRM** | **REPRESENTATION RECEIVED FROM THE FIRMS** | **COMMITTEE RECOMMENDATION** |
| 1 | Page 39, Para 1 | Item No. 3 - Combo RT-PCR COVID-19 Tests | M/s J. P. Industries | What is your desired minimum or maximum pack size in terms of No. of reactions per pack for "combo RT-PCR covid-19 Kit" say for 200 reaction or 500 reaction or 1000 reaction or any other packing as per the availability with the bidders | No change required |
| 2 | Page 39, Para 1 | Suitable for in-vitro qualitative detection of SARS-CoV-2 nucleic acids in throat (oropharyngeal) swabs, nasopharyngeal swabs, anterior nasal swabs, mid-turbinate nasal swabs, nasal washes, nasal aspirates and broncho alveolar lavage fluid (BALF) from individual who are suspected of COVID-19 | M/s Advancells Group | 1. In RT PCR kit, does the kit have to work with RNA Extractor kit or can we bid RT PCR kit<br>which is blood based and require no RNA Extraction<br>2. If bidding for such kit will it mean that the bid amount will be adjusted as RNA extraction<br>and VTM both will not be required for this kit? | Not Acceptable |
| 3 | Page 39, Para 2 | Should be European CE-IVD or US-FDA approved, if not, should be validated and approved by any of the ICMR validation centres | **No queries** | | No Queries |
| 4 | Page 40, Para 3 | Company should have obtained marketing license for RT-PCR test kits from the Drug Controller General India or it may be parallel obtained. | **No queries** | | No Queries |

| | | | | | |
|---|---|---|---|---|---|
| 5 | Page 40, Para 4 | The Real-Time Fluorescent RT-PCR Kit for Detecting SARS-CoV-2 should use fluorescent probe based TaqMan chemistry with multiplex reaction. Probes should have reporter dyes in the range of Yellow and Green channels, to have compatibility with all types of real time PCR platform (machines) | M/s LifeLine Pharma | The Real-Time Fluorescent RT-PCR Kit for Detecting SARS-CoV-2 should use fluorescent probe based TaqMan chemistry with multiplex reaction. Probes should have commonly used reporter dyes so as to have compatibility with all types of real time PCR platforms. The supplier shall make sure that there kit will also work with QPCR machines having yellow and Green filters only.<br><br>**Reason:**<br>IT will give<br>1. flexibility for labs to use 1 tube per sample with 3 channel machines (85% of labs have such machines) - will do 92+ Samples per hour per machine for these labs<br>2. It will also give flexibility to labs to use two tube per sample if they have only 2 Channel machine using same kit<br>3. By doing this we will achieve mass supply, mass scale without any additional capex need at same cost with same kit | Suitable changes made in the technical specification |
| 6 | | | M/s Thermo Fisher Scientific Invitrogen Bioservices India Pvt. Ltd. | The Real Time Fluorescent RT PCR kit for detecting SARS-CoV-2 should use Fluorescent probe based Taqman Chemistry with multiplex Reaction. Probes should have reporter dyes in the range of spectral separation to have compatibility with common RT PCR machines available. | Suitable changes made in the technical specification |

| | | | | | |
|---|---|---|---|---|---|
| 7 | | | M/s 3B BlackBio Biotech (I) Ltd | In case of multiplexing more than 2 genes,if a target gene is labelled with Texas Red dye(ie orange channel)( The dye has an absorption wavelength that peaks around 589 nm, and an emission maximum around 615 nm) which is available for detection on all four plex - real time PCR platform (machines) ,-So we request you to insert this (orange channel) also ,to make this orange channel also acceptable in the specification | Suitable changes made in the technical specification |
| 8 | | | M/s Siemens Healthcare Private Limited | Real time Fluorescent PCR kit for detection of SARS COV2should use fluorescentprobe-based chemistry assingle-plex or multiplex reaction. Probes shouldhave reporter dyes ascommonly used ones like inGreen, Yellow, Red and Orange channels.<br><br>**Justification:**<br>Real time probe-based chemistries are preferred one for highly specific detection for pathogens, and probe could be of various types. sensitivity and specificity of assay can be 100% with probes like molecular beacon, taqman or hydrolysis probes labelled with multiple types of dyes of different colors and wavelengths. Limiting the specifications to taqman probes with Yellow and green channel only will lead to elimination of various companies and disqualifying without proper reason. | Suitable changes made in the technical specification |

| | | | | | |
|---|---|---|---|---|---|
| 9 | | | M/s Labindia Healthcare Pvt. Ltd. | The Real-Time Fluorescent RT-PCR Kit for Detecting SARS-CoV-2 should use fluorescent probe based TaqMan chemistry with multiplex reaction. Probes should have commonly used reporter dyes so as to have compatibility with all types of real time PCR platforms. Many labs have RT-PCR machines with only 2 channels in which case the supplier of the COVID 19 kits shall make sure that there kit will also work with QPCR machines having yellow and Green filters only. | Suitable changes made in the technical specification |
| 10 | | | M/s Alliance Transfusion Pvt. Ltd. | It can be modified as: The COVID-19 RT-PCR Kit should use commonly used reporter dyes since across the country, various RT-PCR instruments are being used. It should be the responsibility of the kit supplier (selected bidder) to privide compatible kits with all types of real time PCR platforms wether 2 channels or more. The bidders should provide written assurance that their kits shall will work with RT-PCR machines having yellow and Green filters only | Suitable changes made in the technical specification |

| | | | | | |
|---|---|---|---|---|---|
| 11 | | | M/s JITM Skills Pvt ltd | 1. The tender mentions that kits should be ICMR approved and also should have Taqman or / aswell Multiplex chemistry.... Our kits is sybergreen based with 100% accuracy certificate / approval by ICMR. Also our kit is compatible with all the RT-PCR machines being used in India.. Based on the certificates that we have obtained, will that be considered.<br>2. The mentioned quantity are tests or kits . If kits how many tests should be there in kits.<br><br>We JITM Skills pvt ltd is manufacturer of COVID 19 Diagnostic Kits approved by ICMR and developed by IIT Delhi.<br>This is a probe free one-Step RT/q-PCR based detection kit for COOVID 19. The RNA Extracted from the Patient Sample (Nasal swab/throat swab or other Suitable samples will be added to a PCR Plate containing the Master Mix with the required components. The PCR Plates will be subjected to reverse transcription and amplification in a real-time PCR Instrument. This diagnostic assay is based on SYBR Green dye for detection.<br>· Probe Free method\<br>· 100% sensitivity<br>· 100% specificity<br>· Result in less than 90 minutes<br>· The kit does not use fluorescent probes, hence cost effective<br>- Easily scalable | Suitable changes made in the technical specification |

| | | | | | |
|---|---|---|---|---|---|
| 12 | | | M/s Trivitron Healthcare Pvt Ltd | The Real-Time Fluorescent RT-PCR Kit for Detecting SARS-CoV-2 should use Fluorescent probe chemistry with multiplex reaction<br><br>Justification:<br>TaqMan Chemistry is brand name and proprietary of one particular manufacturer that<br>will disqualify other bidders. | Not Acceptable |
| 13 | | | M/s Patel Enterprises | The bidder should provide kits such that they can be used on all the real time PCR platform (machines) including those with only Yellow and Green channels only. However, this should not be at the cost of compromising quality by not having the human housekeeping gene as an internal control to assess sample quality, RNA extraction and RT PCR reaction. The bidder should have kits of various configuration to ensure all the RTPCR instruments can be used without compromising quality. | Suitable changes made in the technical specification |
| 14 | | | M/s Denovo Technologies | The Real-Time Fluorescent RT-PCR Kit for Detecting SARS-CoV-2 should use fluorescent probe based TaqMan chemistry with multiplex reaction or Single plex reaction. Probes should have reporter dyes in the range of Yellow and Green channels, to have compatibility with all types of real time PCR platform (machines) | Suitable changes made in the technical specification |
| 15 | | | M/s J. P. Industries | The technology we are using in covid kit is probe free real time RT-PCR Diagnostic Kit. No requirement of probe makes it easy and accurate to diagnose. Our kit is compatible with all the machines on which probe based kit works. Are we eligible to participate with this product whose specificity and sensitivity both are declared as 100% by ICMR. | Not Acceptable |

| | | | | | |
|---|---|---|---|---|---|
| 16 | Page 40, Para 5 | If the kit is representing only one gene it should be of SARS CoV-2 specific only and should have an internal control of human housekeeping gene. | M/s LifeLine Pharma | This point should be removed and invalid as per WHO/CDC and ICMR guidelines<br><br>Reason:<br>As the tender is for Combo RT-PCR COVID-19 Tests (Screening and confirmation) only one gene kit will be invalid as for Screening it takes 1 Gene and for confirmation it takes minimum 1 gene. + internal control of human housekeeping gene for both testing if done separately.<br>With one gene for screening and confirmation chances of False negatives will be very high and not recommended as per WHO/CDC/ICMR guidelines. | Suitable changes made in the technical specification |
| 17 | | | M/s Siemens Healthcare Private Limited | Multigene detection kits (combination of screening and confirmatory assays) should have screening E gene along with confirmatory genes of ORF/RdRp/N gene of SARS CoV2 along with Internal control, positive control and negative control, to asses sample extraction quality and RT PCR reaction<br><br>**Justification:**<br>Screening and confirmatory gene based kits are being used in high quality controlled markets like in US and EU, with different types of controls, and that could be Internal control , as extraction control using synthetic RNA spiking to clinical samples, and same is part of design of majority of assay manufacturers including Thermo, Seegene, Altona, Labgenomics etc. Adverse selection based on housPekeeping gene will discourage the fair competition and at the end favoring few manufacturers only. Regulatory agencies like FDA and CEIVD are approving kits with internal control for better patient management | Suitable changes made in the technical specification |

| | | | | | |
|---|---|---|---|---|---|
| 18 | | | M/s Thermo Fisher Scientific Invitrogen Bioservices India Pvt. Ltd. | This point pertains to singleplex kit, hence it should not be included in view of all other multiplex specifications in the mentioned tender | Suitable changes made in the technical specification |
| 19 | | | M/s Labindia Healthcare Pvt. Ltd. | This point should be removed as the WHO guidleines have clearly recommended usage of at least two different targets on the COVID-19 virus genome, of which at least one target is preferably specific for COVID-19. We suggest, expunging the above point. | Suitable changes made in the technical specification |
| 20 | | | M/s Gentix Biotech Asia Pvt Ltd | If the kit is representing only one gene it should be of SARS CoV-2 specific only and<br>should have an internal control of human housekeeping gene.<br>Or<br>□ Multiplex detection (combination of screening and confirmatory assays) should have screening E gene along with confirmatory genes<br>of ORF/RdRP/N genes of SARS-CoV-2<br><br>**Justification:**<br>These two point are contradictory it should be either point 5 or point 6<br>Publication attached one gene is better results by avoiding false positive or false negative | Suitable changes made in the technical specification |
| 21 | | | M/s Patel Enterprises | The Point is invalid and should be removedimmediately as tender is for Combo PCR kit with Screening and Detection | Suitable changes made in the technical specification |

| | | | | | |
|---|---|---|---|---|---|
| 22 | | | M/s Alliance Transfusion Pvt. Ltd. | It can be modified as: The WHO guidleines have stated a mimimum of two different targets on the COVID-19 virus genome, of which at least one is specific for COVID-19. In such a case, kits representing only gene of SARS CoV-2 will be compromising on the quality of testing.<br><br>Therefore, the above point should be removed. | Suitable changes made in the technical specification |
| 23 | Page 40, Para 6 | Multiplex detection (combination of screening and confirmatory assays) should have screening E gene along with confirmatory genes of ORF/RdRP/N genes of SARS-CoV-2 along with human housekeeping gene as an internal control to assess sample quality, RNA extraction and RT PCR reaction. | Altona Diagnostics India Pvt Ltd | 1) Include “S Gene” along with ORF/RdRP/N Gene.<br><br>2)Internal control can be a human housekeeping gene or exogenous control. (Reference Document attached. | Suitable changes made in the technical specification |
| 24 | | | M/s Alliance Transfusion Pvt. Ltd. | It can be modified as: The single tube multiplex Real-Time Fluorescent RT-PCR Kit for Detecting SARS-CoV-2 should have screening gene along with preferable 2 confirmatory genes of ORF/RdRP/N genes along with human housekeeping gene as an internal control. The use of 2 confirmatory genes will increase the sensitivity and specifictiy of the testing kits while the single tube format will be recommended as it will do 92+ samples per machine per hour doing screening and confirmation at same time<br><br>Technical Specifications for the Extraction Kit | Suitable changes made in the technical specification |

| | | | | | |
|---|---|---|---|---|---|
| 25 | | | M/s Imperial Life Sciences | Multiplex detection (combination of screening and confirmatory assays) should have screening E gene along with confirmatory genes of ORF/RdRP/N genes of SARS- CoV-2 along with an internal control to assess sample quality, RNA extraction and RT PCR reaction.<br><br>**Reason:**<br>Kit manufacturers utilize different type of internal controls to assess sample quality, RNA extraction and RT PCR reaction. Few companies' kits include Housekeeping genes whereas others have Exogenous RNA sequences as internal control in their assay designs. Both types of kits have been granted CE-IVD approval and US-FDA EUA. | Suitable changes made in the technical specification |
| 26 | | | M/s Labindia Healthcare Pvt. Ltd. | Multiplex detection should have screening E gene along with confirmatory genes of ORF/RdRP/N genes (2 Confirmatory genes will be preferred as it will ease repeat testing) of SARS-CoV-2 along with human housekeeping gene as an internal control in a single tube format to assess sample quality, RNA extraction and RT PCR reaction | Suitable changes made in the technical specification |
| 27 | | | M/s Genes2ME | Multiplex detection (combination of screening and confirmatory assays) should have screening E gene along with confirmatory genes of ORF/RdRP/N genes of SARS-CoV-2 along with an internal control to assess sample quality, RNA extraction and RT PCR reaction.<br><br>**Reason for Amendment**: Test Kit Manufacturers provides different types of Internal controls such as Housekeeping genes, Bacteriophage RNA sequences, etc. in their respective test kits. Restricting only specific type of internal control shall act as a hindrance to participate in tender. | Suitable changes made in the technical specification |

| | | | | | |
|---|---|---|---|---|---|
| 28 | | | M/s Thermo Fisher Scientific Invitrogen Bioservices India Pvt. Ltd. | Multiplex Detection [Combination of screening & confirmatory Assays] kit which should be US-FDA/CEIVD/ICMR approved and should have screening E-Gene/S-Gene with confirmatory Genes of ORF/RdRP/N genes of SARS-CoV-2 along with Internal Control. | Suitable changes made in the technical specification |
| 29 | | | M/s Patel Enterprises | Besides screening E gene, at least any 2 of confirmatory genes such as ORF/RdRP/N genes of SARS-CoV-2 along with human housekeeping gene as an internal control should be present in the multiplex Real-Time Fluorescent RT-PCR Kit for Detecting SARS-CoV-2 kit. The human housekeeping gene as an internal control is specially important to assess sample quality, RNA extraction and RT PCR reaction. | Suitable changes made in the technical specification |
| 30 | | | M/s Perkin Elmer | The kit representing multiplex detection, it should have any two genes ORF/RdRP/N/E genes of SARS-CoV-2 along with human housekeeping gene as an internal control to assess sample quality, RNA extraction and RT PCR reaction | Suitable changes made in the technical specification |
| 31 | | | M/s Denovo Technologies | Multiplex detection or single plex (combination of screening and confirmatory assays) should have screening E gene along with confirmatory genes of ORF/RdRP/N genes of SARS-CoV-2 along with human housekeeping gene or internal control as an internal control to assess sample quality, RNA extraction and RT PCR reaction. | Suitable changes made in the technical specification |

| | | | | | |
|---|---|---|---|---|---|
| 32 | | | M/s LifeLine Pharma | Multiplex detection (combination of screening and confirmatory assays) should have screening E gene along with confirmatory genes of ORF/RdRP/N genes (2 Confirmatory genes will be preferred as it will ease repeat testing) of SARS-CoV-2 along with human housekeeping gene as an internal control in a single tube format to assess sample quality, RNA extraction and RT PCR reaction.<br>**Reason:**<br>It will help as<br>1. Including 2 confirmatory gene over 1 is highly recommended as it will<br>Remove repeat testing (time and cost) as it is recommended that for every Screening positive and Confirmatory negative sample.<br>It will remove chance of false negatives as with 2 genes chances of missing both in test will be rare.<br>There are cases of single gene not detected due to localised mutation. Having 2 confirmatory genes will remove that risk and make detection accurate.<br><br>2. Single tube format will be recommended as it will do 92+ samples per machine per hour doing screening and confirmation at same time compared to 31-42 samples per hour per machine compared to 2/3 tube format. | Suitable changes made in the technical specification |
| 33 | Page 40, Para 7 | The assay should be robust and compatible with RNA extracted using different viral RNA extraction kits available in the market. | | | No Queries |

| | | | | | |
|---|---|---|---|---|---|
| 34 | Page 40, Para 8 | ▯ The kit supplied should be open ended, compatible to any kind of RT-PCR machine available in market. | M/s Gentix Biotech Asia Pvt Ltd | The kit supplied should be open ended, compatible to most of RT-PCR machine (minimum 3) available in market<br><br>**Justification:**<br>CE IVD approved kits are validated on system its compatible to many system but validated on most used systems globally (like BioRad, Thermo and Roche) | No change required |
| 35 | | | M/s Thermo Fisher Scientific Invitrogen Bioservices India Pvt. Ltd. | Multiplex kit requires specific dye combinations which can be detected only by select instrument models and hence will not be compatible with any kind of RT-PCR machine available in market. Suggested Change: Remove this point if the requirement is for multiplex kit. | Not Acceptable |
| 36 | | | M/s Imperial Life Sciences | Point to be added:<br>Multiplex assay with minimum two confirmatory genes from ORF/RdRP/N genes of SARS- CoV-2 should be mandatorily present in the quoted Kit<br><br>**Reason:**<br>Requirement of Minimum two genes in confirmatory assay should be included as it will reduce the Re-testing rate and false negatives ultimately leading to enhanced specificity and sensitivity. It will also save onto cost which is involved in Repeated testing and shall also allow testing more number of samples at the same time | Suitable changes made in the technical specification |

| | | | | | |
|---|---|---|---|---|---|
| 37 | | | M/s Genes2ME | **Addition of New Specification Point:** Multiplex assay having at least two confirmatory genes of<br>ORF/RdRP/N genes of SARS-CoV-2 should be there in the test kit.<br><br>**Reason for Amendment:** Addition of this point will make the test specifications more superior. This will save lot of time and efforts which goes in repeat testing on the sample. By addition of 2 genes for confirmation will increase the sensitivity of the Test. | Suitable changes made in the technical specification |
| 38 | | | M/s Thermo Fisher Scientific Invitrogen Bioservices India Pvt. Ltd. | **Please, consider addition of following latest and important aspect of Combo RTPCR COVID-19 TESTS:**<br>1. The kit should offer multiplex solution- all the target genes should be in single tube, so<br>as to run maximum samples in single run. The throughput should be 90+ samples in<br>less than 2 hours on Real Time PCR.<br>2. The kit should detect target S gene for both screening and confirmation with reduced<br>homology to other similar coronavirus strains.<br>3. The kit should target 100% of all currently available complete genomes for 2019 nCoV.<br>4. The kit should have high sensitivity and LOD with ~10 GCE/rxn | Suitable changes made in the technical specification |
| 39 | | | M/s Agappe Diagnostics Ltd | Eligibility: Whether US-FDA is essential for all the three proposed items | Not item not specified |

| | | | | | |
|---|---|---|---|---|---|
| 40 | | | M/s HORIBA India Pvt. Ltd. | • Dual Targets suggested by US CDC and WHO for RdRp and N genes & the kit is approved by ICMR would the same qualify for tender.<br>• Offering a Single-Tube Real-Time RT-PCR Reaction for maximum utilization<br>• Need information Expected preferred LOD (Limit of Detection)<br>• Need information on % CV of the kit preferred requirement Intra & Inter day performance<br>• Expected minimum TAT (expected turnaround Time for RT PCR) kits<br>• If a kit is approved by ICMR can the same be quoted – attached for reference | Suitable changes made in the technical specification |