1. REAL TIME PCR BASED MOLECULAR TESTS

1.1. The tests must work on suitable samples through the method of multiplex real-time polymerase chain reaction (Real-Time PCR).

1.2. The bidder must contact the laboratory prior to the bid and issue a notification about the kits they would offer which must be compatible with the laboratory's systems in addition to including in the bid dossier the product specifications of the kits.

1.3. The bidder must procure nucleic acid extraction kits which must be compatible with the clinical samples to be worked on and must be as many as the number of given PCR kits in addition to establishing a fully automated robotic nucleic acid extraction system compatible with the kit(s).

1.4. The kits must be compatible with open systems such as BIORAD CFX96, ABI 7500 or Corbett Rotor-Gene 6000.

1.5. Free-of-charge replacements between test items to be used in the same device must be available upon the laboratory's request.

1.6. The kit panel to be offered for PCR analysis to identify respiratory viral infection agents must allow the identification of at least the respiratory infection viral agents of Influenza A and B viruses, influenzavirus H1N1, parainfluenza virus 1-4, Respiratory Syncytial Virus (RSV) A and B, adenovirus, seasonal coronaviruses (including SARS-CoV-2), rhinovirus/enterovirus, bocavirus and metapneumovirus. If the multiplex kit panel to be offered lacks any/a few of the defined microorganisms, the bidder must deliver free-of-charge to the laboratory the monoplex/multiplex real-time PCR kits compatible with the offered system, the quantity being as many as the number of tests the laboratory demands (not to exceed the total number of tests).

1.7. The kit panel to be offered for PCR analysis to identify respiratory bacterial infection agents must allow the identification of at least Mycoplasma pneumoniae, Chlamydophila pneumonia, Legionella pneumophila and Bordetella pertussis. If the multiplex kit panel to be offered lacks any/a few of the defined microorganisms, the bidder must deliver free-of-charge to the laboratory the monoplex/multiplex real-time PCR kits compatible with the offered system, the quantity being as many as the number of tests the laboratory demands (not to exceed the total number of tests).

1.8. In order to identify rash disease agents in the sample taken from serum/rash, at least the following microorganisms must be identifiable in the Multiplex Real Time PCR panel: Measles, Enterovirus, HHV-6, HHV-7 and PV-B19. If the offered kit fails to

include any of these agents, the same number of kits defining the agent in monoplex or multiplex format must be procured by the bidder. It must be suitable for PCR-based simultaneous testing of viral agents.

1.9. The expiry date of all delivered kits must not be shorter than 1 year from the date of delivery.

1.10. Gradually and simultaneously with each kit delivery, the bidder must provide free-of-charge flexible dacron or "flock" nasopharyngeal ecuvion from a brand deemed appropriate by the laboratory in numbers that are 10% more than the number of respiratory panel tests, in addition to viral extraction liquid tube compatible with the kit as well as a tube with K2 EDTA which will be used to draw blood for blood-based samples, compatible with the laboratory systems and from a brand preferred by the laboratory. The bidder must replace free-of-charge the tube lots with vacuum problems.

1.11. The expiry date of transport mediums must not be shorter than 1 year in the delivery phase.

1.12. The kit panel to be offered for PCR analysis to identify GIS (Gastro-intestinal System) agents must allow the identification of at least Clostridium difficile toxin A/B, enteroaggregative E. coli (EAEC), Enteroinvasive E. coli (EIEC)/Shigella spp., Enteropathogenic E. coli (EPEC), Enterotoxigenic E. coli (ETEC), Shigatoxigenic E. coli (STEC) stx1/stx2, Shigatoxigenic E. coli (STEC) O157:H7, Campylobacter spp., Plesiomonas shigelloides, Salmonella spp., Vibrio cholerae, V. parahaemolyticus, C. vulnificus, Yersinia enterocolitica, Adenovirus F40/41, Astrovirus, Norovirus GI/GII, Rotavirus A, Sapovirus (GI/GII/GIV/GV), Cryptosporidium spp., Cyclospora cayetenensis, Entamoeba histolytica and Giardia intestinalis. If the multiplex kit panel to be offered lacks any/a few of the defined microorganisms, the bidder must deliver free-of-charge to the laboratory the monoplex/multiplex real-time PCR kits compatible with the offered system, the quantity being as many as the number of tests the laboratory demands (not to exceed the total number of tests).

1.13. The kit panel to be offered for PCR analysis to identify Central Nervous System multiplex PCR Panel infection agents must allow the identification of at least HSV1, HSV2, VZV, enterovirus, mumps virus, parechovirus, Escherichia coli, Neisseria meningitidis, Haemophilus influenzae, Listeria monocytogenes, Streptococcus pneumoniae, Streptococcus agalactiae and Cryptococcus neoformans/gattii. If the multiplex kit panel to be offered lacks any/a few of the defined microorganisms, the bidder must deliver free-of-charge to the laboratory the monoplex/multiplex real-time

PCR kits compatible with the offered system, the quantity being as many as the number of tests the laboratory demands (not to exceed the total number of tests).

1.14. The bidder, along with the offered kits, must provide free-of-charge an adequate amount of all the kits and reagents to be used for isolation and PCR steps as well as all the chemicals and plastic consumables (tubes, pipettes, pipette tips, 8-pack strips and caps compatible with relevant devices, disposable gloves etc.) required for the test to work and recommended in kit prospectuses.

1.15. Together with the kits, the bidder must provide free-of-charge three sets of (suitable for 0,2-20; 10-200; 100-1000 microliter intervals) automatic pipettes from a brand selected by the laboratory to be used for sample processing and PCR stages.

1.16. The bidder must give the laboratory three mini-spin/vortexes for sample preparation and PCR procedures.

1.17. All reagents, devices and equipment required for work on the tests must be provided by the bidder. Purchased tests must be kept in the Laboratory until they are worked on, notwithstanding the tender expiration date.

1.18. The real-time PCR devices to be installed must have at least 5 channels.

1.19. All the products offered must be in their original packaging and the kits must have the test name, test number, lot number, expiry date and the manufacturer written on them.

1.20. The PCR master mix containing the enzymes, primers and probes must be included in the kit.

1.21. There must be internal controls in the original packaging of kits. Internal controls must be added to the samples during the DNA/RNA extraction phase.

1.22. The bidder must assume technical support and maintenance of the devices it installed. Repairing all kinds of malfunctions that may arise until the purchased kits are consumed and procuring spare supplies must be handled by the bidder.

1.23. Offered devices and kits must be suitable for in vitro diagnostic use and have a CE certificate.

1.24. All the kits to be offered must have the T.C. Ministry of Health UTS (Product Tracking System) registry.

1.25. In case of a device malfunction, the bidder must respond to the device no later than 2 hours after being informed via telephone and/or fax etc. so as not to cause any disruptions in the laboratory work. The device must be restored to working condition within 24 hours at the latest and in cases where this is not possible, it must be replaced

within a week at the latest with another device having the same features so that patients' results can be produced on time.

1.26. The firm that installed the system must provide laboratory personnel with the necessary training and training materials for the system's use as well as training certificates for the trained personnel.

1.27. Certificates of authorisation approved by the manufacturer must be provided for offered devices. There must also be personnel training certificates indicating technical service qualifications.

1.28. An uninterruptible power supply compatible with system capacity that will allow the system to run for at least 15 more minutes must be installed along with the system so as to prevent sample loss in the event of a power outage.

2. MOLECULAR SYNDROMIC CLOSED SYSTEM PANELS

2.1 The tests must work on suitable samples through the method of multiplex real time polymerase chain reaction (Real-Time PCR).

2.2 The tests must consist of the following panels

Molecular syndromic panel - Upper respiratory tract infection agents

Molecular syndromic panel – Meningitis agents

Molecular syndromic panel – Gastroenteritis agents

Molecular syndromic panel – Rash disease agents

2.3 The tests must be worked on with suitable (validated) samples in a closed system by placing them directly into the device following the sample pipetting into a cartridge. The tests must yield results in 45 to 90 minutes without requiring any intervention. After sample loading through the system to be offered, they must realise fully automatically the phases such as nucleic acid isolation and real-time PCR and no manual intervention must be needed.

2.4 The system must contain a number of devices enough to yield results for at least 2 (two) patients through simultaneous work.

2.5 The syndromic panel for identifying respiratory tract viral infection agents must allow the identification of at least the following microorganisms: Influenza A and B viruses, influenzavirus H1N1, influenzavirus H3, parainfluenza virus 1-4, Respiratory Syncytial Virus (RSV) A/B, adenovirus, seasonal coronaviruses and SARS-CoV-2, rhinovirus/enterovirus and bocavirus, metapneumovirus, Mycoplasma pneumoniae,

Bordetella pertussis, Legionella pneumophila. If the kit panel to be offered lacks any/a few of the defined microorganisms, the bidder must deliver free-of-charge to the laboratory the monoplex/multiplex real-time PCR kits compatible with the existing system(s) in the laboratory, the quantity being as many as the number of kits the laboratory demands for this panel.

2.6 The syndromic panel for identifying meningitis/encephalitis agents must allow the identification of at least the following microorganisms: HSV1, HSV2, CMV, HHV6, VZV, parechovirus, enterovirus, Escherichia coli, Neisseria meningitidis, Haemophilus influenzae, Listeria monocytogenes, Streptococcus pneumoniae, Streptococcus agalactiae and Cryptococcus neoformans/gattii. If the kit panel to be offered lacks any/a few of the defined microorganisms, the bidder must deliver free-of-charge to the laboratory the monoplex/multiplex real-time PCR kits compatible with the existing system(s) in the laboratory, the quantity being as many as the number of kits the laboratory demands for this panel.

2.7 The syndromic panel for identifying gastroenteritis agents must allow the identification of at least the following microorganisms: Clostridium difficile toxin A/B, enteroagregative E. coli (EAEC), Enteroinvasive E. coli (EIEC)/Shigella spp., Enteropathogenic E. coli (EPEC), Enterotoxigenic E. coli (ETEC), Shigatoxigenic E. coli (STEC) stx1/stx2, Shigatoxigenic E. coli (STEC) O157:H7, Campylobacter spp., Plesiomonas shigelloides, Salmonella spp., Vibrio cholerae, V. parahaemolyticus, C. vulnificus, Yersinia enterocolitica, Adenovirus F40/41, Astrovirus, Norovirus GI/GII, Rotavirus A, Sapovirus (GI/GII/GIV/GV), Cryptosporidium spp., Cyclospora cayetenensis, Entamoeba histolytica and Giardia intestinalis.

2.8 Gradually and simultaneously with each kit delivery, the bidder must provide free-of-charge flexible dacron or “flock” nasopharyngeal ecuvion from a brand deemed appropriate by the laboratory, together with virus transport medium and as many as the number of respiratory tract PCR tests.

2.9 Gradually and simultaneously with each kit delivery, the bidder must provide free-of-charge faecal containers into which faecal samples are to be transferred, compatible with the offered system and from a brand deemed appropriate by the laboratory.

2.10 The bidder, along with the offered kits, must provide free-of-charge an adequate amount of all the kits and reagents as well as all the chemicals and other consumables (tubes, pipettes, pipette tips, disposable gloves etc.) required for the test to work and recommended in kit prospectuses.

2.11 The bidder, along with the kits, must provide free-of-charge two automatic pipettes from a brand deemed appropriate by the laboratory, compatible with the pipette tips to be delivered, for the purpose of working on the test.

2.12 All reagents, devices and equipment required for work on the tests must be provided by the bidder.

2.13 As long as the tests are being worked on, the successful bidder must conduct in accordance with laboratory accreditation criteria the maintenance/repair/calibration procedures of all kinds for the system it installed and procure spare parts. Repairing all kinds of malfunctions that may arise until the purchased kits are consumed and procuring spare supplies are under the bidder's responsibility.

2.14 Technical maintenance service must be available 24 hours a day, 7 days a week and on all holidays/official holidays.

2.15 In case of a device/module malfunction, the bidder must respond to the device no later than 4 hours after being informed via telephone and/or fax etc. so as not to cause any disruptions in the laboratory work. The device/module must be restored to working condition within 24 hours at the latest.

2.16 In the event that a device/module needs to be taken away from the laboratory for any reason (maintenance/repair etc.), the firm must commit to installing within 48 hours new device/modules as many as those taken away.

2.17 During device delivery, operating files (usage, maintenance, calibration documents etc.) of all devices must be handed over to the laboratory in full.

2.18 All the products offered must come in the manufacturer's original packaging, and the kits must have the test name, test number, lot number, expiry date and the manufacturer written on them.

2.19 The kits must be storable at room temperature, and performance loss must not occur until the expiry date.

2.20 The kits' shelf life must be at least 1 year from the date of delivery to the laboratory. The bidders must commit to replacing free-of-charge the kits with a remaining shelf life of two months with the same or different syndromic panel kits having a longer shelf life, provided that notification is given beforehand.

2.21 The system to be installed must not be older than eight years.

2.22 Offered devices and kits must be suitable for in vitro diagnostic use and have a CE certificate.

2.23 All the kits to be offered must have T.C. Ministry of Health UTS registry.

2.24 The firm that installed the system must provide laboratory personnel with the necessary training and training materials for the system's use as well as training certificates for the trained personnel.

2.25 Certificates of authorisation approved by the manufacturer must be provided for offered devices. There must also be personnel training certificates indicating technical service qualifications.

2.26 An uninterruptible power supply compatible with system capacity that will allow the system to run for at least 15 more minutes must be installed along with the system so as to prevent sample loss in the event of a power outage.

2.27 During the bidding phase, the firms must procure in original packaging the samples (approximately 50 tests) of the kits they would offer, and in terms of microorganisms in the kit panel, must agree to perform a demonstration through the work on patient samples which are priorly found to be positive by the laboratory. The laboratory reserves the right to refuse a firm deemed unsuccessful in the demonstration.

3. ANTIGEN TESTS

3.1.Rotavirus/adenovirus/norovirus antigen test kit

3.1.1. The test must be able to simultaneously identify the presence of rotavirus, adenovirus and norovirus in faecal samples.

3.1.2. The test must be able to separately identify from faecal samples the Rotavirus antigen (including all subgroups A – G) and Adenovirus antigen (including serotypes 40 and 41). It must be able to identify from faecal samples the Genogroup I (GI) ve Genogroup II (GII) Norovirus antigen.

3.1.3. There must be no need to perform any additional procedures (centrifugation etc.) on faecal samples during the sample preparation phase.

3.1.4. The test must be in cassette form, yield results in a single stage and work with the immunochromatographic method. The antibodies used in the test membrane must be monoclonal.

3.1.5. All the equipment required to perform the test (calibrator, positive and negative controls, diluent, pipette etc.) must be in the kit, ready to use. For kits lacking control, the firm must externally provide positive and negative controls in sufficient amounts to perform quality control for each new lot it has delivered.

3.1.6. The test cassette must have separate fields showing control and patient results.

3.1.7. The duration of test finalisation must be no more than 30 minutes, including running time.

3.1.8. The test must have a sensitivity of at least 90% and a specificity of at least 95%. Test sensitivity and specificity and working procedure must be explicitly stated in the test's original kit prospectus.

3.1.9. The product must be delivered in its original packaging in a moisture-proof state.

3.1.10. Product name, abbreviation, content, lot number, quantity, production and/or expiry date and the manufacturer's name must be on the original package.

3.1.11. The kit to be offered must be CE/IVD approved and the certificate of approval must be presented during the bidding stage.

3.1.12. The kits delivered must have a minimum of 1 year shelf life. Upon the laboratory's demand, kits which have 2 months until expiration must be replaced with the ones having longer expiration dates.

3.1.13. The firm must submit to the approval of the laboratory the kit it would offer by demonstrating it prior to the tender and must enclose within the tender dossier the kit's certificate of conformity received from the laboratory officer.

3.2.*Legionella pneumophila* urine antigen test kit

3.2.1. The kit to be offered must be able to qualitatively identify the presence of *L. neumophila* serogroup-1 antigen in urine.

3.2.2. The test must be in cassette form, yield results in a single stage and work with the immunochromatographic method. The antibodies used in the test membrane must be monoclonal.

3.2.3. All the equipment required to perform the test (calibrator, positive and negative controls, diluent, pipette etc.) must be in the kit, ready to use. Should these supplies in the test run out early or become insufficient, the firm must procure free-of-charge the sufficient amount of supplies for the remaining tests.

3.2.4. The test cassette must have separate fields showing control and patient results.

3.2.5. The duration of test finalisation must be no more than 15 minutes, including running time.

3.2.6. The product must be delivered in its original packaging in a moisture-proof state.

3.2.7. Product name, abbreviation, content, lot number, quantity, production and/or expiry date and the manufacturer's name must be on the original package.

3.2.8. In terms of evaluating the test's performance, the kit must have been compared with one of the methods of culture, DFA and/or IFA. The test kit's sensitivity and specificity must not be lower than 95%.

3.2.9. The kit must be storable at room temperature.

3.2.10. The kits must have a minimum of 1 year shelf life. Upon the laboratory's demand, kits which have 2 months until expiration must be replaced with the ones having longer expiration dates.

3.3.Group A streptococcus antigen test kit

3.3.1. It must be suitable for identifying *Streptococcus pyogenes* antigen from throat swab samples using the latex agglutination method.

3.3.2. The work must not require any equipment other than the kit.

3.3.3. Test results must be obtainable in 10 minutes at the latest.

3.3.4. Test preparates must be separately packaged in aluminium to guard against moisture. Original package contents, lot number and expiry date must separately be stated on each package.

3.3.5. The test's sensitivity against the culture method must not be lower than 94% while the specificity must not be lower than 98%.

3.3.6. Swabs required to collect samples must come with the kit.

3.3.7. Positive and negative controls must come with the kit.

3.3.8. The kits, including the reagents, must be storable at room temperature between 2ºC and 30ºC without needing heating or cooling to attain room temperature to work on the reagents.

3.3.9. The kits must come with sterile swabs, reagents, and instructions.

3.3.10. A kit package must be for at least 20 tests.

3.3.11. The kits must have a minimum of 1 year shelf life. Upon the laboratory's demand, kits which have 2 months until expiration must be replaced with the ones having longer expiration dates.

3.4.SarsCov2-Influenza A+B-RSV antigen test kit

3.4.1. The test must be able to identify Sarscov2, Influenza A+B and RSV antigen from nasopharyngeal and nasal swabs. The kit membrane must be coated with monoclonal antibodies.

3.4.2. The test's working principle must be based on the colour chromatographic immunoassay technique.

3.4.3. Test results must be obtainable in 10 minutes at the latest.

3.4.4. To avoid misinterpretation of the results, the test must be in single cassette format with sample wells for each test, separate interpretation parts and differently coloured control lines and test lines.

3.4.5. The test must be able to display results for SarsCov2-Influenza A+B and RSV separately.

3.4.6. Test preparates must be separately packaged in aluminium to guard against moisture. Original package contents, lot number and expiry date must separately be stated on each package.

3.4.7. Test sensitivity must be ≥90% whereas the specificity must be over 90%.

3.4.8. The kits, including the reagents, must be storable at room temperature between 2ºC and 30ºC without needing heating or cooling to attain room temperature to work on the reagents.

3.4.9. Swabs required to collect samples must come with the kit.

3.4.10. The kit must come with separate positive controls each for Sarscov2, RSV, Influenza A+B types.

3.4.11. A kit package must be for at least 20 tests.

3.5.*Streptococcus pneumoniae* specific surface antigen identification kit (CSF/Urine)

3.5.1 For diagnoses of pneumococcal pneumonia or pneumococcal meningitis, the test must be able to identify *Streptococcus pneumoniae* specific surface antigen from the urine of pneumonia patients or the cerebrospinal fluid of meningitis patients using the immunochromatographic method.

3.5.2 The kit's test strip must be coated with anti-*Streptococcus pneumoniae* antibody.

3.5.3 The work must not require any equipment other than the kit.

3.5.4 The test procedure must not require a centrifuge and the results must be obtainable in 15 minutes at the latest.

3.5.5 In order to prevent any contamination and achieve higher sensitivity, the sampling procedure must be completed by placing a test swab directly into the test cassette and sealing the cassette with the sticker found on its side. After that, the test must start working.

3.5.6 Test cassettes must be separately packaged in aluminium to guard against moisture. Original package contents, lot number and expiry date must separately be stated on each package.

3.5.7 Aluminium packaging must contain desiccant tablets to ensure that test cassettes work correctly and remain completely unaffected by moisture.

3.5.8 Each kit must have a minimum of one positive and negative control swab in its original packaging that can be stored at room temperature.

3.5.9 In terms of the test's performance evaluation, the minimum urine sample sensitivity and specificity must be 85% and 94% respectively while cerebrospinal fluid (CSF) sample sensitivity and specificity must not be lower than 97% and 99% respectively.

3.5.10 The kit must be storable at room temperature.

3.5.11 Each kit must come with test cassettes, reagents, sterile swabs, positive and negative control swabs and instructions.

3.6. Cryptococcus-Giardia-Amoeba antigen test kit

3.6.1. The test must be able to separately identify from faecal samples the *Cryptosporidium parvum*, *Giardia lamblia* and *Entamoeba histolytica* and have the feature to distinguish one from the other.

3.6.2. The chitin membrane must be coated with monoclonal antibodies.

3.6.3. The test's working principle must be based on the colour chromatographic immunoassay technique so as to minimise laboratory errors.

3.6.4. The work must not require any equipment other than the kit. The test must be in cassette form for ease of use.

3.6.5. The test procedure must not require a centrifuge and the results must be obtainable in 15 minutes at the latest.

3.6.6. The control lines and test result lines on the test cassette must be in different colours to prevent misinterpretation of test results.

3.6.7. Test cassettes must be separately packaged in aluminium to guard against moisture. Original package contents, lot number and expiry date must separately be stated on each cassette package.

3.6.8. Aluminium packaging must contain desiccant tablets to ensure that test cassettes work correctly and remain completely unaffected by moisture.

3.6.9. Each kit must have at least one positive control swab in its original packaging, which is storable at room temperature.

3.6.10. Diluting agent must be kept ready in faecal matter collection tubes to prevent contamination. There must be no need to fill sample tubes by counting drops from a separate bottle.

3.6.11. The test's sensitivity and specificity for Cryptococcus, Giardia and Entamoeba must not be lower than 95%.

3.6.12. The kits, including the reagents and positive controls, must be storable at room temperature between 2ºC and 30ºC without needing heating or cooling to attain room temperature to work on the reagents.

3.6.13. Each kit must come with separate test cassettes, faecal matter collection tubes containing diluting reagent, positive control swabs and instructions.

3.7.Cholera Ag kit

3.7.1. The test must be in cassette format, and test lines must be pre-coated with monoclonal anti-*V.cholerae* O1 antibodies and test monoclonal anti-*V.cholerae* O139 antibodies.

3.7.2. No external equipment must be needed during application. All required equipment must be found in the package.

3.7.3. The test work carried out with culture and sensitivity tests must yield 95% sensitivity and higher than 95% specificity.

3.7.4. The test must yield results in 20 minutes at the latest.

3.7.5. Test cassettes must be separately packaged in aluminium to guard against moisture. Original package contents, lot number and expiry date must separately be stated on each cassette package.

3.7.6. Each kit must come with a minimum of one positive and negative control in its original packaging that can be stored at room temperature.

3.7.7. A box must contain at least 20 tests.

3.7.8. The kit must be storable between 4 and 30 Celsius.

3.8.Malaria antigen kit

3.8.1. The test must be able to identify malaria infection agents from whole blood.

3.8.2. The test must be able to identify Plasmodium falciparum and other types of Plasmodium antigens in whole blood via immunochromatography.

3.8.3. The test must be able to identify as antigens the Plasmodium faciparum's Histidin-Rich Protein II (HRP-II) and plasmodium lactate dehydrogenase (pLDH) of Plasmodium species.

3.8.4. The work must not require any equipment other than the kit. The test must be in cassette form for ease of use.

3.8.5. The test procedure must not require a centrifuge, and the results must be obtainable in 30 minutes at the latest.

3.8.6. Test result lines and the control line appearing on the test cassette must be able to distinguish the results.

3.8.7. Test cassettes must be separately packaged in aluminium to guard against moisture. Original package contents, lot number and expiry date must separately be stated on each cassette package.

3.8.8. The test sensitivity must be 95%, while the specificity must be higher than 95%.

3.8.9. The kits, including the reagents and positive controls, must be storable at room temperature between 2ºC and 30ºC without needing heating or cooling to attain room temperature to work on the reagents.