Corrigendum
In tender document
Tender Enquiry No. 24/Diagnostic kit/402/2018-Rish(Admn)

Dated: 16-08-2018

As per schedule, Pre- Bid meeting of "Rate Contract for Diagnostic Kits for Serology Lab" was held on 08-08-2018 at 03.00 PM, in the tender opening room.

After consideration by Technical Specification Committee Specification of aforesaid tender is now read as following:

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<tr>
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<th>Unit Qty./Pack size</th>
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</table>
| 01    | ANA- IFA Kit *    | • Should contain Hep-2 cell / cell line20-10.  
• Should have much higher proportion of mitotic cells.  
• Should have facility to upgrade the kit with multiple substrates.  
• Should have Primate liver as additional substrate for parallel detection and confirmation of ANA and liver antibodies.  
• Should have reagent incubation tray for test incubation.  
• Test system should not have requirement of humidity chamber. | 5x10=50 /kit       |
| 02    | ANCA – IFA Kit*   | • Should have ethanol fixed granulocytes and formalin fixed granulocytes in one reaction field.  
• Should have facility to upgrade the assay with multiple substrates.  
• Should have reagent tray system for assay incubation.  
• Test system should be free from need of humidity chamber. | 5x5=25/kit         |
| 03    | Anti-cardiolipin IgM & IgG ELISA*#  | • Solid phase ELISA  
• Preferred make: Calbiotech, Diapro, DRG | 96 well/kit       |
<p>| 04    | Anti-CCP ELISA kit*# | • Test system should Highly purified Cyclic Citrullinated peptide coated microwells. | 96 well/kit       |</p>
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| 05   | Anti-dsDNA IFA Kit*       | • Should have *Crithidia lucillae* coated biochips in reaction field.  
• Should have facility to upgrade the assay with multiple substrates.  
• Should have reagent tray system for assay incubation.  
• Test system should be free from need of humidity chamber. | 5x3=15 /kit       |
| 06   | Anti-dsDNA NCX ELISA*#    | • Nucleosome-complexed (NcX) dsDNA coupled to the solid phase.  
• Test system should have Highly purified antigen coated in micro-wells.  
• Test system should be equivalent or better than Farr assay dsDNA.  
• Test system should not have more than 3 standards/calibrators.  
• Should have total incubation time less than 80minutes.  
• Should be compatible with all Elisa readers.  
• Should have higher clinical (55-60 %) and analytical sensitivity.  
• Quantitative, in international units per milliliter (IU/ml).  
  o Calibration serum 1: 800 IU/ml  
  o Calibration serum 2: 100 IU/ml ; cut-off  
  o Calibration serum 3: 10 IU/ml  
• Diluent: Serum or plasma; 1: 201 in sample buffer. | 96 well/kit      |
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<td>• 30 min / 30 min / 15 min. Room temperature. Fully automatable.</td>
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</table>
| 07    | Anti HBc IgM ELISA* | • 96 well ELISA format  
• HRP labelled,  
• 5mcl serum or plasma sample  
• 2 levels control  
• Sensitivity: 2,5 PEI Units/ml  
• Incubation: 60 min+30 min+30min  
• Calibration: PEI Anti-HBc IgM Reference Material | 96 well/kit |
| 08    | Anti HBc Total ELISA* | • 96 well ELISA format  
• HRP labelled,  
• 50 mcl serum or plasma sample  
• 2 levels control  
• Sensitivity: 1,869 PEI Units/ml  
• Incubation: 60 min+30 min  
• Calibration: PEI Anti-HBc Total Reference Material | 96 well/kit |
| 09    | Anti MPO ELISA IgG (ANCA) *## | • Test system should have Highly purified antigen coated in micro-wells.  
• Test system should not have more than 3 standards/calibrators.  
• Should have total incubation time less than 80minutes.  
• Should be compatible with all Elisa readers.  
• Should have higher clinical and analytical sensitivity.  
• Should have higher clinical and analytical specificity | 96 well/kit |
| 10    | Anti PR3 HN-HR ELISA IgG (ANCA) *## | • Test system should have Highly purified native and recombinant antigen coated in micro-wells.  
• Test system should not have more than 3 standards/calibrators.  
• Should have total incubation time less than 80minutes.  
• Should be compatible with all Elisa readers. | 96 well/kit |
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| 11    | Anti-Streptolysin O – *# | - Should have higher clinical and analytical sensitivity.  
- Should have higher clinical and analytical specificity. | 100 tests/kit |
| 12    | C-Reactive Protein*# | - Latex agglutination based rapid test  
- Preferred make: Tulip, Randox, SPAN | 100 tests/kit |
| 13    | ELISA for HBV HBeAg /Anti HBeAg antibody detection* | - 96 well ELISA format  
- HRP labelled,  
- 100 (ag)/50 (ab) mcl serum or plasma sample  
- 3 levels control  
- Sensitivity: HBe Ag : 0.59 PEI Units/ml-Anti-HBe : 0.30 PEI U  
- Incubation : 60 min+30 min  
- Calibration: PEI HBeAg Standard | 96 well/kit |
| 14    | Anti HCV antibody ELISA – 3rd generation*# | - 3rd generation ELISA  
- Preferred make: Tulip, Biorad, Biomeriuxe, J Mitra | 96 well/kit |
| 15    | Anti HIV Antibody ELISA**# | - 3rd gen ELISA kits  
- Preferred make: Tulip, Biorad, Biomeriuxe, J Mitra | 96 well/kit |
| 16    | Anti HCV antibody – 4th Generation ELISA* | - 4th Generation ELISA  
(Antibody & Antigen both detectable) | 96 well/kit |
| 17    | ELISA kit CMV – IgG*# | - Solid phase ELISA  
- Preferred make: Tulip, Biorad, Biomeriuxe, J Mitra, Euroimmune | 96 well/kit |
| 18    | ELISA Kit CMV - IgM*# | - Solid phase ELISA  
- Preferred make: Tulip, Biorad, Biomeriuxe, J Mitra, Euroimmune | 96 well/kit |
| 19    | ELISA kit – Dengue IgG*# | - Solid phase ELISA  
- Preferred make: Calbiotech, Tulip, J Mitra, Biorad | 96 well/kit |
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| 20    | ELISA Kit – Dengue IgM*# | ● Solid phase ELISA  
● Preferred make: Calbiotech, Tulip, J Mitra, Biorad | 96 well/kit |
| 21    | ELISA Kit – HEV IgM *# | ● Solid phase ELISA  
● Preferred make: Diapro, Tulip, Biorad, Biomeriuxe, J Mitra | 96 well/kit |
| 22    | ELISA Kit – HSV 1 & 2 IgM*# | ● Solid phase ELISA  
● Preferred make: Tulip, Biorad, Biomeriuxe, J Mitra, Euroimmune | 96 well/kit |
| 23    | ELISA Kit – Parvo B19 IgM*# | ● Solid phase ELISA  
● Preferred make: Calbiotech, Tulip, J Mitra, Biorad | 96 well/kit |
| 24    | ELISA Kit- Toxoplasma IgM*# | ● Solid phase ELISA  
● Preferred make: Tulip, Biorad, Biomeriuxe, J Mitra, Euroimmune | 96 well/kit |
| 25    | ELISA kit – anti-HBS antibody*# | ● Solid phase ELISA  
● Preferred make: Diapro Tulip, Biorad, Biomeriuxe, J Mitra, Euroimmune | 96 well/kit |
| 26    | ELISA Kit- Chikungunya IgM*# | ● Solid phase ELISA  
● Preferred make: Calbiotech, Tulip, J Mitra, Biorad | 96 well/kit |
| 27    | ELISA Dengue NS1 antigen detection*# | ● Solid phase ELISA  
● Preferred make: Calbiotech, Tulip, J Mitra, Biorad | 96 well/kit |
| 28    | ELISA kit – HAV IgM*# | ● Solid phase ELISA  
● Preferred make: Diapro, Tulip, Biorad, Biomeriuxe, J Mitra, Euroimmune | 96 well/kit |
| 29    | ELISA Kit –HSV 1 & 2 IgG*# | ● Solid phase ELISA  
● Preferred make: Tulip, Biorad, Biomeriuxe, J Mitra, Euroimmune | 96 well/kit |
| 30    | ELISA kit – Rubella IgG*# | ● Solid phase ELISA  
● Preferred make: Tulip, Biorad, Biomeriuxe, J Mitra, Euroimmune | 96 well/kit |
| 31    | ELISA kit- Scrub typhus IgM*# | ● Solid phase ELISA  
● Preferred make: Inbios, Tulip, Biorad, Biomeriuxe, J Mitra, Euroimmune | 96 well/kit |
| 32    | ELISA kit- Toxoplasma IgG*# | ● Solid phase ELISA  
● Preferred make: Tulip, Biorad, Biomeriuxe, J Mitra, Euroimmune | 96 well/kit |
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| 33    | ELISA for HBsAg*#                             | - Solid phase ELISA  
  - Preferred make: Tulip, J Mitra, Inbios                                                                                                         | 96 well/kit       |
| 34    | ELISA kit – Rubella IgM*#                     | - Solid phase ELISA  
  - Preferred make: Euroimmune, Tulip, Biorad, Biomeriuxe, J Mitra, Euroimmune                                                                 | 96 well/kit       |
| 35    | ELISA for Taenia solium/Cysticercosis antibody*# | - Solid phase ELISA  
  - Preferred make: Calbiotech, Tulip, J Mitra, Biorad                                                                                                                   | 96 well/kit       |
| 36    | HCV –core antigen ELISA*#                     | - Solid phase ELISA  
  - Preferred make: Calbiotech, Tulip, Biorad, Biomeriuxe, J Mitra, Euroimmune                                                                 | 96 well/kit       |
| 37    | Immunoblot strip for ANA profile*             | - Test system should have separate membrane strip for incubation of each serum sample.  
  - Test membrane should have dsDNA, Nucleosome, Histone, Sm/Rnp, PCNA, SS-A/Ro 60, SS-A/Ro 52, SS-B/La, CENP-B, Scl70, nRNP, AMA M2, Jo-1, PMScl, Mi-2 and DFS70 coated on it.  
  - Total time for performing the analysis is about 105 minutes.  
  - The incubation should be performed on automated platform also.  
  - All incubation steps can be processed at room temperature.  
  - Each membrane should have inbuilt control band to check correct completion of incubation.  
  - Positive and negative results should be easily and reliable differentiated from each other. The intensity of the antigen bands should correlate with the antibody titre.  
  - The membrane strips do not contain any superfluous proteins.                                                                 | 16 strips/kit     |
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<td>38</td>
<td>JE IgG ELISA*#</td>
<td>- Solid phase ELISA&lt;br&gt;Preferred make: Calbiotech, Tulip, J Mitra, Biorad</td>
<td>96 well/kit</td>
</tr>
<tr>
<td>39</td>
<td>JE IgM Capture ELISA*#</td>
<td>- Solid phase ELISA&lt;br&gt;Preferred make: Calbiotech, Tulip, J Mitra, Biorad</td>
<td>96 well/kit</td>
</tr>
<tr>
<td>40</td>
<td>JE virus NS1 antigen ELISA*#</td>
<td>- Solid phase ELISA&lt;br&gt;Preferred make: Calbiotech, Tulip, J Mitra, Biorad</td>
<td>96 well/kit</td>
</tr>
<tr>
<td>41</td>
<td>Latex Agglutination Kit For Detection Of Haemophilus Influenzae Type B, Streptococcus Pneumoniae, Escherichia Coli K1, Group B Streptococcus And Neisseria Meningitidis (A, C, Y, W135) *#</td>
<td>- Latex agglutination based rapid test&lt;br&gt;Preferred make: Thermo-fisher, Biorad, Biomeriuxe etc</td>
<td>25 tests/kit</td>
</tr>
<tr>
<td>42</td>
<td>Latex agglutination test for streptococci*#</td>
<td>- Latex agglutination tests for rapid identification of group A streptococci directly from throat swabs.</td>
<td>30 test/kit</td>
</tr>
<tr>
<td>43</td>
<td>RA-factor test (rapid) *#</td>
<td>- Latex agglutination based rapid test&lt;br&gt;Preferred make: Tulip, Randox, SPAN</td>
<td>100 tests/kit</td>
</tr>
<tr>
<td>44</td>
<td>Rapid card test for Dengue IgG, IgM &amp; NS1*#</td>
<td>- Rapid ICT based test&lt;br&gt;Preferred make: Zyphre/Tulip, SD Bioline, J Mitra</td>
<td>10 tests/kit</td>
</tr>
<tr>
<td>45</td>
<td>Rapid test for HBsAg *#</td>
<td>- Antigen detection Sensitivity must be upto 0.5ng/ml</td>
<td>100 test/kit</td>
</tr>
<tr>
<td>46</td>
<td>Rapid test for Anti-HCV antibodies*#</td>
<td>- Rapid ICT based test&lt;br&gt;Preferred make: Tulip, J Mitra, Biorad</td>
<td>100 tests/kit</td>
</tr>
<tr>
<td>47</td>
<td>Rapid plasma regain test*#</td>
<td>- Floculation based rapid card test</td>
<td>100 tests/kit</td>
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<tr>
<td>48</td>
<td>Rapid test for enteric fever- antibody detection *</td>
<td>• Preferred make: Tulip, SPAN, J Mitra</td>
<td>50 tests/kit</td>
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<td>• Rapid immune-chromatographic methods</td>
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<td>• Should be unique double barrel device</td>
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<td>• It should be able to detect and differentiate IgM and IgG class of antibodies</td>
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<td>• Specificity &amp; Sensitivity should be close to 100%.</td>
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<tr>
<td>49</td>
<td>Rapid test for enteric fever antigen detection *</td>
<td>• ICT based rapid test for detection of Salmonella typhi &amp; paratyphi LPS antigen</td>
<td>10 tests/kit</td>
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<td>• Sample: Serum or stool</td>
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<td>• Time of detection: 20 mins</td>
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<tr>
<td>50</td>
<td>Rapid test for antibody to HIV1 and HIV 2 (ICT/Lateral flow based) *#</td>
<td>• ICT based test (Lateral flow)</td>
<td>100 tests/kit</td>
</tr>
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<td></td>
<td></td>
<td>• Preferred make: Qualpro/Tulip, J Mitra, Biorad</td>
<td></td>
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<tr>
<td>51</td>
<td>Rapid test for antibody to HIV1 and HIV 2 (Vertical flow/Tridot/Triline) *#</td>
<td>• ICT based test (Vertical flow)</td>
<td>100 tests/kit</td>
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<td>• Preferred make: J Mitra, Qualpro, Tulip</td>
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<tr>
<td>52</td>
<td>Capillus HIV rapid test *</td>
<td>• Rapid test for anti-HIV antibody based on Latex aggregation principle.</td>
<td>100 tests/kit</td>
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<td>• Must give results within 7 minutes</td>
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<tr>
<td>53</td>
<td>Rapid test for malaria Pf &amp; Pv antigen detection*</td>
<td>• 4 band Rapid ICT test for malaria pan/pv/pf</td>
<td>25 tests/kit</td>
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<td>• Detection and differentiation of P. falciparum, P. vivax, P. ovale &amp; P. malariae infection.</td>
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<td>• True speciation of the “big two” i.e. P. falciparum &amp; P. vivax through specific Pf HRP 2 &amp; Pv pLDH bands.</td>
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<td>• Indirect speciation between P.v, P.o &amp; P.m infection through Pv pLDH and Pan specific pLDH band</td>
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<td>• Detection of mixed infection of P. falciparum &amp; P. vivax</td>
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<tr>
<td>54</td>
<td>Rapid test for Scrub typhus antibody detection *#</td>
<td>• Rapid card test</td>
<td>30 tests/kit</td>
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<td></td>
<td></td>
<td>• Preferred make: SD Bioline, J Mitra, Tulip</td>
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<tr>
<td>55</td>
<td>ELISA for Total IgE*#</td>
<td>• Test system should have Highly purified Polyclonal anti-Human IgE coated in micro-wells.</td>
<td>96 well/kit</td>
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<td>• Test system should have linearity</td>
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| 56    | Enzyme Immune based test for Enteric fever *# |  - Dot –ELISA based test for of antibody to OMP antigen of *Salmonella typhi*
  - Must be able to detect both IgM and IgG antibodies (simultaneously) to the extracted proteins of *Salmonella typhi* only.
  - Assay time: 1 hour
  - Sample volume: 3 µl each | 100 tests /kit |
| 57    | VDRL antigen *  |  - VDRL Antigen for CSF sample
  - Natural or synthetically derived | 10 /pack |
| 58    | Widal tube & slide agglutination kit*# |  - Both tube test and slide test must be possible to perform
  - Preferred make: J Mitra, Tulip, Span | 50mlx4 /pack |
| 59    | TORCH Immunoblot Profile IgG * |  - Test system should have separate membrane strip for incubation of each serum sample.
  - Test membrane should have Toxoplasma gondii, CMV, Rubella, HSV-1, HSV-2 separately coated on it.
  - Total time for performing the analysis is about 105 minutes.
  - The incubation can performed on automated platform also.
  - All incubation steps can be processed at room temperature.
  - Each membrane should have inbuilt control band to check correct completion of incubation.
  - Positive and negative results should be easily and reliable differentiated from each other. The intensity of the antigen bands shold correlates with the antibody titer. | 16 tests /kit |
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<td>● The membrane strips do not contain any superfluous proteins.</td>
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| 60    | TORCH Immunoblot Profile IgM* | ● Test system should have separate membrane strip for incubation of each serum sample.  
● Test membrane should have *Toxoplasma gondii*, CMV, ROP-1, Rubella, HSV-1, HSV-2 separately coated on it.  
● Test kit must have IgG/ RF absorbent.  
● Total time for performing the analysis is about 105 minutes.  
● The incubation can be performed on automated platform also.  
● All incubation steps can be processed at room temperature.  
● Each membrane should have inbuilt control band to check correct completion of incubation.  
● Positive and negative results should be easily and reliable differentiated from each other. The intensity of the antigen bands should correlates with the antibody titer.  
● The membrane strips do not contain any superfluous proteins.  
● The incubated membrane test strips must be stored for long periods.  
● Result evaluation software should be provided free of cost. | 16 tests/kit |
<p>| 61    | TRUST *#         | ● Toluidine Red Unheated Serum test kit for syphilis – microfloculation based | 50 tests/kit |</p>
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|       |                   |   • High sensitivity & Specificifity  
       |                   |   • Preferred make: Tulip, J Mitra, Biorad | |
| 62    | Immunoblot based allergy profile (Food)*# |   • At least 20 food based allergens (India specific) must be covered.  
       |                   |   • CCD marker indicator band must be present. | 16 test/kit |
| 63    | Immunoblot based allergy profile (Inhalation)*# |   • At least 20 inhalation based allergens (India specific) must be covered.  
       |                   |   • CCD marker indicator band must be present. | 16 test/kit |
| 64    | Immunoblot based allergy profile (pediatric)**# |   • At least 20 pediatric allergens (India specific) must be covered.  
       |                   |   • CCD marker indicator band must be present. | 16 test/kit |

*“Kit demo” against neat and diluted reactive/positive serum samples (as deemed fit by end user), in front of an expert committee, is mandatory and essential part of technical evaluation. Decision of technical expert committee will be final – no show at demo invitation implies automatic disqualification

# “Preferred kits” are selected on the basis of end-users experience. However, kits of other make can be considered, and can be called for kit demo/validation in consultation with end-users. Decision of technical expert committee will be final.