

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: -

Sr no	Name of the items	Specifications	Unit Qty./Pack size
01	ANA- IFA Kit *	<ul style="list-style-type: none"> • 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*	<ul style="list-style-type: none"> • 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*#	<ul style="list-style-type: none"> • Solid phase ELISA • Preferred make: Calbiotech, Diapro, DRG 	96 well/kit
04	Anti-CCP ELISA kit*#	<ul style="list-style-type: none"> • Test system should Highly purified Cyclic Citrullinated peptide coated microwells. 	96 well/kit

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		<ul style="list-style-type: none"> • Test system should be of 2nd generation. • Test system should have clinical sensitivity more than 78% and specificity more than 98%. • Should be compatible with all Elisa readers. 	
05	Anti-dsDNA IFA Kit*	<ul style="list-style-type: none"> • Should have <i>Crithidia lucillae</i> 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*#	<ul style="list-style-type: none"> • 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). <ul style="list-style-type: none"> ○ Calibration serum 1: 800 IU/ml ○ Calibration serum 2: 100 IU/ml ; cut-off ○ Calibration serum 3: 10 IU/ml • Diluent: Serum or plasma; 1: 201 in sample buffer. 	96 well/kit

Sr no	Name of the items	Specifications	Unit Qty./Pack size
		<ul style="list-style-type: none"> • 30 min / 30 min / 15 min. Room temperature. Fully automatable. 	
07	Anti HBc IgM ELISA*	<ul style="list-style-type: none"> • 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*	<ul style="list-style-type: none"> • 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) *#	<ul style="list-style-type: none"> • 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) *#	<ul style="list-style-type: none"> • 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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		<ul style="list-style-type: none"> Should have higher clinical and analytical sensitivity. Should have higher clinical and analytical specificity. 	
11	Anti-Streptolysin O – *#	<ul style="list-style-type: none"> Latex agglutination based rapid test Preferred make: Tulip, Randox, SPAN 	100 tests/kit
12	C-Reactive Protein*#	<ul style="list-style-type: none"> Latex agglutination based rapid test Preferred make: Tulip, Randox, SPAN 	100 test/kit
13	ELISA for HBV HBeAg /Anti HBeAg antibody detection*	<ul style="list-style-type: none"> 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 – 3 rd generation*#	<ul style="list-style-type: none"> 3rd generation ELISA Preferred make: Tulip, Biorad, Biomeriuxe, J Mitra 	96 well/kit
15	Anti HIV Antibody ELISA*#	<ul style="list-style-type: none"> 3rd gen ELISA kits Preferred make: Tulip, Biorad, Biomeriuxe, J Mitra 	96 well/kit
16	Anti HCV antibody – 4 th Generation ELISA*	<ul style="list-style-type: none"> 4th Generation ELISA (Antibody & Antigen both detectable) 	96 well/kit
17	ELISA kit CMV –IgG*#	<ul style="list-style-type: none"> Solid phase ELISA Preferred make: Tulip, Biorad, Biomeriuxe, J Mitra, Euroimmune 	96 well/kit
18	ELISA Kit CMV - IgM*#	<ul style="list-style-type: none"> Solid phase ELISA Preferred make: Tulip, Biorad, Biomeriuxe, J Mitra, Euroimmune 	96 well/kit
19	ELISA kit – Dengue IgG*#	<ul style="list-style-type: none"> Solid phase ELISA Preferred make: Calbiotech, Tulip, J Mitra, Biorad 	96 well/kit

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20	ELISA Kit – Dengue IgM*#	<ul style="list-style-type: none"> • Solid phase ELISA • Preferred make: Calbiotech, Tulip, J Mitra, Biorad 	96 well/kit
21	ELISA Kit – HEV IgM *#	<ul style="list-style-type: none"> • Solid phase ELISA • Preferred make: Diapro, Tulip, Biorad, Biomeriuxe, J Mitra 	96 well/kit
22	ELISA Kit –HSV 1 & 2 IgM*#	<ul style="list-style-type: none"> • Solid phase ELISA • Preferred make: Tulip, Biorad, Biomeriuxe, J Mitra, Euroimmune 	96 well/kit
23	ELISA Kit – Parvo B19 IgM*#	<ul style="list-style-type: none"> • Solid phase ELISA • Preferred make: Calbiotech, Tulip, J Mitra, Biorad 	96 well/kit
24	ELISA kit- Toxoplasma IgM*#	<ul style="list-style-type: none"> • Solid phase ELISA • Preferred make: Tulip, Biorad, Biomeriuxe, J Mitra, Euroimmune 	96 well/kit
25	ELISA kit – anti-HBS antibody*#	<ul style="list-style-type: none"> • Solid phase ELISA • Preferred make: Diapro Tulip, Biorad, Biomeriuxe, J Mitra, Euroimmune 	96 well/kit
26	ELISA Kit- Chikungunya IgM*#	<ul style="list-style-type: none"> • Solid phase ELISA • Preferred make: Calbiotech, Tulip, J Mitra, Biorad 	96 well/kit
27	ELISA Dengue NS1 antigen detection*#	<ul style="list-style-type: none"> • Solid phase ELISA • Preferred make: Calbiotech, Tulip, J Mitra, Biorad 	96 well/kit
28	ELISA kit – HAV IgM*#	<ul style="list-style-type: none"> • Solid phase ELISA • Preferred make: Diapro, Tulip, Biorad, Biomeriuxe, J Mitra, Euroimmune 	96 well/kit
29	ELISA Kit –HSV 1 & 2 IgG*#	<ul style="list-style-type: none"> • Solid phase ELISA • Preferred make: Tulip, Biorad, Biomeriuxe, J Mitra, Euroimmune 	96 well/kit
30	ELISA kit – Rubella IgG*#	<ul style="list-style-type: none"> • Solid phase ELISA • Preferred make: Tulip, Biorad, Biomeriuxe, J Mitra, Euroimmune 	96 well/kit
31	ELISA kit- Scrub typhus IgM*#	<ul style="list-style-type: none"> • Solid phase ELISA • Preferred make: Inbios, Tulip, Biorad, Biomeriuxe, J Mitra, Euroimmune 	96 well/kit
32	ELISA kit- Toxoplasma IgG*#	<ul style="list-style-type: none"> • Solid phase ELISA • Preferred make: Tulip, Biorad, Biomeriuxe, J Mitra, Euroimmune 	96 well/kit

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33	ELISA for HBsAg*#	<ul style="list-style-type: none"> • Solid phase ELISA • Preferred make: Tulip, J Mitra, Inbios 	96 well/kit
34	ELISA kit – Rubella IgM*#	<ul style="list-style-type: none"> • Solid phase ELISA • Preferred make: Euroimmune, Tulip, Biorad, Biomeriuxe, J Mitra, Euroimmune 	96 well/kit
35	ELISA for Taenia solium/Cysticercosis antibody*#	<ul style="list-style-type: none"> • Solid phase ELISA • Preferred make: Calbiotech, Tulip, J Mitra, Biorad 	96 well/kit
36	HCV –core antigen ELISA*#	<ul style="list-style-type: none"> • Solid phase ELISA • Preferred make: Calbiotech, Tulip, Biorad, Biomeriuxe, J Mitra, Euroimmune 	96 well/kit
37	Immunoblot strip for ANA profile*	<ul style="list-style-type: none"> • 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

Sr no	Name of the items	Specifications	Unit Qty./Pack size
		<ul style="list-style-type: none"> The incubated membrane test strips must be stored for long periods. Result evaluation software should be provided free of cost. Test system should have been validated/ calibrated against CDC/ WHO reference sera. FDA approved test system will be preferred. 	
38	JE IgG ELISA*#	<ul style="list-style-type: none"> Solid phase ELISA Preferred make: Calbiotech, Tulip, J Mitra, Biorad 	96 well/kit
39	JE IgM Capture ELISA*#	<ul style="list-style-type: none"> Solid phase ELISA Preferred make: Calbiotech, Tulip, J Mitra, Biorad 	96 well/kit
40	JE virus NS1 antigen ELISA*#	<ul style="list-style-type: none"> Solid phase ELISA Preferred make: Calbiotech, Tulip, J Mitra, Biorad 	96 well/kit
41	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) *#	<ul style="list-style-type: none"> Latex agglutination based rapid test Preferred make: Thermo-fisher, Biorad, Biomeriux etc 	25 tests/kit
42	Latex agglutination test for streptococci*#	<ul style="list-style-type: none"> Latex agglutination tests for rapid identification of group A streptococci directly from throat swabs. 	30 test/kit
43	RA-factor test (rapid) *#	<ul style="list-style-type: none"> Latex agglutination based rapid test Preferred make: Tulip, Randox, SPAN 	100 tests/kit
44	Rapid card test for Dengue IgG, IgM & NS1*#	<ul style="list-style-type: none"> Rapid ICT based test Preferred make: Zyphre/Tulip, SD Bioline, J Mitra 	10 tests/kit
45	Rapid test for HBsAg *#	<ul style="list-style-type: none"> Antigen detection Sensitivity must be upto 0.5ng/ml 	100 test/kit
46	Rapid test for Anti-HCV antibodies*#	<ul style="list-style-type: none"> Rapid ICT based test Preferred make: Tulip, J Mitra, Biorad 	100 tests/kit
47	Rapid plasma regain test*#	<ul style="list-style-type: none"> Flocculation based rapid card test 	100 tests/kit

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		<ul style="list-style-type: none"> Preferred make: Tulip, SPAN, J Mitra 	
48	Rapid test for enteric fever- antibody detection *	<ul style="list-style-type: none"> Rapid immune-chromatographic methods Should be unique double barrel device It should be able to detect and differentiate IgM and IgG class of antibodies Specificity & Sensitivity should be close to 100%. 	50 tests/kit
49	Rapid test for enteric fever antigen detection *	<ul style="list-style-type: none"> ICT based rapid test for detection of Salmonella typhi & paratyphi LPS antigen Sample: Serum or stool Time of detection: 20 mins 	10 tests/kit
50	Rapid test for antibody to HIV1 and HIV 2 (ICT/Lateral flow based) *#	<ul style="list-style-type: none"> ICT based test (Lateral flow) Preferred make: Qualpro/Tulip, J Mitra, Biorad 	100 tests/kit
51	Rapid test for antibody to HIV1 and HIV 2 (Vertical flow/Tridot/Triline) *#	<ul style="list-style-type: none"> ICT based test (Vertical flow) Preferred make: J Mitra, Qualpro, Tulip 	100 tests/kit
52	Capillus HIV rapid test *	<ul style="list-style-type: none"> Rapid test for anti-HIV antibody based on Latex aggregation principle. Must give results within 7 minutes 	100 tests/kit
53	Rapid test for malaria Pf & Pv antigen detection*	<ul style="list-style-type: none"> 4 band Rapid ICT test for malaria pan/pv/pf Detection and differentiation of <i>P. falciparum</i>, <i>P. vivax</i>, <i>P. ovale</i> & <i>P. malariae</i> infection. True speciation of the "big two" i.e. <i>P. falciparum</i> & <i>P. vivax</i> through specific Pf HRP 2 & Pv _ pLDH bands. Indirect speciation between <i>P.v</i>, <i>P.o</i> & <i>P.m</i> infection through Pv pLDH and Pan specific pLDH band Detection of mixed infection of <i>P. falciparum</i> & <i>P. vivax</i> 	25 tests/kit
54	Rapid test for Scrub typhus antibody detection *#	<ul style="list-style-type: none"> Rapid card test Preferred make: SD Bioline, J Mitra, Tulip 	30 tests/kit
55	ELISA for Total IgE*#	<ul style="list-style-type: none"> Test system should have Highly purified Polyclonal anti-Human IgE coated in micro-wells. Test system should have linearity 	96 well/kit

Sr no	Name of the items	Specifications	Unit Qty./Pack size
		<p>at least 440 IU/L.</p> <ul style="list-style-type: none"> • Calibrations reference should be on WHO. • Should have minimal incubation time. • Should have minimum number of calibrators. • Should be compatible with all elisa readers. 	
56	Enzyme Immune based test for Enteric fever *#	<ul style="list-style-type: none"> • Dot –ELISA based test for of antibody to OMP antigen of <i>Salmonella typhi</i> • Must be able to detect both IgM and IgG antibodies (simultaneously) to the extracted proteins of <i>Salmonella typhi</i> only. • Assay time: 1 hour • Sample volume: 3 µl each 	100 tests /kit
57	VDRL antigen *	<ul style="list-style-type: none"> • VDRL Antigen for CSF sample • Natural or synthetically derived 	10 /pack
58	Widal tube & slide agglutination kit*#	<ul style="list-style-type: none"> • Both tube test and slide test must be possible to perform • Preferred make: J Mitra, Tulip, Span 	50mlx4 /pack
59	TORCH Immunoblot Profile IgG *	<ul style="list-style-type: none"> • 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

Sr no	Name of the items	Specifications	Unit Qty./Pack size
		<ul style="list-style-type: none"> • 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. 	
60	TORCH Immunoblot Profile IgM*	<ul style="list-style-type: none"> • Test system should have separate membrane strip for incubation of each serum sample. • Test membrane should have <i>Toxoplasma gondii</i>, 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 correlate 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
61	TRUST *#	<ul style="list-style-type: none"> • Toluidine Red Unheated Serum test kit for syphilis – microflocculation based 	50 tests/kit

Sr no	Name of the items	Specifications	Unit Qty./Pack size
		<ul style="list-style-type: none"> • High sensitivity & Specificity • Preferred make: Tulip, J Mitra, Biorad 	
62	Immunoblot based allergy profile (Food)*#	<ul style="list-style-type: none"> • 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)*#	<ul style="list-style-type: none"> • 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)*#	<ul style="list-style-type: none"> • At least 20 pediatric allergens (India specific) must be covered. • CCD marker indicator band must be present. 	16 test/kit
<p>* “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. <u>Decision of technical expert committee will be final</u> – no show at demo invitation implies automatic disqualification</p> <p># “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. <u>Decision of technical expert committee will be final.</u></p>			