



Testing Service Agreement - Tuberculosis 、 Virology 、 Parasitology and Lead in Blood

Public Health Laboratory
Health Bureau, Macao SAR Government
V.2019.01



Routine Testing Service Agreement

1. Tuberculosis Laboratory

No.	Test Item	Test Method		Specimen Type For details, See "Clinical Specimen Collection and Submission Guidelines"	Result/Report					
		Method (Reference Standard)	Remark		Result	Warning / Critical Values*	TAT	Frequency of Test	Specimen Retained	Biological Reference Interval
1	Acid-Fast Bacilli (AFB) Microscopy	Fluorescent Stain Or Ziehl-Neelsen Stain (WHO_Mycobacteriology-laboratory- manual, 2014)	IVD	Decontamination: Respiratory specimens (Sputum · Induced Sputum · Bronchial Lavage · Bronchoalveolar Lavage · Tracheal aspiration) · Gastric-aspiration/ Gastric-lavage · Urine · Swab · Lymph Node · Pus · Biopsy · Skin lesion · Others Direct: Pleural · Ascetic · Pericardial · Synovial · Joint · Bile · Amniotic · CSF ^{※#}	- Negative - Positive (Scanty AFB/1+/2+/3+)	CSF: Positive ^(#) (Per 7 days) Others: Positive ⁽¹⁾	1 working day	Daily	Original specimen: 2 days.	Negative
2	Mycobacterial Culture	1) Conventional, LJ (Solid Culture) 2) Automated Culture System, BACTEC™ MGIT™ 960 (Liquid Culture) (WHO_Mycobacteriology-laboratory- manual, 2014; Package insert : BACTEC™ MGIT™ 960 L000180JAA(02), 2015)	IVD	Same as above · Fezes	- Negative (8 weeks) - Positive - Positive and Contaminated - Contaminated	CSF: Positive ^(#) (Per 7 days)	3-8 weeks	Daily	Original specimen: 2 days.	Negative
		Automated Blood Culture System, BACTEC 9050 (Liquid Culture) (Package insert: BACTEC™ Myco F Lytic Culture Vials PP162JAA(04), 2015)	IVD	Blood ^{※#} · Bone Marrow ^{※#}	- Negative (6 weeks) - Positive - Positive and Contaminated - Contaminated	Positive ^(#) (Per 7 days)	3-6 weeks	Daily	--	Negative
3	MTBC Nucleic Acid Amplification Test [@]	RT-PCR, Xpert MTB/RIF Assay (Package insert: Xpert® MTB/RIF Assay 301-0191 Rev D 2014)	IVD (New Case Only)	Initial Smear Positive Sample* (Except Fezes · Urine · Blood · Bone Marrow)	- Detected - Not Detected - Invalid - Indeterminate	Detected ⁽¹⁾	2 working days	Daily	Original specimen: 2 days, Positive aliquot: 2 months.	Not Detected

※ : Deliver immediately at ambient temperature.

: Positive result for AFB Microscopy and Culture from blood · bone marrow and CSF specimens shall be reported to clinical immediately. AFB Microscopy results are reported within 24 hours.

@ : Proceed according to preset workflow.



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		Method (Reference Standard)	Remark		Result	Warning / Critical Values*	TAT	Frequency of Test	Specimen Retained	Biological Reference Interval
4	Identification of Mycobacteria [ⓐ]	Immunochromatographic assay, MGIT TBc (Package insert: BD MGIT™ TBc Identification Test, 8085917(02), 2015)	IVD	Mycobacterial culture positive isolates from liquid media (pure culture)	- <i>Mycobacterium Tuberculosis</i> Complex (MTBC) - Negative	MTBC (New Case) ⁽¹⁾	1-3 working days	3x/wk	--	N/A
		Immunochromatographic assay, Capilia TB-Neo (Package insert: Capilia™ TB-Neo, Ver 5.0 of December 2016)	IVD	Mycobacterial culture positive isolates from media (pure culture)	- <i>Mycobacterium Tuberculosis</i> Complex (MTBC) - Negative	MTBC (New Case) ⁽¹⁾	1-3 working days	3x/wk	--	N/A
		Line Probe Assays, GenoType Mycobacterium CM/AS (Package insert: GenoType Mycobacterium AS v1.0_298-16, 2016 ; GenoType Mycobacterium CM v1.0_299-24, 2016)	IVD	Mycobacterial culture positive isolates (pure culture)	- Identification of <i>Mycobacterium</i> species: Mycobacterium CM : <ul style="list-style-type: none"> • <i>M.avium</i> ssp. • <i>M.abscessus</i> • <i>M.chelonae</i> • <i>M.chelonae</i> group • <i>M.fortuitum</i> group • <i>M.intracellulare</i> • <i>M.interjectum</i> • <i>M.marinum</i>/<i>M.ulcerans</i> • <i>M.haemophilum</i> group • <i>M.gordonae</i> • <i>M.kansasii</i> • <i>M.malmoense</i> • <i>M.peregrinum</i> • <i>M.scrofulaceum</i> • <i>Mtb</i> complex • <i>M.xenopi</i> Mycobacterium AS : <ul style="list-style-type: none"> • <i>M. asiaticum</i> • <i>M. celatum</i> • <i>M. gastri</i> • <i>M. goodii</i> • <i>M. heckeshornense</i> • <i>M. haemophilum</i> • <i>M. intermedium</i> • <i>M. kansasii</i> • <i>M. genavense</i>/<i>M. triplex</i> • <i>M. lentiflavum</i> • <i>M. mucogenicum</i> • <i>M. phlei</i> • <i>M. shimoidei</i> • <i>M. simiae</i> • <i>M. smegmatis</i> • <i>M. szulgai</i> • <i>M. ulcerans</i> - Mycobacterium genus	Mtb complex (New Case) ⁽¹⁾	2 weeks	Weekly	--	N/A

ⓐ : Proceed according to preset workflow.



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		Method (Reference Standard)	Remark		Result	Warning / Critical Values*	TAT	Frequency of Test	Specimen Retained	Biological Reference Interval
4	Identification of Mycobacteria @ (cont.d)	Biochemical Tests (Traditional method)	Standard Method (In Development)	Mycobacterial culture positive isolates (pure culture)	<ul style="list-style-type: none"> - NTM, Runyon I (Photochromogen) - NTM, Runyon II (Scotochromogen) - NTM, Runyon III (Nonchromogen) - NTM, Runyon IV (Rapid grower) - Ungrouped mycobacteria 	--	4 weeks	Weekly	--	N/A
		MALDI-TOF Mass Spectrometry, Vitek MS (Package insert: VITEK® MS Mycobacterium/ Nocardia Kit 20894C, 2016/10; VITEK MS V3.0 Knowledge Base, 161150-556-A- en – 2016/06)	IVD (In Development)	Mycobacterial culture positive isolates from solid media (pure culture)	<ul style="list-style-type: none"> - Identification of <i>Mycobacterium</i> species 	<i>Mtb</i> complex (New Case) ⁽¹⁾	1-2 weeks	1-2x/wk	--	N/A
5	Drug Susceptibility Test, DST @ (1 st line, MTBC)	MGIT Proportion Method (WHO_Mycobacteriology-laboratory- manual,2014; Package insert: BACTEC™ MGIT™ 960 SIRE Kits 8008200(02), 2015; BACTEC™ MGIT™ 960 PZA Kit L005486JAA(01), 2014)	IVD	Initial or relapsed, MTBC pure culture	<ul style="list-style-type: none"> - Sensitive - Resistant (DST is a qualitative test <i>in vitro</i> , results are for reference only)	--	3 weeks after ID	2x/wk		N/A
6	Drug Susceptibility Test @ (2 nd line, MTBC)	Agar Proportion Method (CLSI. Susceptibility testing of mycobacteria, nocardia, and other aerobic actinomycetes. Approved standard M24-A Vol.23 No.18)	Standard Method MDR-TB only (In Development)	Initial or relapsed MDR-TB, MTBC pure culture	<ul style="list-style-type: none"> - Sensitive - Resistant (DST is a qualitative test <i>in vitro</i> , results are for reference only)	--	4 weeks after 1 st line DST	Weekly	Long Term storage of strain.	N/A
7	Drug Susceptibility Test @ (NTM-RGM)	Etest (Package insert: Etest Application Sheet EAS002, Rapid Growing Mycobacteria, AB BIODISK 2007- 06)	IVD (In Development)	Initial or relapsed NTM, Rapid growing mycobacteria (RGM) pure culture	<ul style="list-style-type: none"> - Sensitive - Intermediate - Resistant (DST is a qualitative test <i>in vitro</i> , results are for reference only)	--	2 weeks after ID	Weekly		N/A

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		Method (Reference Standard)	Remark		Result	Warning / Critical Values*	TAT	Frequency of Test	Specimen Retained	Biological Reference Interval
8	Screening of Latent TB Infection (Interferon Gamma Release Assay)	Enzyme-linked Immunosorbent Assay(ELISA), QFT-Plus (Package insert: QuantiFERON®-TB Gold Plus (QFT®-Plus) ELISA, 1083163 Rev.03, 2016)	IVD	Whole Blood [※]	- Negative - Positive - Indeterminate	--	1 week	2x/wk	Plasma : 28 days.	Negative

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2. Virology Laboratory

A) Virology Tests (Serological)

No.	Test Item	Test Method		Specimen Type For details, See “Clinical Specimen Collection and Submission Guidelines”	Result/Report					
		Method (Reference Standard)	Remark		Result	Warning / Critical Values*	TAT	Frequency of Test	Specimen Retained	Biological Reference Interval
1	Anti-HAV-IgG	Chemiluminescent Microparticle Immunoassay (Package insert : Abbott Architect HAVAb-IgG, 6C29)	IVD	Blood (Serum/Plasma)	Negative/Positive	--	5 working days	Daily	Original specimen: 7 days, Centrifuged plasma or serum: 3 months.	Negative
2	Anti-HAV-IgM	Chemiluminescent Microparticle Immunoassay (Package insert : Abbott Architect HAVAb-IgM, 6C30)	IVD		Negative/Positive/Inconclusive	--				Negative
3	HBsAg	Chemiluminescent Microparticle Immunoassay (Package insert : Abbott Architect HBsAg Qualitative II, 2G22)	IVD	Blood (Serum/Plasma)	Negative/Positive	--	5 working days	Daily		Negative
4	HBsAg (Confirmatory) [@]	Chemiluminescent Microparticle Immuno Assay (Package insert : Abbott Architect HBsAg Qualitative II Confirmatory, 2G23)	IVD		Positive/Inconclusive	--				Negative
5	Anti-HBs	Chemiluminescent Microparticle Immunoassay (Package insert : Abbott Architect Anti-HBs, 7C18)	IVD		Negative/Positive(mIU/mL)	--				Vaccinated: Positive Unvaccinated: Negative
6	HBeAg	Chemiluminescent Microparticle Immunoassay (Package insert : Abbott Architect HBeAg, 6C32)	IVD		Negative/Positive	--				Negative

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		Method (Reference Standard)	Remark		Result	Warning / Critical Values*	TAT	Frequency of Test	Specimen Retained	Biological Reference Interval
7	Anti-HBe	Chemiluminescent Microparticle Immunoassay (Package insert : Abbott Architect Anti-HBe, 6C34)	IVD	Blood (Serum/Plasma)	Negative/Positive	--	5 working days	Daily	Original specimen: 7 days, Centrifuged plasma or serum: 3 months.	Negative
8	Anti-HBc	Chemiluminescent Microparticle Immunoassay (Package insert : Abbott Architect Anti-HBc II, 8L44)	IVD		Negative/Positive	--				Negative
9	Anti-HBc-IgM	Chemiluminescent Microparticle Immunoassay (Package insert : Abbott Architect Anti-HBc IgM, 6C33)	IVD		Negative/Positive	--				Negative
10	Anti-HCV	Chemiluminescent Microparticle Immunoassay (Package insert : Abbott Architect Anti-HCV, 6C37)	IVD	Blood (Serum/Plasma)	Negative/Positive	--	5 working days	Daily	Original specimen: 7 days, Centrifuged plasma or serum: 3 months.	Negative
11	Anti-HCV (Confirmatory)@	Immunoblot (Package insert : Fujirebio INNO-LIA HCV Score, 80538)	IVD		Negative/Positive/Inconclusive	--	7 working days	Weekly		Negative
12	HDV-Ag	Enzyme Immuno Assay (Package insert : DIA.PRO HDV Ag, DAG.CE)	IVD	Blood (Serum/Plasma)	Negative/Positive/Inconclusive	--	7 working days	Weekly	Original specimen: 7 days, Centrifuged plasma or serum: 3 months.	Negative
13	Anti-HDV	Enzyme Immuno Assay (Package insert : DIA PRO HDV Ab, DAB.CE)	IVD		Negative/Positive/Inconclusive	--				Negative

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14	Anti-HDV-IgM	Enzyme Immuno Assay (Package insert : DIA PRO HDV IgM, DIM.CE)	IVD	Blood (Serum/Plasma)	Negative/Positive/Inconclusive	--	7 working days	Weekly	Original specimen: 7 days, Centrifuged plasma or serum: 3 months.	Negative
15	Anti-HEV-IgG	Enzyme-linked Immunosorbent Assay (Package insert : Wanti HEV-IgG ELISA, WE-7296)	IVD	Blood (Serum/Plasma)	Negative/Positive/Inconclusive	--	7 working days	Weekly		Negative
16	Anti-HEV-IgM	Enzyme-linked Immunosorbent Assay (Package insert : Wanti HEV-IgM ELISA, WE-7196)	IVD		Negative/Positive/Inconclusive	--				Negative
17	Anti-HIV + HIV 1-Ag	Electrochemiluminescence Immunoassay (Package insert : Roche Elecsys HIV Duo, 07229542190)	IVD	Blood (Serum/Plasma)	Negative/Positive	--	5 working days	Daily		Negative
		Enzyme Linked Fluorescent Assay (Package insert : bioMerieux VIDAS HIV DUO Ultra, 30443)	IVD		Negative/Positive/Inconclusive	--		2x/wk		Negative
18	Anti-HIV-1 [@]	Western Blot (Package insert : MP Diagnostics HIV Blot 2.2 Western Blot Assay, 11030)	IVD	Blood (Serum/Plasma)	Negative/Positive/Inconclusive	Positive ⁽¹⁾	5 working days	2x/wk		Negative
19	Anti-HIV-2 [@]	Western Blot (Package insert : MP Diagnostics HIV-2 Blot 1.2 Western Blot Assay, 11021)	IVD		Negative/Positive/Inconclusive	Positive ⁽¹⁾	7 working days	Weekly		Negative
20	HIV-1 Ag [@]	Enzyme Immuno Assay (Package insert : BioRad Genscreen HIV-1 Ag Assay, 71120)	IVD	Blood (Serum/Plasma)	Negative/Positive	--	5 working days	Weekly		Negative
	HIV-1 Ag (Confirmatory) [@]	Enzyme Immuno Assay (Package insert : BioRad Genscreen HIV-1 Ag Confirmatory Assay, 71121)	IVD		Negative/Positive	Positive ⁽¹⁾	7 working days	Weekly		Negative

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21	Anti-HTLV-I/II [@]	Chemiluminescent Microparticle Immunoassay (Package insert : Abbott Architect rHTLV I/II, 6L61)	IVD	Blood (Serum/Plasma)	Negative/Positive	--	7 working days	Weekly	Original specimen: 7 days, Centrifuged plasma or serum: 3 months.	Negative
		Western Blot (Package insert : MP Diagnostics HTLV Blot 2.4 Western Blot Assay, 11080)	IVD		Negative/Positive/Inconclusive	--	10 working days	Weekly		Negative
22	T-Lymphocyte count (Combo) (1) CD3 (2) CD4 (3) CD8	Flow Cytometry (Package insert : BD FACSCount reagent for enumerating CD3 · CD4 and CD8 T-lymphocyte, 340167)	IVD	Whole Blood (EDTA)	<ul style="list-style-type: none"> - Test value (cells/μL) - Below LOD CD3: <100 cells/μL CD4: <50 cells/μL CD8: <100 cells/μL - Above LOD CD3: >3500 cells/μL CD4: >2000 cells/μL CD8: >2000 cells/μL 	CD4 < 200 cells/μL ⁽¹⁾	4 working days	2x/wk	Original specimen: 1 day.	Under establishment
23	Anti-Treponema pallidum	Chemiluminescent Microparticle Immunoassay (Package insert : Abbott Architect Syphilis TP, 8D06)	IVD	Blood (Serum/Plasma)	Negative/Positive	--		Daily		Negative
24	Anti-Treponema pallidum (Confirmatory) [@]	Treponema Pallidum Particle Agglutination (Package insert : Fujirebio Serodia-T.PPA., 201626)	IVD		Negative/Positive(titer)	--		4 working days		3x/wk
25	RPR [@]	Rapid Plasma Reagin (Package insert : Axis-Shield RPR, FRPR500)	IVD	Blood (Serum/Plasma) · CSF*	Negative/Positive(titer) * The result in CSF is for reference.	Positive ⁽¹⁾		3x/wk		Negative

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26	Anti-Toxoplasmosis -IgG	Electrochemiluminescence Immunoassay (Package insert : Roche Elecsys Toxo IgG, 07028008190)	IVD	Blood (Serum/Plasma)	Negative/Positive(IU/mL)/ Inconclusive	--	5 working days	Daily	Original specimen: 7 days, Centrifuged plasma or serum: 3 months.	Negative
27	Anti-Toxoplasmosis -IgM	Electrochemiluminescence Immunoassay (Package insert : Roche Elecsys Toxo IgM, 07028024190)	IVD		Negative/Positive/Inconclusive	Positive ⁽¹⁾				Negative
28	Anti-CMV-IgG	Electrochemiluminescence Immunoassay (Package insert : Roche Elecsys CMV IgG, 07027117190)	IVD	Blood (Serum/Plasma)	Negative/Positive(U/mL)/ Inconclusive	--				Negative
29	Anti-CMV-IgM	Electrochemiluminescence Immunoassay (Package insert : Roche Elecsys CMV IgM, 07027133190)	IVD	Blood (Serum/Plasma)	Negative/Positive/Inconclusive	Positive ⁽¹⁾	6 working days	Weekly	Vaccinated: Positive Unvaccinated: Negative	Negative
30	Anti-Rubella Virus -IgG	Electrochemiluminescence Immunoassay (Package insert : Roche Elecsys Rubella IgG, 07027770190)	IVD		Negative/Positive(IU/mL)/ Inconclusive	--				Negative
31	Anti-Rubella Virus -IgM	Electrochemiluminescence Immunoassay (Package insert : Roche Elecsys Rubella IgM, 07027796190)	IVD	Blood (Serum/Plasma)	Negative/Positive/Inconclusive	Positive ⁽¹⁾	6 working days	Weekly	Vaccinated: Positive Unvaccinated: Negative	Negative
32	Anti-HSV-IgG	Enzyme-linked Immunosorbent Assay (Package insert : SERION ELISA classic Herpes Simplex Virus 1/2 IgG, ESR105G)	IVD		Negative/Positive(U/mL)/ Inconclusive	--				Negative
33	Anti-HSV-IgM	Enzyme-linked Immunosorbent Assay (Package insert : SERION ELISA classic Herpes Simplex Virus 1/2 IgM, ESR105M)	IVD		Negative/Positive/Inconclusive	Positive ⁽¹⁾				Negative



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34	Anti-Chlamydia-IgG	Enzyme-linked Immunosorbent Assay (Package insert : Serion ELISA Classic Chlamydia IgG, ESR137G)	IVD	Blood (Serum/Plasma)	Negative/Positive/Inconclusive	--	6 working days	Weekly	Original specimen: 7 days, Centrifuged plasma or serum: 3 months.	Negative		
35	Anti-EBV (EA+EBNA)-IgA	Enzyme-linked Immunosorbent Assay (Package insert : MeDiPro Anti-EBV IgA, TM-0001E)	IVD	Blood (Serum/Plasma)	Negative/Positive/Inconclusive	--	6 working days	Weekly		Negative		
36	Anti-EBV(EA)-IgG	Indirect Immunofluorescence Assay (Package insert : Euroimmun EBV-EA IgG, FI2795-1010G)	IVD (In Development)		Negative/Positive	--				Negative		
37	Anti-EBV(VCA)-IgG	Chemiluminescent Microparticle Immunoassay (Package insert : Abbott Architect EBV VCA IgG, 3P65)	IVD		Negative/Positive/Inconclusive	--				Negative		
38	Anti-EBV (VCA) -IgM	Chemiluminescent Microparticle Immunoassay (Package insert : Abbott Architect EBV VCA IgM, 3P66)	IVD		Negative/Positive/Inconclusive	--				6 working days	Weekly	Negative
39	Anti-EBV (EBNA-1) -IgG	Chemiluminescent Microparticle Immunoassay (Package insert : Abbott Architect EBNA-1 IgG, 3P67)	IVD		Negative/Positive/Inconclusive	--				Negative		
40	Anti-VZV-IgG	Enzyme-linked Immunosorbent Assay (Package insert : SERION ELISA classic Varicella-Zoster Virus IgG, ESR104G)	IVD		Negative/Positive(mIU/mL)/ Inconclusive	--				Vaccinated: Positive Unvaccinated: Negative		
41	Anti-VZV-IgM	Enzyme-linked Immunosorbent Assay (Package insert : SERION ELISA classic Varicella-Zoster Virus IgM, ESR104M)	IVD		Negative/Positive/Inconclusive	--			Negative			



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42	Anti-Measles Virus -IgG	Enzyme-linked Immunosorbent Assay (Package insert : SERION ELISA classic Measles Virus IgG, ESR102G)	IVD	Blood (Serum/Plasma)	Negative/Positive(mIU/mL)/ Inconclusive	--	4 working days	2x/wk	Original specimen: 7 days, Centrifuged plasma or serum: 3 months.	Vaccinated: Positive Unvaccinated: Negative
43	Anti-Measles Virus -IgM	Enzyme-linked Immunosorbent Assay (Package insert : SERION ELISA classic Measles Virus IgM, ESR102M)	IVD		Negative/Positive/Inconclusive	Positive ⁽¹⁾				Negative
44	Anti-Parotitis Virus -IgG	Enzyme-linked Immunosorbent Assay (Package insert : SERION ELISA classic Mumps Virus IgG, ESR103G)	IVD	Blood (Serum/Plasma)	Negative/Positive(U/mL)/ Inconclusive	--	6 working days	Weekly	Original specimen: 7 days, Centrifuged plasma or serum: 3 months.	Vaccinated: Positive Unvaccinated: Negative
45	Anti-Parotitis Virus -IgM	Enzyme-linked Immunosorbent Assay (Package insert : SERION ELISA classic Mumps Virus IgM, ESR103M)	IVD		Negative/Positive/Inconclusive	--				Negative
46	Anti-Dengue Virus -IgG	Enzyme-linked Immunosorbent Assay (Package insert : Panbio Dengue IgG Indirect ELISA, 01PE30)	IVD	Blood (Serum/Plasma)	Negative/Positive/Inconclusive	--	2 working days	Daily	Original specimen: 7 days, Centrifuged plasma or serum: 3 months.	Negative
47	Anti-Dengue Virus -IgM	Enzyme-linked Immunosorbent Assay (Package insert : Panbio Dengue IgM Capture ELISA, 01PE20)	IVD		Negative/Positive/Inconclusive	--				Negative
48	Anti-Chikungunya Virus-IgG	Indirect Immunofluorescence Assay (Package insert : Euroimmun Anti-Chikungunya virus IIFT/IgG, F1293A-1005-G)	IVD		Negative/Positive	--				2 working days



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49	Anti-Chikungunya Virus-IgM	Indirect Immunofluorescence Assay (Package insert : Euroimmun Anti-Chikungunya virus IIFT/IgM, F1293A-1005-M)	IVD	Blood (Serum/Plasma)	Negative/Positive	--	2 working days	Daily	Original specimen: 7 days, Centrifuged plasma or serum: 3 months.	Negative



B) Virology Tests (Molecular/Culture Identification)

No.	Test Item	Test Method		Specimen Type For details, See "Clinical Specimen Collection and Submission Guidelines"	Result/Report					
		Method (Reference Standard)	Remark		Result	Warning / Critical Values*	TAT	Frequency of Test	Specimen Retained	Biological Reference Interval
1	HBV DNA	Real time PCR (Package insert : Roche Cobas HBV Quantitative nucleic acid test for use on cobas 6800/8800 system, 07000979190)	IVD	Blood (Plasma)	- Not Detected - Below LOD <10 IU/mL - Test Value (IU/mL) - Above LOD >1.0E9 IU/mL	--	5 working days	Daily		Not Detected
2	HCV RNA	Real time PCR (Package insert : Roche CobasHCV Quantitative nucleic acid test for use on cobas 6800/8800 systems, 06997732190)	IVD	Blood (Plasma)	- Not Detected - Below LOD <15 IU/mL - Test value (IU/mL) - Above LOD >1.0E8 IU/mL	--	14 working days	3x/months		Not Detected
3	HIV-I RNA	Real time PCR (Package insert : Roche CobasHIV-1 Quantitative nucleic acid test for use on cobas 6800/8800 systems, 07000995190)	IVD	Blood (Plasma)	- Not Detected - Below LOD <20 copies/mL - Test value (copies/mL) - Above LOD >1.0E7 copies/mL	--	20 working days	Monthly	Original specimen: 7 days, Centrifuged plasma : 3 months.	Not Detected
4	HCV Genotyping	Real time PCR (Package insert : Roche Cobas HCV Genotyping test for use on the cobas 4800 system, 06984274190)	IVD	Blood (Plasma)	- Not Detected - Inconclusive - Genotype 1 - Genotype 1a - Genotype 1b - Genotype 2 - Genotype 3 - Genotype 4 - Genotype 5 - Genotype 6 (Except subtype c-l)	--	30 working days	Monthly		Not Detected



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5	Chlamydia trachomatis DNA	Real time PCR (Package insert : Cepheid Xpert CT/NG, GXCT/NG-CE-10)	IVD	Urine · Virginal Swab · Cervical Swab	Negative/Positive	--	5 working days	3x/wk	Original Specimen: 1 day, Aliquot Specimen: 3 months.	Negative
6	Neisseria gonorrhoeae DNA									
7	Dengue Virus RNA [@]	Real time PCR (Package insert : TIB LightMix Reflex Dengue Typing, 40-0700-24)	RUO	Blood (Serum/Plasma)	- Negative - Dengue Virus Type 1 - Dengue Virus Type 2 - Dengue Virus Type 3 - Dengue Virus Type 4	--	2 working days	Daily	Original specimen: 7 days, Centrifuged plasma or serum: 3 months.	Negative
8	Zika Virus RNA	Real time PCR (Package insert : Altona RealStar Zika virus RT-PCR Kit 1.0 Assay, 591013)	IVD	Blood (Serum/Plasma) · Urine	Negative/Positive	--	2 working days	Daily		Negative
9	Chikungunya Virus RNA [@]	Real time PCR (Singapore NPHL method & PMC: 2907414)	--	Blood (Serum/Plasma)	Negative/Positive	--	2 working days	Daily		Negative
10	Norovirus RNA	Real time PCR (Package insert : Altona RealStar Norovirus RT-PCR Kit 2.0 Assay, 052013)	IVD	Fezes	Negative/Positive	--	5 working days	3x/wk		Negative
11	Rotavirus RNA	Real time PCR (Package insert : Fast-track Diagnostics Viral Gastroenteritis Qualitative Assay, FTIyo-3s-64-L)	IVD	Fezes	Negative/Positive	--	5 working days	3x/wk	Original Specimen: 7 days, Aliquot Specimen: 3 months.	Negative
12	Enterovirus (Combination) (1) EV RNA (2) EV71 RNA	Real time PCR (Hong Kong PHLC method)	--	Fezes · Rectal Swab · CSF · Throat Swab*	(1) Negative/Positive * The positive result in Throat Swab is for reference. (2) Negative/Positive	CSF : Positive (H)	5 working days	3x/wk		Negative

[@] : Proceed according to preset workflow.



No.	Test Item	Test Method		Specimen Type For details, See "Clinical Specimen Collection and Submission Guidelines"	Result/Report					
		Method (Reference Standard)	Remark		Result	Warning / Critical Values*	TAT	Frequency of Test	Specimen Retained	Biological Reference Interval
13	Influenza Virus RNA	Real time PCR (Package insert : TIB LightMix Modular Influenza A, 530101-96 Influenza B, 58-0102-96 Influenza A H1 (H1N1 sw), 50-0100-96 Influenza A H3, 61-0103-96)	RUO	Nasopharyngeal Swab 、 Throat Swab 、 Nasopharyngeal Aspirate	- Negative - Influenza A Virus - Influenza B Virus - Influenza A Virus/H1 - Influenza A Virus/H3	--	5 working days	2x/wk	Original Specimen: 7 days, Aliquot Specimen: 3 months.	Negative
14	Respiratory Virus Detection (Combination) (1) Influenza Virus RNA (2) RSV RNA (3) ParainfluenzaVirus RNA (4) Adneovirus DNA (5) Human metapneumovirus RNA (6) Coronavirus RNA (7) Entero/Rhinovirus RNA (8) Human Bocavirus DNA (9) Chlamydoiphila pneumoniae DNA (10) Mycoplasma pneumoniae DNA (11) Legionella pneumophila DNA	Multiplex RT-PCR (Package insert : Luminex NxTAG Respiratory Pathogen Panel, I051C0449)	IVD	Nasopharyngeal Swab 、 Nasopharyngeal Aspirate 、 Bronchoalveolar Lavage 、 Throat Swab 、 Sputum	(1) - Negative - Influenza A Virus - Influenza B Virus - Influenza A Virus/H1 - Influenza A Virus/H3 (2) Negative/Positive (3) - Negative - Parainfluenza Virus 1 - Parainfluenza Virus 2 - Parainfluenza Virus 3 - Parainfluenza Virus 4 (4) Negative/Positive (5) Negative/Positive (6) - Negative - Coronavirus 229E - Coronavirus HKU1 - Coronavirus NL63 - Coronavirus OC43 (7) Negative/Positive (8) Negative/Positive (9) Negative/Positive (10) Negative/Positive (11) Negative/Positive	--	3 working days	Daily	Original Specimen: 7 days, Aliquot Specimen: 3 months.	Negative



No.	Test Item	Test Method		Specimen Type For details, See "Clinical Specimen Collection and Submission Guidelines"	Result/Report					
		Method (Reference Standard)	Remark		Result	Warning / Critical Values*	TAT	Frequency of Test	Specimen Retained	Biological Reference Interval
15	HSV DNA	Real time PCR (Package insert : Altona RealStar HSV PCR Kit 1.0 Assay, 061013)	IVD	Blood (Plasma) · CSF · Human cutaneous and mucocutaneous lesion swabs	- Negative - Herpes Simplex Virus 1 - Herpes Simplex Virus 2	CSF : Herpes Simplex Virus 1 (H) CSF : Herpes Simplex Virus 2 (H)	3 working days	Daily		Negative
16	EBV DNA	Real time PCR (Package insert : Altona RealStar EBV PCR Kit 1.0 Assay, 13101)	IVD	Blood (Plasma) · CSF	Negative/Positive(IU/mL)	CSF : Positive (H)	5 working days	3x/wk	Original Specimen: 7 days, Aliquot Specimen: 3 months.	Negative
17	BKV DNA	Real time PCR (Package insert : Altona RealStar BKV PCR Kit 1.0 Assay, 031013)	IVD	Blood (Plasma) · Urine	Negative/Positive(IU/mL)	--	7 working days	Weekly		Negative



3. Parasitology Laboratory

No.	Test Item	Test Method		Specimen Type For details, See “Clinical Specimen Collection and Submission Guidelines”	Result/Report					
		Method (Reference Standard)	Remark		Result	Warning / Critical Values*	TAT	Frequency of Test	Specimen Retained	Biological Reference Interval
1	Microscopy (Except Coccidia)	Microscopy for stool specimen: Concentration by Formalin-Ethyl Acetate Sedimentation, (Clinical Microbiology Procedure Handbook, 4 th edition, 2016, ASM)	--	Fezes	Not detected/Parasite species	Detected ⁽¹⁾ Parasite species	2 working days	Daily	1 Day	Not Detected
		Microscopy for Sputum Specimen: Direct Mount and Stained Preparation, (Clinical Microbiology Procedure Handbook, 4 th edition, 2016, ASM)	Standard Method (In development)	Sputum						
		Microscopy and Sedimentation for Urine Specimen (Clinical Microbiology Procedure Handbook, 4 th edition, 2016, ASM)	--	Urine						
		Detection of Blood Parasites: Merck IVD 1.09204.100	IVD (In development)	Blood						
2	Microscopy (Coccidia only)	Special Stains for Coccidia: Modified Kinyou’ s Acid-Fast Stain (cold) and Microscopy (Clinical Microbiology Procedure Handbook, 4 th edition, 2016, ASM)	--	Fezes	Not detected/Parasite species	Detected ⁽¹⁾ Parasite species	4 working days	2x/wk	4 Days	Not Detected



No.	Test Item	Test Method		Specimen Type For details, See "Clinical Specimen Collection and Submission Guidelines"	Result/Report					
		Method (Reference Standard)	Remark		Result	Warning / Critical Values*	TAT	Frequency of Test	Specimen Retained	Biological Reference Interval
3	Detection of Pinworm	Detection of Pinworm: Cellulose Tape Preparation, (Clinical Microbiology Procedure Handbook, 4 th edition, 2016, ASM)	--	Cellophane Swab	Not detected/Parasite species	Detected ⁽¹⁾ Parasite species	2 working days	Daily	1 Day	Not Detected
4	Detection of <i>Trypanosoma spp</i>	Triple Centrifugation Concentration, (Clinical Microbiology Procedure Handbook, 4 th edition, 2016, ASM)	Standard Method (In development)	Blood	Not detected/Parasite species	Detected ⁽¹⁾ Parasite species	2 working days	Daily	1 Day	Not Detected
5	Detection of Filariasis	KNOTT Concentration (Clinical Microbiology Procedure Handbook, 4 th edition, 2016, ASM)	Standard Method (In development)	Blood	Not detected/Parasite species	Detected ⁽¹⁾ Parasite species	2 working days	Daily	1 Day	Not Detected
6	Anti-Echinococcus granulosus, IHA	Enzyme-linked Immunosorbent Assay (Package insert : Hydatidosis ELISA IgG, Vircell, 2016/01)	IVD (In development)	Blood	Negative/Positive	Positive ⁽¹⁾	2 working days	Daily	1 Day	Negative
7	Microscopy for Urogenital Discharge	Urogenital Specimens: Direct Saline Mount (Clinical Microbiology Procedure Handbook, 4 th edition, 2016, ASM)	Standard Method (In development)	Swab	Not detected/Parasite species	Detected ⁽¹⁾ Parasite species	2 working days	Daily	1 Day	Not Detected
8	Identification of Worms	Detection of Tapeworm: India Ink Stain (Clinical Microbiology Procedure Handbook, 4 th edition, 2016, ASM)	Standard Method (In development)	Worms	Non-human parasites/ Parasite species	Detected ⁽¹⁾ Parasite species	5 working days	Daily	5 Days	N/A



4. Chemistry Laboratory

No.	Test Item	Test Method		Specimen Type For details, See "Clinical Specimen Collection and Submission Guidelines"	Result/Report					
		Method (Reference Standard)	Remark		Result	Warning / Critical Values*	TAT	Frequency of Test	Specimen Retained	Biological Reference Interval
1	Lead (Pb) in Blood	Quality assurance of blood lead monitoring in environmental lead pollution, Zheng Xingquan 2000	--	Whole Blood (in EDTA tube)	- <Detection Limit (<2.5µg/dL) - Results (µg/dL)	>10µg/dL ⁽¹⁾ (Adults) >5µg/dL ⁽¹⁾ (children and pregnant women)	2 working days	When needed	Original Specimen: 7 days.	≤10µg/dL (Adults) ≤5µg/dL (children and pregnant women)



Emergency Testing Service Agreement

No.	Test Item	Test Method		Specimen Type For details, See "Clinical Specimen Collection and Submission Guidelines"	Result/Report					
		Method (Reference Standard)	Remark		Result	Warning / Critical Values*	TAT	Frequency of Test	Specimen Retained	Biological Reference Interval
1	Detection of Avian Influenza (Combination) (1) Influenza A Virus, H5 subtype avian influenza virus RNA (2) Influenza A Virus, H7 subtype avian influenza virus RNA (3) Influenza A Virus, H9 subtype avian influenza virus RNA	Real Time PCR (Package insert : TIB LightMix Modular Influenza A H5, 58-0105-96 Influenza A H7, 64-0634-96 Influenza A H9, 53-0109-96)	RUO	Throat Swab · Nasopharyngeal Swab · Nasopharyngeal Aspirate · Tracheal Aspirate · Bronchoalveolar Lavage	Negative/ Positive	Positive ^(H)	5 hours	Test upon request	Original Specimen: 7 days, Aliquot Specimen: 3 months.	Negative
2	SARS Coronavirus RNA	Real Time PCR (Hong Kong PHLC Method)	--	Throat Swab · Nasopharyngeal Swab · Nasopharyngeal Aspirate · Fezes		Positive ^(H)				Negative
3	MERS Coronavirus RNA	Real Time PCR (Package insert : RealStar MERS-CoV RT-PCR Kit 1.0, 391012)	IVD	Throat Swab · Nasopharyngeal Swab · Nasopharyngeal Aspirate · Sputum · Bronchoalveolar Lavage · Tracheal Aspirate · Fezes · Blood		Positive ^(H)				Negative



No.	Test Item	Test Method		Specimen Type For details, See "Clinical Specimen Collection and Submission Guidelines"	Result/Report					
		Method (Reference Standard)	Remark		Result	Warning / Critical Values*	TAT	Frequency of Test	Specimen Retained	Biological Reference Interval
4	Ebola Virus RNA	Real Time PCR (Package insert : TIB LightMix Modular Ebola Virus Zaire (2014), 53-0649-96)	RUO	Blood (Plasma)	Negative/ Positive	Positive ⁽ⁱⁱ⁾	5 hours	Test upon request	Original Specimen: 7 days, Aliquot Specimen: 3 months.	Negative
5	Yellow Fever Virus RNA	Real Time PCR (Package insert : FTD Tropical fever Africa, FTD-37-64)	IVD	Blood (Plasma) · Urine		Positive ⁽ⁱⁱ⁾				Negative

Remarks : IVD : In Vitro Diagnostic.
 RUO : Research Use Only.

Warning / Critical Values*

- (i) Warning : issue report within 5 hours after confirmation of test result.
- (ii) Critical Values : notify clinical physician immediately after confirmation of test result.