



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

**Public Health Laboratory
Health Bureau, Macao SAR Government**

V.2021.01



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)	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 ⁽ⁱⁱ⁾ (Per 7 days) Others: Positive ⁽ⁱ⁾	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))	IVD	Same as above · Fezes	- Negative (8 weeks) - Positive - Positive and Contaminated - Contaminated	CSF: Positive ⁽ⁱⁱ⁾ (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))	IVD	Blood ^{※#} · Bone Marrow ^{※#}	- Negative (6 weeks) - Positive - Positive and Contaminated - Contaminated	Positive ⁽ⁱⁱ⁾ (Per 7 days)	3-6 weeks	Daily	--	Negative
3	MTBC Nucleic Acid Amplification Test [@]	RT-PCR, Xpert (Package insert: Xpert® MTB/RIF Ultra 301-5987)	IVD (New Case Only)	Initial Smear Positive Sample* (Except Fezes · Urine · Blood · Bone Marrow)	- Detected - Not Detected - Invalid - Indeterminate * Reference only for non-sputum samples	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))	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)	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 IFU-298; GenoType Mycobacterium CM IFU-299A)	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

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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; VITEK MS Knowledge Base, 161150)	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; Package insert: BACTEC [™] MGIT [™] 960 SIRE Kits 8008200(02); BACTEC [™] MGIT [™] 960 PZA Kit L005486JAA(01))	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 M24. Susceptibility testing of mycobacteria, nocardia, and other aerobic actinomycetes)	Standard Method MDR-TB only	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)	Sensititre RAPMYCOI (Package Insert: Trek Diagnostic Systems, Sensititre [®] , Broth Microdilution (MIC) Method: For Rapidly Growing Mycobacteria (RGM), Slowly Growing Nontuberculosis Mycobacteria, Nocardia and other Aerobic Actinomycetes, 033- NONTBMYCO_CE-GB)	IVD	Pure culture of the following species: <i>M. fortuitum</i> <i>M. chelonae</i> <i>M. abscessus</i> (Same ID result for ≥ 3 months)	<ul style="list-style-type: none"> - Sensitive - Intermediate - Resistant (DST is a qualitative test <i>in vitro</i> , results are for reference only)	--	4 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	Drug Susceptibility Test [@] (NTM-SGM)	Sensititre SLOMYCOI (Package Insert: Trek Diagnostic Systems, Sensititre®, Broth Microdilution (MIC) Method For Rapidly Growing Mycobacteria (RGM), Slowly Growing Nontuberculosis Mycobacteria, Nocardia and other Aerobic Actinomycetes, 033-NONTBMYCO_CE-GB)	IVD	Pure culture of the following species: <i>MAC Complex</i> <i>M. kansasii</i> (In development) (Same ID result for ≥ 3 months)	- Sensitive - Intermediate - Resistant - (DST is a qualitative test <i>in vitro</i> , results are for reference only)	--	4 weeks after ID	Weekly	Long Term storage of strain.	N/A
9	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)	IVD	Whole Blood [※]	- Negative - Positive - Indeterminate	--	1 week	2x/wk	Plasma : 28 days.	Negative

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※ : Deliver immediately at ambient temperature.



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	Electrochemiluminescence Immunoassay (Package insert : Roche Elecsys Anti-HAV II, 08086664190)	IVD	Blood (Serum/Plasma)	Negative/Positive	--	5 working days	Daily		Negative
2	Anti-HAV-IgM	Electrochemiluminescence Immunoassay (Package insert : Roche Elecsys Anti-HAV IgM, 07026773190)	IVD	Blood (Serum/Plasma)	Negative/Positive	--	5 working days	Daily	Original specimen: 7 days, Centrifuged plasma or serum: 3 months.	Negative
3	HBsAg	Electrochemiluminescence Immunoassay (Package insert : Roche Elecsys HBsAg II, 07251076190)	IVD	Blood (Serum/Plasma)	Negative/Positive/Inconclusive	--	5 working days	Daily		Negative

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		Method (Reference Standard)	Remark		Result	Warning / Critical Values*	TAT	Frequency of Test	Specimen Retained	Biological Reference Interval
4	HBsAg (Confirmatory) [@]	Electrochemiluminescence Immunoassay (Package insert : Roche Elecsys HBsAg Confirmatory Test, 11820648122)	IVD	Blood (Serum/Plasma)	Negative/Positive/Inconclusive	--	5 working days	Daily	Original specimen: 7 days, Centrifuged plasma or serum: 3 months.	Negative
5	Anti-HBs	Electrochemiluminescence Immunoassay (Package insert : Roche Elecsys Anti-HBs II, 07026854190)	IVD	Blood (Serum/Plasma)	Negative/Positive(IU/L)	--	5 working days	Daily		Vaccinated: Positive Unvaccinated: Negative
6	HBeAg	Electrochemiluminescence Immunoassay (Package insert : Roche Elecsys HBeAg, 07027427190)	IVD	Blood (Serum/Plasma)	Negative/Positive	--	5 working days	Daily		Negative
7	Anti-HBe	Electrochemiluminescence Immunoassay (Package insert : Roche Elecsys Anti-HBe, 07026838190)	IVD	Blood (Serum/Plasma)	Negative/Positive	--	5 working days	Daily		Negative

[@] : 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
8	Anti-HBc	Electrochemiluminescence Immunoassay (Package insert : Roche Elecsys Anti-HBc II, 07026790190)	IVD	Blood (Serum/Plasma)	Negative/Positive	--	5 working days	Daily	Original specimen: 7 days, Centrifuged plasma or serum: 3 months.	Negative
9	Anti-HBc-IgM	Electrochemiluminescence Immunoassay (Package insert : Roche Elecsys Anti-HBc IgM, 07026811190)	IVD	Blood (Serum/Plasma)	Negative/Positive	--	5 working days	Daily		Negative
10	Anti-HCV	Electrochemiluminescence Immunoassay (Package insert : Roche Elecsys Anti-HCV II, 07026889190)	IVD	Blood (Serum/Plasma)	Negative/Positive/Inconclusive	--	5 working days	Daily		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		Negative

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13	Anti-HDV	Enzyme Immuno Assay (Package insert : DIA PRO HDV Ab, DAB.CE)	IVD	Blood (Serum/Plasma)	Negative/Positive/Inconclusive	--	7 working days	Weekly	Original specimen: 7 days, Centrifuged plasma or serum: 3 months.	Negative
14	Anti-HDV-IgM	Enzyme Immuno Assay (Package insert : DIA PRO HDV IgM, DIM.CE)	IVD		Negative/Positive/Inconclusive	--				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
		Immunochemical Assay (Package insert : Alere HIV Combo, 7D2843)	IVD		Negative/Positive	--		2x/wk		Negative
18	Anti-HIV 1/2 (Confirmatory) [@]	Immunochemical Assay (Package insert : BioRad Geenius HIV 1/2 Confirmatory Assay, 72460)	IVD	Blood (Serum/Plasma)	Negative Anti-HIV-1 Positive Anti-HIV-1 indeterminate Anti-HIV-2 Positive Anti-HIV-2 indeterminate Indeterminate Positive (untypable)	Positive ⁽¹⁾	3 working days	2x/wk	Negative	
19	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	
20	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

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21	Anti-HTLV	Electrochemiluminescence Immunoassay (Package insert : Roche Elecsys HTLV-I/II, 07028202190)	IVD	Blood (Serum/Plasma)	Negative/Positive	--	7 working days	Weekly	Original specimen: 7 days, Centrifuged plasma or serum: 3 months.	Negative
22	Anti-HTLV (Confirmatory) [@]	Western Blot (Package insert : MP Diagnostics HTLV Blot 2.4 Western Blot Assay, 11080)	IVD		Negative/Positive/Inconclusive	--	10 working days	Weekly		
23	T-Lymphocyte count (Combo) (1) CD3 (2) CD4 (3) CD8	Flow Cytometry (Package insert : AQUIOS Tetra-1 Panel, B23533)	IVD	Whole Blood (EDTA)	- Test value (cells/ μ L) - Below LOD CD3: <55 cells/ μ L CD4: <35 cells/ μ L CD8: <45 cells/ μ L - Above LOD CD3: >4700 cells/ μ L CD4: >3000 cells/ μ L CD8: >1600 cells/ μ L	CD4 < 200 cells/ μ L ^(t)	4 working days	2x/wk	Original specimen: 1 day.	Under establishment
24	Anti-Treponema pallidum	Electrochemiluminescence Immunoassay (Package insert : Roche Elecsys Syphilis, 07251378190)	IVD	Blood (Serum/Plasma)	Negative/Positive	--	4 working days	Daily	Original specimen: 7 days, Centrifuged plasma or serum: 3 months.	Negative

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		Method (Reference Standard)	Remark		Result	Warning / Critical Values*	TAT	Frequency of Test	Specimen Retained	Biological Reference Interval
25	Anti-Treponema pallidum (TPPA) [@]	Treponema Pallidum Particle Agglutination (Package insert : Fujirebio Serodia-T.PPA., 201626)	IVD	Blood (Serum/Plasma)	Negative/Positive(titer)/ Indeterminate	--	4 working days	3x/wk	Original specimen: 7 days, Centrifuged plasma or serum: 3 months.	Negative
26	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⁾	4 working days	3x/wk		Negative
27	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		Negative
28	Anti-Toxoplasmosis -IgM	Electrochemiluminescence Immunoassay (Package insert : Roche Elecsys Toxo IgM, 07028024190)	IVD		Negative/Positive/Inconclusive	Positive ⁽¹⁾				Negative
29	Anti-CMV-IgG	Electrochemiluminescence Immunoassay (Package insert : Roche Elecsys CMV IgG, 07027117190)	IVD	Blood (Serum/Plasma)	Negative/Positive(U/mL)/ Inconclusive	--	5 working days	Daily		Negative
30	Anti-CMV-IgM	Electrochemiluminescence Immunoassay (Package insert : Roche Elecsys CMV IgM, 07027133190)	IVD		Negative/Positive/Inconclusive	Positive ⁽¹⁾				Negative
31	Anti-Rubella Virus -IgG	Electrochemiluminescence Immunoassay (Package insert : Roche Elecsys Rubella IgG, 07027770190)	IVD	Blood (Serum/Plasma)	Negative/Positive(IU/mL)	--	5 working days	Daily		Vaccinated: Positive Unvaccinated: Negative
32	Anti-Rubella Virus -IgM	Electrochemiluminescence Immunoassay (Package insert : Roche Elecsys Rubella IgM, 07027796190)	IVD		Negative/Positive/Inconclusive	Positive ⁽¹⁾				Negative

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		Method (Reference Standard)	Remark		Result	Warning / Critical Values*	TAT	Frequency of Test	Specimen Retained	Biological Reference Interval
33	Anti-HSV-IgG	Enzyme-linked Immunosorbent Assay (Package insert : SERION ELISA classic Herpes Simplex Virus 1/2 IgG, ESR105G)	IVD	Blood (Serum/Plasma)	Negative/Positive(U/mL)/ Inconclusive	--	6 working days	Weekly		Negative
34	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
35	Anti-Chlamydia-IgG	Enzyme-linked Immunosorbent Assay (Package insert : Serion ELISA Classic Chlamydia IgG, ESR137G)	IVD	Blood (Serum/Plasma)	Negative/Positive/Inconclusive	--				Negative
36	Anti-EBV (EA+EBNA)-IgA	Enzyme-linked Immunosorbent Assay (Package insert : MeDiPro Anti-EBV IgA, TM-0001E)	IVD	Blood (Serum)	Negative/Positive/Inconclusive	--				6 working days
37	Anti-EBV(EA)-IgG	Indirect Immunofluorescence Assay (Package insert : Euroimmun EBV-EA IgG, FI2795-1010G)	IVD (In Development)	Blood (Serum/Plasma)	Negative/Positive	--	Negative			
38	Anti-EBV(VCA)-IgG	Chemiluminescent Microparticle Immunoassay (Package insert : Abbott Architect EBV VCA IgG, 3P65)	IVD	Blood (Serum/Plasma)	Negative/Positive/Inconclusive	--				Negative
39	Anti-EBV (VCA) -IgM	Chemiluminescent Microparticle Immunoassay (Package insert : Abbott Architect EBV VCA IgM, 3P66)	IVD		Negative/Positive/Inconclusive	--				Negative



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		Method (Reference Standard)	Remark		Result	Warning / Critical Values*	TAT	Frequency of Test	Specimen Retained	Biological Reference Interval
40	Anti-EBV (EBNA-1) -IgG	Chemiluminescent Microparticle Immunoassay (Package insert : Abbott Architect EBNA-1 IgG, 3P67)	IVD	Blood (Serum/Plasma)	Negative/Positive/Inconclusive	--	6 working days	Weekly	Original specimen: 7 days, Centrifuged plasma or serum: 3 months.	Negative
41	Anti-VZV-IgG	Enzyme-linked Immunosorbent Assay (Package insert : SERION ELISA classic Varicella-Zoster Virus IgG, ESR104G)	IVD	Blood (Serum/Plasma)	Negative/Positive(mIU/mL)/ Inconclusive	--	6 working days	Weekly		Vaccinated: Positive Unvaccinated: Negative
42	Anti-VZV-IgM	Enzyme-linked Immunosorbent Assay (Package insert : SERION ELISA classic Varicella-Zoster Virus IgM, ESR104M)	IVD		Negative/Positive/Inconclusive	--				Negative
43	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		Vaccinated: Positive Unvaccinated: Negative
44	Anti-Measles Virus -IgM	Enzyme-linked Immunosorbent Assay (Package insert : SERION ELISA classic Measles Virus IgM, ESR102M)	IVD		Negative/Positive/Inconclusive	Positive ^(†)				Negative
45	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		Vaccinated: Positive Unvaccinated: Negative
46	Anti-Parotitis Virus -IgM	Enzyme-linked Immunosorbent Assay (Package insert : SERION ELISA classic Mumps Virus IgM, ESR103M)	IVD		Negative/Positive/Inconclusive	--			Negative	



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47	Anti-Dengue Virus -IgG	Enzyme-linked Immunosorbent Assay (Package insert : Panbio Dengue IgG Indirect ELISA, 01PE30)	IVD	Blood (Serum)	Negative/Positive/Inconclusive	--	2 working days	Daily	Original specimen: 7 days, Centrifuged plasma or serum: 3 months.	Negative
48	Anti-Dengue Virus -IgM	Enzyme-linked Immunosorbent Assay (Package insert : Panbio Dengue IgM Capture ELISA, 01PE20)	IVD		Negative/Positive/Inconclusive	--				Negative
49	Anti-Chikungunya Virus-IgG	Indirect Immunofluorescence Assay (Package insert : Euroimmun Anti-Chikungunya virus IIFT/IgG, F1293A-1005-G)	IVD	Blood (Serum/Plasma)	Negative/Positive	--	2 working days	Daily		Negative
50	Anti-Chikungunya Virus-IgM	Indirect Immunofluorescence Assay (Package insert : Euroimmun Anti-Chikungunya virus IIFT/IgM, F1293A-1005-M)	IVD		Negative/Positive	--				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)	<ul style="list-style-type: none"> - 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)	<ul style="list-style-type: none"> - 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-1 RNA	Real time PCR (Package insert : Roche CobasHIV-1 Quantitative nucleic acid test for use on cobas 6800/8800 systems, 07000995190)	IVD	Blood (Plasma)	<ul style="list-style-type: none"> - 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	Sanger Sequencing (Reference: T.H.J.LAM et al. British Journal of Biomedical Science 2010 67(2). Evaluation of in-house and commercial genotyping assays for molecular typing of hepatitis C virus in Hong Kong)	--	Blood (Plasma)	<ul style="list-style-type: none"> - Not Detect - Inconclusive - Genotype 1a - Genotype 1b - Genotype 2 - Genotype 3 - Genotype 4 - Genotype 5 - Genotype 6 	--	30 working days	Monthly		Not Detected



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		Method (Reference Standard)	Remark		Result	Warning / Critical Values*	TAT	Frequency of Test	Specimen Retained	Biological Reference Interval
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 (RUO), FTD3-32-64)	RUO	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 (Ⓜ)	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) Parainfluenza Virus RNA (4) Adenovirus DNA (5) Human metapneumovirus RNA (6) Coronavirus RNA (7) Enterovirus/Rhinovirus RNA (8) Human Bocavirus DNA (9) Chlamydia 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 ^(II) CSF : Herpes Simplex Virus 2 ^(II)	3 working days	Daily	Original Specimen: 7 days, Aliquot Specimen: 3 months.	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 ^(II)	5 working days	3x/wk		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
18	CMV DNA	Real time PCR (Package insert : Altona RealStar CMV PCR Kit 1.0 Assay, 021013)	IVD	Blood (Plasma)	Negative/Positive(IU/mL)	--	7 working days	Weekly		Negative
19	Rubella Virus RNA	Real time PCR (Package insert : IRR Rubella virus real-time RT-PCR kit, GR-319)	IVD	Nasopharyngeal Swab · Throat Swab	Negative/Positive	Positive ^(I)	3 working days	Daily		Negative
20	Measles Virus RNA	Real time PCR (Package insert : IRR Measles virus real-time RT-PCR kit, GR-322)	IVD	Nasopharyngeal Swab · Throat Swab	Negative/Positive	Positive ^(I)	3 working days	Daily		Negative
21	SARS-CoV-2 RNA	Real time PCR (Package insert: Roche Cobas SARS-CoV-2 Qualitative assay for use on the cobas 6800/8800 systems, 09175431190)	EUA IVD	Nasopharyngeal Swab · Throat Swab, Nasal swab	Negative/ Positive	Positive ^(I)	1 working day	Daily		Negative
		Real time PCR (Package insert: Cepheid GeneXpert Xpert® Xpress SARS-CoV-2, XPRSARS-COV2-10)	EUA IVD	Nasopharyngeal Swab · Throat Swab, Nasal swab	Negative/ Positive	Positive ^(I)	1 working day	Daily	Original Specimen: 7 days	Negative
		Real time PCR (Package insert: Shanghai BioGerm 2019 novel Coronavirus Nucleic Acid Detection Kit, ZC-HX-201-2)	IVD	Nasopharyngeal Swab · Throat Swab, sputum	Negative / Positive	Positive ^(I)	1 working day	Daily		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		Detected ⁽¹⁾ Parasite species				
		Microscopy and Sedimentation for Urine Specimen (Clinical Microbiology Procedure Handbook, 4 th edition, 2016, ASM)	--	Urine		Detected ⁽¹⁾ Parasite species				
		Detection of Blood Parasites: Merck IVD 1.09204.100	IVD (In development)	Blood		Detected ⁽¹⁾ Parasite species				
2	Microscopy (Coccidia only)	Special Stains for Coccidia: Modified Kinyoun’ s Acid-Fast Stain (cold) and Microscopy (Clinical Microbiology Procedure Handbook, 4 th edition, 2016, ASM)	--	Fezes	Not detected/Parasite species	Detected ⁽⁴⁾ 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, REF: G1006)	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	ICP/MS (J. Environ Occup Med, Sep. 2013 Vol.30 No.9 – Determination of 17 Elements in Whole Blood by Inductively Coupled Plasma Mass Spectrometry)	--	Whole Blood (in EDTA tube)	- <Detection Limit ($<0.4\mu\text{g/dL}$) - Results ($\mu\text{g/dL}$)	$>10\mu\text{g/dL}$ ⁽¹⁾ (Adults) $>5\mu\text{g/dL}$ ⁽¹⁾ (children and pregnant women)	2 working days	When needed	Original Specimen: 7 days.	$\leq 10\mu\text{g/dL}$ (Adults) $\leq 5\mu\text{g/dL}$ (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.

EUA: Emergency Use Authorization

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.