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Date)

General Circular letter No. 2 – 118/2024

Deputy Director General - National Hospital of Sri Lanka,

Director of National Hospital Kandy, Karapitiya

All Provincial and Regional Directors of Health Services,

All Directors of Teaching/ Provincial/ District General Hospitals,

All Directors of Specialized Hospitals,

All Medical Superintendents of Base Hospitals,

All Medical Officer In Charge of Divisional Hospitals/ Primary Medical Care Units,

Rational Use of Laboratory Investigations

Laboratory investigations are essential for patient care, aiding in diagnosis, monitoring, and disease screening. Rational use of laboratory tests involves selecting the right test for the right patient at the right time, based on clinical evidence, and patient needs, while considering cost-effectiveness.

The irrational use of laboratory investigations has widened the healthcare budget and workload, associated with poor quality, errors, and threats to patient safety.

To address this issue, the "Guideline for Rational Use of Laboratory Investigations" has been developed by co-groups of experts and attached herewith. You are hereby instructed to adhere to this guideline to ensure the rational use of laboratory investigations and thereby improve overall patient care.

Dr. Asela Gunawardena
Director General of Health Services

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Guideline for

Rational Use of Laboratory Investigations

(General Circular letter No. 2 – 118/2024)

Ministry of Helath

2024

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General Circular letter No. 2 – 118/2024
Revised date: 21/10/2024

Guideline for Rational Use of Laboratory Investigations

1. Introduction

Laboratory investigations have become an integral part of modern-day healthcare services, crucial for the screening, diagnosis, and monitoring of diseases. However, there is growing evidence that these investigations are used irrationally, leading to unnecessary costs and resource wastage. Therefore, it is essential to promote the rational use of laboratory investigations to address these issues.

Rational use of laboratory investigations involves judicious application of tests based on clinical evidence, patient needs, and cost-effectiveness. It involves selecting the right test for the right patient at the right time, ensuring that each ordered investigation has a clear clinical indication and is likely to influence patient management.

Improving the rational use of laboratory investigations requires addressing all phases of the investigation process. In the pre-analytical phase, strategies include rationalizing the prescription process by establishing clear clinical guidelines, implementing tiered authorization levels, creating a hierarchical laboratory network and introducing investigation norms for each level, limiting after-hours testing, increasing awareness among both clinicians and patients and enhancing cost awareness. During the analytical phase, decision support systems and mechanisms to reduce duplicate testing should be implemented, alongside strengthening supervision and accountability within laboratories. In the post-analytical phase, regular audits and feedback, comprehensive interpretation of results, and close clinician-laboratory collaboration are essential.

This guideline aims to improve the rational use of laboratory investigations across different levels of the health system within the state sector by improving the prescription process, monitoring, and evaluation.

Irrational use of laboratory investigations includes practices such as unnecessary testing without clinical indication, overutilization, duplication of tests, the unwarranted use of high-end investigations, and duplication without indication. These practices result in wastage of scarce resources, increased healthcare costs, delays in obtaining test results, and increased potential to harm patients.

2. Justification

In the context of the state sector, where resources are often limited, the rational use of laboratory investigation is crucial to ensure equity and sustainability of the health system. By aligning laboratory investigations with the level of health institutions, this guideline seeks to promote the optimal utilization of resources. Furthermore, it will promote effective management of workload, and quality of investigations performed by introducing tiered authorization levels, while facilitating patient referral systems across various levels of healthcare institutions.

3. Objectives

The primary objective is to improve the rational use of laboratory investigations within the state health system by: 1) rationalizing the prescription process and 2) establishing a monitoring and evaluation mechanism.

4. Rationalizing the prescription process

The rational prescription of investigation is a systematic approach aimed at optimizing the use of diagnostic tests within healthcare settings. It involves the careful selection of investigations based on clinical necessity, evidence-based guidelines, and the prescriber's level of expertise. This process ensures that tests are ordered appropriately, avoiding unnecessary or redundant investigations, which can lead to increased costs and potential harm to patients.

4.1 Principles of rational prescription of investigations

The following principles guide the rational ordering of investigations:

- ***Clinical justification***

Every investigation ordered should have a clear clinical indication based on the patient's symptoms, history, and examination findings. Tests should be requested to confirm the diagnosis, monitor the progression of a disease, or guide treatment decisions.

- ***Cost-effectiveness***

The economic impact of ordering investigations should be considered carefully. Investigations should be chosen after careful consideration of cost and benefits. Some profile investigations (eg. liver profiles and kidney profiles), which consist of a combined set of tests, are often

ordered for prescribers' convenience. This practice can result in performing unnecessary tests that do not relate to patient management, thus leading to wastage of resources. Therefore, when ordering profile investigations, it is advisable to order only the lipid profile as a profile investigation, while all the other profile investigations should be ordered as individual investigations based on requirements.

- ***Ethical considerations***

Ethical principles such as justice, beneficence, and non-maleficence as well as public health ethics should guide the ordering of investigations. This includes ensuring equitable access to necessary tests for all patients and avoiding the overuse of resources.

4.2 Strategies to improve rational prescription

Establishing a hierarchical diagnostic laboratory framework and setting investigation norms for each level, introducing tiered authorization levels, and introducing after-hour essential investigation lists would effectively improve the rational use of prescription process by improving rational prescription.

4.2.1 Hierarchical laboratory framework and setting investigations norms

4.2.1.1 Hierarchical laboratory framework

Laboratories are classified based on the types of institutions they are established (Table 1). It helps delineate the scope of laboratory services that can be expected at each level, ensuring that tests are ordered and performed in a manner that aligns with the services provided by the institutions, their capabilities, and the availability of resources. This classification will effectively facilitate patient referral system across different levels of healthcare institutions. Furthermore, it helps healthcare administrators assess resource gaps, the performance of laboratories, and the effective allocation of resources.

Table 1: Hiarachial classification of laboratory network

Level of laboratory	Institution	Service provided
Level V	National referral laboratories (MRI)	National reference center for special investigations.
Level IV- A	National Hospitals, Teaching Hospitals, and Specialized Hospitals*	Hematological, biochemical, histopathological, and microbiological investigations including virological, immunological, and hormonal assays.
Level IV - B	District General Hospitals	Hematological, biochemical, histopathological, and microbiological investigations including hormonal assays.
Level III- A	Base Hospital - A	Hematological, biochemical, histopathological, and microbiological investigations. (Pathological investigations are done based on the service need and the availability of resources)
Level III -B	Base Hospital - B	Hematological, and biochemical investigations.
Level II	Divisional Hospital A, B, or C	Basic hematological, and biochemical investigations.
Level I**	PMCU	Blood sugar and serum cholesterol levels using point-of-care devices.

* Laboratories of specialized hospitals such as Apeksha Hospital, Lady Ridgeway Hospital for Children, Castel Street Hospital for Women, De Soysa Maternity Hospital, Sirimavo Bandaranayake Specialized Children's Hospital, and German-Sri Lanka Friendship Hospital for Women are categorized under Level IV laboratories.

** Physically established laboratory and designated Medical Laboratory Technologists are not present at Level I laboratories. Only investigations that can be performed by point-of-care devices are conducted at this level.

4.2.1.2 Investigation norms for laboratory levels and types

Investigation norms based on the level of laboratories will ensure standardized practices across similar levels and differentiate facilities available between various levels. These norms are essential for ensuring that each laboratory is equipped and authorised to perform investigations appropriate to its capabilities and availability of resources. Furthermore, it will promote efficiency in healthcare delivery by ensuring standardized practices that meet the institutional capacity.

The investigation norms for laboratory level by type are listed in Table 2, Table 3, Table 4, and Table 5

Table 2 : Norms for hematological investigations by laboratory level

No	Investigation	Laboratory level				
		IV A	**IV B**	**III A**	**III B**	**II**
1	FBC	✓	✓	✓	✓	✓
2	ESR	✓	✓	✓	✓	✓
3	Reticulocyte count	✓	✓	✓	✓	✓
4	BT*	✓	✓	✓	✓	-
5	PT/INR	✓	✓	✓	✓	-
6	Blood Picture**	✓	✓	✓**	✓**	-
7	APTT	✓	✓	✓	-	-
8	Thrombin time	✓	✓	✓	-	-
9	Plasma Fibrinogen (Functional) ***	✓	✓	✓	-	-
10	Factor correction (Mixing study)	✓	✓	✓	-	-
11	Inhibitor screening	✓	✓	✓	-	-
12	Clot solubility test	✓	✓	✓	-	-
13	Kleihaeuer test	✓	✓	✓	-	-
14	Plasma/urine Hb	✓	✓	✓	-	-
15	Osmotic fragility test	✓	✓	✓	-	-
16	Brewers test	✓	✓	✓	-	-
17	Ham test	✓	✓	✓	-	-
18	Urine Haemosiderin	✓	✓	✓	-	-
19	Sickling test	✓	✓	✓	-	-
20	NAP score	✓	✓	✓	-	-
21	Red cell inclusions	✓	✓	✓	-	-
22	Heat stability test	✓	✓	✓	-	-
23	Methaemoglobin	✓	✓	✓	-	-
24	Cryoglobulin	✓	✓	✓	-	-
25	Bone marrow aspirate & trephine biopsy	✓	✓	✓	-	-
26	D Dimer	✓	✓		-	-

Table 2 (Continued)

No	Investigation	Laboratory level				
		IV A	**IV B**	**III A**	**III B**	**II**
27	DRVVT	✓	✓	-	-	-
28	Thermoelectrometry/Thromboelastogram	✓	✓	-	-	-
29	Hb quantification by HPLC/electrophoresis	✓	✓	-	-	-
30	Clotting Factor assay ***	✓	-	-	-	-
31	Inhibitor assay	✓	-	-	-	-
32	vWAg:Ricof activity ***	✓	-	-	-	-
33	vWF multimer analysis ***	✓	-	-	-	-
34	Platelet function ***	✓	-	-	-	-
35	Flowcytometry ***	✓	-	-	-	-
36	RT-PCR ***	✓	-	-	-	-

* BT - Should be performed on request by a hematologist since its clinical utility has diminished due to less reliability and reproducibility. It's important to perform the test and interpret the result of BT cautiously and in conjunction with other clinical and laboratory findings (Particularly in the case of thrombocytopenia and antiplatelet therapy). It is better to avoid it as a pre-operative investigation.
**Blood Picture – Blood smear and blood samples should be referred to an apex hospital where a Hematologist is available, through an organized referral system
*** Only in selected centres
✓ Appropriate
- Not applicable

Table 3: Norms for biochemical investigations available by laboratory level

No	Investigation	Level of laboratory				
		IV A	**IV B**	**III A**	**III B**	**II**
1	Blood sugar	✓	✓	✓	✓	✓
2	CRP	✓	✓	✓	✓	✓
3	Lipid profile	✓	✓	✓	✓	✓
4	Serum creatinine	✓	✓	✓	✓	✓
5	Troponin I	✓	✓	✓	✓	✓
6	Urine ketone bodies	✓	✓	✓	✓	✓
7	Urine protein	✓	✓	✓	✓	✓
8	Total cholesterol	✓	✓	✓	✓	✓
9	Serum Electrolytes	✓	✓	✓	✓	✓
10	ALT	✓	✓	✓	✓	✓
11	AST	✓	✓	✓	✓	-
12	ALP	✓	✓	✓	✓	-
13	Urine creatinine	✓	✓	✓	✓	-
14	Blood urea	✓	✓	✓	✓	-
15	CSF full report	✓	✓	✓	✓	-
16	Bilirubin - Total	✓	✓	✓	✓	-
17	Bilirubin - Direct	✓	✓	✓	✓	-
18	Gamma GT	✓	✓	✓	✓	-
19	Serum Calcium	✓	✓	✓	✓	-
20	Serum Globulin	✓	✓	✓	✓	-
21	Albumin	✓	✓	✓	✓	-
22	Creatinine kinase	✓	✓	✓	✓	-
23	Fluid full report	✓	✓	✓	✓	-
24	Uric acid	✓	✓	✓	✓	-
25	HbAIC	✓	✓	✓	✓	-
26	LH	✓	✓	✓	-	-
27	Progesterone	✓	✓	✓	-	-
28	Prolactin	✓	✓	✓	-	-
29	ANA	✓	✓	✓	-	-
30	CA 125	✓	✓	✓	-	-
31	CEA	✓	✓	✓	-	-
32	Renin	✓	✓	✓	-	-
33	FSH	✓	✓	✓	-	-
34	Serum Chloride	✓	✓	✓	-	-

Table 3 (Continued)

No	Investigation	Level of laboratory				
		IV A	**IV B**	**III A**	**III B**	**II**
35	S. ferritin	✓	✓	✓	-	-
36	Beta hCG	✓	✓	✓	-	-
37	Iron	✓	✓	✓	-	-
38	LDH	✓	✓	✓	-	-
39	Serum Protein	✓	✓	✓	-	-
40	Serum Phosphorous	✓	✓	✓	-	-
41	Amylase	✓	✓	✓	-	-
42	D-Dimers	✓	✓	✓	-	-
43	Urine micro-Albumin	✓	✓	✓	-	-
44	TSH	✓	✓	✓	-	-
45	Free T3	✓	✓	✓	-	-
46	Free T4	✓	✓	✓	-	-
47	Serum Lithium	✓	✓	-	-	-
48	Serum Magnesium	✓	✓	-	-	-
49	PTH	✓	✓	-	-	-
50	Procalcitonin	✓	✓	-	-	-
51	Serum Cortisol	✓	✓	-	-	-
52	Testosterone	✓	✓	-	-	-
53	Vitamin D level	✓	✓	-	-	-
54	Insulin	✓	✓	-	-	-
55	Osmolality	✓	✓	-	-	-
56	PSA	✓	✓	-	-	-
57	TIBC	✓	✓	-	-	-
58	AFP	✓	✓	-	-	-
59	Aldosterone	✓	-	-	-	-
60	Ammonia	✓	-	-	-	-
61	Fructosamine	✓	-	-	-	-

✓ Appropriate
- Not applicable

Table 4: Norms for histopathological investigations available by laboratory level

No.	Investigation	Level of laboratory		
		IV A	**IV B**	**III A**
1	Tissue biopsy	✓	✓	✓
2	Cytology – FNAC	✓	✓	✓
3	Cytology - Exfoliate (Urine, CSF, sputum)	✓	✓	✓
4	PAP smear	✓	✓	✓
5	Pathological postmortem	✓	✓	✓
6	IHC	✓	-	-
Cytological Investigations to be performed in a Histopathology department				
7	Special stain	✓	✓	✓
8	Immunofluorescence	✓	-	-
9	Molecular test	✓	-	-
10	Frozen section	✓	-	-

✓ Appropriate

- Not applicable

Table 5 : Norms for microbiological investigations available by laboratory level

No	Investigation	Level of laboratory				
		IV A	IV B	III A	III B	II
1	ZN stain for Acid Fast Bacilli (AFB)	✓	✓	✓	✓	✓*
2	Blood culture	✓	✓	✓	-	-
3	CSF and other sterile fluid culture	✓	✓	✓	-	-
4	Gram stain	✓	✓	✓	-	-
5	Serology **	✓	✓	✓	-	-
6	Stool microscopy for ova and cysts	✓	✓	✓	-	-
7	Urine culture & ABST	✓	✓	✓***	-	-
8	Microscopy: Direct fungal smear	✓	✓	✓***	-	-
9	Microscopy: India ink	✓	✓	✓***	-	-
10	Respiratory secretion culture (Broncho alveolar lavage, Sputum, Endotracheal secretions etc.)	✓	✓	✓***	-	-
11	Stool culture	✓	✓	✓***	-	-
12	Pus aspirate culture	✓	✓	✓***	-	-
13	Tissue biopsy/ culture	✓	✓	✓***	-	-
14	Swab culture (when pus or tissue cultures are not possible)	✓	✓	✓***	-	-
15	Identification of bacteria using biochemical tests (catalase, coagulase, oxidase, urease, KIA & etc.)	✓	✓	✓***	-	-
16	Identification of bacteria using commercially available biochemical test kits	✓	✓	✓***	-	-
17	Antibiotic susceptibility using disc diffusion test	✓	✓	✓***	-	-
18	MIC determination by E strips	✓	✓	✓***	-	-
19	Xpert (MTB/RIF) Assay for Mycobacterium tuberculosis	✓	✓	✓***	-	-
20	CSF antigen detection test	✓	✓	✓***	-	-
21	Streptococcal grouping by latex agglutination test	✓	✓	✓***	-	-
22	Dengue NS1 antigen (ICT)	✓	✓	✓***	-	-
23	Dengue antibodies (ICT)	✓	✓	✓***	-	-
24	PCR (following local assessment, depending on the indications & facilities in the institution)	✓	✓	-	-	-
25	Hepatitis B surface antigen (ICT)	✓	✓	-	-	-
26	HIV screening test (ICT)	✓	✓	-	-	-
27	Legionella urinary antigen	✓	✓	-	-	-

Table 5 (Continued)

No	Investigation	Level of laboratory				
		IV A	IV B	III A	III B	II
28	Clostridium dificille GDH antigen in stool	✓	✓	-	-	-
29	Identification of bacteria using automated platforms	✓	-	-	-	-
30	Mycobacterial culture **	✓	-	-	-	-
31	Fungal culture **	✓	-	-	-	-
32	Genotypic detection of antibiotic-resistant markers- following local assessment -at reference lab	✓	-	-	-	-
33	Antibiotic susceptibility using automated platforms	✓	-	-	-	-
34	Drug susceptibility testing for mycobacteria **	✓	-	-	-	-
35	Leptospira serology (ICT)	✓	-	-	-	-
36	Mycoplasma serology (EIA/ Chemiluminescence) **	✓	-	-	-	-
37	Leptospira serology (EIA/ Chemiluminescence)**	✓	-	-	-	-
38	Hepatitis B surface antigen (EIA/ Chemiluminescence)	✓	-	-	-	-
39	Hepatitis B surface antibody titer (EIA/ Chemiluminescence)	✓	-	-	-	-
40	Hepatitis C antibody (EIA/ Chemiluminescence)	✓	-	-	-	-
41	Therapeutic drug monitoring (serum antibiotic level monitoring) **	✓	-	-	-	-
42	Clostridium difficille toxin A and B detection in stool at reference lab	✓	-	-	-	-
43	Melioidosis antibodies **	✓	-	-	-	-

* Only if a trained microscopist is available

** Following local assessment

*** by a trained MLT under a Microbiologist's supervision

✓ Appropriate

- Not applicable

4.2.2. Tiered authorization levels

Three distinct levels of prescribers have been identified as Consultants/Senior Registrars, Medical Officers/Registrars, and House Officers. Specific investigation norms have been established for each level of prescriber based on their role and responsibility to ensure the appropriate selection of investigations while taking into account the clinical needs.

Investigation norms by prescriber level are listed in Table 6, Table 7, Table 8, and Table 9.

Table 6: List of authorised hematological investigations by prescriber level

No	Investigation	Consultant/ Senior Registrar	Medical Officer/ Registrar	Intern Medical Officer
1	FBC	✓	✓	✓
2	ESR	✓	✓	✓
3	Reticulocyte count	✓	✓	✓
4	PT/INR	✓*	✓	✓
5	APTT	✓	✓	-
6	Blood Picture	✓	✓	-
7	BT*	✓	-	-
8	Thrombin test	✓	-	-
9	Pl Fibrinogen (Functional)**	✓	-	-
10	Factor correction (Mixing study)	✓	-	-
11	Inhibitor screening	✓	-	-
12	Clot solubility test	✓	-	-
13	Kleihaeuer test	✓	-	-
14	Plasma/urine Hb	✓	-	-
15	Osmotic fragility test	✓*	-	-
16	Brewers test	✓*	-	-
17	Ham test	✓*	-	-
18	Urine Haemosiderin	✓*	-	-
19	Sickling test	✓*	-	-
20	NAP score	✓*	-	-
21	Red cell inclusions	✓*	-	-
22	Heat stability test	✓*	-	-
23	D Dimer	✓*	-	-

Table 6 (Continued)

No	Investigation	Consultant/ Senior Registrar	Medical Officer/ Registrar	Intern Medical Officer
24	Methaemoglobin	✓*	-	-
25	Cryoglobulin	✓*	-	-
26	Bone marrow aspiration and trephine biopsy	✓*	-	-
27	DRVVT	✓*	-	-
28	Clotting Factor assay **	✓*	-	-
29	Inhibitor assay	✓*	-	-
30	vWAg:Ricof activity **	✓*	-	-
31	vWF multimer analysis **	✓*	-	-
32	Platelet function test **	✓*	-	-
33	Thermoelectrometry/Thromboelastogram	✓*	-	-
34	Hb quantification by HPLC/electrophoresis	✓*	-	-
35	Flowcytometry **	✓*	-	-
36	RT-PCR **	✓*	-	-

* In consultation with a consultant hematologist

** - Only in selected centres

✓ Appropriate

- Not applicable

Table 7: List of authorised biochemical investigations by level of prescriber

No.	Investigation	Consultant/ Senior Registrar	Medical Officer/ Registrar	Intern Medical Officer
1	Troponin I	✓	✓	✓
2	ALP	✓	✓	✓
3	Serum Electrolytes	✓	✓	✓
4	Amylase	✓	✓	✓
5	Bilirubin - Total	✓	✓	✓
6	Bilirubin - Direct	✓	✓	✓
7	Blood sugar	✓	✓	✓
8	CRP	✓	✓	✓
9	Serum creatinine	✓	✓	✓
10	ALT	✓	✓	✓
11	AST	✓	✓	-
12	Beta hCG	✓	✓	-
13	CSF full report	✓	✓	-
14	Lipid profile	✓	✓	-
15	Serum Globulin	✓	✓	-
16	Serum Calcium	✓	✓	-
17	Albumin	✓	✓	-
18	Total Cholesterol	✓	✓	-
19	Serum Chloride	✓	✓	-
20	Serum Protein	✓	✓	-
21	Urine Protein	✓	✓	-
22	Uric Acid	✓	✓	-
23	Urine Creatinine	✓	✓	-
24	Serum Phosphorous	✓	✓	-
25	Fluid full report	✓	✓	-
26	Gamma GT	✓	✓	-
27	Iron	✓	✓	-
28	Serum Magnesium	✓	✓	-
29	Urine Micro-Albumin	✓	✓	-
30	Ammonia	✓	✓	-
31	Blood Urea	✓	✓	-

Table 7 (Continued)

No.	Investigation	Consultant/ Senior Registrar	Medical Officer/ Registrar	Intern Medical Officer
32	HbAIC	✓	✓	-
33	Serum Lithium	✓	✓	-
34	TIBC	✓	-	-
35	AFP	✓	-	-
36	Aldosterone	✓	-	-
37	ANA	✓	-	-
38	CA 125	✓	-	-
39	CEA	✓	-	-
40	Creatinine Kinase	✓	-	-
41	D-Dimers	✓	-	-
42	TSH	✓	-	-
43	Free T3	✓	-	-
44	Free T4	✓	-	-
45	Fructosamine	✓	-	-
46	FSH	✓	-	-
47	Insulin	✓	-	-
48	LDH	✓	-	-
49	LH	✓	-	-
50	Procalcitonin	✓	-	-
51	Progesterone	✓	-	-
52	Prolactin	✓	-	-
53	PSA	✓	-	-
54	PTH	✓	-	-
55	Renin	✓	-	-
56	S. Cortisol	✓	-	-
57	S. ferritin	✓	-	-
58	Testosterone	✓	-	-
59	Osmolality	✓	-	-
60	Vitamin D level	✓	-	-

✓ Appropriate

- Not applicable

Table 8: List of authorised microbiological investigations by level of prescriber

No.	Investigation	Consultant/ Senior Registrar	Medical Officer/ Registrar	Intern Medical Officer
1	Gram stain	✓	✓	✓
2	ZN stain for Acid Fast Bacilli (AFB)	✓	✓	✓
3	Microscopy: Direct Fungal smear	✓	✓	✓
4	Microscopy: India ink	✓	✓	✓
5	Stool microscopy for ova and cysts	✓	✓	✓
6	Blood culture	✓	✓	✓
7	Urine culture	✓	✓	✓
8	CSF and other sterile fluid culture	✓	✓	✓
9	Respiratory secretion culture (Sputum, Endotracheal secretions, Broncho alveolar lavage, etc.)	✓	✓	✓
10	Stool culture	✓	✓	✓
11	Pus aspirate culture	✓	✓	✓
12	Tissue/biopsy culture	✓	✓	✓
13	Swab culture (when pus or tissue cultures are not possible)	✓	✓	✓
14	Mycobacterial culture *	✓	✓	✓
15	Fungal culture *	✓	✓	✓
16	Identification of bacteria using biochemical tests (catalase, coagulase, oxidase, urease, KIA & etc)	✓	✓	✓
17	Identification of bacteria using commercially available biochemical test kits	✓	✓	✓
18	Antibiotic susceptibility using disc diffusion test	✓	✓	✓
19	Streptococcal grouping by latex agglutination test	✓	✓	✓
20	Dengue NS1 antigen (ICT)	✓	✓	✓
21	Dengue antibodies (ICT)	✓	✓	✓
22	Leptospira serology (ICT)	✓	✓	✓
23	Hepatitis B surface antigen (ICT)	✓	✓	✓
24	Genotypic detection of antibiotic-resistant markers *	✓	✓	-
25	Serology	✓	✓	-
26	CSF antigen detection test	✓	✓	-

Table 8 (Continued)

No.	Investigation	Consultant/ Senior Registrar	Medical Officer/ Registrar	Intern Medical Officer
27	HIV screening test (ICT)	✓	✓	-
28	Identification of bacteria using automated platforms	✓	-	-
29	PCR	✓	-	-
30	Antibiotic susceptibility using automated platforms	✓	-	-
31	MIC determination by E strips	✓	-	-
32	Drug susceptibility testing for mycobacteria *	✓	-	-
33	Xpert(MTB/RIF) Assay for Mycobacterium tuberculosis	✓	-	-
34	Legionella urinary antigen	✓	-	-
35	Clostridium difficille toxin A and B detection in stool	✓	-	-
36	Clostridium difficille GDH antigen in stool	✓	-	-
37	Mycoplasma serology (EIA/ Chemiluminescence) *	✓	-	-
38	Leptospira serology (EIA/ Chemiluminescence) *	✓	-	-
39	Melioidosis antibodies *	✓	-	-
40	Hepatitis B surface antigen (EIA/ Chemiluminescence)	✓	-	-
41	Hepatitis B surface antibody titer (EIA/ Chemiluminescence)	✓	-	-
42	Hepatitis C antibody (EIA/ Chemiluminescence)	✓	-	-
43	Therapeutic drug monitoring (serum antibiotic level monitoring) *	✓	-	-

* Following local assessment

✓ Appropriate

- Not applicable

Table 9: List of authorised histopathological investigations by level of prescriber

No	Investigation	Consultant	Medical Officer/ Registrar	Intern Medical Officer
1	PAP	✓	✓	-
2	Biopsies	✓	-	-
3	Cytology – FNAC	✓	-	-
4	Cytology Exfoliation (Urine, CSF, sputum)	✓	-	-
5	IHC	✓*	-	-
6	Pathological postmortem	✓	-	-
Cytological Investigations to be performed in a Histopathology department				
7	Immunofluorescence	✓**	-	-
8	Special stains	✓**	-	-
9	Molecular tests	✓**	-	-
10	Frozen sections	✓**	-	-

* Decided by consultant histopathologist

** Decide collaboration with histopathologist

✓ Appropriate

- Not applicable

4.2.3. After-hour essential investigation list

Healthcare institutions are obligated to provide continuous 24/7 patient care services and laboratory investigations are essential for it. Conducting laboratory investigations incurs costs, which can rise significantly when it is conducted after hours, mainly due to high operational costs. However, certain tests are essential for patient management, and decision-making. On the other hand, they will have a profound impact on patient outcomes. Therefore, considering cost-benefit a list of essential investigations has been selected to be conducted after hours (Table 10).

Table 10: Investigations recommended to be performed after-hours

No.	Investigation	Level of laboratory			
		IV A	IV B	III A	III B
1	Full Blood Count	✓	✓	✓	✓
2	PCV	✓	✓	✓	✓
3	Platelet count	✓	✓	✓	✓
4	PT/INR	✓	✓	✓	✓
5	CSF Sugar	✓	✓	✓	✓
6	CSF Full Count	✓	✓	✓	✓
7	S. Creatinine	✓	✓	✓	✓
8	S. Electrolyte	✓	✓	✓	✓
9	SGOT	✓	✓	✓	✓
10	SGPT	✓	✓	✓	✓
11	Troponin I	✓	✓	✓	✓
12	Amylase	✓	✓	✓	✓
13	Bilirubin - Total	✓	✓	✓	✓
14	Bilirubin -Direct/indirect (Only for pediatric patients)	✓	✓	✓	✓
15	Blood sugar	✓	✓	✓	✓
16	CRP	✓	✓	✓	✓
17	S. Calcium	✓	✓	✓	✓
18	UFR	✓	✓	✓	✓
19	APTT for heparin monitoring	✓	✓	✓	-
20	Blood Picture	✓	✓	✓	-
21	ROTEM	✓	✓	-	-
22	Thermoelectrometry / Thromboelastogram	✓	✓	-	-

✓ Appropriate

- Not applicable

5. Monitoring and evaluation of rational use of investigations

Monitoring and evaluation of the rational use of investigations should involve assessing compliance with Genara Circular No 2 – 118/2024 through regular audits. These audits will be conducted quarterly, as outlined below. The results of the audit should be reviewed during the institutional Laboratory Review Committee meetings. Additionally, a report summarizing the audit findings must be submitted to the Director - Laboratory Services within the first two weeks of the current month.

For any clarification, please contact the officer of Director - Laboratory Services on 112673135.

5.1. Instructions for assessing compliance with General Circular No 2-118/2024

The audit should be conducted by a team designated by the head of the institution.

Frequency: Audits should be conducted quarterly.

Timing: The audit for the previous quarter should be completed within the first month of the following quarter.

Sample selection: Five hundred (500) investigation prescription forms, or 5% of the total forms received during the auditing month (whichever is smaller), should be considered as the sample size. A proportionate sample from every sub-section of the laboratory should be selected randomly for audit.

Audit results should be recorded using the format given below and a summary of the audit should be provided.

5.1.1 Instructions for filling the "Institutional audit format for assessing the compliance with General Circular No 2-118/2024"

Figure 1 : Institutional audit format for assessing the compliance with General Circular No 2-118/2024

Rational Use of Laboratory Investigations – Audit Format

Institution……. **Year & quarter of the audit ……**

No	BHT no/ Clinic no/ OPD no	Name of the Investigation	**Appropriateness for level of Lab[1]**	**Sub-section of laboratory[2]**						**Place of priscription[3]**			**Prescriber[4]**				**Appropriateness of Prescriber[5]**	**Completeness of Request Form[6]**						**Investigation done during[7]**			***If Investigation done after hours*** Is it recommended
				Hematology	Bio-chemistry	Histo-pathology	Microbiology	Night lab	Other	Inward	OPD	Clinic	Intern House Officer	SHO/MO/ Registrar	SR/ Consultant	Unidentified		Name of Patient	Age	BHT no/ Clinic no	Date	Clinical history	Signature of Prescriber	Routine hours	Afterhours	Uncertain	
1																										
⬇																										
500																										
Total																										

Instructions for completing audit format

1- Appropriateness for the level of lab –Decide the appropriateness of the investigation with the level of the laboratory as described above. Mark the cage as "1" if appropriate or "0" if inappropriate.
2- Sub-Section of laboratory – Select and mark only the appropriate cage with "1"
3- Place of prescription – Mark only the appropriate cage with "1"
4- Prescriber – Identify the prescriber and mark only the appropriate cage with "1"
5- Appropriateness of prescriber – Decide whether the prescriber is appropriate for the investigation prescribed and mark the cage with "1" if appropriate or "0" if not appropriate.
6- Completeness of request form – Makr each cage with "1" if the relevant sub-section is present and "0" if absent.
7- Investigation done during – Mark the relevant cage with "1"

8- ***If the Investigation is done after hours*** Is it recommended – Decide whether the investigation is recommended to be conducted after hours. If recommended mark the cage with "1" or if not-recommended mark it with "0".

Figure 2: Example of "Institutional audit format for assessing the compliance with General Circular No 2-118/2024"

Rational Use of Laboratory Investigations – Audit Format

Institution……BH B - Kiribathgoda…… **Year & Month of the audit ……May 2024……**

No	BHT no/ Clinic no/ OPD no	Name of the Investigation	**Appropriateness for level of Lab**	Sub-section of laboratory						Place of prescription			Prescriber				**Appropriateness of Prescriber[5]**	Completeness of Request Form `						Investigation done during			***If Investigation done Afterhours*** Is it recommended
				Hematology	Bio-chemistry	Histo-pathology	Microbiology	Night lab	Other	Inward	OPD	Clinic	Intern House Officer	SHO/MO/ Registrar	SR/ Consultant	Unidentified		Name of Patient	Age	BHT no/ Clinic no	Date	Clinical history	Signature of Prescriber	Routine hours	Afterhours	Uncertain	
1	2214/24	FBC	1	1						1				1			1	1	0	1	0	1	1	1			
	2273/24	CRP	1		1					1					1		1	1	1	1	0	0	1	1			
	2817/24	Amylase	0		1							1		1			0	1	1	1	1	1	1	1			
499	2941/24	UFR	1					1		1						1	1	1	1	1	0	1	0		1		1
500																											
Total			3	1	2			1		3		1		2	1	1	3	4	3	4	1	3	3	3	1		1

* Only in relevant investigations

5.1.2 Rational Use of Laboratory Investigations – Institutional Return

Every institution should send a monthly summary of the audit in the format listed below.

Figure 3: Institutional Return for Rational Use of Laboratory Investigations

Rational Use of Laboratory Investigations – Institutional Return

Name of the institution: .....

Month and year of the audit : .....

Total number of investigations performed during the month:.....

Number of afterhour investigations performed during the month:.....

Total number of request forms audited		
Total no of afterhour investigations audited		
	Number	Percentage
1. Appropriateness of investigations by prescriber		
2. Appropreateness of investigations by laboratory level		
3. Appropreateness of after-hours investigations		
4. Average completeness of documentation		

Rational Use of Laboratory Investigations – Audit Format

Institution……. **Year & quarter of the audit ……**

No	BHT no/ Clinic no/ OPD no	Name of the Investigation	**Appropriateness for level of Lab[1]**	**Sub-section of laboratory[2]**						**Place of priscription[3]**			**Prescriber[4]**				**Appropriateness of Prescriber[5]**	**Completeness of Request Form[6]**						**Investigation done during[7]**			***If Investigation done after hours*** Is it recommended
				Hematology	Bio-chemistry	Histo-pathology	Microbiology	Night lab	Other	Inward	OPD	Clinic	Intern House Officer	SHO/MO/ Registrar	SR/ Consultant	Unidentified		Name of Patient	Age	BHT no/ Clinic no	Date	Clinical history	Signature of Prescriber	Routine hours	Afterhours	Uncertain	
Total																											