

Laboratory Hand Book

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REVISION AND AMENDMENT

Version Change History and Description of Amendment

Revision	Version	Page	Description of	Amendment	Effective	Name &	Name &
No	No	No	Amendment	Date	Date	Signature of	Signature of
						Reviewer	approval



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National HIV Reference Laboratory

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Acknowledgement

The Ethiopian Public Health Institute National HIV Reference Laboratory would like to acknowledge the technical expertise, quality team and the management for their active participation and dedication in the development of this handbook.



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Contact Information and Service Hours

Location	Contact address	Responsible person
Clinical Chemistry Laboratory	0112758328	Mr. Kissi Mudie
Reception	0112133574	Mr. Asmamaw
HIV Molecular lab		Mrs. Kidist Zealiyas
Immunology and Haematology	0112305050	Mr. G/medhin G/micael
National HIV Reference Laboratory Office	0112788057/58	Mr. Atsbeha/Dr. Desta

Service Hours: Laboratories are open for 24 hours (from Monday to Sunday) including holidays.

The address of NHIVRL is clearly written as:

Address

Name of Laboratory: Ethiopian Public Health Institute

National HIV Reference Laboratory

Location: Gullele Sub city Arbegnoch Street

EPHI compound HIV building #3

P.O.Box: 1242/5654

Phone No:-+251-11 -2 788057/58

Fax No: - +251-11-2-78-04-31

Email: NHIVRL@ethionet.et

Website: www.ephi.gov.et

Addis Ababa, Ethiopia



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Vision and Mission of NHIVRL

Vision

To be center of Excellency in HIV research and laboratory diagnostic services in Africa.

Mission

- To provide quality, reliable and cost effective diagnostic services in Molecular, Immunology & hematology and Clinical Chemistry services to our customers.
- To conduct HIV and HIV related research and surveillance activities.
- To provide technical support to regional laboratories and health facilities.
- To provide training on research, surveillance and diagnostic services.
- To provide National EQA program to regional laboratories and federal hospitals.
- To provide advisory service to our customers.



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Background

Since its inception about 70 years ago, the present Institute (Ethiopia Public Health Institute) has contributed a lot for the improvement of public health and nutrition problems of the country in different names and organizational structures. Based on health and nutrition priority areas, the Institute had been setting different strategies at different times to address the public health problem. Currently the Institute is focusing on priority disease research and strengthening the national public health laboratory services in the country. Moreover, the main target area of National Human Immuno Deficiency Virus Reference laboratory (NHIVRL) is conducting HIV surveillance, Research, Capacity building, clinical chemistry test, Immunology & Hematological activities and advanced molecular techniques.

Ethiopian Public Health Institute National HIV Reference Laboratory is responsible for the provision of high level diagnostic laboratory testing services for patients and specimens referred from all Regional and Federal Health facilities. In addition to being the largest clinical laboratory it provides specialized testing and diagnostic consultation for the entire country. The NHIVRL demonstrates and provides leadership and support to:

- Standardize integrated laboratory services for the national laboratory system
- Improve the capacity of the Regional/Federal Laboratories
- Expand and strengthen the External Quality Assessment Programs
- Expand and strengthen standardized training programs for laboratory personnel and other health care `workers
- Improve the management of equipment service and maintenance.
- Develop a Laboratory networking and implementation of an LIS system

This handbook provides information on services offered, quality assurance, laboratory operations, sample collection, transport and agreed turnaround times for end customers.

Scope of the Handbook

This handbook provides a high quality laboratory services and information on how to request laboratory tests of NHIVRL to the health providers and customers.



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Definition of Terms

Test: The intended analysis type required to be analyzed

Patient preparation: The requirements that the patient has to do before sample collection.

Specimen: Biological material which is obtained in order to detect or to measure one or more quantities

Sample: One or more parts taken from a system and intended to provide information on the system.

Container: The appropriate means of holding the sample for storage and transportation.

Specimen volume: The adequate amount of sample required to successfully complete the test.

Transport conditions: The required conditions for transporting the sample. Example, at room temperature, refrigerated, screw caped, triple packed... etc.

Storage condition and stability: The viability and /or integrity of the desired analyte with specified storage temperature for a limited period of time.

Test Requisition: A complete request for the specific test using a standardized request form with all required data for the testing process.

Turn Around Time (TAT): The duration from the time of receipt of the sample at the reception to the time of report delivery to the patient, clinician or referring laboratory.

Reference Range: The clinically acceptable range of a certain analyte for the target population.

Method: The analytical procedure that is used to conduct the test and detect the analyte.

Panic values: Interval of examination results for an alert (critical) test that indicates an immediate risk to the patient of injury or death



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Test Requisition and Result Reporting

Test services provides to the customers who come with complete request forms from authorized Health facilities. Service can also be provided for collected samples with appropriate package, transport temperature and complete, appropriate request forms. All services are charged and free services should be accompanied with support letters from appropriate government body.

Ordered tests are completed and reported according to the established TAT.

Results will be delivered to the customers through;

- Facility representatives (with regularly scheduled service hours)
- Short Message Services(SMS) from the reference laboratory to physician's office
- Directly to the customers
- Postal service

Quality Assurance Programs

Quality assurance program is an integral part of daily operations at NHIVRL. The program is overseen and administered by qualified technical experts working for continual improvement of testing quality.

All tests provided are conducted after Quality control (QC) passed. QC is a system or process for monitoring the quality of laboratory testing performance.

All laboratories participate in External quality Assessment scheme, a tool to assess laboratory performances.

NHIVRL are also enrolled in ISO accreditation schemes which will assure quality of laboratory services provided.

List of NHIVRL laboratory tests

Laboratory tests provided by NHIVRL are:-

- Clinical chemistry tests
- Immunology and hematology tests
- ➤ HIV Molecular tests



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Clinical chemistry tests

Liver function panel

1. Alpha-Fetoprotein, AFP

Patient preparation	Not necessary
Sample Type	Serum
Container	Red-Stopper tube or Serum-Separator tube
Volume	2 ml of serum or 3-5 ml of whole blood
Transport	Serum should be transported immediately on ice
Storage	Keep serum in refrigerator 2-8°c for 7 days or store in freezer at -20°c temp. up to 3 months
Stability	Serum is stable for 7 days at 2-8°c and for 3 month at -20°c
Method	Electrochemiluminescence immunoassay
Reference range	Up to 5.8 U/ml (Including non-Pregnant women)
Turnaround time	48hrs

2. Albumin

Patient preparation	Not necessary
Sample Type	Serum
Container	Red-Stopper tube or Serum-Separator tube
Volume	2 ml of serum or 3-5 ml of whole blood
Transport	Serum should be transported immediately on ice
Storage	Keep serum in refrigerator 2-8°c for 3 Days or store in freezer at -20°c temp. up to 6 months and indefinitely at -70°c
Stability	Serum is stable for less than 3 days at 2-8°c and 6 month at -20°c and at -70°c for indefinitely
Method	Photometric
Reference range	Adults 18-60 years 3.5-5.0 g/dl
	Aged > 60 years3.4-4.8 g/dl
	Children 4 days -14 years3.8 -5.4 g/dl
	Newborns 0-4 Days2.8-4.4 g/dl
Turnaround time	48hrs

3. Alkaline Phosphatase (ALP)

Patient preparation	Not necessary
Sample Type	Serum
Container	Red-Stopper tube or Serum-Separator tube
Volume	2 ml of serum or 3-5 ml of whole blood
Transport	Serum should be transported immediately on ice
Storage	Keep serum in refrigerator 2-8°c for 5 days or store in freezer at -20°c for up to 3 months
	up to 3 months





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Stability Serum is stable for 5 days at 2-8°c and for 3 month at -20°c Method Photometric Reference range Adults: 40-1291U/I for Male and 35-104IU/I for Female Aged 1 Days -250 U/L Aged 2 Days -231 U/L Aged 6 days -6 months -449 U/L Age 1-3 Years -281 U/L Aged 4-6 years -200 U/L Aged 3-17 Years (M) -300U/L Aged 13-17 Years (M) -390U/L Turnaround time 48hrs 4. Alanine Aminotransferase, ALT/GPT Patient preparation Not necessary Sample Type Serum Container Red-Stopper tube or Serum-Separator tube Volume 2 ml of serum or 3-5 ml of whole blood Transport Serum is stable for 7 days at 2-8°c or 1 day at 20-25°c Stability Serum is stable for 7 days at 2-8°c or 1 day at 20-25°c Method Photometric Reference range Females up to 31 U/L Male up to 41 U/L Male up to 41 U/L Turnaround time 48hrs 5. Asparate Aminotransferase/AST/GOT Red-Stopper tube or Serum-Sep		
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Aged 1 Days	Method	
Aged 2 Days	Reference range	
Aged 6 days - 6 months		
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Aged 7-12 Years		
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Sample TypeSerumContainerRed-Stopper tube or Serum-Separator tube	6. Bilirubin Total	
Container Red-Stopper tube or Serum-Separator tube	Patient preparation	Not necessary
Container Red-Stopper tube or Serum-Separator tube	Sample Type	Serum
· • • • • • • • • • • • • • • • • • • •		Red-Stopper tube or Serum-Separator tube
	Volume	-



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T	C	
Transport	Serum should be transported immediately.	
Storage	Keep serum in refrigerator 2-8°c for 7 days or store in freezer at -20°c temp. up to 6 months	
Stability	Serum is stable for 7 days at 2-8°c and for 6 month at -20°c	
Method	Photometric	
Reference range	Adults and Children<1.0mg/dl	
	Neonates premature (3-5D)<15.0 mg/dl	
	Neonates premature (2D)<8mg/dl	
	Neonates premature (1D)< 6.0mg/dl	
	Neonates (3-5D)<12.0 mg/dl	
	Neonates (2D)<7mg/dl	
	Neonates (1D)<6mg/dl	
Turnaround time	48hrs	
7. Bilirubin Direc		
Patient preparation	Not necessary	
Sample Type	Serum	
Container	Red-Stopper tube or Serum-Separator tube	
Volume Transport	2 ml of serum or 3-5 ml of whole blood	
Transport	Serum should be transported immediately 2-8c.	
Storage	Serum is stable for 2 days at room temperature, 7 days at 2-8°c and for 6 mor at -20°c	
Stability	Serum is stable for 2 days at room temp. 2-8°c for 7 days or Store in at -20°c temp. for 6 months Protect Specimens from exposure to light.	
Method	Photometric	
Reference range	0-0.2 mg/dl	
Turnaround time	48hrs	
8. GGT		
Patient preparation	Not necessary	
Sample Type	Serum	
Container	Red-Stopper tube or Serum-Separator tube	
Volume	2 ml of serum or 3-5 ml of whole blood	
Transport	Serum should be transported immediately 2-8c.	
Storage	2-8°c	
Stability	Serum is stable for 7 days at 2-8°c and 7 days at room temperature 15-25°c,1year at (-15)-(-25°c)	
Method	Enzymatic colorimetric assay	
Reference range	Men: 8-61u/l Women: 5-36 u/l	
Turnaround time	48hrs	



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Patient preparation	Not necessary
Sample Type	Serum
Container	Red-Stopper tube or Serum-Separator tube
Volume	2 ml of serum or 3-5 ml of whole blood
Transport	Serum should be transported immediately 2-8c.
Storage	7 days at 15-25°c. 4 days at 2-8°c and for 6 weeks at -20°c
Stability	Serum is stable for 7 days at room temp. 2-8°c for 4 days or Store in at -20°c temp. For 6 weeks. LDH is affected by cooled and frozen samples.
Method	UV-assay
Reference range	240-480u/l at 37°c
Turnaround time	48hrs

Tumor Marker Panel

1 Carbohydrate Antigen 125 CA-125

1. Carbohydrate Antigen 125, CA-125	
Patient preparation	Not necessary
Sample Type	Serum
Container	Red-Stopper tube or Serum-Separator tube
Volume	2 ml of serum or 3-5 ml of whole blood
Transport	Serum should be transported immediately 2-8c.
Storage	Keep serum in refrigerator 2-8°c for 7 Days or store in freezer at -20°ctemp. up to 3 months
Stability	Serum is stable for 7 days at 2-8°c and for 3 month at -20°c
Method	Electrochemiluminescence immunoassay
Reference range	Up to 35 U/L
Turnaround time	48hr
2. Carbohydrate Antigen 15-3 (CA-15-3)	
Patient preparation	Not necessary
Sample Type	Serum
Container	Red-Stopper tube or Serum-Separator tube

	<u> </u>
Patient preparation	Not necessary
Sample Type	Serum
Container	Red-Stopper tube or Serum-Separator tube
Volume	2 ml of serum or 3-5 ml of whole blood
Transport	Serum should be transported immediately 2-8c.
Storage	Keep serum in refrigerator 2-8°c for 7 Days or store in freezer at -20
	temp. up to 3 months
Stability	Serum is stable for 7 days at 2-8°c or 3 Months at -20°c
Method	Electrochemiluminescence immunoassay
D. C	II + 00 II 1
Reference range	Up to 25 U/ml
Turnaround time	48hrs

Turnaround time

3. Carbohydrate Antigen 19-9, CA-19-9

Patientpreparation	Not necessary
Sample Type	Serum
Container	Red-Stopper tube or Serum-Separator tube
Volume	2 ml of serum or 3-5 ml of whole blood



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Transport	Serum should be transported immediately 2-8c.
Storage	Keep serum in refrigerator 2-8°c for 7 Days or store in freezer at -20°c temp. up to 1 months
Stability	Serum is stable for 7 days at 2-8°c and for 1 month at -20°c
Method	Electrochemiluminescence immunoassay
Reference range	Up to 27 U/ml
Turnaround time	48hr
4. Carcinoembryon	nic Antigen (CEA)
Patient preparation	Not necessary
Sample Type	Serum
Container	Red-Stopper tube or Serum-Separator tube
Volume	2 ml of serum or 3-5 ml of whole blood
Transport	Serum should be transported immediately 2-8c.
Storage	Keep serum in refrigerator 2-8°c for 7 Days or store in freezer at -20°c temp. up to 6 months.
Stability	Serum is stable for 7 days at 2-8°c or 3 Months at -20°c
Method	Electrochemiluminescence immunoassay
Reference range	Up to 25 U/ml
Turnaround time	48hr
5. Thyroglobulin,	 Γσ
Patient preparation	Not necessary
Sample Type	Serum
Container	Red-Stopper tube or Serum-Separator tube
Volume	2 ml of serum or 3-5 ml of whole blood
Transport	Serum should be transported immediately 2-8c.
Storage	Keep serum in refrigerator 2-8°c for 7 Days or store in freezer at -20°c temp. up to 1 months
Stability	Serum is stable for 7 days at 2-8°c and for 1 month at -20°c
Method	Electrochemiluminescence immunoassay
Reference range	2-70 ng/ml
Turnaround time	24 hr
6. CA72-4	N
Patient preparation	Not necessary
Sample Type	Serum
Container	Red-Stopper tube or Serum-Separator tube
Volume	2 ml of serum or 3-5 ml of whole blood
Transport	Serum should be transported immediately 2-8c.
Storage	Serum is stable for 30 days at 2-8°c, 3 months °c at -20°c
Stability	stable for 30 days at 2-8°c, 3 months °c at -20°c
Method	Electrochemiluminescence immunoassay
Reference range	5.6-8.2U/ml



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Turnaround time	48hrs
7. Acid Phosphatas	e
patient preparation	Not necessary
Sample Type	Serum
Container	Red-Stopper tube or Serum-Separator tube
Volume	2 ml of serum or 3-5 ml of whole blood
Transport	Serum should be transported immediately 2-8c.
Storage	Serum is stable for 8 days at room temp. 8 days at 2-8°c and for 4 month at -20°c
Stability	Serum is stable for 8 days at room temp. 2-8°c for 8 days or Store in at (-15)-(-20) °c temp. for 4 months Protect Specimens from exposure to light.
Method	Colorimetric
Reference range	Men: < 6.6 U/L Women:< 6.5 U/L
Turnaround time	48hr
8. Prostate-specific antigen Total, TPSA	

Patient preparation	Not necessary
Sample Type	Serum
Container	Red-Stopper tube or Serum-Separator tube
Volume	2 ml of serum or 3-5 ml of whole blood
Transport	Serum should be transported immediately 2-8c.
Storage	Keep serum in refrigerator 2-8°c for 5 Days or store in freezer at -20°c temp. up to 6 months
Stability	Serum is stable for 5 days at 2-8°c and for 6 month at -20°c
Method	Electrochemiluminescence immunoassay

Reference range

Age	Reference Range
<40	Up to 1.4
40-50	Up to 2.0
50-60	Up to 3.1
60-70	Up to 4.1
>70	Up to 4.4

Turnaround time 24 hr

9. Prostate-Specific Antigen Free, FPSA

Patient preparation	Not necessary
Sample Type	Serum
Container	Red-Stopper tube or Serum-Separator tube
Volume	2 ml of serum or 3-5 ml of whole blood
Transport	Serum should be transported immediately 2-8c.
Storage	Keep serum in refrigerator 2-8°c for 5 Days or store in freezer at -20°c temp. up
	to 6 months



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Stability	Serum is stable for 5 days at 2-8°c and for 6 month at -20°c
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Method Electrochemiluminescence immunoassay

Reference range Not applicable

If Total PSA results between 4-10, uses free PSA to calculate % free PSA. The ratio is useful when used in conjugation with the Elecsys total PSA tests as an aid in distinguishing Prostate Cancer from being Prostatic conditions in Male Age 50 years or older who have a digital examination that is not suspicious for prostate Cancer.

%FPSA= \underline{FPSA} X 100 TPSA

Turnaround time 24 hrs

10. Human Chorionic Gonadotropin (HCG-Beta), Beta Subunit

Patient preparation	Not necessary
Sample Type	Serum
Container	Red-Stopper tube or Serum-Separator tube
Volume	2 ml of serum or 3-5 ml of whole blood
Transport	Serum should be transported immediately 2-8c.
Storage	Keep serum in refrigerator 2-8°c for 3 Days or store in freezer at -20°c temp. up
	to 12 months
Stability	Serum is stable for 3 days at 2-8°c and for 12 month at -20°c
Method	Electrochemiluminescence immunoassay
Reference range	Up to 2.6 mIU/ml for Male,
	up to 8.30 mIU/ml for postmenopausal women
	Un to 5.2 mHJ/ml for non prognant promononousel woman

Up to 5.3 mIU/ml for non-pregnant premenopausal women

Turnaround time 72 hrs

Lipid Panel

1. Cholesterol, Total

1. Cholesterol, To	otai			
Patient preparation	Fasting for 12 hours is required prior to the test. Water is permitted. No			
	alcohol is allowed	d for 24 hours	prior to the te	st.
Sample Type	Serum			
Container	Red-Stopper tub	e or Serum-Se	eparator tube	
Volume	2 ml of serum or	3-5 ml of wh	ole blood	
Transport	Serum should be transported immediately 2-8c.			8c .
Storage	Keep serum in refrigerator 2-8°c for5- 7 Days or store in freezer at -20°c temp. up to 3 months			
Stability	Serum is stable for 5- 7 days at 2-8°c and for 3 month at -20°c			
Method	Photometric			
Reference range	Clinical Interpretations according to the recommendations of the European Atherosclerosis Society *			
		mmol/l	mg/dl	Lipid metabolism
				disorder
	Cholesterol	< 5.2	< 200	NO
	Triglycerides	<2.3	< 200	



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Cholesterol	5.2-7.8	200- 300	YES, if HDL-Cholesterol <0.9 mmol/l (<35mg/dl)
Cholesterol	>7.8	>300	Yes
Triglycerides	>2.3	>200	

Turnaround time

48hrs

1. High-density lipoprotein, HDL

7 1				
Patient preparation	Not necessary			
Sample Type	Serum			
Container	Red-Stopper tube or Serum-Separator tube			
Volume	2 ml of serum or 3-5 ml of whole blood			
Transport	Serum should be transported immediately 2-8c.			
Storage	Keep serum in refrigerator 2-8°c for 7 Days or store in freezer at -70°c temp. up			
	to 1 months			
Stability	Serum is stable for 7 days at 2-8°c and for 1 month at -70°c			
Method	Electrochemiluminescence immunoassay			
Reference range	No risk Moderate risk High risk			
	IVO IISK IVIOGETATE IIISK IIIISK			

	No risk	Moderate risk	High risk
Females	>65 mg/dl	45-65 mg/dl	<45 mg/dl
Males	>55 mg/dl	35-55 mg/dl	<35 mg/dl

Turnaround time 24 hrs

2. LDL

Patient Not necessary

preparation

Sample Type Serum

Container Red-Stopper tube or Serum-Separator tube **Volume** 2 ml of serum or 3-5 ml of whole blood

Transport Serum should be transported immediately 2-8c.

Storage Keep serum in refrigerator 2-8°c for 7 Days or store in freezer at -70°c temp. up to

12 months

Stability Serum is stable for 7 days at 2-8°c and for 12 month at -70°c

Method colorimetric

Reference rangeoptimalAbove optimalBorderline highHighVery highUnitadult<100</td>100-129130-159160-189≥ 190mg/dl

Turnaround time 24 hrs

3. Triglycerides

Patient preparation	Fasting is required for 12 hours before the test. Water intake is allowed.
Sample Type	Serum
Container	Red-Stopper tube or Serum-Separator tube
Volume	2 ml of serum or 3-5 ml of whole blood
Transport	Serum should be transported immediately 2-8c.
Storage	Keep serum for 7 days 2-8°c or





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	3 months at -20°c t	emp. or several y	years at -70°c
Stability	Serum is stable for	7 days at at 2-8°	°c, for 6 month at -20°c and several years
	at -70°c		
Method	Photometric		
Reference range	Clinical interpretat	ions according to	the recommendations of the European
G	Atherosclerosis So	•	
		mg/dl	Lipid metabolism disorder
	Cholesterol	<200	No
	Triglycerides	< 200	
	Cholesterol	200-300	Yes, if HDL-Cholesterol
			<035 mg/dl
	Cholesterol	>300	Yes
	Triglycerides	>200	
Turnaround time	24 hrs		

Turnaround time

Cardiac Panel

1. Creatine Kinase Total, CK

Patient preparation	Do not administer any intramuscular injections for 1 hour prior to the test.
Sample Type	Serum
Container	Red-Stopper tube or Serum-Separator tube
Volume	2 ml of serum or 3-5 ml of whole blood
Transport	Serum should be transported immediately 2-8c.
Storage	Keep serum in refrigerator 2-8°c for 7 Days or store in freezer at -20 temp. up to 4 Weeks or at room temp. for 2 days
Stability	Serum is stable for 7 days at 2-8°c or 4 Weeks at -20°c or room temp. for 2 days
Method	Photometric
Reference range	Females26-192U/L
	Males39-308 U/L
	Note
	Myocardial infarction: There is a high probability of Myocardial damage when the
	following three conditions are fulfilled.
	1. CK Men>190U/L
	2. CK Women>167U/L
	3. CK-MB>24 U/L
	The CK-MB activity accounts for 6-25% of the total CK activity.
Turnaround time	2 hours

2. Creatine Kinase (CK), MB

Patient preparation	Inform the patient that this test is often performed on three consecutive days, and
	again in one week, necessitating multiple Venipuncture.
Sample Type	Serum
Container	Red-Stopper tube or Serum-Separator tube
Volume	2 ml of serum or 3-5 ml of whole blood
Transport	Serum should be transported immediately 2-8c.
Storage	Keep serum in refrigerator 2-8°c for 5 Days or room temp. for only 2 hours.
Stability	Serum is stable for 5 days at 2-8°c and for or room temp. for only 2 hours.
Method	Photometric
Reference range	Reference rang 7-25U/L
	Note





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	Myocardial infarction: There is a high probability of Myocardial damage when
	the following three conditions are fulfilled.
	1. CK Men>190U/L 2. CK Women>167U/L
	3. CK-MB>24 U/L
	The CK-MB activity accounts for 6-25% of the total CK activity
Turnaround time	2 hrs
3. Troponin T hs S	STAT
Patient preparation	Not necessary
Sample Type	Serum
Container	Red-Stopper tube or Serum-Separator tube
Volume	2 ml of serum or 3-5 ml of whole blood
Transport	Serum should be transported immediately 2-8c.
Storage	Keep serum for 7 days at 2-8°c
	3 months at -20°c temp. or several years at -70°c
Stability	Stable for 24 hrs at 2-8°c, 12 month at -20°c freeze only once.
Method	Immunoassay
Reference range	0-14pg/ml
Turnaround time	24 hrs
4. D-Dimer	
Patient preparation	Not necessary
Sample Type	Serum
Container	Red-Stopper tube or Serum-Separator tube
Volume	2 ml of serum or 3-5 ml of whole blood
Transport	Serum should be transported immediately 2-8c.
Storage	Keep serum for 7 days at 2-8°c
	3 months at -20°c temp. or several years at -70°c
Stability	3 months at -20°c temp. or several years at -70°c
	•
Stability	3 months at -20°c temp. or several years at -70°c Stable for 8 hrs at room temp. 4 days at 2-8°c, 6 month at(-15)- (-25)°c
Stability Method	3 months at -20°c temp. or several years at -70°c Stable for 8 hrs at room temp. 4 days at 2-8°c, 6 month at(-15)- (-25)°c Immunoturbidimetric assay
Stability Method Reference range	3 months at -20°c temp. or several years at -70°c Stable for 8 hrs at room temp. 4 days at 2-8°c, 6 month at(-15)- (-25)°c Immunoturbidimetric assay < 0.5 µg /U/mL
Stability Method Reference range Turnaround time	3 months at -20°c temp. or several years at -70°c Stable for 8 hrs at room temp. 4 days at 2-8°c, 6 month at(-15)- (-25)°c Immunoturbidimetric assay < 0.5 µg /U/mL
Stability Method Reference range Turnaround time 5. CRP hs	3 months at -20°c temp. or several years at -70°c Stable for 8 hrs at room temp. 4 days at 2-8°c, 6 month at(-15)- (-25)°c Immunoturbidimetric assay < 0.5 µg /U/mL 24 hrs
Stability Method Reference range Turnaround time 5. CRP hs Patient preparation	3 months at -20°c temp. or several years at -70°c Stable for 8 hrs at room temp. 4 days at 2-8°c, 6 month at(-15)- (-25)°c Immunoturbidimetric assay < 0.5 µg /U/mL 24 hrs Not necessary
Stability Method Reference range Turnaround time 5. CRP hs Patient preparation Sample Type	3 months at -20°c temp. or several years at -70°c Stable for 8 hrs at room temp. 4 days at 2-8°c, 6 month at(-15)- (-25)°c Immunoturbidimetric assay < 0.5 µg /U/mL 24 hrs Not necessary Serum
Stability Method Reference range Turnaround time 5. CRP hs Patient preparation Sample Type Container	3 months at -20°c temp. or several years at -70°c Stable for 8 hrs at room temp. 4 days at 2-8°c, 6 month at(-15)- (-25)°c Immunoturbidimetric assay < 0.5 µg /U/mL 24 hrs Not necessary Serum Red-Stopper tube or Serum-Separator tube
Stability Method Reference range Turnaround time 5. CRP hs Patient preparation Sample Type Container Volume	3 months at -20°c temp. or several years at -70°c Stable for 8 hrs at room temp. 4 days at 2-8°c, 6 month at(-15)- (-25)°c Immunoturbidimetric assay < 0.5 µg /U/mL 24 hrs Not necessary Serum Red-Stopper tube or Serum-Separator tube 2 ml of serum or 3-5 ml of whole blood
Stability Method Reference range Turnaround time 5. CRP hs Patient preparation Sample Type Container Volume Transport	3 months at -20°c temp. or several years at -70°c Stable for 8 hrs at room temp. 4 days at 2-8°c, 6 month at(-15)- (-25)°c Immunoturbidimetric assay < 0.5 µg /U/mL 24 hrs Not necessary Serum Red-Stopper tube or Serum-Separator tube 2 ml of serum or 3-5 ml of whole blood Serum should be transported immediately 2-8c.
Stability Method Reference range Turnaround time 5. CRP hs Patient preparation Sample Type Container Volume Transport Storage	3 months at -20°c temp. or several years at -70°c Stable for 8 hrs at room temp. 4 days at 2-8°c, 6 month at(-15)- (-25)°c Immunoturbidimetric assay < 0.5 µg /U/mL 24 hrs Not necessary Serum Red-Stopper tube or Serum-Separator tube 2 ml of serum or 3-5 ml of whole blood Serum should be transported immediately 2-8c. Stable for 11days at 15-25°c. 2 months at 2-8°c, 3 years at(-15)- (-25)°c
Stability Method Reference range Turnaround time 5. CRP hs Patient preparation Sample Type Container Volume Transport Storage Stability	3 months at -20°c temp. or several years at -70°c Stable for 8 hrs at room temp. 4 days at 2-8°c, 6 month at(-15)- (-25)°c Immunoturbidimetric assay < 0.5 μg /U/mL 24 hrs Not necessary Serum Red-Stopper tube or Serum-Separator tube 2 ml of serum or 3-5 ml of whole blood Serum should be transported immediately 2-8c. Stable for 11days at 15-25°c. 2 months at 2-8°c, 3 years at(-15)- (-25)°c Stable for 11days at 15-25°c. 2 months at 2-8°c, 3 years at(-15)- (-25)°c



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7D 1.40	< 0.5 < 5.0 < 47.6
Turnaround time	24 hrs
Renal function panel	
1. Creatinine	
Patient preparation	Not necessary
Sample Type	Serum
Container	Red-Stopper tube or Serum-Separator tube
Volume	2 ml of serum or 3-5 ml of whole blood
Transport	Serum should be transported immediately 2-8c.
Storage	Keep serum at room temperature for 7 days, or 7 days at 2-8°c or 3months at - 20°c temp.
Stability	Serum is stable for 7 days at room temp. 2-8°c for 7 days or Store in at -20°c temp. for 3 months
Method	Photometric
Reference range	Adult Females
	Adult Males0.70-1.20mg/dl
	Children
	Neonates (Premature)0.29-1.04mg/dl
	Neonates (Full term)0.24- 0.85mg/dl 2-12 M0.17-0.42mg/dl
	1-<3Y0.24-0.41mg/dl
	3-<5Y0.31-0.47mg/dl
	5-<7Y0.32-0.59mg/dl
	7-<9Y0.40-0.60mg/dl
	9-<11Y0.39-0.73mg/dl
	11-<13Y0.53-0.79mg/dl
	13-<15Y0.57-0.87mg/dl
Turnaround time	24 hrs
2. Total Protein	
Patient preparation	Not necessary
Sample Type	Serum
Container	Red-Stopper tube or Serum-Separator tube
Volume	2 ml of serum or 3-5 ml of whole blood
Transport	Serum should be transported immediately 2-8c.
Storage	Keep serum in refrigerator 2-8°c for 3 Days or store in freezer at -20°c temp.
~	up to 6 months
Stability	Serum is stable for 2 days at 2-8°c and for 6 month at -20°c
Method	Photometric
Reference range	Adults(ambulatory)6.4-8.3g/dl
	>3years
	1-2 years5.6-7.5g/dl
	7 months-1years5.1-7.3g/dl
	1 week
	Newborn
	Premature3.6-6.0g/dl
Turnaround time	Umbilical cord4.8-8.0 g/dl 24 hrs
Turnarvunu tille	4T III 3





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3. Cystatin C

Patient preparatio	n Not necessary
Sample Type	Serum
Container	Red-Stopper tube or Serum-Separator tube
Volume	2 ml of serum or 3-5 ml of whole blood
Transport	Serum should be transported immediately 2-8c.
Storage	
Stability	Serum is stable for 7 days at 4 ° C _{25, 26} . 7 days at (-20)-(-25) °c, 24 months at -
	25°c.
Method	Immunoturbidimetric assay
Reference range	
Turnaround time	24 hrs
4. Potassium, K+	
Patient preparatio	Not necessary
Sample Type	Serum
Container	Red-Stopper tube or Serum-Separator tube
Volume	2 ml of serum or 3-5 ml of whole blood
Transport	Serum should be transported immediately 2-8c.
Storage	Keep serum in refrigerator 48 hours at room temperature, 2-8°c for 7 Days or
Storage	store in freezer at -20°c temp. up to 1 months
Stability	Serum is stable for 7 days at 2-8°c and for 1 month at -20°c
Method	Ion selective Method
Reference range	3.5 – 5.1 mmol/l
Turnaround time	24 hrs
5. Uric Acid	211113
Patient preparatio	n Not nagaggary
	Not necessary Serum
Sample Type Container	Red-Stopper tube or Serum-Separator tube
Volume	2 ml of serum or 3-5 ml of whole blood
Transport	Serum should be transported immediately 2-8c.
Storage	Keep serum for 5 days 2-8°c at -20°c temp. up to 6 months
Stability	Serum is stable for 5 days at 2-8°c and for 6 month at -20°c
Method	Photometric
Reference range	Females<5.7md/dl
Reference range	Males (≤65years)<7.0mg/dl
	` ' '
Turnaround time	Females(≥65years)<8.4 mg/dl 24 hrs
6. Urea/BUN	24 1113
Patient preparatio	n Not necessary
Sample Type	Serum
Container	Red-Stopper tube or Serum-Separator tube
Volume	2 ml of serum or 3-5 ml of whole blood
Transport	Serum should be transported immediately 2-8c.
Storage	Keep serum for 7 days at room temperature, or 7 days at 2-8°c or 1 year at - 20°c.
	20 0.



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Stability Serum is stable for 7 days at room temperature, or 7 days at 2-8°c or 1 year at

-20°c.

Method Photometric 10-50 mg/dl Reference range

> Conversion Factors from Urea to Bun mg/dl urea X 0.467= mg/dl urea nitrogen

Turnaround time 24 hrs

Anemia Panel

1. Ferritin	
Patient preparation	Not necessary
Sample Type	Serum
Container	Red-Stopper tube or Serum-Separator tube
Volume	2 ml of serum or 3-5 ml of whole blood
Transport	Serum should be transported immediately 2-8c.
Storage	Keep serum in refrigerator 2-8°c for 7 Days or store in freezer at -20°c temp. up to 6 months
Stability	Serum is stable for 7 days at 2-8°c and for 6 month at -20°c
Method	Electrochemiluminescence immunoassay
Reference range	Malesng/ml
	Femalesng/ml
Turnaround time	72hrs
2. Transferrin	
Patient preparation	Fasting is required for 12 hours before the test. Water intake is allowed.
Comple Type	Comm

Sample Type Serum Container Red-Stopper tube or Serum-Separator tube 2 ml of serum or 3-5 ml of whole blood Volume Serum should be transported immediately 2-8c. **Transport Storage** Keep serum for 7 days at room temp. or 7 days at 2-8°c or in freezer at -20°c temp. up to 6 months

Serum is stable for 7 days at room temp.,7 days at 2-8°c and for 6 month at

Method Immunoturbidimeteric assay

Reference range 2.0-3.6g/L**Turnaround time** 24hrs

2 Folate, Serum

Stability

Patient preparation Not necessary

Sample Type	Serum
Container	Red-Stopper tube or Serum-Separator tube
Volume	2 ml of serum or 3-5 ml of whole blood
Transport	Serum should be transported immediately 2-8c.
Storage	Keep serum at room temperature for 2 hours, in refrigerator at 2-8°c for days or store in freezer at -20 temp. up to 1 months
Stability	Serum is stable for 2 hours at room temp. 2-8°c for 2 days and 1 Months at 20°c
Method	Electrochemiluminescence immunoassay
Reference range	0.640-20.0 ng/ml
Turnaround time	72hrs

3. Vitamin B12 OR Cyanocobalamin





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Patient preparation	Fasting specimen preferred; must draw before Schilling's test, transfusions or B12 therapy is started.
Sample Type	Serum
Container	Red-Stopper tube or Serum-Separator tube
Volume	2 ml of serum or 3-5 ml of whole blood
Transport	Serum should be transported immediately 2-8c.
Storage	Keep serum for 2 days 2-8°c, 2 months at -20°c temp. freeze once only.
Stability	Serum is stable for 2 days at
•	2-8°c and for 2 month at -20°c.
Method	Electrochemiluminescence immunoassay
Reference range	197-866 pg/ml
Turnaround time	72hrs
<u>4.</u> Iron	
Patient preparation	Not necessary
Sample Type	Serum
Container	Red-Stopper tube or Serum-Separator tube
Volume	2 ml of serum or 3-5 ml of whole blood
Transport	Serum should be transported immediately 2-8 °C.
Storage	Keep serum for 2 days 2-8°c, 2 months at -20°c temp. freeze once only
Stability	7 days at 15-25 °C,3 weeks at 2-8 °C, several years at (-15)-(-25) °C
Method	Colorimetric assay
Reference range	5.83-34.5 μmol/L (33-193 μg/dL)
Turnaround time	24 hrs
Thyroid Function par	nel
1. Triiodothyronine	
Patient preparation	Fasting for 8 to 10 hours is required before the test.
Sample Type	Serum
Container	Red-Stopper tube or Serum-Separator tube
Volume	2 ml of serum or 3-5 ml of whole blood
Transport	Serum should be transported immediately 2-8c.
Storage	Keep serum in refrigerator 2-8°c for 2 Days or store in freezer at -20°c temp. up
	to 6 months
Stability	Serum is stable for 2 days at 2-8°c and for 6 month at -20°c
Method	Electrochemiluminescence immunoassay
Reference range	15 – 65 pg/ml
Turnaround time	24 hrs
2. Thyroxin, T4	
Patient preparation	Not necessary
Sample Type	Serum
Container	Red-Stopper tube or Serum-Separator tube
Volume	2 ml of serum or 3-5 ml of whole blood
Transport	Serum should be transported immediately 2-8c.
Storage	Keep serum in refrigerator 2-8°c for 7 Days or store in freezer at -20°c temp. up
C4 - 1:11:4	to 1 months
Stability	Serum is stable for 7 days at 2-8°c and for 1 month at -20°c
Method	Electrochemiluminescence immunoassay





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Reference range	$5.1 - 14.1 \mu g/dl$
Turnaround time	24hrs
3. Free Triiodothyr	onine, FT3
Patient preparation	Not necessary
Sample Type	Serum
Container	Red-Stopper tube or Serum-Separator tube
Volume	2 ml of serum or 3-5 ml of whole blood
Transport	Serum should be transported immediately 2-8c.
Storage	Keep serum in refrigerator 2-8°c for 7 Days or store in freezer at -20°c temp. up to 1 months
Stability	Serum is stable for 7 days at 2-8°c and for 1 month at -20°c
Method	Electrochemiluminescence immunoassay
Reference range	2.0- 4.4 pg/dl
Turnaround time	48hrs
4. Thyroxin Free, F	T4
Patient preparation	Not necessary
Sample Type	Serum
Container	Red-Stopper tube or Serum-Separator tube
Volume	2 ml of serum or 3-5 ml of whole blood
Transport	Serum should be transported immediately 2-8c.
Storage	Keep serum in refrigerator 2-8°c for 7 Days or store in freezer at -20°c temp. up
	to 1 months
Stability	Serum is stable for 7 days at 2-8°c and for 1 month at -20°c
Method	Electrochemiluminescence immunoassay
Reference range	0.93 -1.70 ng/dl
Turnaround time	48hrs
	ting hormone, TSH
Patient preparation	Not necessary
Sample Type	Serum
Container	Red-Stopper tube or Serum-Separator tube
Volume	2 ml of serum or 3-5 ml of whole blood
Transport	Serum should be transported immediately 2-8c.
Storage	Keep serum for 7days 2-8°c at -20°c temp. up to 1 months
Stability	Serum is stable for 7 days at 2-8°c and for 1 month at -20°c
Method	Electrochemiluminescence immunoassay
Reference range	Adults0.27- 4.2 μIU/ml
Turnaround time	24 hrs
6. Anti-TPO	
Patient preparation	Not necessary
Sample Type	Serum
Container	Red-Stopper tube or Serum-Separator tube
Volume	2 ml of serum or 3-5 ml of whole blood
Transport	Serum should be transported immediately 2-8c.



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Storage Keep serum for 3days 2-8°c at -20°c temp. up to 1 months

Stability Stable for 3 days at 2-8 °C, at least 1 month at -20 °C. Freeze only once

Method **Immunoassay** 2-34 IU/ML Reference range

Turnaround time 24 hrs

7. Anti-TG

Patient preparation Not necessary

Sample Type Serum

Container Red-Stopper tube or Serum-Separator tube 2 ml of serum or 3-5 ml of whole blood Volume

Transport Serum should be transported immediately 2-8c.

Storage Keep serum for 3days 2-8°c at -20°c temp. up to 1 months

Stability Stable for 3 days at 2-8 °C, at least 1 month at -20 °C. Freeze only once

Method Immunoassay 115 IU/ML Reference range

Turnaround time 24 hrs

8. Anti-TSHR

Patient preparation Not necessary

Sample Type Serum

Container Red-Stopper tube or Serum-Separator tube 2 ml of serum or 3-5 ml of whole blood Volume

Transport Serum should be transported immediately 2-8c.

Storage Keep serum for 3days 2-8°c at -20°c temp. up to 1 months

Stability Stable for 3 days at 2-8 °C, at least 1 month at -20 °C. Freeze only once

Method Immunoassay Reference range 0-1.75IU/L **Turnaround time** 24 hrs

9. Parathyroid Hormone, PTH, Parathormone

Patient preparation Fasting for 8 to 10 hours is required before the test.

Sample Type Serum

Container Red-Stopper tube or Serum-Separator tube 2 ml of serum or 3-5 ml of whole blood Volume

Transport Serum should be transported immediately 2-8c.

Storage Keep serum in refrigerator 2-8°c for 2 Days or store in freezer at -20°c temp. up

to 6 months

Stability Serum is stable for 2 days at 2-8°c and for 6 month at -20°c

Method Electrochemiluminescence immunoassay

Reference range 15 - 65 pg/ml

Turnaround time 72hrs

10. T- Uptake

Patient preparation Not necessary

Sample Type Serum



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Container	Red-Stopper tube or Serum-Separator tube
Volume	2 ml of serum or 3-5 ml of whole blood
Transport	Serum should be transported immediately 2-8c.
Storage	Keep serum for 8 hours at room temperature or up to 48 hours at 2-8°c or longer period of time at -20°c or below
Stability	Serum is stable for 8 hours at room temperature, 48 hours 2-8°c, d longer period of time at -20°c or below
Method	Electrochemiluminescence immunoassay
Reference range	
Turnaround time	24 hrs

Electrolyte Panel

1. Potassium, K+

Patient preparation	Not necessary
Sample Type	Serum
Container	Red-Stopper tube or Serum-Separator tube
Volume	2 ml of serum or 3-5 ml of whole blood
Transport	Serum should be transported immediately 2-8c.
Storage	Keep serum in refrigerator 48 hours at room temperature, 2-8°c for 7 Days or
	store in freezer at -20°c temp. up to 1 months
Stability	Serum is stable for 7 days at 2-8°c and for 1 month at -20°c
Method	Ion selective Method
Reference range	3.5 - 5.1 mmol/l
Turnaround time	24hrs

2. Chloride

Patient preparation	Not necessary
Sample Type	Serum
Container	Red-Stopper tube or Serum-Separator tube
Volume	2 ml of serum or 3-5 ml of whole blood
Transport	Serum should be transported immediately 2-8c.
Storage	Keep serum in refrigerator 48 hours at room temperature, 2-8°c for 7 Days or
	store in freezer at -20°c temp. up to 1 months
Stability	Serum is stable for 48 hrs at room temp. 2-8°c for 7 days or Store in freezer
	at or 4 Weeks at -20°c temp. up to 1 months
Method	Ion selective method (ISE)
Reference range	97 – 111 mmol/l
Turnaround time	48hrs
3. Sodium, Na+	
Patient Preparation	Not necessary

5. Doulding Man	
Patient Preparation	Not necessary
Sample Type	Serum
Container	Red-Stopper tube or Serum-Separator tube
Volume	2 ml of serum or 3-5 ml of whole blood
Transport	Serum should be transported immediately 2-8c.
Storage	Keep serum in refrigerator 48 hours at room temperature, 2-8°c for 7 Days or store in freezer at -20°c temp. up to 1 months
	store in freezer at -20 c temp, up to 1 months
Stability	Serum is stable for 48 hours at room temp. 7 days at 2-8°c and for 1 month at -20°c
Method	Ion selective Method





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Reference range 136 – 145mmol/l **Turnaround time** 24 hr

Infertility Panel

1 Follicle-Stimulating Hormone, FSH

Patient preparation	Not necessary
Sample Type	Serum

Container Red-Stopper tube or Serum-Separator tube
Volume 2 ml of serum or 3-5 ml of whole blood

Transport Serum should be transported immediately 2-8c.

Storage Keep serum in refrigerator 2-8°c for 14 Days or store in freezer at -20°c temp.

up to 6 months

Stability Serum is stable for 14 days at 2-8°c and for 6 month at -20°c

Method Electrochemiluminescence immunoassay

Reference range Follicular 3.5-12.5

Ovulation 4.7-21.5 Luteal 1.7-7.7

Postmenopause 25.8-134.8

Men 1.24-7.8

Turnaround time 12hrs

2 Luteinizing Hormone LH

2. Luteinizing Hormone, LH

Patient preparation	Not necessary		
Sample Type	Serum		

Container Red-Stopper tube or Serum-Separator tube
Volume 2 ml of serum or 3-5 ml of whole blood

Transport
Serum should be transported immediately 2-8c.
Storage

Stability Serum is stable for 14 days at 2-8°c and for 6 month at -20°c

Method Electrochemiluminescence immunoassay

Reference range

Referenc	e Range			
Male	Women			
	Follicular	Ovulation	Luteal	postmenopause
1.7-8.6	2.4-12.6	14.0-95.6	1.0-11.4	7.7-58.5

Note: for detail reference range please contact us.

Turnaround time 24 hrs

3. Prolactin, PRL

Patient preparation No fasting is required prior to the test. The patient should rest 30 minutes prior

to the test. The sample should be drawn in the morning.

Sample Type Serum

Container Red-Stopper tube or Serum-Separator tube **Volume** 2 ml of serum or 3-5 ml of whole blood

Transport Serum should be transported immediately 2-8c.

Storage Keep serum in refrigerator 2-8°c for 14 Days or store in freezer at -20°c temp.

up to 6 months

Stability Serum is stable for 14 days at 2-8°c and for 6 month at -20°c

Method Electrochemiluminescence immunoassay





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Reference range Male 4.04-15.2 and Female 4.79-23.3

Note: For Detail age specific reference range please contact us or refer to

patient result report

Turnaround time 24 hrs

4. Progesterone, PROG

Patient preparation Not necessary

Sample Type Serum

ContainerRed-Stopper tube or Serum-Separator tubeVolume2 ml of serum or 3-5 ml of whole blood

Transport Serum should be transported immediately 2-8c.

Storage Keep serum in refrigerator 2-8°c for 5 Days or store in freezer at -20°c temp. up

to 6 months

Stability Serum is stable for 5 days at 2-8°c and for 6 month at -20°c

Method Electrochemiluminescence immunoassay

Reference range Follicular 0.20 -1.5

Ovulation 0.80- 3.00 Luteal 1.7-27.0 Postmenopause 0.1-0.8

Men 0.2-1.4

Turnaround time 24 hrs

5. Estradiol, E2

Patient preparation Not necessary

Sample Type Serum

ContainerRed-Stopper tube or Serum-Separator tubeVolume2 ml of serum or 3-5 ml of whole blood

Transport Serum should be transported immediately 2-8c.

Storage Keep serum in refrigerator 2-8°c for 2 Days or store in freezer at -20°c temp. up

to 6 months

Stability Stable for 2 days at 2-8°c and for 6 month at -20°c

Method Electrochemiluminescence immunoassay

Reference range

Male	Female			
	Follicular	Ovulation	Luteal	postmenopause
7.63-42.6	12.5-166	85.8-498	43.8-211	<5.00-54.7

1st trimester 215-4300pg/ml

Children(1-10 years) Boys 5.0-20.0 Girls 6.0-27.0

Turnaround time 48hr

6. Testosterone

Patient preparation Not necessary

Sample Type Serum

Container Red-Stopper tube or Serum-Separator tube **Volume** 2 ml of serum or 3-5 ml of whole blood



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Transport Serum should be transported immediately 2-8c.

Storage Keep serum in refrigerator 2-8°c for 7 Days or store in freezer at -20°c temp.

up to 6 months

Stability Serum is stable for 7 days at 2-8°c and for 6 month at -20°c

Method Electrochemiluminescence immunoassay

Reference range

Reference Range	
Men	women
2.8 – 8.0 ng/ml	0.06 - 0.82 ng/ml
Boys	
<1 year	0.12 - 0.21 ng/ml
1 – 6 years	0.03 - 0.32 ng/ml
7 – 12 years	0.03 – 0.68 ng/ml
13 – 17 years	0.28 – 11.1 ng/ml

Note: contact us for age specific reference range or see patient result report

Turnaround time 24 hrs

Metabolic Panel

1 Glucose, Fast Blood Sugar, FBS

Patient preparation	Not necessary
Sample Type	Serum
Container	Red-Stopper tube or Serum-Separator tube
Volume	2 ml of serum or 3-5 ml of whole blood
Transport	Serum should be transported immediately 2-8c.
Storage	Keep serum at room temperature for 8hrs or 72 hrs at 2-8°c
Stability	Serum is stable at room temp. for 8 hrs and 72 hrs at 2-8°c.
Method	Photometric
Reference range	55-115mg/dl According to Tietz* Adults70-105mg/dl >60 years80-115 mg/dl >70 years83-115mg/dl Children60-110mg/dl Newborns(1Days)40-60mg/dl Newborns (>1Days)50-80mg/dl
Turnaround time	24 hrs
Insulin	

Patient preparation

Fasting for 8 hours is required prior to the test. Water is permitted.

Sample Type Serum

Container Red-Stopper tube or Serum-Separator tube

Volume 2 ml of serum or 3-5 ml of whole blood

Serum should be transported immediately 2-8c. **Transport**

Storage Keep serum in refrigerator 2-8°c for 2 Days or store in freezer at -20°c temp. up

to 6 months

Stability Serum is stable for 2 days at 2-8°c and for 6 month





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Method	Electrochemiluminescence immunoassay		
Reference range	$2.6-24.9~\mu U/mL$		
Turnaround time	24 hrs		
3 Calicum, Ca++			
Patient preparation	Not necessary		
Sample Type	Serum		
Container	Red-Stopper tube or Serum-Separator tube		
Volume	2 ml of serum or 3-5 ml of whole blood		
Transport	Serum should be transported immediately 2-8c.		
Storage	Keep serum in refrigerator 2-8°c for 7 Days or 1Months at -20°c		
Stability Method	Serum is stable for 7 days at 2-8°c or 1Months at -20°c ion-selective electrode (ISE)		
Reference range	8.6-10.3 mg/dl or 2.15 to 2.56 mmol/l		
Turnaround time	48hrs		
4 Fructosamine	TOTAL OF THE PARTY		
Patient preparation	Not necessary		
Sample Type	Serum		
Container	Red-Stopper tube or Serum-Separator tube		
Volume	2 ml of serum or 3-5 ml of whole blood		
Transport	Serum should be transported immediately 2-8c.		
Storage	Keep serum for 3days at 15-25 °C, 2-8°c for 2 weeks or 2 Months		
	at (-15)-(-25) °C		
Stability	3 days at 15-25 °C,2 weeks at 2-8 °C,2 months at (-15)-(-25) °C		
Method	Colorimetric assay		
Reference range	228-563μmol/L		
Turnaround time	48hrs		
5 Vitamin D tota	1		
Patient preparation	Not necessary		
Sample Type	Serum		
Container	Red-Stopper tube or Serum-Separator tube		
Volume	2 ml of serum or 3-5 ml of whole blood		
Transport	Serum should be transported immediately 2-8c.		
Storage	Keep serum for 8 hrs at 18-25 °C,4days at 2-8°c,24 weeks at-20 °C		
Stability	Stable for 8 hrs at 18-25 °C, 4 days at 2-8 °C,24 weeks at -20 °C		
Method	Electrochemiluminescence		
Reference range	Clinical assessment should be taken into consideration when interpreting results		
Turnaround time	48hrs		
6 HbA1c			
Patient preparation	Not necessary		
Sample Type	Whole blood		
~ Type			



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Container	K ₂ ,K ₃ , Na ₂ / potas	sium fluoride EDTA ,Li h	eparin tube
Volume	3-5 ml of whole b		
Transport		transported immediately at	t room temperature.
Storage		d for 3days at 15-25 °C,7	*
Stability	Stable for 3 days	at 15-25 °C,7 days at 2-8°	c,6 months at-20 °C
Method	Turbidimetric inh	ibition immunoassay	
Reference range	5.7%-6.4% risk of diabetes,	of developing diabetes ,20%	√₀= poorly controlled
Turnaround time	72hrs		
7 Mg			
Patient preparation	Not necessary		
Sample Type	Serum		
Container	Red-Stopper tube or S	Serum-Separator tube	
Volume	2 ml of serum or 3-5 r		
Transport		sported immediately 2-8c.	
Storage	Keep serum for 8 hrs	at 18-25 °C,4days at 2-8°c	e,24 weeks at-20 °C
Stability		5-25 °C,7 days at 2-8 °C,1	year at (-15)-(-25) °C
Method	Colorimetric endpoint	t method	
Reference range	NewNewborn	0.62-0.91 mmol/L	(1.5-2.2 mg/dL)
	5 months-6 years	0.70-0.95 mmol/L	(1.7-2.3 mg/dL)
	6-12 years	0.70-0.86 mmol/L	(1.7-2.1 mg/dL
	12-20 years	0.70-0.91 mmol/L	(1.7-2.2 mg/dL)
	Adults	0.66-1.07 mmol/L	(1.6-2.6 mg/dL)
	60-90 years	0.66-0.99 mmol/L	(1.6-2.4 mg/dL)
	> 90 years	0.70-0.95 mmol/L	(1.7-2.3 mg/dL)
Turnaround time	48hr	or or or or minor in	(11. 2.5 mg, 42)
8 Amylase	ЮШ		
Patient preparation	Not necessary		
Sample Type	Serum		
Container	Red-Stopper tube or Ser	rum-Separator tube	
Volume	2 ml of serum or 3-5 ml of whole blood		
Transport	Serum should be transported immediately 2-8c.		
Storage	7 Days at 20-25°c or 1 month at 2-8°c		
Stability	Serum is stable for 7 Days at 20-25°c or 1 month at 2-8°c		
Method	Photometric		
Reference range	all age group 28-100U/L		
Turnaround time	48hrs		



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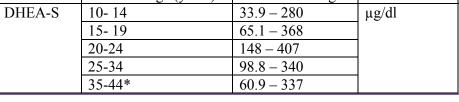
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Patient preparation	Fasting and limited physical activity for 10 to 12 hours is required prior to the test.	
Sample Type	Serum	
Container	Red-Stopper tube or Serum-Separator tube	
Volume	2 ml of serum or 3-5 ml of whole blood	
Transport	Serum should be transported immediately 2-8c.	
Storage	Keep serum in refrigerator 2-8°c for 5 Days or store in freezer at -20°c temp. up to 3 months	
Stability	Serum is stable for 5 days at 2-8°c or -20°c for 3 months.	
Method	Electrochemiluminescence immunoassay	
Reference range	6.2 – 19.4 μg/dl (Morning Hours) and 2.3 – 11.9 μg/dl(Afternoon Hours)	
Turnaround time	48hrs	
10 Cyfra 21-1		
Patient preparation	Fasting and limited physical activity for 10 to 12 hours is required prior to the test.	
Sample Type	Serum	
Container	Red-Stopper tube or Serum-Separator tube	
Volume	2 ml of serum or 3-5 ml of whole blood	
Transport	Serum should be transported immediately 2-8c.	
Storage	Keep serum in refrigerator 2-8°c for 5 Days or store in freezer at -20°c temp. up to 3 months	
Stability	Serum is stable for 5 days at 2-8°c or -20°c for 3 months.	
Method	Electrochemiluminescence immunoassay	
Reference range	Up to 2.2ng/ml	
Turnaround time	5 days	

11 Dehydroepiandosteronesulphate, DHEA-S				
Patient preparation	Not necessary			
Sample Type	Serum	Serum		
Container	Red-Stopper t	Red-Stopper tube or Serum-Separator tube		
Volume	2 ml of serum or 3-5 ml of whole blood			
Transport	Serum should be transported immediately 2-8c.			
Storage	Keep serum in refrigerator 2-8°c for 2 Days or store in freezer at -20° temp. up to 2 months			
Stability	Serum is stable for 2 days at 2-8°c and for 2 month at -20°c.			
Method	Electrochemiluminescence immunoassay			
Reference range		Female - Age (years)	Reference Range	Units
	DHEVC	10 14	22.0 280	ug/d1





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45-54* 35.4 - 256 55-64 18.9 - 205 65-74 9.40 - 246 >75 12.0 - 154 Males - Age (years) 10- 14 15- 19 70.2 - 492 20-24 211 - 492 25-34 160 - 449 35-44 88.9 - 427 45-54 44.3 - 331 55-64 51.7 - 295 65-74 33.6 - 249 >75 16.2 - 123 Children < 1 week 1 - 4 weeks 31.6 - 431 1 - 12 months 3.4 - 124 1 - 4 years 0.47 - 19.4 5 - 10 years 2.8 - 85.2			
65-74 9.40 - 246 >75 12.0 - 154 Males - Age (years) 10- 14 15- 19 70.2 - 492 20-24 211 - 492 25-34 160 - 449 35-44 88.9 - 427 45-54 44.3 - 331 55-64 51.7 - 295 65-74 33.6 - 249 >75 16.2 - 123 Children < 1 week	45-54*	35.4 - 256	
>75 Males - Age (years) 10- 14 24.4 - 247 15- 19 70.2 - 492 20-24 211 - 492 25-34 160 - 449 35-44 88.9 - 427 45-54 44.3 - 331 55-64 51.7 - 295 65-74 33.6 - 249 >75 16.2 - 123 Children <1 week 108 - 697 1 - 4 weeks 31.6 - 431 1 - 12 months 3.4 - 124 1 - 4 years 0.47 - 19.4	55-64	18.9 - 205	
Males - Age (years) 10- 14 24.4 - 247 15- 19 70.2 - 492 20-24 211 - 492 25-34 160 - 449 35-44 88.9 - 427 45-54 44.3 - 331 55-64 51.7 - 295 65-74 33.6 - 249 >75 16.2 - 123 Children < 1 week	65-74	9.40 - 246	
10- 14 24.4 - 247 15- 19 70.2 - 492 20-24 211 - 492 25-34 160 - 449 35-44 88.9 - 427 45-54 44.3 - 331 55-64 51.7 - 295 65-74 33.6 - 249 >75 16.2 - 123 Children < 1 week	>75	12.0 - 154	
15- 19 70.2 - 492 20-24 211 - 492 25-34 160 - 449 35-44 88.9 - 427 45-54 44.3 - 331 55-64 51.7 - 295 65-74 33.6 - 249 >75 16.2 - 123 Children < 1 week	Males - Age (years)		
20-24 211 – 492 25-34 160 – 449 35-44 88.9 – 427 45-54 44.3 – 331 55-64 51.7 – 295 65-74 33.6 – 249 >75 16.2 – 123 Children < 1 week 108 – 697 1 – 4 weeks 31.6 – 431 1 – 12 months 3.4 – 124 1 – 4 years 0.47 – 19.4	10- 14	24.4 - 247	
25-34	15- 19	70.2 - 492	
35-44 88.9 - 427 45-54 44.3 - 331 55-64 51.7 - 295 65-74 33.6 - 249 >75 16.2 - 123 Children < 1 week 108 - 697 1 - 4 weeks 31.6 - 431 1 - 12 months 3.4 - 124 1 - 4 years 0.47 - 19.4	20-24	211 – 492	
45-54	25-34	160 - 449	
55-64 51.7 - 295 65-74 33.6 - 249 >75 16.2 - 123 Children 108 - 697 1 - 4 weeks 31.6 - 431 1 - 12 months 3.4 - 124 1 - 4 years 0.47 - 19.4	35-44	88.9 - 427	
65-74 33.6 - 249 >75 16.2 - 123 Children < 1 week 108 - 697 1 - 4 weeks 31.6 - 431 1 - 12 months 3.4 - 124 1 - 4 years 0.47 - 19.4	45-54	44.3 – 331	
>75 Children < 1 week 108 - 697 1 - 4 weeks 31.6 - 431 1 - 12 months 3.4 - 124 1 - 4 years 0.47 - 19.4	55-64	51.7 – 295	
Children < 1 week	65-74	33.6 - 249	
< 1 week 108 – 697 1 – 4 weeks 31.6 – 431 1 – 12 months 3.4 – 124 1 – 4 years 0.47 – 19.4	>75	16.2 - 123	
1 - 4 weeks 31.6 - 431 1 - 12 months 3.4 - 124 1 - 4 years 0.47 - 19.4	Children		
$ \begin{array}{r} 1 - 12 \text{ months} & 3.4 - 124 \\ 1 - 4 \text{ years} & 0.47 - 19.4 \end{array} $	< 1 week	108 - 697	
1 - 4 years $0.47 - 19.4$	1-4 weeks	31.6 – 431	
	1 - 12 months	3.4 - 124	
5 - 10 years $2.8 - 85.2$	1 – 4 years	0.47 - 19.4	
	5 – 10 years	2.8 - 85.2	

Turnaround time

72hrs

12 Digoxin

Patient preparation	Not necessary
Sample Type	Serum
Container	Red-Stopper tube or Serum-Separator tube
Volume	2 ml of serum or 3-5 ml of whole blood
Transport	Serum should be transported immediately 2-8c.
Storage	Keep serum in refrigerator 2-8°c for 2 Days or store in freezer at -20°c temp. up to 6 months
Stability	Serum is stable for 2 days at 2-8°c and for 6 month at -20°c
Method	Electrochemiluminescence immunoassay
Reference range	0.9-2.0 ng/ml (concentrations above 2.0ng/ml are generally considered toxic.
Turnaround time	48hrs

Drug monitoring panel

1. Lithium, Li+

Patient preparation	Not necessary
Sample Type	Serum
Container	Red-Stopper tube or Serum-Separator tube
Volume	2 ml of serum or 3-5 ml of whole blood
Transport	Serum should be transported immediately 2-8c.
Storage	Keep serum in refrigerator for 48 hours at room temperature, 2-8°c for 7 Days or store in freezer at -20°c temp. up to 1 months
Stability	Serum is stable for 7 days at 2-8°c and for 1 month at -20°c





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Method	Ion selective Method
Reference range	Therapeutic Con 0.6-1.2mmol/l,
	Toxic Concentration>2.0 mmol/l
	Note: A lithium Concentration in excess of 1.5 mmol/l in a specimen drawn 12 h
	after lithium intake indicates an increased risk of toxicity*
Turnaround time	24 hrs
2. Carbamazepi	
Patient preparation	Not necessary
Sample Type	Serum
Container	Red-Stopper tube or Serum-Separator tube
Volume	2 ml of serum or 3-5 ml of whole blood
Transport	Serum should be transported immediately 2-8c.
Storage	Keep serum in refrigerator for 48 hours at room temperature, 2-8°c for 7 Days of store in freezer at -20°c temp. for longer period
Stability	Serum is stable for 7 days at 2-8°c and for longer period at -20°c
Method	Spectrophotometrically
Reference range	Therapeutic Con 4 - 8 μg/mL (16.9 - 33.8 μmol/L),
	Toxic Concentration 6 -12 μg/mL (25.4 - 50.8 μmol/L)
Turnaround time	72 hrs
3. Phenobarbita	l
Patient preparation	Not necessary
Sample Type	Serum
C4-:	D - 1 Ct t-1 C C t-1 -
Container	Red-Stopper tube or Serum-Separator tube
Volume	2 ml of serum or 3-5 ml of whole blood
	**
Volume	2 ml of serum or 3-5 ml of whole blood Serum should be transported immediately 2-8c.
Volume Transport	2 ml of serum or 3-5 ml of whole blood Serum should be transported immediately 2-8c. Keep serum in refrigerator 2-8°c for 4 Days or store in freezer at -20°c temp. u
Volume Transport Storage	2 ml of serum or 3-5 ml of whole blood Serum should be transported immediately 2-8c. Keep serum in refrigerator 2-8°c for 4 Days or store in freezer at -20°c temp. uto 1-2 months
Volume Transport Storage Stability	2 ml of serum or 3-5 ml of whole blood Serum should be transported immediately 2-8c. Keep serum in refrigerator 2-8°c for 4 Days or store in freezer at -20°c temp. uto 1-2 months 1-2 months capped at (-15-(-25 °C)4 days capped at 2-8 °C
Volume Transport Storage Stability Method	2 ml of serum or 3-5 ml of whole blood Serum should be transported immediately 2-8c. Keep serum in refrigerator 2-8°c for 4 Days or store in freezer at -20°c temp. uto 1-2 months 1-2 months capped at (-15-(-25°C)4 days capped at 2-8°C Spectrophotometrically
Volume Transport Storage Stability Method Reference range	2 ml of serum or 3-5 ml of whole blood Serum should be transported immediately 2-8c. Keep serum in refrigerator 2-8°c for 4 Days or store in freezer at -20°c temp. u to 1-2 months 1-2 months capped at (-15-(-25 °C)4 days capped at 2-8 °C Spectrophotometrically 15-40 μg/mL
Volume Transport Storage Stability Method Reference range Turnaround time	2 ml of serum or 3-5 ml of whole blood Serum should be transported immediately 2-8c. Keep serum in refrigerator 2-8°c for 4 Days or store in freezer at -20°c temp. u to 1-2 months 1-2 months capped at (-15-(-25 °C)4 days capped at 2-8 °C Spectrophotometrically 15-40 μg/mL
Volume Transport Storage Stability Method Reference range Turnaround time 4. Phenytoin	2 ml of serum or 3-5 ml of whole blood Serum should be transported immediately 2-8c. Keep serum in refrigerator 2-8°c for 4 Days or store in freezer at -20°c temp. uto 1-2 months 1-2 months capped at (-15-(-25°C)4 days capped at 2-8°C Spectrophotometrically 15-40 μg/mL 72 hrs Phenytoin measurements be collected at least 2 hours after an intravenous dose
Volume Transport Storage Stability Method Reference range Turnaround time 4. Phenytoin Patient preparation	2 ml of serum or 3-5 ml of whole blood Serum should be transported immediately 2-8c. Keep serum in refrigerator 2-8°c for 4 Days or store in freezer at -20°c temp. Uto 1-2 months 1-2 months capped at (-15-(-25 °C)4 days capped at 2-8 °C Spectrophotometrically 15-40 μg/mL 72 hrs Phenytoin measurements be collected at least 2 hours after an intravenous dose of fosphenytoin and at least 4 hours after an intramuscular dose
Volume Transport Storage Stability Method Reference range Turnaround time 4. Phenytoin Patient preparation Sample Type	2 ml of serum or 3-5 ml of whole blood Serum should be transported immediately 2-8c. Keep serum in refrigerator 2-8°c for 4 Days or store in freezer at -20°c temp. u to 1-2 months 1-2 months capped at (-15-(-25°C)4 days capped at 2-8°C Spectrophotometrically 15-40 μg/mL 72 hrs Phenytoin measurements be collected at least 2 hours after an intravenous dose of fosphenytoin and at least 4 hours after an intramuscular dose Serum
Volume Transport Storage Stability Method Reference range Turnaround time 4. Phenytoin Patient preparation Sample Type Container	2 ml of serum or 3-5 ml of whole blood Serum should be transported immediately 2-8c. Keep serum in refrigerator 2-8°c for 4 Days or store in freezer at -20°c temp. uto 1-2 months 1-2 months capped at (-15-(-25°C)4 days capped at 2-8°C Spectrophotometrically 15-40 μg/mL 72 hrs Phenytoin measurements be collected at least 2 hours after an intravenous dose of fosphenytoin and at least 4 hours after an intramuscular dose Serum Red-Stopper tube or Serum-Separator tube



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Stability	Serum is stable for 7 days at 2-8°c and for 1-2 months at -20°c
Method	Spectrophotometrically
Reference range	10-20 μg/mL
Turnaround time	72 hrs
5. Valproic acid	
Patient preparation	Specimens for valproic acid analysis should be drawn just prior to dose, preferably in the fasting state
Sample Type	Serum
Container	Red-Stopper tube or Serum-Separator tube
Volume	2 ml of serum or 3-5 ml of whole blood
Transport	Serum should be transported immediately 2-8c.
Storage	Keep serum in refrigerator for 2 days at room temperature, 2-8°c for 7 Days or store in freezer at -20°c temp. up to 3 months
Stability	Serum is stable for 7 days at 2-8°c and for 1 month at -20°c
Method	Spectrophotometrically
Reference range	Therapeutic Con 50-100 μg/mL Toxic Concentration >100μg/mL

Other tests

Turnaround time

1. Adrenocorticotropic hormone, ACTH

72 hrs

The patient should consume a low-carbohydrate diet for 48 hours before the **Patient preparation**

test. Fasting and limited physical activity for 10 to 12 hours before the test

is required.

Sample Type Serum Container Red-Stopper tube or Serum-Separator tube Volume 2 ml of serum or 3-5 ml of whole blood Serum should be transported immediately 2-8c **Transport Storage** Keep serum in refrigerator 2-8°c for 7 Days or store in freezer at -20°c temp. up to 3 months **Stability** Serum is stable for 7 days at 2-8°c and for 3 month at -20°c Method Electro-chemiluminescence immunoassay Reference range 6.0-76.0 pg/mL**Turnaround time** 72hrs



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Test	Critical Low Value	Critical High Value



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Amylase		> or = 300 U/L
Calcium Total	< 6.0 mg/dl	> 13.0mg/dl
Creatinine Kinase (CK)		> 300 U/L
Creatinine		> 8.0mg/dl
Glucose	< 50mg/dl	> 400md/dl
Phosphorus	< 0.49 mmol/L	
Potassium	<2.5 mmol/L	> 6.5 mmol/L
Sodium	< 120 mmol/L	> 155 mmol/L
Total Bilirubin		> 171 um5.0mg/dl (> 5 days)
		> 18mg/dl (0 – 5 days)
Uric Acid	< 1.5mg/dl	> 12.0mg/dl
Calcium ,ionized	<2.5 mg/dl	>6.5.0 mg/dl
APTT		>> > 70sec
PT		> 42 s INR > 4.5



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Immunology and hematology

Complete blood count, Full Blood Count, CBC, FBC

Patient preparation	Not necessary
Sample Type	Whole Blood
Container	Lavender-stopper (EDTA whole blood) tube
Volume	3-5 ml of whole blood
Transport	At room temperature
Storage	Keep whole blood at room temperature for 8 hours.
Stability	8 hrs for Haematological parameters

Method Automated cell counter

Reference range

Parameters	Range for Females	Range for Males
WBC	3.98 – 10.04	4.23 – 9.07
Neut%	34.0 – 71.1	34.0 – 67.9
Lymph%	19.3 – 51.7	21.8 - `53.1
Mono%	4.7 – 12.5	5.3 – 12.2
Eo%	0.7 - 5.8	0.8 - 7.0
Baso%	0.1 – 1.2	0.2 - 1.2
Neut#	1.56 – 6.13	1.78 – 5.38
Lymph#	1.18 – 3.74	1.32 - 3.57
Mono#	0.24 - 0.36	.0454
Ео#	0.04 - 0.36	0.04 - 0.54
Baso#	0.01 - 0.08	0.01 - 0.08
RBC	3.93 – 5.22	4.63 – 6.08
HGB	11.2 – 15.7	13.7 – 17.5
HCT	34.1 – 44.9	40.1 – 51.0
MCV	79.4 – 94.8	79.0 – 92.2
MCH	25.6 – 32.2	25.7 – 32.2
MCHC	32.2 – 35.5	32.3 – 36.5
RDW-CV	11.7 – 14.4	11.6 – 14.4
RDW-SD	36.4 – 46.3	35.1 – 43.9
PLT	182 – 369	163 – 337
MPV	9.4 -12.3	9.4 – 12.4

Turnaround time 24 hours

T Lymphocyte Differentiation

Patient preparation Not necessary





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Sample	Type	Whole Blood
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Lavender-stopper (EDTA whole blood) tube Container

Volume > than 1/3 of the standard tube

Transport At room temperature

Keep whole blood at room temperature for 8 hours. Storage

Stability 48 hrs for flowcytometry parameters

Method Automated cell counter

Expected Values

Analyte	Adult Ethiopian Reference Range		Units
	Male	Female	
CD3 Cell	6962738	871-2413	cells/µL
	62.090.7	58.3—87.0	%
CD4 Cell	3061249	4561368	cells/µL
	24.7—53.7	29.0—57.9	%
CD8 Cell	3181891	2731418	cells/µL
	23.0—60.7	17.4—50.1	%

Turnaround time 24 hours





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HIV Molecular Tests

DNA-PCR for Early Infant Diagnoses (EID)

Patient preparation	Not necessary
Sample Type	DBS
Container	Lavender-stopper (EDTA whole blood) tube
	Or use What man 903 Dried Blood Spots (DBS) card.
Volume	3-5 ml of whole blood or 4-5 full spots of on a What man 903 DBS.
Transport	DBS Sample transported at room temperature
Storage	Store at -20°c for prolonged period
Stability	DBS Stable at room Temperature up to 3 months and -70/-80 for long period of time
Method	Real Time PCR
Reference range	Negative/Positive
Turnaround time	10 days

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Patient preparation	Not necessary
Sample Type	Plasma
Container	Lavender-stopper (EDTA whole blood) tube
Volume	3-5 ml of whole blood
Transport	Whole blood Sample transported at room temperature
Storage+	Keep whole blood at room temperature for 4 hours, but no longer than 6 hours and separate plasma as soon as possible and store until test done at -20°c for not more than one month.
Stability	Plasma is stable for 24 hours at room temperature, or 5 days at 2-8°c or 1 month at -20°c and for longer period at -70 °c and colder.
Method	RT-PCR
Reference range	<low detection="" limit(ldl)<="" th=""></low>
Turnaround time	10 days





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REFERENCES

- 1. Tietz Text book of Clinical chemistry and Molecular diagnostics.2006
- 2. e- Lab Doc Roche manual
- 3. HIV molecular test manual
- 4. BD FACSCalibur test for CD4 manual
- 5. Sysmix 1800xt test for hematology taste