SHIVA DIAGNOSTICS
LAB NFORMATION

Table of contents

Information for patients and users:

Following are the information available for patients and users laboratory services.

5.4.2(a) Location of the lab:

Shiva Diagnostic centre is located at **No.26, Mohammed pettai street (Near bus stand), Cheyyar-604407**

5.4.2.(b) Services offered by the Lab: The laboratory provides services in the following discipline

- **Clinical Biochemistry**
- **Haematology**
- **Clinical pathology**
- **Microbiology& serology**

5.4.2. C. Opening Hours of the Laboratory:

Morning 6.30 am to 8.30 pm available.

5.4.2.(d) The examination offered by the laboratory:

List of Tests Performed - Clinical Biochemistry:

S.No.	Material of Test	Specific tests Performed	Test Method
1.	Plasma	Glucose	Glucose oxidase/ peroxidase hexokinase
2.	Serum	Alkaline Phosphatase	2 Amino -2- methyl – propanol buffer
3.	Serum	ALT (SGPT)	IFCC without pyridoxal phosphate
4.	Serum	AST (SGOT)	IFCC without pyridoxal phosphate
5.	Serum	Creatinine	Jaffe compensated
6.	Serum	Calcium	Arsenazo III
7.	Serum	Bilirubin (Total)	Diazotizedsulfanillic/ dichlorophenyl diazonium
8.	Serum	Bilirubin (Direct)	Dichlorophenyl diazonium BA400/ BA200
9.	Serum	Cholesterol Total	Cholesterol Oxidase-Peroxidase
10	Serum	HDL –Cholesterol	Direct toos
11.	Serum	Chloride	ISE Direct
12.	Serum	Albumin	Bromo Cresol Green
13.	Serum	LDL-Cholesterol	Homogenous method
14.	Whole blood (EDTA)	Glycosylated Haemoglobin A1c	HPLC
15.	Serum	Sodim	ISE Direct
16.	Serum	Potassium	ISE Direct
17.	Serum	Urea	Urease (color/ UV)/GLDH
18.	Serum	Uric acid	Uricase/ peroxidase
19.	Serum	Total protein	Biuret
20	serum	Triglycerides	Glycerol phosphate oxydase/ peroxydase

List of Tests Performed – Haematology

S.No.	Product/ Material ofTest	Specific tests performed	Test method
1.	EDTA Blood	Blood Group	Tube/Slide Agglutination, Gel method
2	Citrated Blood	ESR	Westegren
3.	EDTA Blood	Haemoglobin	Colorimetric method
4.	EDTA Blood	MCH	Calculated
5.	EDTA Blood	MCHC	Calculated
6.	EDTA Blood	MCV	Measured(RBC Histogram)
7.	EDTA Blood	PCV/Haematocrit	Automated
8.	EDTA Blood	Peripheral Smear	Microscopy
9.	EDTA Blood	Platelet Count	Electrical Impedance
10.	EDTA Blood	PS for Malaria Parasite	Microscopy
11.	EDTA Blood	RBC Count	Electrical Impedance
12.	EDTA Blood	Reticulocyte Count	Microscopy
13.	EDTA Blood	Total WBC Count	Electrical Impedance
14.	Citrated Plasma	PT with INR	Opto Mechanical Measuring
15.	Citrated Plasma	APTT	Opto Mechanical Measuring

List of test performed-Clinical Pathology

S.No.	Product/ Materialof Test	Specific tests performed	Test method
1.	Urine	Routine*	Physical exam./Microscopy
2.	Urine	Albumin	Reflectance Spectrophotometry method /Strip Method/Sulphosalicylic Acid
3.	Urine	Sugar	Reflectance Spectrophotometry method /Strip Method / Benedict's Method
4.	Urine	Acetone	Reflectance Spectrophotometry method /Strip Method/Rothera's Method
5.	Urine	pH	Reflectance Spectrophotometry method /Strip Method.
6.	Urine	Bile Salt	Reflectance Spectrophotometry method /Hay's Sulphur Method
7.	Urine	Bile Pigment	Reflectance Spectrophotometry method /Strip Method/Fouchet's Method
8.	Urine	Specific gravity	Reflectance Spectrophotometry method /Strip Method
9.	Urine	Urobilinogen	Reflectance Spectrophotometry method /Strip Method
10	Urine	Pregnancy	Card method
11.	Stool	Stool R/M	Manual /Srip test
12..	Stool	Occult Blood	Hemospot -Guaiac Method
13.	Stool	Reducing Substance	Benedict's test

5.4.2 (d) Biological Reference range:

Biological Reference range –Clinical Biochemistry

S.NO	Specific tests Performed	Test Method	Reference Range	Units
1.	Serum Albumin	Bromo cresol green	3.5 -5.3	g/dL
2.	Serum Alkaline Phosphatase	2 amino-2 methyl propanal buffer	30.0 -120.0	U/L
3.	Serum ALT (SGPT)	(IFCC) without pyridoxal phosphate	Upto 45.0 New born/Infants 13-45	U/L
4.	Serum AST (SGOT)	(IFCC) without pyridoxal phosphate	Upto 35.0 New born:25-75 Infants 15-60	U/L
5.	Serum Bilirubin (Total)	Diazotized sulfanillic / Dichlorophenyl diazonium	0.10-1.40	mg/dL
6.	Serum Bilirubin (Direct)	Dichlorophenyl diazonium BA400/ BA 200	0.00-0.40	mg/dL
7.	Calcium	Arsenazo I II	8.6 -10.3	mg/dL
9.	Cholesterol Total	Cholesterol Oxidase- Peroxidase	Desirable:<200 Borderline high201- 239 High >240	mg/dL

10.	Plasma Glucose Random Fasting Post Prandial	GOD-POD	Fbs :70-110 mg/dl Ppbs 70-140mg/dl	mg/dL
11.	Glycosylated Haemoglobin A1c	HPLC	Normal: 4.0-6.0 Good control: 6.01-7.0 Fair control:7.01-8.0 poor control:>8.01	%
12.	HDL –Cholesterol	Homogenous Method	>40 Low <60 High	mg/dL
13.	Potassium	ISE	3.5-5.0	mEq/L
14.	Protein	Biuret	6.6 -8.7	g/dL
15.	Sodium	ISE	135-150	mEq/L
16.	Triglycerides	GPO-POD	<150 Normal 150-199 Borderlinehigh 200-499 High >500 Very high	mg/dL
17.	Urea	Urease -GLDH	21-43	mg/dL
18.	Uric acid	Uricase	Male- 3.5-7.2 Female -2.6-6.0	mg/dL

Reference: Tietz Text book of clinical chemistry and molecular Diagnostics Fifth edition

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Biological Reference Values for Haematology

S.NO	Product/ material of test	Specific tests Performed	Test Method	Reference Values		Units
				Male	female	
1.	EDTA Blood	Total WBC Count	Electrical Impedance	4,000-11,000	4,000-11,000	Cells/cumm
2	EDTA Blood	Lymphocyte%	Derived from Histogram	20-45	20-45	%
3	EDTA Blood	Neutrophils%	Derived from Histogram	40-75	40-75	%
4.	EDTA Blood	Monocytes%	Leishman's Stain	02-10	02-10	%
5.	EDTA Blood	Basophils%	Leishman's Stain	0-1	0-1	%
6.	EDTA Blood	Eosinophils	Leishman's Stain	00-06	00-06	%
7.	EDTA Blood	RBC	Electrical Impedance	4.0- 5.5	4.0- 5.5	Mili/cumm
8.	EDTA Blood	Haemoglobin	Photometric	12.0- 16.0	12.0-16.0	(gm/dL)
9.	EDTA Blood	HCT/PCV	Calculated	35 – 48 %	35 – 48 %	%
10.	EDTA Blood	MCV	Calculated	80 -100	80 -100	(fL)

11.	EDTA Blood	MCH	Calculated	27- 32	27- 32	(pg)
12.	EDTA Blood	MCHC	Calculated	31.0- 35.0	31.0- 35.0	(g/dL)
13.	EDTA Blood	RDW%	Derived from histogram	11.0- 16.0	11.0- 16.0	%
14.	EDTA Blood	Platelet Count	Electrical Impedance	140000-450000	140000-450000	Cells/ cumm
15.	EDTA Blood	Blood grouping/ Rh typing	Slide/Tube/Gel agglutination (Forward/reverse)	Negative	Negative	NA
16.	EDTA Blood	MP/MF	Immuno chromatography /Microscopic	Negative	Negative	NA
17.	Citrate Blood	ESR	Westegren /Automated	0-15	0-20	(mm in 1 hour)
18	EDTA Blood	Peripheral Smear	Leishman's Stain	-	-	NA
19.	EDTA Blood	Reticulocyte count	Brilliant Cresyl blue	1.1-2.7	0.9-2.4	%

Ref: 1. Interpretation of Diagnostic Tests-jacques Wallach (Lippincott Williams Wilkin) 8th Edition

2. Dacie and Lewis practical Hematology 12th Edition

Biological Reference Values- Clinical Pathology

S.NO	Product/ material of test	Specific tests Performed	Test Method	Reference Values
1.	Urine	Specific gravity	Reflectance photometry / Bromothymolblue / Strip Method	1.010-1.030
2.	Urine	PH	Reflectance photometry/ Methyl red phenolphthalein indicator/Strip Method	5.5 -6.0
3.	Urine	Leucocytes	A)Reflectance photometry/ Esterases /Strip Method/ B)Microscopic	Negative
4.	Urine	Nitrite	Reflectance photometry/ Griess test /Strip Method	Negative
5.	Urine	Protein	A. Reflectance photometry/ Protein error pH indicator /Strip Method B.SulphoSalicyclic acid Test	Negative
6.	Urine	Sugar	A) Reflectance photometry GOD-POD /Strip Method B) Benedict's Method	Negative
7.	Urine	ketone bodies	A) Reflectance Photometry/ Legal's/Strip Method B)Rothera's Method	Negative
8.	Urine	Urobilinogen	A)Reflectance photometry /Azo dye /Strip Method B)Ehrlich test	Normal in urine
9.	Urine	Bilirubin	Reflectance photometry A)Diazonium salt B)Hay' s Test & Fouchet's Test	Negative
10.	Urine	Blood	Reflectance photometry /Peroxidase	Negative
11.	Urine	Deposits	Microscopy	Negative
12.	Stool	Pregnancy	Immuno chromatography	Negative
13.	Stool	Reducing Substance	Benedict's Test	Negative
14.	Stool	Occult Blood	Hemospot –Guaiac	Negative

Ref: 1. Interpretation of Diagnostic Tests-jacques Wallach (Lippincott Williams Wilkin) 8th Edition

2. Dacie and Lewis practical Hematology 12th Edition

List of tests and Turnaround time by Shiva diagnostics:

Turnaround time for Clinical Biochemistry parameters:

S.No	Material of Test	Specific tests performed	Test method	Volume	Storage	TAT
1.	Serum	Glucose	Glucose oxidase/ peroxidase Hexokinase	3.5ml	**2-8°c**	4hrs
2.	Serum	urea	Urease(color/uv)/GLDH	3.5ml	**2-8°c**	4hrs
3.	Serum	creatinine	Jaffe compensated	3.5ml	**2-8°c**	4hrs
4.	Serum	Uric acid	Uricase/ peroxidase	3.5ml	**2-8°c**	8hrs
5.	Plasma	T. cholestrol	Chlosesterol oxidase/ peroxidase	2.0ml	**2-8°c**	8 hrs
6.	Serum	AST (SGOT)	Ifcc without pyridoxal phosphate	3.5ml	**2-8°c**	8 hrs
7.	Serum	ALT (SGPT)	Ifcc without pyridoxal phosphate	3.5ml	**2-8°c**	8hrs
8.	Serum	ALP	2 Amino -2 methyl propanol buffer	3.5ml	**2-8°c**	8hrs
9.	Serum	Total protein	Biruet	3.5ml	**2-8°c**	8hrs
10.	Serum	Albumin	Bromocresol green	3.5ml	**2-8°c**	8hrs
11.	Serum	Total bilirubin	Diazotized sulfanillic / Dichlorophenyl diazonium	3.5ml	**2-8°c**	8hrs
12.	Serum	Direct bilirubin	Dichlorophenyl diazonium BA400/ BA 200	3.5ml	**2-8°c**	8hrs
13.	Serum	HDL	Direct toos	3.5ml	**2-8°c**	8hrs
14.	Serum	Caclium	Arseno III	3.5ml	**2-8°c**	8hrs
15	Serum	Sodium	ISE	3.5ml	**2-8°c**	8hrs
16.	Serum	Triglycerides	G OD -POD	3.5ml	**2-8°c**	8hrs
17.	Serum	Urea	Urease & GLDH	3.5ml	**2-8°c**	8hrs
18.	Serum	Uric acid	Uricase	3.5ml	**2-8°c**	8hrs

Turnaround time for Haematology parameters:

S.No	Test Material	Specific tests performed	Test method	Volume	Storage	TAT
1.	EDTA blood	Blood Group	Gel/Tube/Slide agglutination	2ml	**2-8°c**	4hrs
2.	Citrate Blood	ESR	Westegren/Automated	2ml	**2-8°c**	4hrs
3.	EDTA Blood	Haemoglobin	Photometric method	2ml	**2-8°c**	2hrs
4.	EDTA Blood	MCH	Calculated	2ml	**2-8°c**	2hrs
5.	EDTA Blood	MCHC	Calculated	2ml	**2-8°c**	2hrs
6.	EDTA Blood	MCV	Measured (Histogram)	2ml	**2-8°c**	2hrs
7.	EDTA Blood	PCV/ Haematocrit	Automated	2ml	**2-8°c**	2hrs
8.	EDTA Blood	Peripheral Smear	Microscopy	2ml	**2-8°c**	4hrs
9.	EDTA Blood	Platelet Count	Electrical Impedance	2ml	**2-8°c**	2hrs
10.	EDTA Blood	PS for Malaria Parasite	Immuno chromatography	2ml	**2-8°c**	4hrs
11.	EDTA Blood	RBC Count	Electrical Impedance	2ml	**2-8°c**	2hrs
12.	EDTA Blood	Reticulocyte Count	Microscopy	2ml	**2-8°c**	4hrs
13.	EDTA Blood	Total WBC Count	Electrical Impedance	2ml	**2-8°c**	2hrs
14.	Citrate Plasma	PT with INR	Opto Mechanical Measuring	4ml	**2-8°c**	4hrs
15.	Citrate Plasma	APTT	Opto Mechanical Measuring	2ml	**2-8°c**	4hrs

Critical Alert Value

HEMATOLOGY CRITICAL VALUES

Test	Lower Limit	Upper Limit
Haematocrit(Adult)	<20%	>60%
Haematocrit(Newborn)	<33%	>71%
Haemoglobin(Adult)	<7 g/dL	>20 g/dL
Haemoglobin(Newborn)	<10 g/dL	>22 g/dL
WBC(Adult)	<2,000 Cells/µl	>30,000 Cells/ µl
WBC(Children)	2,000 Cells/ µl	43,000 Cells/ µl
Platelets	< 0.50(50,000)Lakhs/ µl	>10 Lakhs/ µl
Blasts	Any seen (first report only)	
Fibrinogen	<100 mg/dL	>700 mg/dL
Prothrombin time	-	>30 Seconds
Partial thromboplastin time	-	>100 Seconds
Urine Analysis Microscopic	Presence of pathological crystals (Urate, cysteine, eucine,or tyrosine)	-
Urine Glucose/ ketones	Strongly Positive glucose and ketones	-
CSF WBC(0 -1Y)	-	>30 Cells/ µl (Excluding Peripheral blood contamination)
CSF WBC(1 - 4Y)	-	>20 Cells/ µl (Excluding Peripheral blood contamination)
CSF WBC(5 -17Y)	-	>10 Cells/ µl (Excluding Peripheral blood contamination)
MP	-	Positive

Ref: 1. Interpretation of Diagnostic Tests-jacques Wallach (Lippincott Williams Wilkin) 8th Edition

2. Dacie and Lewis practical Hematology 12th Edition

BIO CHEMISTRY CRITICAL VALUE

Test	Lower Limit	Upper Limit
Albumin	1.7 gm/dL	6.8 gm/dL
Ammonia(Children)	-	109 µmol/L
Bilirubin(newborn)	-	15 mg/dL
Calcium	6.0 mg/dL	13 mg/dL
Calcium(Children)	6.5 mg/dL	12.7 mg/dL
Chlorite	80 mEq/L	120 mEq/L
Creatinine	-	When abnormal for the first time 2.0 mg/dL & any increase than the previous value.≥5 mgs
Creatinine(Children)	-	When abnormal for the first time 1.3 mg/dL & any increase than the previous value .≥3.8 mgs
Glucose	40 mg/dL	450 mg/dL
Glucose(Children)	46 mg/dL	445 mg/dL
Glucose(Newborn)	30 mg/dL	325 mg/dL
Glucose ,CSF	40 mg/dL	200 mg/dL
Glucose , CSF (Children)	31 mg/dL	-
Phosphorus	1.0 mg/dL	8.9 mg/dL
Potassium	2.8 mmol/L	6.2 mmol/L
Potassium(Newborn)	2.8 mmol/L	7.8 mmol/L
Protein(Children)	3.4 gm/dL	9.5 gm/dL
Protein ,CSF(Children)	-	188 mg/dL
Sodium	120 mEq/L	160 mEq/L
Uric acid	-	13 mg/dL
Uric acid(Children)	-	12 mg/dl
CK-MB	-	>25 U/L
TropT	Negative	Positive

Ref: Tietz Text book of clinical chemistry and molecular Diagnostics Fifth edition

Limit for requesting additional tests:

Time limit for accepting additional test request:

Departments	**Analyte**	**Time limit**
Clinical Biochemistry	Electrolytes	Within 2 hours of sample collection
Clinical Biochemistry	Others Parameters	Within 4 hours of sample collection
Haematology	CBC	< 2hours of sample collection
Haematology	Blood Group	< 1 hours of sample collection
Haematology	Coagulation profile (PT, APTT)	Within 4 hours of sample collection (Store 2-8°)
Clinical Biochemistry	All the enzymes	Within 8 hours of sample collection

5.4.2. (e) Instruction for completion of request form:

The laboratory is having hard copy of test request forms. Forms are made available at registration counter sample collection area, The test request form is havingall the details needed .The patient/clinicians/any health care providers is requested to put the tick in relevant boxes fill the required column and put his signature. Whenever requested by the patient, staff at registration counter can fill the form as per the request of the patient and get patient signature. For the request is made through Meditos software as well as through hard copy.

5.4.2. (f) Instruction for preparation of the patients:

Instructions for preparation of the patients are available in the reception / front office.

5.4.2.(g) Instruction for patient collected sample :

Lab does not accept samples collected elsewhere and brought to lab by patients. This is to avoid misinterpretation in patient identity. However samples collected by Lab/doctors accompanied by proper requisition will be accepted provided the sample meets the criteria for acceptance. Anyway, the results will not be given in the report form having NABL symbol.

5.4.2 (h) Instruction for transportation of samples :

Sample collected in the phlebotomy section of the laboratory is immediately given to the analytical section across the counter. Samples collected from home collection of the sample collection are taken to the lab within 10-45minutes time by keeping it in a temperature controlled container. The samples in the container will be accompanied by the TRF and the log sheet. The samples are handed over to the staff at the registration counter. He/She verifies the temperature in the transport container and subsequently makes the necessary accession entries.

Specimens for bilirubin determination should be kept away from daylight and florescent light to avoid photo degradation of bilirubin. Polypropylene and polyethylene containers are usually suitable for specimen transport. Polystyrene containers should not be used since they may crack when frozen.

Corrugated, fiberboard or Styrofoam boxes designed to fit around a single specimen tube should be used for transport. These boxes are designed internally, specifically to avoid the tubes knock against order

5.4.2(i) patient consent form information:

All procedures carried out on a patient need the informed Consent of the patient .For most routine laboratory procedures consent can be inferred when the patient himself and herself at a laboratory with a request form and willingly submits to the usual collecting procedure ,for example ,venipuncture..

5.4.2.(j) Sample acceptance and rejection criteria of the lab:

Laboratory sample acceptance and rejection criteria.

S.No.	Acceptance Criteria	Rejection criteria	Action taken (for rejection sample)	Corrective a ction
1	The container is properly labeled with the patient andtest details	Unlabeled / Wrongly labeled sample	If collection is made by non invasive procedure (like Urine, Sputum or throat swab) – C**ollection is repeated.** If collection is made by invasive procedure (needle aspiration, body fluids) continue the processing of sample after discussing with the referring physicians.	Problem is recorded in the sample rejection register and the corrective action takenis documented
2	Samples matches with the test Requestform	If samples does not match with the Request form	The sample need not be processed**.** Verify with requester and ask for a fresh sample	Record the problem and the Corrective action(CA) in the sample rejection Register
3	Sample collected Proper and non leaking Specimen container	Sample collected in, unsuitable broken or leaking container.	The sample need not be processed Inform the requester and request fora fresh sample	Record the problem and the CA in the sample rejection register taken
4	When sample received within acceptable time	Prolonged tra time beyond one hour for any sample nsport	The sample need not be processed Inform the requester and ask for a fresh sample.	Record the problem and the CA in the sample rejection register

5	Specimen suitable as per Transport temperature	Specimen brought beyond acceptable temperature (>25ºC)	The sample need not be processed**.** Inform the requester and request for a fresh sample	Record the problem and CA in the samplerejection register
6.	Plasma for coagulation tests PT, APTT, Fibrinogen, , FDP, Factor Assays Samples collected in 3.2% sodium citrate tubes filled correctly	Samples collected in tubes other than 3.2% citrate Vacutainer tubes Samples either over filled or under filled tubes.	The sample need not be processed: Inform the requester and request for a fresh sample.	Record the problemand the CA in the sample rejection register
7.	Whole blood for ESR: Samples collected in 3.8% sodium citrate tubes filled correctly.	Samples Collected in any other tubes or not in collected in 3.2 % sodium citrate tubes over filled or under filled.	The sample need not be processed: Inform the requester and request for a fresh sample	Record the problemand the CA in the sample rejection register
8.	Whole blood for CBC: Samples collected in K2EDTA tubes filled correctly.	Samples collected in any other tubes than K2EDTA tubes either over filled or under filled tubes.	The sample need not be processed: Inform the requester and request for a fresh sample	Record the problemand the CA in the sample rejection register
9.	Serum :With out Visible or Gross Hemolysis& Turbidity	With Gross Hemolysis& Turbidity	The sample need not be processed: Inform the requester and request for a fresh sample	Record the problemand the CA in the sample rejection register

Note: The details are recorded in the sample rejection register

5.4.2.(k) Factors that affect laboratory values:

Most of the lab errors occur in the pre analytical areas, like front office, specimen collection, handling and transport. Care has to be taken to avoid such errors. Factors not related to testing process such as patient identification and patient posture and the time of specimen drawn etc., contribute to the total laboratory error. Hence the staff concerned is to be vigilant to avoid inclusion of such errors

Age, activity, bed rest, food ingestion, alcohol ingestion, menstrual cycle, obesity, oral contraceptives, posture, pregnancy, race, sex, smoking, and time of day are examples of physiological factors that influence the analytical results. Impact of these factors will vary depending upon the tests. Many biological parameters show rhythms. The circadian rhythm (the change in a 24-hour period) is the most important for laboratory testing.

- Lipemic, haemolysed, icteric samples also will affect different kinds of tests.
- Care need to be given so that the sample is not getting lysed.
- Vacutainer with appropriate anticoagulant only should be used.
- Vacutainer should not be opened and sample collected.

5.4.2.(l) Clinical advice on ordering of examinations and interpretation ofexamination results can be had from the following consultants:

BIOCHEMISTRY : DR.A.C., SHARMILA

PATHOLOGY : DR. P. GAYATHRI

5.4.2(m)The laboratory policy on protection of personal information:

1. All the staffs are made to give declaration that they will maintain confidentiality. They are also counseled to do so.

2. The soft copy information is all protected at various levels and password protected.

5.4.2.(n) Laboratory Complaint Procedure:

The laboratory has "Feedback" form available at registration counter .The form contains provision for making complaint. Patient can use this form fill it up drop in the suggestion box available at sample collection area. The forms are taken care of by the quality manager.

The quality manager takes appropriate action in consultation with lab director/management. If client feels it immediate, he can contact Quality manager or Lab director.