

**SRI VENKATESWARA INSTITUTE OF
MEDICAL SCIENCES**

**PRIMARY SAMPLE COLLECTION
MANUAL**

BIOCHEMISTRY DEPARTMENT

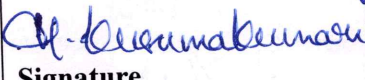
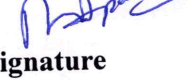
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1. Introduction:

This manual is designed to give an overall view of the services available in the Biochemistry Department. It is intended as a quick reference guide for all Biochemistry users.

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SVIMS Laboratory	ISO clause:7.2.4	Version number: 01	Issue Date:01/08/2024
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All Biochemistry services undergo continuous review through quality assurance and audit activities. The laboratory is committed to performing its activities in accordance with the requirements of the International Standard **ISO 15189** (2022 version).

This manual is intended for users of the Biochemistry Services both within the hospital, and those from outside hospitals.

Laboratory management are committed to:-

- Staffrecruitment, training, development and retention at all levels to provide a full and effective service to its users.
- The proper procurement and maintenance of such equipment and other resources as are needed for the provision of the service.
- The collection, transport and handling of all specimens in such a way as to ensure the correct performance of laboratory examinations.
- The use of accredited examination procedures and methods that will ensure the highest achievable quality of all tests performed.
- Reporting results of examinations in ways which are timely, confidential, accurate and clinically useful.
- The assessment of user satisfaction, in addition to internal audit and external quality assessment, in order to produce continual quality improvement.

2. Guide to use this document:

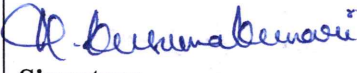
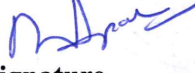
- A **controlled hardcopy** of this manual has been issued to each ward and other relative locations as authorised by the Laboratory Manager.
- For internal users acontrolledelectronic version of the manual is stored on the shared drive of the network in a folder titled “Clinical Lab” and is accessed through the sub folder titled “Primary Sample Collection Manual”.
- The document is stored in Adobe Acrobat format which allows all computer users in laboratory to read the document while preventing modification.
- The laboratory tests, profiles and any require information can be located in the manual.

3. General information

- **Biochemistry department opening times**

Department/activity	Opening Hours
Phlebotomy Out-patient Service	Monday to Saturday

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	OP Collection centre: 7.00am –3:00pm SVIMS Clinic& SPMC(W)hospital:7am- 1.00 pm
Phlebotomy In-patient Service	Round the clock
Sample Reception	Round the clock
STAT lab parameters	Round the clock
Routine and Emergency Laboratory parameters	Monday to Saturday 8:00am – 4:pm
Emergency out of hours service	Monday to Saturday, 4:00pm –8:00am Sunday and Holidays-(24 Hours)

• **Biochemistry Department Telephone Numbers**

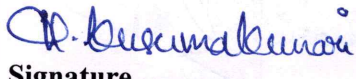
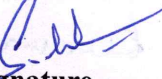
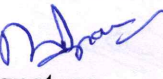
There are a number of different disciplines within the Biochemistry Department. Where medicaland scientific advice is required on medical indications and appropriate selection of available procedures the Biochemistry Department welcomes your queries. For telephone queries use the provided listing.

Section	Phone number with extension
Office	0877-2287777 ext. 2233
HOD Biochemistry	0877-2287777 ext.2427
Faculty	0877-2287777 ext.2239
Clinical-lab Reception	0877-2287777 ext.2232

- **Central Website:**<https://svimstpt.ap.nic.in>
- **Laboratory Fees:** A list of Biochemistry tests charges isavailable from: Annexure 1
- **Staffing**

The Biochemistry department team consists of:-

- Head of the Department
- Deputy Lab director
- Lab Manager/ Clinical lab unit in-charge faculty
- Residents (Senior and Junior)

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- Technical Staff
- Support Services
 - Secretarial
 - Housekeeping

4. Laboratory request forms, sample tubes, urine bottles and 24 hours urine containers

- This section deals with the information that is required to be documented on the laboratory requestform and the samplebottle prior to the analyses of samples.

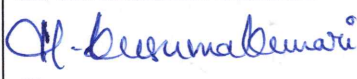
The following essential information must be documented in a legible manner on the request form including the backcopy:-

1. Patient's UHID Number (In-Patient/ Out-Patient Numbers)
2. Patient's Full Name (Surname, First name)
3. Patient's Address
4. Patient's location (Hospital Ward or room number).
When the requesting Physician is at an external location to that of the Sri Venkateswara Institute of Medical Sciences, the complete hospital address to be provided.
5. Patient's gender and age
6. The name and contact Number of the requesting clinician
7. Specimen type
8. Examination(s) required
9. Date and time of specimen collection
10. Relevant clinical information appropriate to the test(s) requested must be supplied e.g. History of administration of drugs etc.
11. A clear indication as to whether the tests requested are STAT or routine
12. The signature of the person completing the form

- **Labelling the Specimen Container**

The following **essential** information should be documented in a **legible** manner on the sample container:-

1. Patient's full name

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- 2. Hospital number (UHID), confirmation number
 - 3. Barcode
- All of the above indicators are mandatory.

• **Quality of samples**

Laboratory personnel must inspect prior to testing each specimen received for:-

- Adequacy
- Fasting status
- Evidence of Haemolysis
- Gross Lipemic
- Grossly icteric

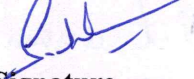
In such instances, a **second specimen** may be requested or the **issued report** will have an appended comment noting the presence of haemolysis, lipemiaand icterus.

- **Non-Conforming sample bottles, forms or sample quality issues:** Where the requirements with respect to labelling the request form and sample container or sample quality issues are not met the following will apply

Non conformities of errors are documented as given below

SPECIMEN ISSUES	ACTION	DOCUMENTATION
➤ No sample received ➤ Sample collected at incorrect time or date and time of collection not indicated ➤ Samplesunlabelled ➤ Unique identifiers are not correct or absent from the sample (Full name, DOB/ age, hospital no.)	➤ A second sample must be collectedor the originator accepts responsibility for same in emergency cases or where the sample cannot be replaced. ➤ If tested the report will show the non-conforming event.	➤ Originator signs for the correction of the error on a sample Reception form.

FORM ISSUES	ACTION	DOCUMENTATION
➤ No request form provided with sample Inadequate or incorrect patient Details:- • Hospital number • Name • Address • Date of birth/ age	➤ A second sample is requested if the originator does not correct the error. ➤ If tested or appropriate the Report will show the non-conforming event	➤ Originator signs for the correction of the error on specimen reception form.

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• Ward or location • Gender • Clinic information ➤ Incorrect test requested ➤ No patient details on vacutainer ➤ Ordering Physician not identified ➤ Sample collected at incorrect time or date and time of collection not indicated ➤ Miscellaneous form issue		
SPECIMEN APPEARANCE/ QUALITY ISSUES	ACTION	DOCUMENTATION
➤ Evidence of Haemolysis ➤ Gross Lipemia ➤ Age of specimen ➤ Miscellaneous quality issues	➤ The Biochemistry department will make a decision on whether or not the sample is suitable for testing and a second sample is requested as appropriate. ➤ The Biochemistry department may report results within a multi test profile on analytes unaffected by the sample quality, while not reporting affected analytes in the profile. ➤ If tested or appropriate the report will show the non-conforming event as remark.	Not applicable

Additional testing

If on sending a specimen for testing and **further additional testing** is required, please contact the appropriate section of the Biochemistry department to investigate the feasibility of using the initial specimen for analysis as age of specimen may impact on the validity of test results. Ideally, a request form should accompany such a request but the lack of the request form should not impede the processing of an urgent request.

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Non-Conforming Issues and Credit: It is the policy of the Biochemistry department to refund the amount as per policy of institute where non-conforming issues lead to the non-testing of samples.

Types of samples analysed in the laboratory:

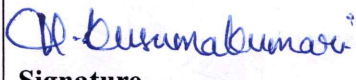
- 1. Blood – plain-serum, plasma-heparinized, sodium fluoride and potassium oxalate, trisodium citrate
- 2. Urine – spot and 24 hours
- 3. CSF
- 4. Pleural fluid
- 5. Pericardial fluid
- 6. Ascitic fluid
- 7. Dialysate

Sample collection requirements

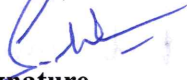
The sample volume requirements vary depending on the type and number of tests ordered, specimen type, instrument used, etc. The optimal amount of specimen is 1.0 mL serum; the minimum is 0.5 mL serum or plasma.

- (a) Additive free tubes - for all investigations except blood glucose and fibrinogen
- (b) Sodium fluoride and potassium oxalate tubes- blood glucose and lactate
- (c) Trisodium citrate/EDTA - Fibrinogen
- (d) Heparinized sample (syringe) transported in ice slurry- ABG
- (e) Heparinized tube - can be used similar to additive free tubes
- (f) Thymol preservative - 24 hrs urine
- (g) HCl preservative- 24 hrsnephtrines
- (h) Sealed additive free tubes transported in an upright position- bicarbonate

Parameter	Sample type	Anticoagulant/ Preservative	Sample collection precautions and patient preparation
Glucose	Plasma	Sodium fluoride & potassium	FBS: Sample collected after fasting for 8 to 10 hours PPBS: Sample collected after 2 hours of food

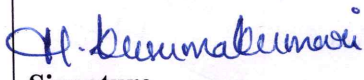
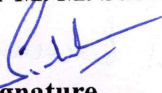
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Oral glucose tolerance test (OGTT):	Plasma	oxalate Sodium fluoride & potassium oxalate The tube should be shaken gently but thoroughly for complete mixing.	intake OGTT: Discontinue medications known to effect glucose tolerance. Unrestricted carbohydrate diet and activity 3days prior to the test (at least 150g/ day) Fasting sample is collected after 10 to 12 hours of fasting, preferably taken between 7 a.m. to 9 a.m. 75 grams of glucose dissolved in 250ml of water is given to drink slowly for over 5minutes and sample is collected after 2 hours
Bicarbonate	Serum	Nil	Sample to be transported in a closed plain tube in an upright position immediately after collection to the lab. In case of delay up to 1 hr, samples to be placed on ice and transported in a closed plain tube in an upright position.
Chloride	serum CSF Urine random -24 hrs urine	Nil Nil Nil Thymol crystals 500mg	--
Urea creatinine calcium phosphorus proteins sodium potassium	24 hrs Urine	Thymol crystals 500mg	Add the given preservative (thymol crystals) to the urine collection 10 liters can before starting urine collection. The first early morning urine at 6AM must be voided and discarded on day 1 of the urine collection. Collect the next urine sample in the urine collection can. From now, whenever urine is passed, it must be collected in the urine collection can till 6AM the next day. The next day first early morning sample at 6 AM must be collected. Each time, collect urine in an empty container

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			and transfer slowly into the 24 hrs urine collection can
Microalbumin	Spot urine	Nil	Morning urine sample, preferably a mid-stream clean catch, first voided urine should be collected.
Lactate	Plasma	sodium fluoride & potassium oxalate	Subject should be at rest and hand and arm movements to be avoided as physical exercise causes an increase in lactate levels. The collected sample must be transported immediately without any time delay from the point of sample collection to the laboratory placed on ice to avoid changes in lactate levels.
Nephtrines	24 hrs Urine	10-15ml of 6MHCl	Day 1 6 am first urine sample – void (do not collect) ↓ Collect next urine samples in containers □ transfer immediately to 24 hrs urine collection can. Now add the preservative to the 24 hrs urine collection can. ↓ From now, whenever urine is passed, it must be collected in the container and then transferred immediately to the 24 hrs urine collection can till 6am the next day. Day 2 6 am – collect urine in container □ transfer immediately to 24 hrs urine collection can with preservative ↓ Stop urine collection PRECAUTION! 24 hrs urine preservative is HCl (acid) – Avoid spillage and avoid contact with body!

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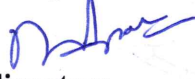
			Each time, collect urine in an empty container and transfer slowly into the 24 hrs urine collection can – Avoid splashing of acid!
Calcium Triglycerides Phosphorous Total protein Albumin Iron Magnesium Tumour markers (AFP, CEA, CA125, PSA, HCG)	Serum	Nil	Sample collected after fasting for 8 to 10 hours

Sample collection devices:

All specimens are collected in appropriate containers.In view of introduction of vacutainers for blood collection, following tubes are used for blood sample collection for biochemistry tests

- BD Vacutainer® Plus Plastic Serum Tubes have spray-coated silica and are used for serum determinations in chemistry. Samples processed in these tubes may also be used for routine blood donor screening, immunohematology, and diagnostic testing of serum for infectious disease. For Tube Size of 13X 75 mm, the Draw Volume is 5 mL and colour of the cap is red.
- BD Vacutainer® Heparin Tubes are spray-coated with either lithium heparin or sodium heparin and are used for plasma determinations in chemistry. For Tube Size of 13X 75 mm, the Draw Volume is 2 mL and colour of the cap is green.
- BD Vacutainer® Fluoride Tubes contain a glycolytic inhibitor and are used for glucose determinations on plasma. Unless otherwise noted, all BD Vacutainer® Fluoride Tubes contain a mixture of potassium oxalate and sodium fluoride. For Tube Size of 13X 75 mm, the Draw Volume is 2 mL and colour of the cap is grey.

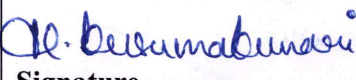
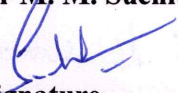
5. Blood collection tubes:

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COMMON LABORATORY TEST	TUBE CAP	ADDITIVE
Glucose and Lactate	Grey	Sodium fluoride and potassium oxalate
Blood Chemistry (Serum) Urea, Creatinine, Uric acid; Sodium, Potassium, Chloride; Amylase, ADA, CPK, CPK-MB, Cholinesterase, LDH, Lipase, LFT, Lipid profile; Lp(a), Homocysteine; hsCRP; Iron, Ferritin, TIBC, Magnesium, calcium, phosphorus; Phenytoin, Phenobarbitone, Carbamazepine; AFP, CA-125, CEA, HCG, PSA, Free PSA; IL-6	Plain red	No additive
D-Dimer	Light blue	Sodium citrate
Fibrinogen	Lavender ("purple")	EDTA

Sample receipt timings

1. Fasting blood samples will be received from 7:00AM to 10:00AM
2. Fasting blood samples are mandatory for the following tests:
 - a. Fasting blood glucose
 - b. Triglycerides
 - c. Calcium
 - d. Phosphorus
 - e. Total protein
 - f. Albumin
 - g. Magnesium
 - h. Iron
 - i. Tumor markers
3. 24 hrs urine samples will be received from 7:00AM to 10:00AM
4. In Emergency situations all fasting samples and received and processed with Clinician signature and seal on request except Fasting Blood sugar.

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Sample rejection

- 1. Inadequate volume of sample
- 2. Incorrect anticoagulant
- 3. Incorrect time of sample collection
- 4. Whole blood stored in the refrigerator without separation
- 5. Improper sample collection
- 6. 24hrs Metanephrines are collected with Thymol crystals

Sample recollection requested for

- 1. Homolysis
- 2. Lipemia
- 3. Sample mix up
- 4. Sample not received to the Lab
- 5. All the above rejected samples will be requested for collection using correct anti-coagulant or preservative
- 6. When the sample values are not correlating with old values

6.Sample transport and storage:

It is the policy of the Biochemistry Department to treat all specimens and samples as potentially infectious or high risk. Therefore, we advise you to take universal precautions in the collection, packaging and the delivery of samples being sent to the Biochemistry department for analysis.

- Samples reception from within the hospital
 - During the routineBiochemistryopening timesblood samples will be collected by the Phlebotomy team in the OPD and IP samples will be collected by nursing staff. The samples are transported by porters at regular intervals (not exceeding 2hrs). The responsibility of proper storage in collection area and transport rests with phlebotomy In-charge.

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- Outside routine Biochemistry opening times blood samples will be taken by either medical doctors or nurses in the ward and transported under controlled temperature by porters without delay.
- All specimens being sent to the laboratory should be placed in a prescribed sample box for transport.

• **Samples reception from outside of the Hospital**

- Samples are accepted directly at the reception of biochemistry, room no 21 in 2nd floor of SVIMS hospital.
- Substances needed for the collection of samples will be supplied at the reception of Clinical Biochemistry lab Room no 21.
- Samples to be sent should be stored in a secure (preferably plastic) primary container.

• **Disposal of waste material used in specimen collection**

All materials used in specimen collection should be treated as potentially hazardous and discarded using appropriate colour coded bags. Please refer to the current hospital guidelines for Waste Management prepared by the Infection Control Committee.

7. Storage of examined samples for archive and look back purposes:

ID	Specimen Description	Storage Requirement	Storage Location	Minimum Retention Period	Responsibility
1.	Blood for routine analysis	Room temperature	Biochemistry clinical lab	12 hrs	Sample separation in charge
2.	Body Fluids and 24 hours urine sample	Room temperature	Biochemistry Clinical lab	24 hrs	Sample separation in charge
3.	Tumour markers	-10°C	Refrigerator in separation room	15 days after release of reports	Technician in charge of

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			of clinical lab of Biochemistry		special tests
4.	24hrs urine metanephrines	-20°C	Refrigerator in sample storage room	24hrs	Sample separation in charge

- The laboratory has adequate space for efficient functioning, a pleasant ambience and conditions to avoid cross contamination of patient samples.
- Patient samples and materials used in examination processes are stored in a manner that prevents cross contamination and deterioration.
- Integrity of samples is ensured by re-testing of patient samples. Records are maintained in sample integrity register.
- Transplant cases samples are stored in vials in the deep freezer -20°C from the transplant Day 1 to patient discharged time for re-examine/add on test as necessary.
- Apo A1, Apo B, Cystatin C, Lambda Chain, Kappa Chain Samples are stored in the deep freezer at -20°C and test is done once 15 days.
- Haptoglobin samples are stored in the deep freezer -20°C and test was done once in month.
- D-dimer samples are stored in 2-8°C and test was done daily.
- Transplant cases samples are stored in vials in the deep freezer from the transplant Day 1 to patient discharged time for re-examine/ add on test as necessary.

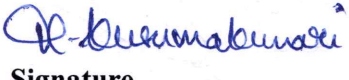
8. External assessment programme

The Biochemistry Department **participates** in relevant available **external third party assessment schemes**. This includes scheme operated by:-

- EQAS (CMC, Vellore)

The Biochemistry Department is **committed** to participating in other schemes as they become available and are required to ensure comprehensive assessment of the test repertoire.

9. Laboratory Tests/Profiles Available:

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The Biochemistry laboratory of Sri Venkateswara Institute of Medical Sciences provides,Routine Clinical Biochemistry tests,Tumour markers, Special tests, TDM and urine nephrines. The detailed list of tests, method of collection, preservatives required and precautions to be taken are as given below

Laboratory tests/ profiles available:

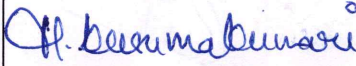
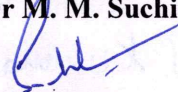
This section outlines the tests that are available in the different section of Biochemistrylaboratory. These tests will be described under the following disciplines:-

S. No.	PANEL	INVESTIGATIONS
1	Diabetic Profile	Glucose- fasting, post prandial, post glucose, Random, Glucose Tolerance Test (GTT), HbA _{1c}
2	Renal function tests	Urea, Creatinine, Uric acid, Cystatin C
3	Electrolytes	Sodium, Potassium, Chloride, Ionized Calcium
4	Enzymes	Amylase, Lipase, LDH, ADA, CPK, CPK-MB, Cholinesterase
5	Liver function tests	Bilirubin – Total and conjugated, total protein, albumin, SGOT, SGPT, ALP
6	Lipid profile	Cholesterol, Triglycerides, HDL, LDL, VLDL
7	CHD risk	Homocysteine, hsCRP, Apo A1. ApoB
8	Acid base status	Osmolality, Bicarbonate, pH,Lactate
9	Anemia markers	Iron, Ferritin, UIBC,
10	Minerals	Magnesium, Calcium, , Phosphorus
11	Tumor markers	AFP, CA-125, CEA, HCG, PSA
12	Special parameters	D-Dimer, Interleukin-6, Haptoglobin, Lambda Chain, Kappa Chain
13	Spot & 24 hours Urine test	Spot & 24 hours Urine Protein, Creatinine, Calcium, Phosphorus, Uric acid & Electrolytes
14	Urine–Special investigations	Metanephrine and normetanephtrines, Microalbumin, Bence Jones proteins
15	Stone Analysis	Renal stone analysis
16	Hormones	T ₃ , T ₄ , TSH, Cortisol

Laboratory Test/ Profile Description

Each laboratory test will be described under the following headings:-

- Test Name
- Sample type

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Where the **sample is blood** and the required additive is stated as none, the requirement should be interpreted as a **clotted sample collected in plain tube**.

- **Sample requirements** including additive, required sample volume and container type.
- **Turnaround time**
Turnaroundtime is defined as the time **from sample receipt** in the Biochemistry department to the time **results are available**.
- **Remarks (includes any special requirements)**
The special requirements column defines for each diagnostic test if (applicable) the following:-
 - Patient preparation, e.g. fasting
 - Special timing for collection of samples e.g. pre and post drug administration
 - Any special handling needs between time of collection and time received by the laboratory (transport requirements, refrigeration, warming, immediate delivery etc.)

Repeat Examination due to Analytical Failure: It is the policy of the Biochemistry department in the event of an analytical failure to:-

- Repeat the test using a back-up instrument.**Or**
- Store the sample in appropriate conditions until the cause of the analytical failure is identified and corrected and then repeat the test. The urgency of the outstanding samples is reviewed by the relevant laboratory Consultant Biochemist or nominee.

Further Examination of the Primary Specimen

Where further testing is relevant to the investigation or diagnosis of the condition or symptoms which gave rise to the original test request then it is the policy of the Biochemistry department to pursue a diagnosis by performance of additional tests using the primary sample.

The Department is not directly involved in outsourcing of tests that are not done by the department.

Emergency out of hours service

If any other test is required the consultant requesting the test should contact the lab in-charge.

10. Reporting of test results:

Blood, Body fluids & Urine: Results, once released, are available on the hospital computer system. Hard copy reports are printed when requested and are available at sample collection centre.

Prepared by Dr. T. Silpa  Signature	Reviewed by Dr M. Kusuma Kumari  Signature	Verified by Dr M. M. Suchitra  Signature	Authority for issue Dr Aparna R Bitla  Signature
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Reports are entered on HIMS with in below mentioned from the time of receipt of sample at laboratory.

STAT parameters: Reported within 2 hours

Routine Samples: Reports are available within 6 hours

Tumor markers: Reports are available within 24 hours

Urine nephrintest: Reports are available once in 7 days

Telephoned Results

It is the policy of the Biochemistry department to telephone reports only when results for specific clinical parameters have reached critical levels. Requests for verbal reports are not entertained except in urgent cases.

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