SARDAR PATEL UNIVERSITY
University Road P. B. 10
Vallabh Vidhyanagar-388120 (Gujarat)
NAAC accredited with Grade 'A'
(10-01-2023 to 09-01-2028)
Phone: 0692-226808/85; Email: exam_spu@spuvvn.edu; Website: www.spuvvn.edu

The Government of India notified **the National Commission for Allied and Healthcare Professions (NCAHP)** Act on **March 28, 2021**. As a common regulatory body, the NCAHP Act provides for regulation and maintenance of standards of education and services by Allied and Healthcare Professionals.

Specialisation: Haematology and Transfusion Medicine

Semester II Haematology and Transfusion Medicine

Code	COURSE NAME	L/P	C	Hours	IA	ESE	Total
M02MLSHT01	Haematology and Haematological Disorders	4	4	60	30	70	100
M02MLSHT02	Haemostatic Disorders	4	4	60	30	70	100
M02MLSHT03	Applied Immunopathology in Haematology	4	4	60	30	70	100
M02MLSHT04	Clinical Pathology	2	2	30	30	70	100
	Practical						
M02MLSHT05	Haematology and Haematological Disorders Practical	2	2	60	30	70	100
M02MLSHT06	Haemostatic Disorders Practical	2	2	60	30	70	100
M02MLSHT07	Applied Immunopathology in Haematology Practical	2	2	60	30	70	100
M02MLSHT08	Clinical Pathology Practical	2	2	60	30	70	100
	Total	**22**	**22**	**450**	**240**	**560**	**800**

L: Lecture, T: Tutorial; P: Practical, C: Credit; I: Internal Assessment; ESE: End Semester Examination

Course name: Blood Banking and Immunohematology Total credits: 4 (60 hours)

Course Rationale: The course is designed for students to apply advanced immunohaematological principles. They can also independently execute donor screening, blood collection and preparation of blood components.

Learning outcome: At the end of the course the students can

- Apply advanced immunohematological principles in laboratory diagnostics.
- Demonstrate competency in antibody detection, identification, and complex serological problem solving.
- Execute donor screening, blood collection, and blood component preparation as per national regulatory standards.
- Evaluate and manage transfusion reactions and special transfusion scenarios.
- Ensure compliance with quality standards, biosafety, and legal regulations in blood banking.

UNIT	M02MLSHT01 Haematology and Transfusion Medicine	C=4 (60hr)
I	Hematopoiesis and Bone Marrow Dynamics: Regulation of hematopoietic stem cells and stages of differentiation; Identification of maturation blockages and marrow failure syndromes; Role of marrow microenvironment and stromal interactions; Cytokine signaling in stem cell survival and lineage commitment; WHO 2022 marrow grading: fibrosis, cellularity, and blast percentages.	5

II	Red cell structure and metabolism: Red cell morphology and structural variants (size, shape, inclusion bodies); Hemoglobin biosynthesis: heme synthesis, globin chain production; Red cell metabolic pathways: Embden-Meyerhof and Pentose phosphate pathways; Functional implications of morphology and metabolism on red cell survival	**5**
III	Red cell destructions- extracellular and intracellular red cell destructions; compensation mechanisms in hemolysis- reticulocytosis, erythroid hyperplasia, bilirubin metabolism; Classification of hemolytic anemia: hereditary vs acquired; Pathophysiology and laboratory diagnosis of: Hereditary spherocytosis and elliptocytosis, G6PD deficiency and its oxidative stress pathways, Paroxysmal nocturnal hemoglobinuria (PNH); diagnostic approaches for hereditary and acquired hemolytic anemias.	**6**
IV	Nutritional & Hypoproliferative Anemias: Classification, pathophysiology and laboratory diagnosis of nutritional anemias- Iron deficiency, folate deficiency, and megaloblastic anemia; Diagnostic interpretation using - Iron studies, megaloblastic indices, folate deficiency; anemia of chronic disease-pathophysiological mechanisms and cytokine-mediated iron sequestration; Hypoproliferative anemias - reticulocyte indices, erythropoietin response, and marrow hypocellularity; Bone marrow biopsy evaluation: cellularity grading, storage iron stains, and dysplastic features; Reticulocyte production index (RPI) and its relevance in marrow functional assessment; Application of WHO and ICSH global anemia classification standards for standardized reporting	**8**
V	Hemoglobin Variants and Thalassemia Syndromes: Classification, pathophysiology and laboratory diagnosis of hemoglobin variants and thalassemia syndromes; WHO guidelines for sickle cell disease and unstable hemoglobin - Structural abnormalities (e.g., HbS, HbE, HbD) and synthesis defects (α- and β-thalassemia); Role of genetic counseling and prenatal diagnostic protocols.	**8**
VI	Acute & Chronic Leukemias: WHO/FAB classifications, pathophysiology and laboratory diagnosis of AML, ALL, CML, CLL including immunophenotyping (CD markers), cytogenetics, flow cytometry and PCR.	**8**
VII	Myeloproliferative & Myelodysplastic Syndromes: Clinical features and lab diagnosis of Polycythemia Vera, Essential Thrombocythemia, Myelofibrosis, Myelodysplastic Syndromes; marrow dysplasia grading, mutation panels (JAK2, CALR, and MPL), ASH guidelines for diagnosis and classification,	**8**
VIII	Plasma Cell Dyscrasias & Related Disorders: classifications, pathophysiology and laboratory diagnosis of multiple myeloma; paraprotein detection (SPEP, IFE, FLC assay); WHO 2022 criteria for plasma cell neoplasms; beta-2 microglobulin and cytogenetic risk stratification in plasma cell myeloma; WHO 2022 plasma cell definitions	**6**
IX	Lymphoid Neoplasms: Classification, etiology, and lab findings of B-lymphoblastic and T-lymphoblastic leukemia/lymphoma; immunophenotyping (CD10, TdT, CD7), cytogenetic markers (MLL, ETV6), and clinical correlations. Mature Lymphoid Neoplasms & Advances: CLL, prolymphocytic	**6**

	leukemia, hairy cell leukemia, Hodgkin and Burkitt lymphomas, diagnostic techniques and recent molecular advances- NGS, FISH, IgH rearrangement; WHO 2022 updates on classification and disease behaviour.	
	Total	**60**

Suggested Readings:

- McKenzie, S. B., Williams, J. L., & Landis-Piwowar, K. (2004). Clinical laboratory hematology (Vol. 1). Pearson education.
- Wickramasinghe, S. N., & McCullough, J. J. (2003). Blood and bone marrow pathology.
- Chou, D. (2007). Henry's clinical diagnosis and management by laboratory methods. *JAMA*, *297*(16), 1827-1833.
- Wintrobe, M. M. (2009). *Wintrobe's clinical hematology* (Vol. 1). Lippincott Williams & Wilkins.
- McKenzie, S. B., Williams, J. L., & Landis-Piwowar, K. (2004). *Clinical laboratory hematology* (Vol. 1). Pearson education.
- Hoffbrand, A, V. et al (2016). Color Atlas of Clinical Hematology (Fourth ed.). New Delhi, India: Elsevier.
- Sood, R. (2006). *Textbook of medical laboratory technology*. Jaypee Brothers Publishers.
- Dacie, J. V. (2006). *Dacie and Lewis practical haematology*. Elsevier Health Sciences.
- Godkar, P. B., & Godkar, D. P. (2006). *Textbook of medical laboratory technology*. Bhalani publishing house.

Course Name: Haemostatic Disorders **Credit: 4 (60 hours)**

Course Rationale: This course equips learners with advanced knowledge of hemostatic physiology, bleeding and thrombotic disorders, and laboratory diagnostic protocols. It bridges molecular mechanisms with practical testing strategies, emphasizing clinical correlations and reflex diagnostics for lifelong laboratory competence.

Learning Outcomes:

1.) Explain normal hemostatic processes and coagulation factor functions in health and disease 2.) Classify and interpret bleeding and thrombotic disorders using laboratory and clinical data 3.) Apply structured diagnostic algorithms and reflex testing protocols for comprehensive hemostasis investigation. 4.) Integrate recent advances in coagulation diagnostics into clinical laboratory practices 5.) Use automation tools and quality protocols for hematology lab efficiency

UNIT	**M02MLSHT02** **Haemostatic Disorders**	**C=4** **(60hr)**
I	Introduction to Hemostasis & Physiology: Normal hemostatic sequence: vascular constriction, platelet plug formation, coagulation cascade, inhibitors (Protein C/S, ATIII), fibrinolysis; interplay of endothelium, platelets, coagulation proteins	6

II	Coagulation Factors & Pathways: Intrinsic/extrinsic/common pathways; nomenclature & roles of factors I–XIII; synthesis, vitamin K dependency, activation sequences; global standards on factor assays	**8**
III	Primary Hemostasis Disorders: Platelet count and function defects, ITP, qualitative platelet disorders, Bernard-Soulier, Glanzmann's thrombasthenia; bleeding time, aggregation studies, genetic tools	**8**
IV	Secondary Hemostasis Disorders: Hemophilia A/B, von Willebrand disease (types, diagnostics, ristocetin cofactor, vWF antigen, collagen binding), factor deficiencies; PT/APTT prolongation patterns	**8**
V	Tertiary Hemostasis & Thrombotic Disorders: DIC, thrombotic thrombocytopenic purpura (TTP), hemolytic uremic syndrome (HUS), acquired inhibitors, circulating anticoagulants; fibrin degradation products, D-dimer testing	**8**
VI	Laboratory screening & special testing: Complete Blood Count, Bleeding Time (BT) and Clotting Time(CT), Prothrombin Time (PT) , Activated Partial Thromboplastin Time (APTT), Thrombin Time (TT), clot retraction, solubility; Specific Factor Assays — Factor VIII, IX, vWF antigen & activity, fibrinogen levels , mixing studies, Lupus Anticoagulant Testing - dilute Russell viper venom test (dRVVT) , **vWF Subtyping & Multimer Analysis** -for vWD classification , **TEG/ROTEM** -viscoelastic testing for clot formation dynamics Platelet function analyzers- **Platelet Aggregometry & PFA-100** — to assess qualitative platelet disorders, **Circulating Anticoagulant Detection** — therapeutic vs autoimmune sources	**8**
VII	Reflex Testing & Algorithmic Diagnosis: Reflex testing principles, laboratory role in algorithm design, cascade testing protocols; interpreting abnormal screening results; reference ranges across age groups	**7**
VIII	Recent Advances & Quality Management in Coagulation: Automation in coagulation labs, POC testing, new reagent technologies, integration with molecular diagnostics; QC/QM protocols; global practice recommendations. (ASH/ICSH)	**7**
	Total	**60**

Suggested Readings:

- McKenzie, S. B., Williams, J. L., & Landis-Piwowar, K. (2004). Clinical laboratory hematology (Vol. 1). Pearson education.
- Wickramasinghe, S. N., & McCullough, J. J. (2003). Blood and bone marrow pathology.
- Chou, D. (2007). Henry's clinical diagnosis and management by laboratory methods. *JAMA*, *297*(16), 1827-1833.
- Wintrobe, M. M. (2009). *Wintrobe's clinical hematology* (Vol. 1). Lippincott Williams & Wilkins.
- McKenzie, S. B., Williams, J. L., & Landis-Piwowar, K. (2004). *Clinical laboratory hematology* (Vol. 1). Pearson education.
- Hoffbrand, A, V. et al (2016). Color Atlas of Clinical Hematology (Fourth ed.). New Delhi, India: Elsevier.
- Sood, R. (2006). *Textbook of medical laboratory technology*. Jaypee Brothers Publishers.

- Dacie, J. V. (2006). *Dacie and Lewis practical haematology*. Elsevier Health Sciences.
- Godkar, P. B., & Godkar, D. P. (2006). *Textbook of medical laboratory technology*. Bhalani publishing house.

Course: Applied Immunopathology in Hematology **Credit: 4 (60 hours)**

Course Rationale: This course equips learners with advanced knowledge of hemostatic physiology, bleeding and thrombotic disorders, and laboratory diagnostic protocols. It bridges molecular mechanisms with practical testing strategies, emphasizing clinical correlations and reflex diagnostics for lifelong laboratory competence.

Learning Outcomes: At the end of the course, Students would be able to:

- Explain the immune mechanisms involved in hematological disorderss.
- Analyze immunopathological basis of hematologic malignancies and autoimmune hematologic diseases.
- Perform and interpret immunohematological and immunodiagnostic tests relevant to hematology.
- Correlate laboratory findings with clinical immunopathology in various hematological conditions.

UNIT	M02MLSHT03 Applied Immunopathology in Hematology	C=4 (60hr)
I	Overview of Immune system: Immune system and Immunologic disorders, Cellular and humoral Immunity, Complement system, Cytokines, Human leucocytic antigen, Major Histocompatibility complex and disease	10
II	Immunopathology of Hematologic Disorders: Autoimmune hemolytic anemia (AIHA), Immune thrombocytopenic purpura (ITP), Paroxysmal nocturnal hemoglobinuria (PNH), Hemophagocytic lymphohistiocytosis (HLH), Hypersplenism and immune cytopenias	13
III	Immunopathology in Hematologic Malignancies: Tumor immunology of leukemia and lymphoma, Immunophenotyping in leukemia/lymphoma diagnosis, Role of monoclonal antibodies and immune escape, Minimal residual disease detection via flow cytometry	13
IV	Immunodiagnostics in Hematology: Direct and Indirect Coombs Test (DAT & IAT), Antibody screening and cross-matching, Immunoassays (ELISA, CLIA) for hematological markers, Flow cytometry principles and interpretation, Autoantibody detection in systemic autoimmune diseases	12
V	Immunotherapy and Targeted Therapy: Immunomodulatory drugs in hematology, Monoclonal antibodies (e.g., Rituximab, Daratumumab), CAR-T cell therapy in leukemia and lymphoma, Graft-versus-host disease (GVHD) and immune regulation in bone marrow transplant	12
	Total	**60**

Suggested Readings:

1. Silberstein, L. E., & Anastasi, J. (2017). Hematology: Basic Principles and Practice. Elsevier Health Sciences.

2. McPherson, R. A., & Pincus, M. R. (2021). Henry's clinical diagnosis and management by laboratory methods E-book. Elsevier Health Sciences.
3. Wintrobe, M. M. (2009). Wintrobe's clinical hematology (Vol. 1). Lippincott Williams & Wilkins.
4. Owen, J, A. (2013). Kuby immunology. New York: W.H. Freeman and Company.

Course: Clinical Pathology **Credit: 2 (30 hours)**

Course Rationale: This course integrates foundational and advanced diagnostic principles in clinical pathology, emphasizing fluid-based diagnostics (urine, CSF, serous fluids, semen, feces, sputum, and cytology). It equips learners to apply structured laboratory techniques, interpret results in clinical contexts, and engage with emerging technologies and automation in pathology.

Learning Outcome:

- Describe and differentiate the physical, chemical, and microscopic characteristics of body fluids in normal and pathological states.
- Apply appropriate diagnostic techniques including reagent strip, cytology, and special stains for identifying abnormal conditions.
- Evaluate laboratory findings to correlate with clinical conditions such as renal disorders, meningitis, infertility, and gastrointestinal pathology.
- Discuss recent advances in fluid-based diagnostics, including automation, molecular integration, and quality assurance.

UNIT	M02MLSHT04 Clinical Pathology	C=2 (30hr)
I	Urine analysis: Collection and preservation; physical, chemical, microscopic exams; urine strip technique; renal pathology; pregnancy tests, urine osmolality, Bence Jones protein, and automation in urinalysis.	4
II	Cerebrospinal Fluid (CSF): CSF formation and handling; differentiation of pathological findings; cell count interpretation; meningitis profiles, CSF glucose/protein ratios, PCR for meningitis pathogens, and cytospin techniques.	3
III	Serous & Synovial Fluids: Formation, collection, exam of pleural, pericardial, peritoneal, synovial fluids; transudates vs exudates; crystals; joint disorder profiles. ADA levels in pleural fluid, synovial fluid viscosity grading, and crystal identification using polarized microscopy.	4
IV	Semen analysis: Sample collection; physical, chemical, microscopic exams; sperm morphology; fertility tests and interpretation. WHO sperm morphology criteria, DNA fragmentation index, and computer-assisted semen analysis (CASA).	4
V	Other Fluids: Amniotic, BAL, Saliva: Composition and analysis of amniotic fluid; maternal urine differentiation; L/S ratio in amniotic fluid, salivary biomarkers. BAL and saliva examination. BAL cytology for infectious diseases.	3

VI	Fecal Analysis: Composition; collection; physical, chemical, microscopic exams; fecal screening tests (occult blood, fat, Hb); clinical correlations. Fecal calprotectin, PCR for parasitic DNA, and automation in stool analysis.	**4**
VII	Sputum Analysis: Formation of Sputum, collection of Sputum, Analysis of Sputum, sputum cytology, Ziehl-Neelsen staining, and GeneXpert for TB.	**3**
VIII	Integrated Interpretation & Case Correlation: Reflex testing interpretation; integration of fluid analysis in diagnostic decisions; pattern recognition across fluids; specimen quality and result impact; AI-assisted image analysis.	**4**
	Total	**30**

Suggested Readings:

- Mundt, L., & Shanahan, K. (2020). *Graff's textbook of urinalysis and body fluids*. Jones & Bartlett Learning.
- Godkar, P. B., & Godkar, D. P. (2006). *Textbook of medical laboratory technology*. Bhalani publishing house.
- Strasinger, S. K., & Di Lorenzo, M. S. (2014). *Urinalysis and body fluids*. FA Davis.
- Sood, R. (2006). *Textbook of medical laboratory technology*. Jaypee Brothers Publishers.
- Chou, D. (2007). Henry's clinical diagnosis and management by laboratory methods. *JAMA*, *297*(16), 1827-1833.
- Polansky, V. D. (2014). *Quick Review Cards for Medical Laboratory Science*. FA Davis.
- World Health Organization. (2021). WHO laboratory manual for the examination and processing of human semen. In *Who laboratory manual for the examination and processing of human semen*.

UNIT	M02MLSHT05 Clinical Haematology Practical	C=2 (60hr)

1. Bone marrow smear review & cellular grading
2. RBC morphology: Peripheral smear reporting
3. Reticulocyte indices & anemia profiling
4. Hemolytic anemia workup: Coombs, osmotic fragility, schistocyte quantification.
5. Hb electrophoresis & variant analysis
6. Leukemia morphology & cytochemical typing
7. Lymphoid neoplasm diagnostics: Case sheets and concept mapping of lab workups.
8. Plasma cell studies & paraprotein reporting, case sheets and concept mapping of lab workups.
9. Lab automation & QC documentation: Analyzer histogram reading, calibration reports, QC charting exercises.
10. Integrated case analysis & report writing: Drafting diagnostic algorithms and structured case interpretations.

***Clinical laboratory rotation/observation can be incorporated wherever possible**

UNIT	M02MLSHT06 Haemostatic Disorders Practical	C=2 (60hr)

1. Perform proper safety precautions
2. Perform collection, transport, and processing of blood samples for coagulation tests,
3. Platelet Count and Peripheral Smear Interpretation- Platelet estimation accuracy, identification of qualitative abnormalities (e.g., Bernard-Soulier syndrome).
4. Bleeding Time (BT) and Clotting Time, PT/APTT Testing, Mixing study, Coagulation Factor Assays and Dilution Studies and Interpretation, Reflex algorithm application; protocol troubleshooting.
5. ROTEM/TEG Simulation and Interpretation
6. D-Dimer and FDP Estimation- Latex agglutination test; immunoassay-based quantification; cut-off setting for DVT/pulmonary embolism
7. vWF Antigen and Activity Estimation- Differentiating type 1 vs type 2 variants; handling pre-analytical interferences.
8. Lab automation & QC documentation: Analyzer histogram reading, calibration reports, QC charting exercises.
9. Integrated case analysis & report writing: Drafting diagnostic algorithms and structured case interpretations.- Analyze anonymized clinical vignettes; chart diagnostic flow using PT/APTT/mixing study/vWF tools; prepare interpretive report.
10. WHO/ISTH Guidelines Review- Critical reading; global framework contextualization.

***Clinical laboratory rotation/observation can be incorporated wherever possible**

UNIT	M02MLSHT07 Applied Immunopathology in Hematology Practical	C=2 (60 hr)

1. Luminex-based anti-HLA class I & II screening
2. HLA-A, C, DRB3/4/5 high-resolution typing
3. Multi-parametric flow panels for leukemias
4. Flow cytometry-based immunophenotyping
5. Direct and Indirect Coomb's test
6. Advanced hematology automation (Mindray CAL 6000): includes reflex testing and parameters like IG (immature granulocyte count), Ret-He, NLR (neutrophil-to-lymphocyte ratio) (DEMO)
7. The practicals can be uptaken in workshop mode at any Advanced NABL lab with above mentioned facility or can be sensitized with demo practical

*****Students can be taken for demo visits to labs where the tests are routinely performed**

UNIT	M02MLSHT08 Clinical Pathology Practical	C=2 (60hr)

1. Collection and biosafe handling of urine, stool, semen, CSF, and body fluids
2. Urine - Manual and dipstick urine analysis, Microscopic examination of urine sediments, Comparative analysis using semi-automated urine analyzers, Rapid HCG pregnancy test and interpretation
3. Stool microscopy for ova, cysts, leukocytes, Detection of fecal occult blood and fecal fat
4. Semen analysis: volume, motility, morphology (WHO protocol)
5. Physical and microscopic examination of pleural, ascitic, synovial, pericardial, and CSF samples, Total and differential cell counts in body fluids, Cytospin preparation and smear interpretation
6. Cytological specimen handling, fixation, and smear preparation, Liquid-based cytology demonstration, Papanicolaou (PAP) staining and interpretation
7. Case-based correlation of lab findings with clinical conditions
8. Identification and analysis of pre-analytical, analytical, and post-analytical errors
9. Quality control exercises and documentation practices

Semester III- Haematology and Transfusion Medicine

Code	COURSE NAME	L/P	C	Hours	IA	ESE	Total
M03MLSHT01	Blood Banking and Immunohematology	4	4	60	30	70	100
M03MLSHT02	Transfusion Medicine	4	4	60	30	70	100
M03MLSHT03	Molecular Hematology	4	4	60	30	70	100
M03MLSHT04	Advanced Haematological Techniques	2	2	30	30	70	100
	Practical						
M03MLSHT05	Blood Banking and Immunohematology Practical	2	2	60	30	70	100
M03MLSHT06	Transfusion Medicine Practical	2	2	60	30	70	100
M03MLSHT07	Molecular Hematology Practical	2	2	60	30	70	100
M03MLSHT08	Advanced Haematological Techniques Practical	2	2	60	30	70	100
	Total	**22**	**22**	**450**	**240**	**560**	**800**

L: Lecture, T: Tutorial; P: Practical, C: Credit; I: Internal Assessment; ESE: End Semester Examination

Course name: Blood Banking and Immunohematology
Total credits: 4 (60 hours)

Course Rationale: The course is designed for students to apply advanced immunohaematological principles. They can also independently execute donor screening, blood collection and preparation of blood components.

Learning outcome: At the end of the course the students can

- Apply advanced immunohematological principles in laboratory diagnostics.
- Demonstrate competency in antibody detection, identification, and complex serological problem solving.
- Execute donor screening, blood collection, and blood component preparation as per national regulatory standards.
- Evaluate and manage transfusion reactions and special transfusion scenarios.
- Ensure compliance with quality standards, biosafety, and legal regulations in blood banking.

UNIT	M03MLSHT01 Blood Banking and Immuno hematology	C=4 (60hr)
I	Advanced Immunohematologic Principles: Principles of Immunohematology, Genetics of ABO blood group system, their subgroups, RBC antigens and consecutive antibodies, Genetics of Rh Blood group and antibodies, Minor blood group systems, Bombay blood group, ABO and Rh incompatibility, Hemolytic Disease of newborn and its management, Alloantibodies Vs auto antibodies, High-titer, low-avidity antibodies, Human leucocytic antigen	15

II	Blood collection and donor selection criteria: **Donor Management:** Donor registration and screening, Phlebotomy in blood banks, blood storage, various anticoagulants used in blood bags, types of blood bags used in blood banks **Blood Collection & Processing:** Whole blood collection, Adverse reactions and their management, Blood transmitted disease and their testing, Labelling, storage, and transportation of blood	**10**
III	Serologic Techniques and Problem Solving: Blood compatibility tests, Antibody screening and identification, DAT and IAT optimization, Enzyme treatment, adsorption/elution techniques,	**10**
IV	Component preparation and storage: Apheresis vs whole blood donation, Component separation techniques, Storage, shelf-life, and transportation protocols, Hemovigilance in component therapy	**10**
V	Molecular Applications in Immunohematology: Molecular genotyping of blood groups**,** Discrepancy resolution between serology and molecular testing**,** Role in prenatal and donor typing	**5**
VI	Regulatory, QC, and Ethics in Blood Banks: NABH, NACO, FDA, CDSCO guidelines, Quality management system (QMS), Inventory management, Incident reporting & blood bank audits, Regulatory framework: Drugs and Cosmetics Act, licensing of blood banks, GMP, GLP, SOPs, and NABH/NABL accreditation, Standard operating procedures (SOPs), External quality assessment (EQA), Regulatory compliance (FDA, NABL, DGHS), Safety and biosafety in blood banks	**10**
	Total	**60**

Suggested Readings:

1. Lee, G. R., Foerster, J., Lukens, J., Paraskevas, F., Greer, J. P., & Rodgers, G. M. (1999). Wintrobe's clinical hematology 10th. *Bethseda, Maryland: Lippincort Williams and Wilkins.*
2. Klatt, E. C. (2014). *Robbins and Cotran atlas of pathology*. Elsevier Health Sciences.
3. Firkin, F., Chesterman, C., Rush, B., & Pennigton, D. (2008). *De Gruchy's Clinical haematology in medical Practice*. John Wiley & Sons.
4. Bain, B. J., Bates, I., & Laffan, M. A. (2016). *Dacie and Lewis Practical Haematology E-Book: Dacie and Lewis Practical Haematology E-Book*. Elsevier Health Sciences.
5. Ajmani, P. S. (2020). *Immunohematology and blood banking: principles and practice*. Springer Nature

SARDAR PATEL UNIVERSITY
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Course: Transfusion Medicine **Total credits: 4 (60 hours)**

Course Rationale: This course aims to provide students with a comprehensive understanding of the scientific principles, laboratory techniques, and clinical applications involved in blood transfusion services. It covers essential areas such as immunohematology, donor selection and screening, blood collection and processing, compatibility testing, transfusion reactions, and hemovigilance systems.

Learning Outcome: At the end of the course the student will be able to:

- Explain the immunological basis and principles of transfusion medicine.
- Evaluate transfusion requirements for different clinical scenarios.
- Identify and manage transfusion reactions and complications.

UNIT	M03MLSHT02 Transfusion Medicine	C=4 (60hr)
I	Hematopoietic stem cells and related cellular products: Bone-Marrow-Derived Hematopoietic Progenitor Cells, Peripheral-Blood-Derived Hematopoietic Progenitor Cells, Umbilical Cord Blood Stem Cells, Mononuclear Cell Preparations	10
II	Specialized transfusion situations: Management of Acute Bleeding and Massive Transfusion, Evaluation of the Bleeding Patient, Management of Platelet Refractory Patient, Management of Transfusion in Obstetrics: Maternal and Fetal Considerations, Management of Infants and Children, Management of Immunocompromised Patient	**12**
III	Transfusion Reactions and Hemovigilance: Classification and types of transfusion reactions, Acute and Delayed Hemolytic Transfusion Reactions, Febrile Nonhemolytic Transfusion Reactions, Allergic Transfusion Reactions, Other Noninfectious Complications of Transfusion, Investigations and reporting protocols of transfusion reactions, Hemovigilance system in India, management of transfusion-related complications.	**12**
IV	Infectious complications of transfusion Hepatitis, CMV and Other Herpesviruses, HIV and HTLV, Other Transfusion-Transmitted Infections, Bacterial Contamination of Blood Products	**10**
V	Therapeutic apheresis Plasma Exchange, Red Blood Cell Exchange, Extracorporeal Photopheresis, Leukocytapheresis, Thrombocytapheresis, Erythrocytapheresis, Therapeutic Phlebotomy	**10**
VI	Quality Assurance, Ethics and Regulatory Aspects Regulatory framework: Drugs and Cosmetics Act, licensing of blood banks; GMP, GLP, SOPs, and NABH/NABL accreditation, Ethical issues and patient rights in transfusion medicine, compliance with quality and regulatory standards.	**6**
	Total	**60**

Suggested Readings:

1. Lee, G. R., Foerster, J., Lukens, J., Paraskevas, F., Greer, J. P., & Rodgers, G. M. (1999). Wintrobe's clinical hematology 10th. *Bethseda, Maryland: Lippincort Williams and Wilkins.*

2. Hillyer, C., Hillyer, K. L., Strobl, F., Jefferies, L., & Silberstein, L. (Eds.). (2001). *Handbook of transfusion medicine*. Academic press.

3. Harmening, D. M. (2018). *Modern blood banking & transfusion practices*. FA Davis.

4. McCullough, J. (2021). *Transfusion medicine. John Wiley & Sons.*

5. Vengelen-Tyler, V. (2019). Technical Manual, American Association of Blood Banks (AABB). *Bethesda, Maryland: American Assocociation of Blood Banks (AABB).*

6. National Blood Policy and Guidelines – NACO, India

Course Name: Molecular Hematology **Total Credits: 4 (60 hours)**

Course Rationale: This course is designed to provide in-depth knowledge of the molecular mechanisms underlying normal hematopoiesis and a wide spectrum of hematologic conditions. Emphasis will be placed on the application of molecular diagnostic techniques such as PCR, RT-PCR, gene sequencing, and next-generation sequencing (NGS) in hematologic investigations.

Learning Outcome: At the end of the course students will be able to:

- Analyze the molecular pathogenesis of hematological malignancies and inherited blood disorders using current scientific principles.
- Apply molecular biology techniques (e.g., PCR, NGS, etc.) for the detection, diagnosis, and monitoring of hematologic diseases.
- Interpret molecular diagnostic results and correlate them with clinical and pathological data for disease classification and prognosis

UNIT	M03MLSHT03 Molecular Hematology	C=4 (60hr)
I	**Basics of molecular hematology** Central dogma, transcriptional regulation of hemopoeitic cells, Post-transcriptional and translational control, mRNA stability and microRNAs in hematology, Non-coding RNAs and their role in blood cell gene regulation, Epigenetic dysregulation in hematologic malignancies, Transcription factors in hematopoesis	6
II	**Molecular Basis of Hematologic Malignancies** Chromosomal abnormalities (translocations, deletions, duplications), Oncogenes and tumor suppressor genes, Molecular pathogenesis of leukemia (AML, ALL, CML, CLL), Lymphomas: Molecular classification and biomarkers, Minimal Residual Disease (MRD) monitoring	**15**

III	**Inherited and Acquired Hematologic Disorders** Hemoglobinopathies: Molecular basis of thalassemias and sickle cell anemia, Coagulation disorders: FVIII, FIX gene mutations, von Willebrand disease, Bone marrow failure syndromes (Fanconi anemia, Diamond-Blackfan anemia), Congenital neutropenias and thrombocytopenias, Iron metabolism genes and disorders	**15**
IV	**Molecular Diagnostic Techniques** PCR, qPCR, RT-PCR, Next-Generation Sequencing (NGS) basics and applications, Microarray and gene expression profiling, FISH and Southern blotting, Bioinformatics tools for hematology (mutation databases, variant interpretation)	**12**
V	**Translational and Precision Hematology** Molecular therapeutics (tyrosine kinase inhibitors, antisense oligonucleotides), Gene editing (CRISPR-Cas9) in hemoglobinopathies, CAR-T cell therapy in hematologic malignancies, Ethical issues in molecular hematology and genetic testing	**12**
	Total	**60**

Suggested Readings:

1. Hoffbrand, A. V. (2024). Hoffbrand's essential haematology. John Wiley & Sons.
2. Provan, D. (2010). Molecular hematology. D. Provan, & J. Gribben (Eds.). Oxford: Wiley-Blackwell.
3. Kaushansky, Kenneth, ed. Williams Hematology. Ninth edition. New York: McGraw-Hill Education, 2016. Print.
4. Strachan, T. (2018). Human Molecular Genetics (5th ed.). Garland Science.
5. Silberstein, L. E., & Anastasi, J. (2017). Hematology: Basic Principles and Practice. Elsevier Health Sciences

Course name: Advanced Hematological Techniques **Total credits: 2 (30 hours)**

Course Rationale: The curriculum will bridge the traditional hematological practices with modern diagnostic tools. Fostering a deeper understanding of blood cell morphology, bone marrow examination, flow cytometry, cytogenetics, and molecular approaches used in the diagnosis of hematologic malignancies and other blood disorders.

Learning Outcome: At the end of the course the student will be able to:

- Apply advanced hematological techniques in diagnostic and research settings.
- Understand and operate hematology analyzers, flow cytometers, and molecular diagnostic tools.
- Correlate laboratory findings with clinical conditions in hematological disorders.

UNIT	**M03MLSHT04** **Advanced Hematological Techniques**	**C=2** **(30hr)**
I	**Automation in Hematology** Basics and principles of automated hematology analyzers (3-part, 5-part, 7-part differentials), Automation in Reticulocyte, and platelet analysis by automation,	8

	Flags and error codes: troubleshooting and interpretation, Operation, maintenance, and QC on hematology analyzers, Interpreting laboratory results and values, laboratory statistics	
II	**Clinical Flow cytometry and cytogenetics** Principles of flow cytometry, cell sorting, sample preparation and gating strategies, panel selection, data analysis and reporting, applications of flow cytometry, Karyotyping and chromosomal aberrations in hematological malignancies: principle and applications	**8**
III	**Laboratory Information Systems (LIS)** Sample tracking from collection to result reporting, Interface with analyzers, middleware, and HIS (Hospital Information Systems), Barcode systems for error reduction and traceability.	**7**
IV	**Quality Assurance & Advanced Data Interpretation** Laboratory organization and management in hematology lab, Quality Assurance, Ethics in hematology lab, Preanalytic and Postanalytic automation and medical decision, specimen rejection criteria, Point of care testing Hematology in under resourced laboratories	**7**
	Total	**30**

Suggested Readings:

1. Hoffbrand, A. V. (2024). Hoffbrand's essential haematology. John Wiley & Sons. 1. McPherson, R. A., & Pincus, M. R. (2017). *Henry's clinical diagnosis and management by laboratory methods.* Edition 23. Elsevier.
2. Bain, B. J., Bates, I., & Laffan, M. A. (2017). Dacie and Lewis practical haematology (12th ed.). Elsevier.
3. Latest CLSI and NABL guidelines

UNIT	**M03MLSHT05** **Blood Banking and Immunohematology Practical**	**C=2** **(60hr)**

1. Preparation of Red Cell Suspensions and daily Quality Control of ABO & Rh D Preparation of Papain cystein and Blood Group Regents
2. Performing ABO Blood Group
3. Performing Antigen Typing – Indirect
4. Performing Direct Anti-Globulin Test
5. Performing Anti-globulin Cross-Match
6. Study of Labelling of Blood Bags and Blood Components
7. Study of Storage of Blood and Blood Components
8. Study of Inventory of Blood Bags and Blood Components
9. Study of Selection of units for cross matching
10. Bilirubin Testing
11. Disposal of Reactive Bags, its components, non-reactive buffy coat units
12. ELISA/ Rapid card based identification of blood borne infections

*** Clinical postings should be incorporated wherever possible

UNIT	M03MLSHT06 Transfusion Medicine Practical	C=2 (60hr)

1. ELISA and rapid tests for HIV, HBV, HCV, syphilis, malaria
2. Nucleic Acid Testing (NAT) – demonstration or simulation
3. Principle of HLA typing (serological/molecular methods)
4. Nucleic Acid Testing (NAT) – demonstration or simulation
5. Blood component separation by apheresis
6. Anticoagulants used for apheresis
7. Therapeutic apheresis
8. Special considerations of therapeutic apheresis in paediatric patients
9. Extracorporeal photopheresis
10. Clinical postings can be incorporated

UNIT	M03MLSHT07 Molecular Haematology Practical	C=2 (60hr)

1. DNA isolation from EDTA whole blood.
2. PCR for β-thalassemia mutations (e.g., IVS1-5, Codon 41/42).
3. Agarose gel electrophoresis for visualization of amplified products.
4. RNA extraction and cDNA synthesis for gene expression.
5. Real-Time PCR for BCR-ABL fusion transcript quantification.
6. Detection of JAK2 V617F mutation via allele-specific PCR.
7. Multiplex PCR for α-thalassemia deletion screening.
8. Hands-on data interpretation and mock reporting using anonymized patient results.

UNIT	M03AHMLS08 Advanced Hematological Techniques Practical	C=2 (60hr)

1. Operation, maintenance, and QC on hematology analyzers
2. Sample prep, acquisition, and basic analysis using flow cytometry
3. Demonstration of PCR and interpretation of results
4. Slide preparation, banding techniques, and interpretation (demo-based)
5. Quality logs, data analysis, and case discussions

***Compulsory clinical postings for hands on experience for hematoanalyzers, PCR and case discussions. This will compensate the hours against credits.