

Standard Operating Procedure		
 LABORATORY ACCREDITATION BUREAU	Subject: Handling of Scopes of Accreditation	SOP 216
Written by: Doug Leonard	Revision 5 Date: 06/08/10	Page 1 of 4

POLICY / POLICY REFERENCE

ISO / IEC Guide 17011

L-A-B Quality System Manual

PURPOSE AND SCOPE

This procedure defines the method for developing, approving, and maintaining Scope of Accreditation by LAB.

RESPONSIBILITY

It is the responsibility of the Applicant Laboratory and L-A-B to develop the Proposed Scope of Accreditation in accordance with the appropriate proposed scope guidelines. The assessor is responsible for approving the Proposed Scope of Accreditation after an assessment. It is the responsibility of the L-A-B Testing and Calibration manager to assure the appropriate Major Field and Discipline parameters are listed correctly on the Scope of Accreditation.

PROCEDURE

1 - Preparation of the Proposed Scope of Accreditation

The applicant laboratory shall prepare a Proposed Scope of Accreditation in accordance with the following guidelines:

Testing Laboratories

- Form 28.9 - Proposed Scope Instructions - Testing
- Form 28.6 - Proposed Scope Template - Testing

Calibration Laboratories

- Form 28.10 - Proposed Scope Instructions - Calibration
- Form 28.8 - Proposed Scope Template - Calibration

Dimensional Inspection

- Form 28.11 - Proposed Scope Instruction - Dimensional Inspection
- Form 28.5 - Proposed Scope Template - Dimensional Inspection

Multiple Disciplines

- Form 28.13 Proposed Scope Template-Combination

Laboratory Procedure Manual Format

**Donnell R. Christian Jr., Stephanie
Drilling**



Laboratory Procedure Manual Format:

Clinical Laboratory Procedure Manuals National Committee for Clinical Laboratory Standards, 1984 **Implementing Quality in Laboratory Policies and Processes** Donnell R. Christian Jr., Stephanie Drilling, 2009-11-24 In order to gain accreditation every laboratory must have a superior quality assurance program The keys to a successful program are the operational and technical manuals and associated documents which define the program and its various components Written by experts with global experience in setting up laboratories Implementing Quality in Labora Handbook of the Laboratory Diagnosis and Treatment of Infertility Brooks A. Keel, Bobby W. Webster, 1990-06-22 This book provides comprehensive detailed and step by step descriptions of materials and methods currently used in laboratory procedures within the infertility clinic It addresses the numerous highly sophisticated procedures resulting from research in the area of laboratory diagnosis and treatment of infertility Among those procedures covered are Clinical Virology Manual Richard L. Hodinka, Stephen A. Young, Benjamin A. Pinsky, 2020-07-10 The definitive clinical virology resource for physicians and clinical laboratory virologists The clinical virology field is rapidly evolving and as a result physicians and clinical laboratory virologists must have a reliable reference tool to aid in their ability to identify and diagnose viral infections to prevent future outbreaks In this completely revised edition of the Clinical Virology Manual Editor in Chief Michael Loeffelholz along with Section Editors Richard Hodinka Benjamin Pinsky and Stephen Young have compiled expert perspectives of a renowned team of clinical virology experts and divided these contributions into three sections to provide the latest information on the diagnosis of viral infections including ebola HIV and Human papillomavirus state of the art diagnostic technologies including next generation sequencing and nucleic acid amplification methods taxonomy of clinically important viruses such as polyomaviruses and zoonotic viruses This comprehensive reference also includes three appendices with vital information on reference virology laboratories at the Centers for Disease Control and Prevention state and local public health laboratories and international reference laboratories and laboratory systems Additionally a new section Diagnostic Best Practices which summarizes recommendations for diagnostic testing and cites evidence based guidelines is included in each viral pathogens chapter Clinical Virology Manual Fifth Edition serves as a reference source to healthcare professionals and laboratorians in providing clinical and technical information regarding viral diseases and the diagnosis of viral infections *Clinical Hematology: Theory & Procedures, Enhanced Edition* Mary Lou Turgeon, 2020-06-29 Clinical Hematology Theory Procedures Enhanced Sixth Edition is a competency based text with built in study tools to help you master the theory of clinical hematology and the procedures used to diagnose and treat disorders of the blood and bone marrow Molecular Pathology in Clinical Practice Debra G.B. Leonard, 2007-11-25 This authoritative textbook embodies the current standard in molecular testing for practicing pathologists and residents and fellows in training The text is organized into eight sections genetics inherited cancers infectious disease neoplastic hematopathology solid tumors HLA typing identity testing and laboratory management

Discussion of each diagnostic test includes its clinical significance available assays quality control and lab issues interpretation and reasons for testing Coverage extends to HIV hepatitis developmental disorders bioterrorism warfare organisms lymphomas breast cancer and melanoma forensics parentage and much more Includes 189 illustrations 45 in full color This textbook is a classic in the making and a must have reference Accreditation Practices for Inspections, Tests, and Laboratories Harvey Schock,1989 *Handbook of the Assisted Reproduction Laboratory* Brooks A. Keel,Jeffrey V. May,Christopher J. DeJonge,2000-05-15 With the advent of Assisted Reproductive Technologies our understanding of the reproductive system in both men and women has progressed in an exponential manner Along with this increase in knowledge has emerged new and advanced laboratories performing unique techniques aimed at diagnosing and treating infertility problems And as these lab

Clinical Chemistry - E-Book Donna Larson,2015-12-17 Gain a clear understanding of pathophysiology and lab testing Clinical Chemistry Fundamentals and Laboratory Techniques prepares you for success as a medical lab technician by simplifying complex chemistry concepts and lab essentials including immunoassays molecular diagnostics and quality control A pathophysiologic approach covers diseases that are commonly diagnosed through chemical tests broken down by body system and category such as respiratory gastrointestinal and cardiovascular conditions Written by clinical chemistry educator Donna Larson and a team of expert contributors this full color book is ideal for readers who may have minimal knowledge of chemistry and are learning laboratory science for the first time Full color illustrations and design simplify complex concepts and make learning easier by highlighting important material Case studies help you apply information to real life scenarios Pathophysiology and Analytes section includes information related to diseases or conditions such as a biochemistry review disease mechanisms clinical correlation and laboratory analytes and assays Evolve companion website includes case studies and animations that reinforce what you ve learned from the book Laboratory Principles section covers safety quality assurance and other fundamentals of laboratory techniques Review questions at the end of each chapter are tied to the learning objectives helping you review and retain the material Critical thinking questions and discussion questions help you think about and apply key points and concepts Other Aspects of Clinical Chemistry section covers therapeutic drug monitoring toxicology transplantation and emergency preparedness Learning objectives in each chapter help you to remember key points or to analyze and synthesize concepts in clinical chemistry A list of key words Is provided at the beginning of each chapter and these are also bolded in the text Chapter summaries consist of bulleted lists and tables highlighting the most important points of each chapter A glossary at the back of the book provides a quick reference to definitions of all clinical chemistry terms Field Manuals United States. War Department,1977 **Practical Veterinary Urinalysis** Carolyn A. Sink,Nicole M. Weinstein,2011-12-14 Practical Veterinary Urinalysis is a comprehensive clinically relevant resource for the veterinary laboratory This bench top guide covers sample handling guidelines interpretation of dry chemical analysis and recommendations for physical and microscopic evaluation Emphasizing diagnostic techniques and

result interpretation Practical Veterinary Urinalysis is an ideal aid for anyone who performs and interprets urinalysis testing Beginning with an overview of renal physiology and urine production the main focus of the book is examination and analysis of urine samples including physical properties chemical analysis and sediment examination Additional chapters review diagnostic tests and considerations for proteinuria advanced diagnostics quality assurance and laboratory set up Practical Veterinary Urinalysis is an invaluable tool for achieving accurate and reliable laboratory results and is a useful addition to any veterinary library

Clinical Hematology: Principles, Applications, and Molecular Concepts Mary Louise Turgeon, 2025-03-05 Clinical Hematology features strong pedagogy that sets the quality benchmark for hematology competency based content needed by MLT and MLS students and is informed by and mapped to ASCLS Entry Level and Professional Body of Knowledge competencies in hematology hemostasis and coagulation and molecular applications

Cytogenetic Laboratory Management Susan Mahler Zneimer, 2017-01-27 Cytogenetic Laboratory Management Cytogenetic Laboratory Management Chromosomal FISH and Microarray Based Best Practices and Procedures Cytogenetic Laboratory Management Chromosomal FISH and Microarray Based Best Practices and Procedures is a practical guide that describes how to develop and implement best practice processes and procedures in the genetic laboratory setting The text first describes good laboratory practices including quality management design control of tests and FDA guidelines for laboratory developed tests and preclinical validation study designs The second focus of the book is on best practices for staffing and training including cost of testing staffing requirements process improvement using Six Sigma techniques training and competency guidelines and complete training programs for cytogenetic and molecular genetic technologists The third part of the text provides stepwise standard operating procedures for chromosomal FISH and microarray based tests including preanalytic analytic and postanalytic steps in testing which are divided into categories by specimen type and test type All three sections of the book include example worksheets procedures and other illustrative examples that can be downloaded from the Wiley website to be used directly without having to develop prototypes in your laboratory Providing a wealth of information on both laboratory management and molecular and cytogenetic testing Cytogenetic Laboratory Management will be an essential tool for laboratorians worldwide in the field of laboratory testing and genetic testing in particular This book gives the essentials of Developing and implementing good quality management programs in laboratories Understanding design control of tests and preclinical validation studies and reports FDA guidelines for laboratory developed tests Use of reagents instruments and equipment Cost of testing assessment and process improvement using Six Sigma methodology Staffing training and competency objectives Complete training programs for molecular and cytogenetic technologists Standard operating procedures for all components of chromosomal analysis FISH and microarray testing of different specimen types This volume is a companion to Cytogenetic Abnormalities Chromosomal FISH and Microarray Based Clinical Reporting The combined volumes give an expansive approach to performing reporting and interpreting cytogenetic

laboratory testing and the necessary management practices staff and testing requirements **The AGT Cytogenetics**

Laboratory Manual Marilyn S. Arsham, Margaret J. Barch, Helen J. Lawce, 2017-04-24 Cytogenetics is the study of chromosome morphology structure pathology function and behavior The field has evolved to embrace molecular cytogenetic changes now termed cytogenomics Cytogeneticists utilize an assortment of procedures to investigate the full complement of chromosomes and or a targeted region within a specific chromosome in metaphase or interphase Tools include routine analysis of G banded chromosomes specialized stains that address specific chromosomal structures and molecular probes such as fluorescence in situ hybridization FISH and chromosome microarray analysis which employ a variety of methods to highlight a region as small as a single specific genetic sequence under investigation The AGT Cytogenetics Laboratory Manual Fourth Edition offers a comprehensive description of the diagnostic tests offered by the clinical laboratory and explains the science behind them One of the most valuable assets is its rich compilation of laboratory tested protocols currently being used in leading laboratories along with practical advice for nearly every area of interest to cytogeneticists In addition to covering essential topics that have been the backbone of cytogenetics for over 60 years such as the basic components of a cell use of a microscope human tissue processing for cytogenetic analysis prenatal constitutional and neoplastic laboratory safety and the mechanisms behind chromosome rearrangement and aneuploidy this edition introduces new and expanded chapters by experts in the field Some of these new topics include a unique collection of chromosome heteromorphisms clinical examples of genomic imprinting an example driven overview of chromosomal microarray mathematics specifically geared for the cytogeneticist usage of ISCN s cytogenetic language to describe chromosome changes tips for laboratory management examples of laboratory information systems a collection of internet and library resources and a special chapter on animal chromosomes for the research and zoo cytogeneticist The range of topics is thus broad yet comprehensive offering the student a resource that teaches the procedures performed in the cytogenetics laboratory environment and the laboratory professional with a peer reviewed reference that explores the basis of each of these procedures This makes it a useful resource for researchers clinicians and lab professionals as well as students in a university or medical school setting *A Laboratory Procedure Guide for Partial Denture Prosthesis* Aloys Charles

Metty, Earl J. Dinger, 1954 **Ruppel's Manual of Pulmonary Function Testing - E-Book** Carl Mottram, 2022-02-01 Selected for Doody s Core Titles 2024 in Respiratory Therapy Master pulmonary function testing procedures and prepare for PFT credentialing exams Ruppel s Manual of Pulmonary Function Testing 12th Edition provides comprehensive coverage of common pulmonary function tests testing techniques and the pathophysiology that may be evaluated by each test It also includes information on equipment measurement software reference values and quality assurance so you can develop the testing skills you need to find and assess lung abnormalities and conditions such as asthma COPD and emphysema Written by Carl D Mottram a well known expert in pulmonary function procedures this bestselling guide helps you get accurate test

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Guidelines for Laboratory Quality Managers Saverio Mannino, 2022-11-22 This useful and extensive set of guidelines is designed to assist food control laboratories in gaining accreditation from an internationally recognized external body providing all of the necessary information and practices in an easy to read step by step fashion Authored by an experienced consultant for laboratory accreditation in many different countries with this text food control lab owners now have all of the up to date information they need to gain accreditation in a single source Guidelines for Laboratory Quality Managers covers the essentials for quality management in the food control laboratory from testing processes to current quality management systems The ISO standards for accreditation are extensively explored including managerial requirements organizational aspects complaint handling procedures internal audits and sampling An entire section is dedicated to the implementation of managerial and technical requirements from quality control to program monitoring and evaluation Analysis selection preparation and validation is covered extensively and an entire section is dedicated to basic statistics from data presentation to distribution Each section comes with helpful tips for lab managers plus definitions and terms Comprehensive easy to use and up to date Guidelines for Laboratory Quality Managers is the guide for accreditation for food control laboratories

Mapping the Chemical Environment of Urban Areas Christopher C. Johnson, Alecos Demetriades, Juan Locutura, Rolf Tore Ottesen, 2011-02-11 This comprehensive text focuses on the increasingly important issues of urban geochemical mapping with key coverage of the distribution and behaviour of chemicals and compounds in the urban environment Clearly structured throughout the first part of the book covers general aspects of urban chemical mapping with an overview of current practice and reviews of different aspects of the component methodologies The second part includes case histories from different urban areas around Europe authored by those national or academic institutions tasked with investigating the chemical environments of their major urban centers

Urinalysis & Body Fluids Susan King Strasinger, Marjorie Schaub Di Lorenzo, 2008-02-20 Practical focused and reader friendly this popular text teaches the theoretical and practical knowledge every clinical laboratory

scientist needs to handle and analyze non blood body fluids and to keep you and your laboratory safe from infectious agents
The 5th Edition has been completely updated to include all of the new information and new testing procedures that are important in this rapidly changing field Case studies and clinical situations show how work in the classroom translates to work in the lab **Quality Assurance Guidelines for Water Quality Investigations** United States. Bureau of Reclamation. QA/QC Implementation Work Group,1992

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