

Cytogenetic Laboratory Management: Chromosomal, FISH and Microarray-Based Best Practices and Procedures

Susan Mahler Zneimer



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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 describes 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 step-wise standard operating procedures for chromosomal, FISH and microarray-based tests, including pre-analytic, analytic and post-analytic steps in testing, and 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 both a wealth of information on laboratory management and molecular and cytogenetic testing, Cytogenetic Laboratory Management will be an essential tool for laboratorians world-wide in the field of laboratory testing and genetics testing in particular.

This book gives the essentials of:

- Developing and implementing good quality management programs in laboratories
- Understanding design control of tests and pre-clinical validations 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.

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