

Contents

Preface

vii

1. General Principle of Immunoassay

Daniel W. Chan

I. Introduction	1
II. Theoretical Basis of Immunoassay	6
III. Optimization of Immunoassay	9
IV. Heterogeneous Immunoassay Systems	13
V. Homogeneous Immunoassay Systems	18
References	21

2. Production of Immunoassay Reagents

Robert G. Hamilton

I. Introduction	25
II. Receptors or Binders	25
III. Unlabeled Ligands—Calibrators	31
IV. Labeled Ligands and Receptors	32
V. Separation Techniques	36
VI. Buffers	41
References	42

3. Practical Guide to Immunoassay Method Evaluation

Carolyn S. Feldkamp and Stuart W. Smith

I. Introduction	49
II. Protocol Outline	51
III. Establishing Objectives and Preparation	51

IV. Evaluation of Precision	53
V. Standard Curves	58
VI. Tracer	67
VII. Sensitivity	70
VIII. Evaluation of Accuracy	72
IX. Antibody Characteristics	79
X. Monitoring Reaction Conditions	86
XI. Clinical Validation	86
XII. Protocol Development: Summary	92
References	93

4. Clinical Validation of Immunoassays: A Well-Designed Approach to a Clinical Study

Mark H. Zweig and E. Arthur Robertson

I. Introduction	97
II. Elements of a Well-Designed Study	98
III. Choosing Decision Levels to Minimize Costs	116
IV. Relation of New Tests to Existing Tests	118
V. A Word about Normal Ranges	119
VI. Summary	120
VII. Illustrative Example: Apolipoprotein A-I	120
Appendix: Preparation of ROC Curves	122
References	126
Selected Literature	126

5. Data Reduction Techniques for Immunoassay

George F. Johnson

I. Purpose of Chapter	129
II. Introduction	129
III. Interpolation Techniques of Data Reduction	130
IV. Models and Statistical Approaches to Data Reduction	132
V. Nonlinear Models in Immunoassay	135
VI. Summary	140
Appendix A: BASIC Program to Fit Four Parameter Model to Data by Nonlinear Least Squares	140
Appendix B: BASIC Program for Point-to-Point Linear Interpolation	146
References	147

6. Immunoassays: Quality Control and Troubleshooting

Marie T. Perlstein

Part A: Quality Control: A Simple, Cost-Effective Approach	149
I. Introduction	149
II. Implementing a QC Program	150
III. Selection of Appropriate Curve Fits for Immunoassay Data	151
IV. Equipment	153
V. Reagents	154
VI. Assay Conditions	155
VII. Technique	156
VIII. Patient Samples	156
IX. Conclusion	157
Part B: Troubleshooting Immunoassays: Where the Practical and Theoretical Meet	157
I. Introduction	157
II. Parallelism	157
III. Reciprocal Plot	159
IV. Scatchard Analysis	160
Index	165