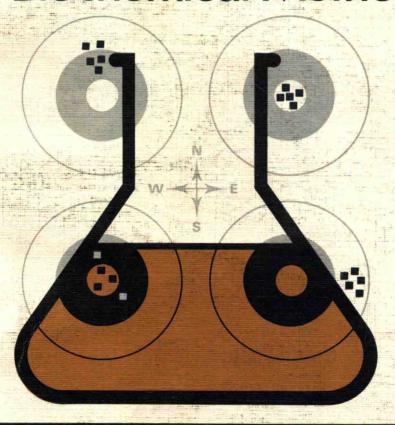




# Assessment and Control of Biochemical Methods



Terry H. Hector

# Assessment and Control of Biochemical Methods

Analytical Chemistry by Open Learning

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Editor: ARTHUR M. JAMES

on behalf of ACOL

Published on behalf of ACOL, London by JOHN WILEY & SONS Chichester · New York · Brisbane · Toronto · Singapore © Crown Copyright, 1986

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#### Library of Congress Cataloging in Publication Data:

Hector, Terry Assessment and control of biochemical methods.

(Analytical chemistry by open learning)
Bibliography: p.
1. Chemistry, Clinical—Quality control—Evaluation.

2. Chemistry, Clinical – Examinations, questions, etc. l. James, A. M. (Arthur M.), 1923–. ll. Title.

III. Series.

RB40.H42 1986 616.07'56 86-19032

ISBN 0 471 91278 6 ISBN 0 471 91279 4 (pbk.)

#### British Library Cataloguing in Publication Data:

Hector, Terry

Assessment and control of biochemical methods.—(Analytical chemistry)

1. Biological chemistry—Technique 2. Chemistry, Analytic—Technique

l. Title Il. James, Arthur M.

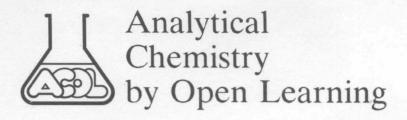
Ill. Analytical chemistry by open learning IV. Series

574.19'285'028 OP519.7

ISBN 0 471 91278 6 ISBN 0 471 91279 4 Pbk

Printed and bound in Great Britain

Assessment and Control of Biochemical Methods



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## **Analytical Chemistry**

This series of texts is a result of an initiative by the Committee of Heads of Polytechnic Chemistry Departments in the United Kingdom. A project team based at Thames Polytechnic using funds available from the Manpower Services Commission 'Open Tech' Project have organised and managed the development of the material suitable for use by 'Distance Learners'. The contents of the various units have been identified, planned and written almost exclusively by groups of polytechnic staff, who are both expert in the subject area and are currently teaching in analytical chemistry.

The texts are for those interested in the basics of analytical chemistry and instrumental techniques who wish to study in a more flexible way than traditional institute attendance or to augment such attendance. A series of these units may be used by those undertaking courses leading to BTEC (levels IV and V), Royal Society of Chemistry (Certificates of Applied Chemistry) or other qualifications. The level is thus that of Senior Technician.

It is emphasised however that whilst the theoretical aspects of analytical chemistry can be studied in this way there is no substitute for the laboratory to learn the associated practical skills. In the U.K. there are nominated Polytechnics, Colleges and other Institutions who offer tutorial and practical support to achieve the practical objectives identified within each text. It is expected that many institutions worldwide will also provide such support.

The project will continue at Thames Polytechnic to support these 'Open Learning Texts', to continually refresh and update the material and to extend its coverage.

Further information about nominated support centres, the material or open learning techniques may be obtained from the project office at Thames Polytechnic, ACOL, Wellington St., Woolwich, London, SE18 6PF.

# How to Use an Open Learning Text

Open learning texts are designed as a convenient and flexible way of studying for people who, for a variety of reasons cannot use conventional education courses. You will learn from this text the principles of one subject in Analytical Chemistry, but only by putting this knowledge into practice, under professional supervision, will you gain a full understanding of the analytical techniques described.

To achieve the full benefit from an open learning text you need to plan your place and time of study.

- Find the most suitable place to study where you can work without disturbance.
- If you have a tutor supervising your study discuss with him, or her, the date by which you should have completed this text.
- Some people study perfectly well in irregular bursts, however most students find that setting aside a certain number of hours each day is the most satisfactory method. It is for you to decide which pattern of study suits you best.
- If you decide to study for several hours at once, take short breaks of five or ten minutes every half hour or so. You will find that this method maintains a higher overall level of concentration.

Before you begin a detailed reading of the text, familiarise yourself with the general layout of the material. Have a look at the course contents list at the front of the book and flip through the pages to get a general impression of the way the subject is dealt with. You will find that there is space on the pages to make comments alongside the

text as you study—your own notes for highlighting points that you feel are particularly important. Indicate in the margin the points you would like to discuss further with a tutor or fellow student. When you come to revise, these personal study notes will be very useful.

When you find a paragraph in the text marked with a symbol such as is shown here, this is where you get involved. At this point you are directed to do things: draw graphs, answer questions, perform calculations, etc. Do make an attempt at these activities. If necessary cover the succeeding response with a piece of paper until you are ready to read on. This is an opportunity for you to learn by participating in the subject and although the text continues by discussing your response, there is no better way to learn than by working things out for yourself.

We have introduced self assessment questions (SAQ) at appropriate places in the text. These SAQs provide for you a way of finding out if you understand what you have just been studying. There is space on the page for your answer and for any comments you want to add after reading the author's response. You will find the author's response to each SAQ at the end of the text. Compare what you have written with the response provided and read the discussion and advice.

At intervals in the text you will find a Summary and List of Objectives. The Summary will emphasise the important points covered by the material you have just read and the Objectives will give you a checklist of tasks you should then be able to achieve.

You can revise the Unit, perhaps for a formal examination, by rereading the Summary and the Objectives, and by working through some of the SAQs. This should quickly alert you to areas of the text that need further study.

Some useful tables are included for reference at the end of the Unit.

## **Study Guide**

The concept of quality and its control in clinical laboratories was introduced in the nineteen forties by S. Levy and E.R. Jennings who based their work on a publication written in 1931 by A.R. Shewhart. Shewart demonstrated the economic importance of laying down exact specifications for mass-produced articles and then monitoring production line output to ensure that variations keep within them.

Clinical biochemistry laboratories rely heavily on automated analytical systems and are often likened to industrial production lines. In the same way that the engineer must pay attention to the design and specifications of his product and ensure that it is of satisfactory quality, the laboratory worker must carefully select and test a new method and establish some means of monitoring its reliability when it is in routine use.

This unit takes you through the processes of method selection, testing, quality control and quality assessment. Statistical notions and techniques as seen from the practice of the biochemical laboratory are introduced, but these have been kept as simple as possible.

It will be assumed that you have an understanding of chemistry equivalent to that of a student who has successfully completed a higher level BTEC course in Chemistry, Applied Biology or Medical Laboratory Sciences. You should have some knowledge of the type of work which is undertaken by clinical biochemistry laboratories and of spectrophotometric analysis from which many of the examples and self assessment questions are taken.

SI units are used throughout the unit but the following two points should be noted:

- Enzyme activity is quoted as U dm<sup>-3</sup>. U represents the international unit of enzyme activity being that which converts 1 micromole of substrate to the reaction products in 1 minute; ie  $\mu$ mol min<sup>-1</sup>.
- The cubic decimetre is used in preference to the litre, however litres do appear in section 5 where EQA reports are reproduced in their original forms.

For reference, a glossary of terms and abbreviations, used in the assessment and control of biochemical methods, is given at the end of the Unit.

## **Bibliography**

The following textbooks would be suitable for further reading and reference:

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### Acknowledgements

This book has benefitted from advice and criticism given by many friends and colleagues, but I would particularly like to thank Carole Hjelm and David Bullock who provided the quality assessment data and read some of the text in its early draft form.

Terry Hector

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# 1. The Selection and Evaluation of Biochemical Assay Methods

#### Overview

In this part we shall discuss the stages involved in the selection and testing of a new method before it is included in the routine workload of the laboratory. Use of automated analytical systems in modern clinical biochemistry laboratories often limits the choice of methods but where some choice does exist it should be made with as complete an understanding as possible of the scientific principles of the method and of its technical advantages and disadvantages.

The three situations which lead to the introduction of a new method into the routine workload of a laboratory are:

- (a) the replacement of an existing method for measuring a particular substance by a new, and hopefully better, methods;
- (b) the introduction of an assay which is routinely used by other laboratories but which has not previously been performed in your own laboratory;
- (c) the development of a new and novel assay which is not in use elsewhere as far as you are aware.

#### 1.1. USE OF THE LITERATURE

In each of the above situations a start can be made on the process of selecting a method by conducting a thorough search of the