
Medical laboratories — Requirements for collection, transport, receipt, and handling of samples

*Laboratoires de biologie médicale — Exigences pour le prélèvement,
le transport, la réception et la manipulation des échantillons*



COPYRIGHT PROTECTED DOCUMENT

© ISO 2017, Published in Switzerland

All rights reserved. Unless otherwise specified, no part of this publication may be reproduced or utilized otherwise in any form or by any means, electronic or mechanical, including photocopying, or posting on the internet or an intranet, without prior written permission. Permission can be requested from either ISO at the address below or ISO's member body in the country of the requester.

ISO copyright office
Ch. de Blandonnet 8 • CP 401
CH-1214 Vernier, Geneva, Switzerland
Tel. +41 22 749 01 11
Fax +41 22 749 09 47
copyright@iso.org
www.iso.org

Contents

Page

Foreword	vi
Introduction	vii
1 Scope	1
2 Normative references	1
3 Terms and definitions	1
4 Quality management	3
5 Pre-examination processes relating to patient samples	4
5.1 General	4
5.2 Laboratory test is ordered	5
5.3 Sample request generation process	5
5.4 Process for providing instructions to patients	5
5.5 Patient identification process	5
5.6 Preparation for sample collection process	5
5.7 Primary sample collection and labelling process	5
5.8 Preparation for transportation process	5
5.9 Sample transport process	5
5.10 Sample receipt process	5
5.11 Process for preparing sample for examination	5
6 Infrastructure and environmental conditions	6
6.1 General	6
6.2 Design	6
6.2.1 General	6
6.2.2 Safety and accessibility	6
6.2.3 Privacy and confidentiality	7
6.2.4 Equipment, supplies and storage	7
6.3 Facility maintenance and environmental conditions	7
6.4 Personnel facilities	7
7 Equipment and supplies	7
7.1 General	7
7.2 Equipment acceptance testing	7
7.3 Inspection and storage	8
7.4 Inventory management	8
7.5 Equipment maintenance and repair	8
7.6 Equipment operation	8
7.7 Computer equipment	9
7.8 Equipment records	9
8 Infection prevention and control (biosafety)	10
8.1 Personal protective equipment	10
8.2 Hand hygiene	10
8.3 Personnel practices	10
8.4 Safe disposal	10
8.5 Patient protection	11
8.6 Cleaning and disinfection	11
8.7 Special precautions	11
9 Personnel	11
9.1 General	11
9.2 Training and competence	11
9.2.1 Personnel training	11
9.2.2 Competence and continuing education	12
9.3 Confidentiality and access to information	12
9.4 Personnel records	12