

ISO 20658:2023-05 (E)

Requirements for the collection and transport of samples for medical laboratory examinations

Contents		Page
Foreword		v
Introduction		vi
1	Scope	1
2	Normative references	1
3	Terms and definitions	1
4	General requirements	4
4.1	General	4
4.2	Ethical conduct	5
4.2.1	General	5
4.2.2	Impartiality	5
4.2.3	Confidentiality	5
4.2.4	Requirements regarding patients, facility personnel and others	6
5	Structural requirements	6
5.1	Legal entity	6
5.2	Facility manager	6
5.2.1	Facility manager competence	6
5.2.2	Delegation of duties	6
5.3	Facility responsibilities and activities	6
5.3.1	Facility activities	6
5.3.2	Structure and authority	7
5.3.3	Advisory services	7
5.3.4	Risk management	7
5.3.5	Emergency situations	7
6	Resource requirements	7
6.1	General	7
6.2	Personnel	8
6.2.1	General	8
6.2.2	Training	8
6.2.3	Competence assessment	9
6.2.4	Continuing education and/or continuing professional development	9
6.2.5	Personnel records	9
6.3	Facilities and environmental conditions	9
6.3.1	General	9
6.3.2	Design	9
6.3.3	Privacy and confidentiality	10
6.3.4	Equipment, supplies and storage	11
6.3.5	Facility maintenance	11
6.3.6	Personnel facilities	11
6.4	Equipment, reagents, and consumables	11
6.4.1	General	11
6.4.2	Verification and storage	11
6.4.3	Inventory management	11
6.4.4	Equipment maintenance and repair	12
6.4.5	Equipment operation and instructions for use	12

6.4.6	Adverse incident reporting	12
6.4.7	Computer equipment	13
6.4.8	Records	13
7	Process requirements	13
7.1	General	13
7.2	Test selection and requesting	14
7.3	Request information	14
7.3.1	General	14
7.3.2	Request to perform sample collection for subsequent laboratory examination	15
7.3.3	Oral requests	16
7.3.4	Handling urgent requests	16
7.4	Patient identification and reception	16
7.4.1	Transcription	16
7.4.2	Information for patients and users	16
7.4.3	Patient identification	16
7.5	Patient preparation	18
7.6	Sample collection	18
7.6.1	General	18
7.6.2	Informed consent before sample collection	19
7.6.3	Instructions for collection activities	19
7.6.4	Patient-collected samples	20
7.7	Blood sample collection	20
7.7.1	General	20
7.7.2	Order of draw	21
7.7.3	Special considerations when performing venepuncture	21
7.7.4	Adult capillary puncture	22
7.7.5	Paediatric blood collection	22
7.7.6	Vascular access devices (VAD)	23
7.7.7	Arterial puncture	24
7.8	Identification of samples	25
7.8.1	General	25
7.8.2	Handling urgent samples	25
7.9	Sample integrity and stability	25
7.9.1	Sample integrity	25
7.9.2	Stability	26
7.9.3	Stabilization of samples	26
7.10	Package and transport of samples	26
7.10.1	General	26
7.10.2	Sample transport	27
7.10.3	Quality and safety monitoring	28
7.11	Infection prevention and control (biosafety)	28
7.11.1	Personal protective equipment (PPE)	28
7.11.2	Hand hygiene	28
7.11.3	Personnel practices	29
7.11.4	Safe disposal	29
7.11.5	Patient protection	29
7.11.6	Cleaning and disinfection	29
7.11.7	Special precautions	30
8	Management system requirements	30
8.1	General requirements	30
8.2	Evaluation of pre-examination processes	30
8.2.1	General	30
8.2.2	Quality indicators	30
8.3	Facility user and personnel feedback	31
8.4	Customer satisfaction	31
Annex A (normative)	Your five moments for hand hygiene	32

Annex B (informative) Disinfectants	33
Annex C (informative) Pre-examination process	35
Annex D (normative) Sample types other than blood	36
Bibliography	40