

QUALITY MANUAL: MODEL ACCORDING EC4 ESSENTIAL CRITERIA v. 2.0

7. PREANALYTICAL PHASE

7.5. INFORMATION AND PREPARATION OF PATIENTS

AUTHOR	VERSION	APPROVED BY	DATE	

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1. INTRODUCTION

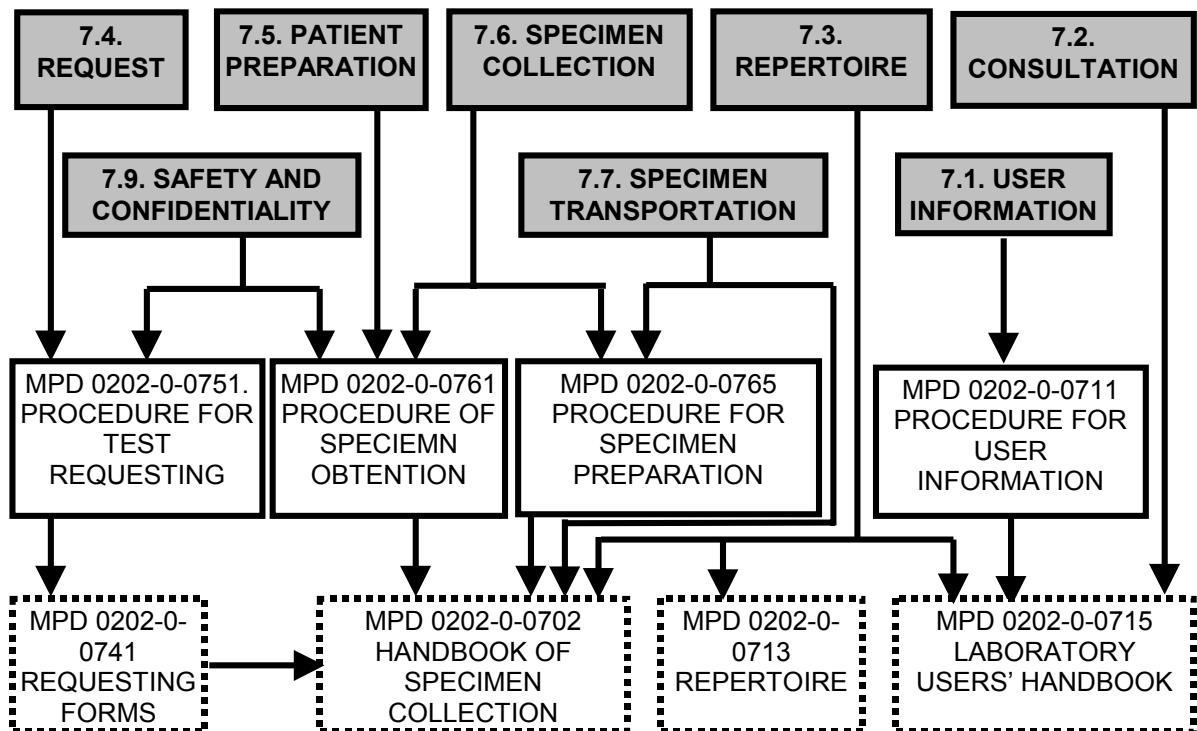
There should be information available for patients regarding special diets or other preparatory measures.

There should be information available for patients concerning collection of urine, farces, and semen.

There should be information for patients concerning opening hours and location of the laboratory.

Waiting time for the patients should meet defined criteria.

1.1. SCOPE



1.2. AIMS

To fulfil the requirements of the following clauses:

ISO 15189	ISO 9000: 2000	ISO 17025
5.4. Pre-examination procedures 5.4.3.		

1.3. PUBLICATION CREDITS

EC4 WG

1.4. REFERENCES

- Jansen RTP, Blaton V, Burnett D, Huisman W, Queraltó JM, Zérah S, Allman B. European Communities Confederation of Clinical Chemistry: Essential criteria for quality systems of medical laboratories. Eur J Clin Chem Clin Biochem 1997; 35(2): 123-132.
- ISO/FDIS 15189, Quality management in the medical laboratory (December 1998). 5.4.3.
- Jansen RTP, Bank CMC, Huisman W, Penders TJ. NVKC Model quality manual. 2nd rev. Ed. Utrecht: NVKC 1996.

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1.5. RELATED DOCUMENTS

MPD 0202-0-0761 Procedure of specimen collection

MPD 0202-0-0701 Laboratory users' handbook

MPD 0202-0-0702 Specimen collection handbook

1.6. ABBREVIATIONS

1.7. RELATED DEFINITIONS

measurable quantity: (measurable property, quantity) attribute of a phenomenon, body, or substance that may be distinguished qualitatively and determined quantitatively. NOTE 1: Phenomenon, body, or substance corresponds to the concept of system as used in clinical laboratory sciences. Qualitatively refers to the need to define a quantity before it can be measured. NOTE 2: Measurable quantity is described by three concepts, here called kind-of-quantity, **component**, and **system**. NOTE 3: "**quantity**" is often used as a short term.

measurand: particular quantity subject to measurement. EXAMPLE Vapour pressure of a given specimen of water at 20 °C. NOTE The specification of a measurand may require statements about other quantities such as time, temperature and pressure.

outpatients' Specimens Collection Unit: premises where specimens are obtained.

quantity: short term of **measurable quantity**.

sample: one or more parts taken from a system and intended to provide information on the system, often to serve as a basis for a decision on the system or its production. EXAMPLES: A volume of serum taken from a larger volume of serum; a simple random subset of measured values of a measurable quantity taken from a set of such values. NOTE 1: The single part forming a cohesive entity and taken from one place and at one time is also called a "sampling unit" or an "item". NOTE 2: Unless otherwise specified, the sample is assumed to be representative of a "static system", that is a system having no appreciable change in relevant measurable quantities during the time of consideration. NOTE 3: When a "dynamic system" is concerned, as is often the case in the clinical laboratory sciences, the calendar time of sampling is a mandatory item of specification to the system of interest. Such a special type of sample has been called a "**specimen**", but this term is not used here. The term specimen has also been used in laboratory medicine as a synonym for a sample, as defined here, of biological origin, or for an entire macroscopic parasite. NOTE 4: The system from which a sample is taken may not be of the same type as that of the measurand. EXAMPLE: A given blood sample may serve for measurement of pH in plasma and haemoglobin concentration) in erythrocytes. NOTE 5: The definition given above covers a sample from any type of system. ISO gives two definitions that apply more to data and materials respectively. (a) sample: One or more sampling units taken from a population and intended to provide information on the population; (b) sample: Representative quantity of material extracted from a batch of reference material). NOTE 6: In some countries the term specimen is used for primary sample (or a subsample of it) which is the sample prepared for sending to or as received by the laboratory and intended for measurement.

sampling: process of drawing or constituting a sample.

sampling procedure: operational requirements and or instructions relating to the use of a particular sampling plan, that is the planned procedure of selection, withdrawal, and preparation of one or more samples from an inspection lot to yield knowledge of the characteristic(s) of the lot. NOTE: In laboratory medicine, the "inspection lot" usually is a person.

specimen: in some countries the term specimen is used for primary sample.

system: demarcated part or phenomenon of the perceivable or conceivable universe, material or immaterial, that may be regarded as a set of elements and a set of relationships between these elements.

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2. INFORMATION PROVIDED BY THE CLINICAL CHEMISTRY DEPARTMENT

The Clinical Chemistry Department provides to the specimen collection units the following information:

- (a) about the reception schedule in the Clinical Chemistry Department (place, time, etc.);
- (b) relevance of the laboratory test performed;
- (c) detailed instructions concerning some assays requiring special precautions;
- (d) function test.

The procedure *MPD 0202-0-0761 Procedure of specimen collection* contains details about information provided by the Clinical Chemistry Department.

This information is compiled in:

- (a) leaflets or individual letters;
- (b) in the handbooks: *MPD 0202-0-0701 Laboratory users' handbook* and *MPD 0202-0-0702 Specimen collection handbook*
- (c) in the Clinical Chemistry Department web site

3. INFORMATION FOR PATIENTS

Leaflets are placed in the Outpatients' Specimen Collection Unit, providing information about the laboratory and explaining the value and importance of blood testing.

The information is also available in the *MPD 0202-0-0701 Laboratory users' handbook*.

The information provided to the patients as leaflets include instructions for the personal provision of specimens, including twenty-four-hour urine specimen provision and semen specimen provision, as well as on particular matters relating to functional testing (diet, fasting, sampling times, etc).

- (a) Opening hours and location of the laboratory
- (b) Collection of specimens
 - urine (see Note)
 - faeces
 - semen
- (c) Information regarding special diets or other preparatory measures
- (d) Functional testing (diet, fasting, sampling times, etc)

Note: Staff at the Unit explicitly draw patients' attention to the relevant instructions and to any hazards associated with specimen provision, such as the presence of hydrochloric acid in some twenty-four-hour specimen bottles.

4. RESPONSABILITIES ON "PATIENT INFORMATION AND PREPARATION"

The head of each area of the Clinical Chemistry Department is responsible of writing and updating the information required for the preanalytical phase of laboratory services. This information is compiled and publicized by the Quality Officer.

The writing, revision and maintenance of documents concerning the preparation and information of patients is responsibility of the Quality Officer.

5. DOCUMENT MANAGEMENT

Updated documents concerning the information and preparation of patients for analytical services are available in the document volume of the LIS.

One copy of these procedures is kept in the Quality System Files. Staff members of the Clinical Chemistry Department receive an update copy as soon as it is available.

6. REVIEW OF DOCUMENTS

Documents concerning the information and preparation of patients for analytical services are revised at least once a year.

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