

QUALITY MANUAL: MODEL ACCORDING EC4 ESSENTIAL CRITERIA. v.2.0.

## 7. PREANALYTICAL PHASE

### 7.3. REPERTOIRE

AUTHOR	VERSION	APPROVED BY	DATE	

CIRCULATION LIST:	NAME	POSITION

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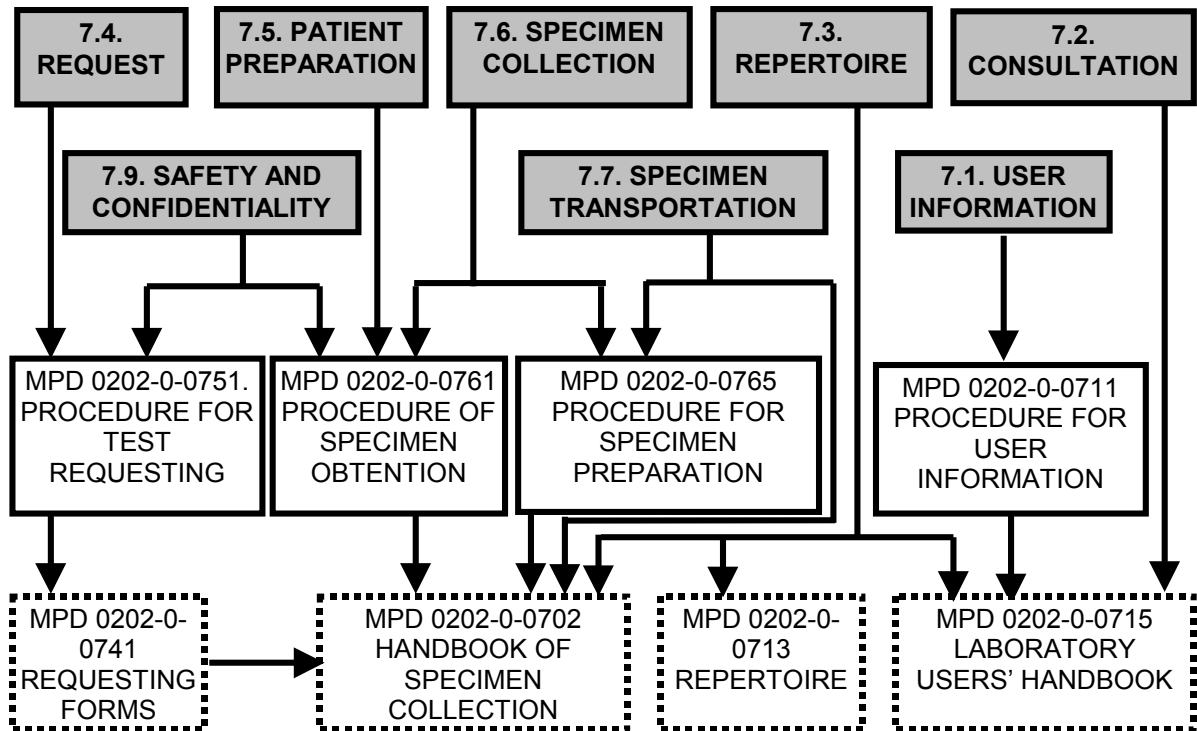
## 1. INTRODUCTION

There should be a list of the STAT and 24 hours repertoire.

There should be a list of the repertoire of all available tests, including required specimen and specimen volume, special precautions, normal turn-around times, and reference ranges.

There should be a defined role for the laboratory in the validation, assessment and quality control of near patient and point of care testing.

The repertoires should be adjusted regularly and be part of the medical audit.



### 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.		
5.5. Examination procedures. 5.5.6.		

### 1.3. PUBLICATION CREDITS

EC4 WG

### 1.4. REFERENCES

- Jansen RTP, Blaton V, Burnett D, Huismann 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. and 5.5.6.

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3. Jansen RTP, Bank CMC, Huisman W, Penders TJ. NVKC Model quality manual. 2<sup>nd</sup> rev. Ed. Utrecht: NVKC 1996.

## 1.5. RELATED DOCUMENTS

QM 09-04 Reference values

MPD 0202-0-0713 Analytical services repertoire

MPD 0202-0-0761 Procedure for specimen collection

MPD 0202-0-0765 Procedure for specimen preparation

MPD 0202-0-0702 Handbook of specimen collection

MPD 0202-0-0715 Laboratory users' handbook

MPD 0202-0-0911 Biological reference values

## 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.

**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. LIST OF THE STAT REPertoire

The analytical services offered by the Clinical Chemistry Department are listed in the document *MPD 0202-0-0713 Analytical services repertoire* which includes the following items:

Test	Required specimen and specimen volume	Special precautions	Turn-around time	Reference ranges	Laboratory
pH BLOOD GASES	blood gas syringe filled with arterial blood, transported in iced water	to be tested immediately	20 minutes		General Chemistry Laboratory
PYRUVATE	special tube, see appropriate test procedure		35 minutes		General Chemistry Laboratory, by arrangement
PROCAINAMIDE LEVEL	2 tubes of whole blood, seal	send no. 29, obtain specimen before intake of food/drink	2 h		TDM
...	...	...	...	...	...

## 3. LIST OF THE 24 HOURS REPertoire

Test	Required specimen and specimen volume	Special precautions	Turn-around time	Reference ranges	Laboratory
PNF	1 tube of whole blood	send no. 01, completed form			
PORPHYRIN	urine collected over a 24-hour period	store in a cool, dark place, deliver before noon. To be tested immediately			Special Test Laboratory
PRECIPITINES	1 tube of whole blood, seal				Protein Chemistry Laboratory
PREGNANETRIOL	urine collected over a 24-hour period	measure volume and prepare 100-ml specimen			Urine Laboratory
...	...	...	...	...	...

## 4. REPertoire OF ALL AVAILABLE TESTS

Test	Required specimen and specimen volume	Special precautions	Turn-around time	Reference ranges	Laboratory
pH BLOOD GASES	blood gas syringe filled with arterial blood, transported in iced water	to be tested immediately			General Chemistry Laboratory
PNF	1 tube of whole blood	send no. 01, completed form			
PORPHYRIN	urine collected over a 24-hour period	store in a cool, dark place, deliver before noon. To be tested immediately			Special Test Laboratory
PRECIPITINES	1 tube of whole blood, seal				Protein Chemistry Laboratory
PREGNANETRIOL	urine collected over a 24-hour period	measure volume and prepare 100-ml specimen			Urine Laboratory

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PROCAINAMIDE LEVEL	2 tubes of whole blood, seal	send no. 29, obtain specimen before intake of food/drink			
PROLACTIN	WITH NEEDLE THAT YOU LEAVE IN 3x1 tube of whole blood	timing: 0, 30 and 60 minutes			Isotope Laboratory by arrangement
PROSTATE-SPECIFIC ANTIGEN	1 tube of whole blood, immediately seal and freeze				Isotope Laboratory
PROTEIN C (ACTIVITY)	1 tube citrated blood, immediately seal (15 min) and freeze				Special Test Laboratory
PROTOPORPHYRIN	1 tube heparinized blood, store in a cool, dark place				Special Test Laboratory
PYRUVATE	special tube, see appropriate test procedure				General Chemistry Laboratory, by arrangement
...	...	...	...	...	...

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## 5. ROLE FOR THE LABORATORY IN THE VALIDATION, ASSESSMENT AND QUALITY CONTROL OF NEAR PATIENT AND POINT OF CARE TESTING

Professional staffs from the Clinical Chemistry Department participate in all the Hospital Committees dealing with point of care testing.

The Clinical Chemistry Department participation in the point of care testing is executive and includes:

- selection of point of care devices
- validation of analytical procedures
- training of personnel
- quality control

The Clinical Chemistry Department prepares an annual report on the use and quality of point of care testing.

## 6. REFERENCE VALUES

According the document *QM 09-04 Reference values* and the procedure MPD 0202-0-0911 Biological reference values the list of reference values is presented as a supplement of the Laboratory newsletter (updated annually) and in the handbook *MPD 0202-0-0715 Laboratory users' handbook*.

## 7. SPECIFICATIONS

According the documents *MPD 0202-0-0761 Procedure for specimen collection*, *MPD 0202-0-0765 Procedure for specimen preparation*, the specifications include:

- (a) kind of specimen;
- (b) kind of container;
- (c) anticoagulant or preservative;
- (d) minimum quantity of specimen

The information is compiled in the *MPD 0202-0-0702 Handbook of specimen collection*.

## 8. RESPONSABILITIES ON "REPertoire"

The Director of the Clinical Chemistry Department is responsible of the analytical services offered by the Clinical Chemistry Department, according the proposals of the Heads of each area.

The writing, revision and maintenance of documents concerning the repertoire is responsibility of the Quality Officer.

## 9. DOCUMENT MANAGEMENT

Updated documents concerning the analytical services procedures and list 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.

## 10. REVIEW OF DOCUMENTS

Documents concerning the repertoire of analytical services are revised at least once a year.

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