

POCT accreditation ISO 15189 and ISO 22870: making the point

Paloma Oliver, Pilar Fernandez-Calle, Antonio Buno

POCT Unit, Department of Laboratory Medicine, La Paz University Hospital, Madrid, Spain

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Corresponding author:

Paloma Oliver.
Department of Laboratory Medicine
La Paz University Hospital
Paseo de la Castellana nº 261
28046, Madrid
Spain
E-mail: palomam.oliver@salud.madrid.org

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ABSTRACT

ISO 22870 lists specific requirements for the quality and competence of point-of-care testing (POCT), which are intended for medical laboratories in conjunction with ISO 15189. POCT characteristics include the availability of a large number of devices 24 h/day, a variety of analytical methods, clinical settings inside and outside the hospital, and general non-laboratory staff. ISO 22870 accreditation for adequate POCT management therefore poses a challenge for laboratory medicine, which is charged with leading and coordinating POCT with a multidisciplinary committee. La Paz University Hospital has a complex multitest and multisite network that has been accredited since 2017. In our experience, the particularly crucial areas for POCT accreditation are method performance verification, internal and external quality assurance, staff training and competency, and continuous improvement. ISO 22870 and ISO 15189 accreditation have led us to improve numerous areas regarding the total testing process and, consequently, our patients' results.

1. ISO 15189 AND ISO 22870 ACCREDITATION

ISO 15189 specifies requirements for quality and competence in medical laboratories and can be employed by medical laboratories to develop their quality management systems and assess their competence [1]. ISO 22870 provides specific requirements applicable to point-of-care testing (POCT) and is intended for use in conjunction with ISO 15189 [2]. ISO 22870 applies when POCT is performed in a hospital, clinic, or healthcare organisation providing ambulatory care.

Neither ISO 15189 nor ISO 22870 should be considered goals in and of themselves but rather should be employed to confirm or recognise the competence of medical laboratories by regulatory authorities and accreditation bodies for the benefit of clinicians and patients.

2. TIMELINE FOR ISO 15189 AND ISO 22870 ACCREDITATION AT LA PAZ UNIVERSITY HOSPITAL

La Paz University Hospital is a tertiary public hospital located in Madrid (Spain) and is a referral centre widely recognised for its range of specialisations. The hospital is one of the largest in

Spain, with approximately 1300 beds in 4 buildings, with several satellite facilities providing specialist services and 23 primary healthcare centres.

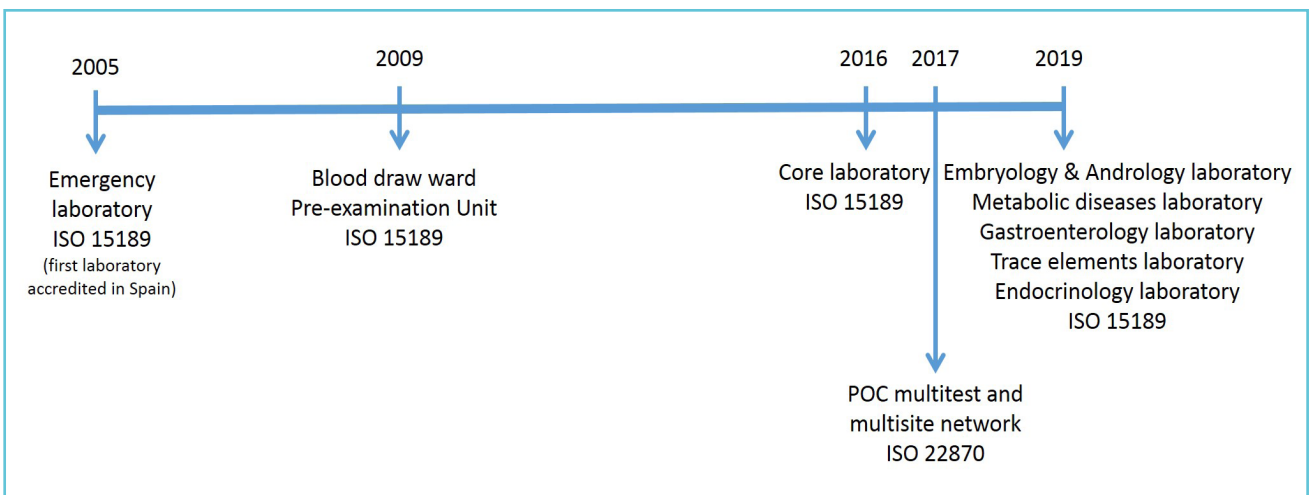
The Laboratory Medicine Department covers various areas, which have been accredited since 2005 (Figure1).

3. POINT-OF-CARE MULTITEST AND MULTISITE NETWORK ACCREDITATION

The POCT Unit of the Laboratory Medicine Department has led the hospital's POCT network over the last 22 years. The core of the POCT Unit includes the POCT Director, the POCT Coordinator and the head of the Quality section. There is also a multidisciplinary POCT committee, which is responsible for making decisions on a wide range of POCT-related topics and consists of the hospital's Board of Directors, hospital administration representatives, physicians and nursing personnel from medical and surgical services and staff from the information technology department, the laboratory medicine team and the POCT Unit.

POCT management has always been conducted in accordance with the requirements of ISO 22870

Figure 1 Timeline for ISO 15189 and ISO 22870 accreditation in La Paz University Hospital



for all the magnitudes included, and considering the previous experience with ISO 15189 in other laboratory areas. Figure 2 illustrates the development in this regard.

The POCT network currently includes 30 ABL90 Flex (Radiometer®) blood gas analysers, 2 DCA Vantage (Siemens®) glycated haemoglobin devices, 266 Accu-Chek Performa (Roche Diabetes®) non-connected glucometers, one Sweat-Chek (Werfen®) sweat test device and 7 recently installed Accu-Chek Inform II (Roche Diagnostics®) connected glucometers (Table 1).

At this time, only the 3 nonconnected glucometers employed in the blood draw ward have been included in the accreditation scope. The lack of connectivity and the large number of devices located in numerous clinical settings are important limitations in meeting the requirements.

4. KEY POINTS AND CHALLENGES IN ISO 22870 ACCREDITATION

As with ISO 15189, ISO 22870 focuses on quality assurance and competence; however, POCT has particular characteristics, including a large number of devices available 24 h/day, various

analytical methods, clinical settings inside and outside the hospital and general non-laboratory staff [3]. Adequate POCT management therefore poses a challenge for laboratory medicine, which is charged with leading and coordinating POCT with a multidisciplinary committee as a specific requirement of ISO 22870 accreditation [2] [4].

Globally, the ISO 22870 accreditation requires compliance with all the steps before implementing a new test and with the required activities to perform after its incorporation in clinical practice (Figure 3). Due to the particular characteristics of POCT, the following areas are particularly crucial: method performance verification, internal and external quality assurance, staff training and competency and continuous improvement [5][4], all of which significantly affect the quality assurance of patient results.

Method performance verification

ISO 22870 requires verification of the main analytical performance of the methods according to the specifications established by laboratory medicine, such as imprecision and systematic error. When implementing a new analytical

Figure 2 Timeline for ISO 22870 accreditation in La Paz University Hospital

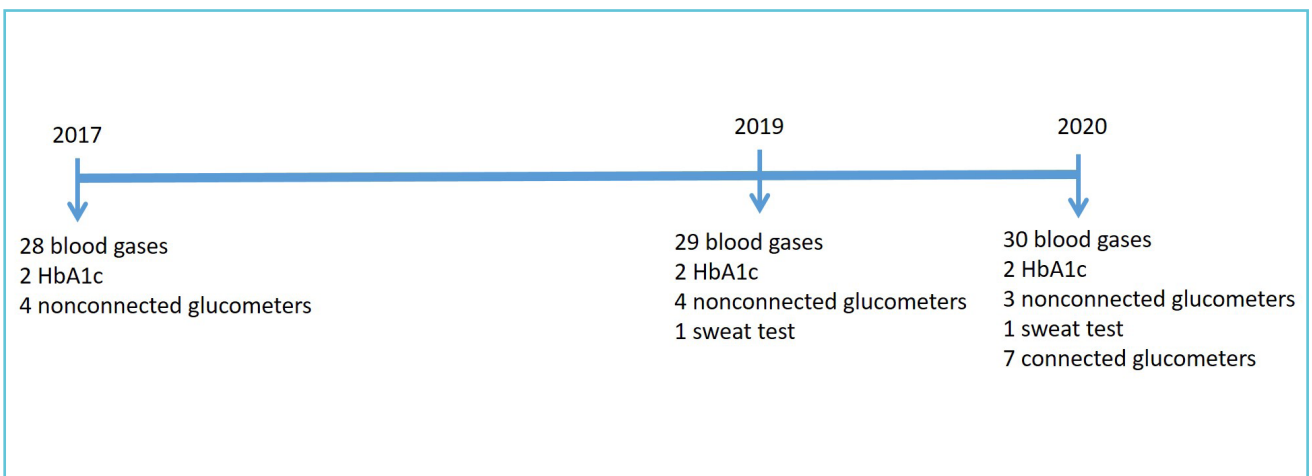
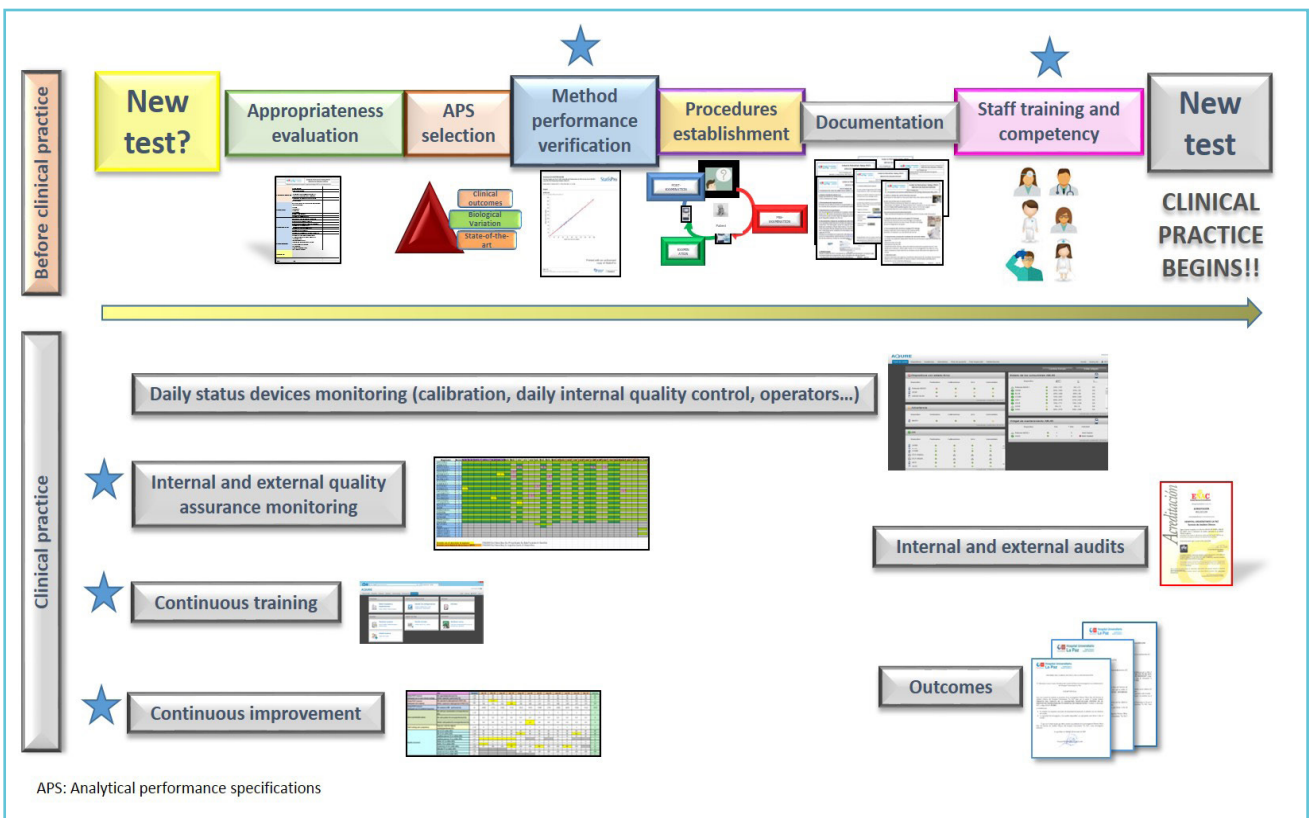


Table 1 Current POCT network at La Paz University Hospital

| POCT (n) | Clinical setting | Analysers |
|-------------------------|---|-----------|
| Blood gases (30) | Emergency Laboratory | 2 |
| | Preanalytical Unit | 2 |
| | Delivery Room | 2 |
| | Paediatric Emergency Department | 1 |
| | Neonatal ICU Department | 3 |
| | Paediatric ICU Department | 1 |
| | Paediatric Reanimation and Surgery Unit | 1 |
| | Paediatric Haemodynamic Unit | 1 |
| | Emergency Department | 2 |
| | Coronary Care Unit | 1 |
| | Pulmonology Department Doctor's office | 1 |
| | Pulmonology Department | 1 |
| | Nephrology Department | 1 |
| | ICU Department 1 | 1 |
| | ICU Department 2 | 1 |
| | Burn Unit | 1 |
| | Reanimation Unit 1 | 1 |
| | Reanimation Unit 2 | 1 |
| | Reanimation Unit 3 | 1 |
| | Surgery Suite 1 | 1 |
| Surgery Suite 2 | 1 | |
| Surgery Suite 3 | 1 | |
| Cantoblanco Hospital | 1 | |
| Carlos III Hospital | 1 | |

| | | |
|---------------------------------------|--|-----|
| HbA1c (2) | Adult Diabetes Unit | 1 |
| | Paediatric Diabetes Unit | 1 |
| Nonconnected glucometers (266) | 84 different departments in the hospital | 266 |
| Sweat Test (1) | Paediatric Pulmonology Unit | 1 |
| Connected glucometers (5) | Neonatal ICU Department | 3 |
| | Paediatric ICU Department | 1 |
| | Paediatric Diabetes Unit | 1 |
| | Burn Unit | 1 |
| | Blood Draw Ward | 1 |

Figure 3 Steps before and after implementing a new test in clinical practice



method, verification of the interchangeability of patient results is important for assessing the method's clinical impact on patient care. POCT commonly involves a large number of devices installed in different locations. A patient can be treated in several clinical settings, such as the emergency department, intensive care unit, and internal medicine. Consequently, the interchangeability of patient results should be previously verified among all POCT devices and against the central laboratory methods [6][7].

In our hospital, we evaluate the analytical performance of a POCT analyser following the Clinical Laboratory Standards Institute protocols. We then assess the interchangeability of patient results with the other POCT and laboratory analysers employed for the same measurand in clinical practice [7].

Internal and external quality assurance

To evaluate internal quality control on a daily basis and monitor the internal and external quality assurance periodically in accordance with ISO 22870 requirements, the connectivity of POCT devices is helpful. When a large number of devices are included in the POCT network, this connectivity becomes indispensable [7]. On the whole, POCT data management systems are improving; however, there remain some limitations, such as the setting of the analytical performance specifications established by the laboratory directly in the analyser and the inability to automatically obtain reports with the imprecision and systematic error results for each measurand at each level from each device. This situation implies that laboratory medicine needs to develop manual procedures to collect and assess this important information, which, in our case, entails the management of more than 4000 results each month. We group and record the internal quality control and external quality assurance results in a manual dashboard to be evaluated according to our analytical

performance specifications as a whole [8]. All deviations are evaluated, and the corresponding corrective actions are taken if necessary (e.g., replace a POCT analyser, remove a defective batch of glucose strips).

Staff training and competency

According to the ISO 22870 requirements, all operators need to be trained before using a POCT device. The particular POCT challenge here when compared with a central laboratory is that the personnel are generally non-laboratory, and there could be a large number of staff with a high rate of turnover [3]. Connectivity and POCT data management systems are once again an essential aspect of this situation [8].

In our hospital, all operators undergo initial training following the particular program established by the laboratory, after which the training is recorded, and the operator becomes an active user in the data management system to use the respective POCT analyser. We also provide online continuous training for the staff who perform POCT after starting the use of an analyser in clinical practice. Based on this training and in collaboration with the clinical departments/units, we annually reassess the competence of all operators, following the ISO 22870 requirements [8].

It is important to document all measurement procedures for the staff in the various clinical settings and in laboratory medicine, including internal quality control, calibrations and other procedures [4]. In our hospital, the latest version of these documents is available to all staff from any computer in the hospital [8].

Continuous improvement

In POCT (and specifically with a complex network such as ours), it is especially important to properly manage the indicators in accordance with ISO 22870 [4]. We select and periodically review the key performance indicators that are

representative of the various aspects of the global POCT process, which is useful for identifying opportunities to improve and evaluate the laboratory's contribution to patient care [9][10].

Table 2 shows the various areas included in our improvement dashboard.

The average of the key performance indicator results from all clinical settings is recorded in the improvement dashboard on a monthly basis. Both the average and each deviation in each particular clinical site below the target is reviewed, and corrective action is taken when necessary

(providing more training for specific staff, performing new procedures for preventing pre-examination errors, etc.).

5. PATIENT CARE OUTCOMES

All of the above tasks related to laboratory medicine and POCT accreditation are performed in the service of patient care, and their impact should therefore also be evaluated. In our hospital, we implement and conduct several projects in collaboration with other professionals in various clinical settings, such as in

Table 2 Improvement dashboard with key performance indicators

| | Objective of the evaluation | Key performance indicators |
|----------------------------|--|--|
| 1. Global POCT process | <p>Adequate use of POCT in each clinical setting</p> <p>Duplicate test requests to laboratory and POCT from the same clinical setting</p> <p>Use of material resources</p> | <p>1.1. Percentage of the tests reported in LIS over the tests performed in POCT analysers</p> <p>1.2. Percentage of the tests reported in LIS by laboratory over the tests reported in LIS by POCT from the same clinical setting</p> <p>1.3. Difference between the number of tests considering the consumables used and the tests performed in POCT analysers</p> |
| 2. Extra-examination phase | <p>Sample and analyser management by POCT operators</p> <p>Patient identification by POCT operators</p> | <p>2.1. Percentage of the tests with pre-examination errors (blood gases) or instrument alerts (glucometers) over the total tests performed in POCT analysers</p> <p>2.2. Percentage of the tests with patient identification errors (electronic medical record ≤ 3 digits) over all the tests reported in LIS by POCT</p> |

| | | |
|----------------------------------|---|---|
| 3. Examination phase | Fulfilment of analytical performance specifications established by laboratory | <p>3.1. Percentage or number of results of variation coefficients within analytical performance specifications over the total results</p> <p>3.2. Percentage or number of results of total errors within the analytical performance specifications over the total results</p> |
| 4. Staff training and competency | Personal identification strategy by POCT operators to ensure that only trained operators use the POCT analysers | 4.1. Percentage of the tests performed by the POCT operator with the highest activity over all the tests performed in every clinical setting |

the Pulmonology and Nephrology Departments [11][12]. These projects include clinical, operative and economic outcomes to gain an overview of the impact of POCT in clinical practice.

6. CONCLUSIONS

In our experience in La Paz University Hospital, ISO 15189 and ISO 22870 accreditation has led us to improve numerous areas regarding the total testing process. Due to the particular characteristics of POCT, the particularly crucial areas for ISO 22870 accreditation are method performance verification, internal and external quality assurance, staff training and competency, and continuous improvement, all of which have an effect on the quality assurance of patient results.

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