

Title: **Development of quality indicators to evaluate the performance of the extra-analytical phases in medical laboratories**

Student: Nil Sanosa I Ferro

Date: June 2019

Supervisor/s: Dra. Luisa Álvarez Domínguez

Centre Diagnòstic Biomèdic

Dra. Àngels Sahuquillo Estrugo

Departament d'Enginyeria Química i Química Analítica

The UNE-EN ISO 15189 standard, in the chapter dedicated to management requirements, has a section that refers to the continuous improvement of the quality management system. In order to achieve this improvement, it is necessary to control the processes and to control them by means of indicators. In this sense, laboratory must incorporate Quality Indicators enabling the quantification and evaluation of all the phases of the analytical process. With the goal of ensuring the quality of the processes and reduce the error rate to a minimum values, laboratories participate in External Quality Assessment Programs, where Quality Indicators calculated by the participating laboratories share their results, allowing direct comparison and evaluate the laboratories performance.

The Biomedical Diagnostic Center of the Hospital de Barcelona will begin to implement and develop Quality Indicators in the extra-analytical phases, which have been demonstrated they are the most vulnerable to error and pose the greatest risk to patient safety. Therefore, this study is the first stone of an ambitious project that is based on the definition and development of a set of indicators, taking into account developments at European level and establishing a methodology for its calculation. Once calculated, we will compare the values obtained with those currently published by scientific societies. With results obtained I am going to evaluate the performance of their laboratories and enable CDB to suggest improvements later.

This study proposes a list of 11 Quality Indicators which give enough information to evaluate the processes performance of the CDB, where more than 6,000,000 determinations per year with more than 1,000,000 samples received from their patients.