perform the validation test of the method, as well as records of equipment maintenance, incidents, improvement actions, personnel training, Standard Operating Procedures, equipment and program manuals, technical data sheet, and more information such as external documentation, degrees of compliance and verification of internal controls.

Results

We obtained accreditation UNE-EN ISO15189 by the National Accreditation Entity with the following scope:

Name Description
CD4 % Percentage of T CD4 T lymphocytes
CD4 lymphocytes Absolute counts of T CD4 cells (cells/mm3)
CD8% Percentage of CD8 T lymphocytes
CD8 lymphocytes Absolute counts of T CD8 cells (cells/mm3)
CD3 % Percentage of CD3 T lymphocytes
CD3 lymphocytes Absolute counts of T CD3 cells (cells/mm3)
CD4/CD8 Ratio CD4/CD8
HLA-B27 HLA-B27

Conclusions

We obtained the ISO 15189 accreditation for the proposed achievements but we had to deal with some obstacles like the absent of internal control for the study of HLA-B27. The implementation of ISO 15189 has been useful to work correctly and a way according to the established standards, but also for the control of risks. The next challenge is to accredit the ISO 15189 in hematological pathologies, for which we will need greater standardization in the procedures (preanalytical, analytical and reporting) and the obtaining of EQC that allow us to perform an adequate intercomparing to the concrete pathology that we want to accredit. For this purpose, Euroflow system could be useful since it has standard procedures for the processing of samples, calibration and analysis described in detail.

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M330

Economic impact of a protocol on adequacy of procalcitonin demand

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Background-aim

Procalcitonin (PCT) is a very demanded test in the emergency units with a high economic cost (8 euros/determination). The synthesis of PCT can be induced directly by bacterial endotoxins or indirectly by proinflammatory cytokines, so it constitutes an early marker of systemic bacterial infections. According to several studies, PCT begins its elevation only 4 hours before the C-Reactive Protein (CRP) does.

The objective of this work is to evaluate the impact of the implementation of a protocol of action in the control of the demand of requests of PCT in the emergency laboratory in function of several CRP values cut-off points (5, 10, 15, 20 and 25 mg/L).

Methods

A retrospective descriptive study of the determinations made during six consecutive months has been carried out, the data have been obtained from Modulab (Werfen), our laboratory information system (LIS). The determination of CRP was performed in an Architect c16000 system (Abbott) by immunoturbidimetry and the determination of PCT in a Cobas E411 system (Roche) by chemiluminescent immunoassay (ECLIA).

Results

In the period of the study, 11,080 requests with CRP and PCT were requested and jointly determined. 14.8% (1,640) of these, had a CRP result <5 mg/L, 21.8% (2.418) CRP <10 mg/L, 26.8% (2,972) CRP <15, 31,3% (3,466) CRP <20 mg/L and 34.7% (3,842) CRP <25 mg/L.

89.9% of the patients with CRP <5 had a negative value of PCT (<0.5 ng/mL), 90.3% with CRP <10, 89.6% with CRP <15, 88.8% with CRP <20 and 87.5% with CRP <25.

PCT was positive in patients with CRP <5 in 10.1% of cases, with CRP <10,9.7%, CRP <15, 10.7%, CRP <20, 11.3%, and CRP < 25 12.5%.

If a filter is established in order not to perform the PCT determination (unless there is a high clinical suspicion) depending on the level of CRP, it is estimated that it could mean an annual saving of 26240 euros (CRP <5), 38688 euros with CRP <10), 42624 euros with CRP <15), 55456 euros with CRP <20) and 61472 euros with CRP <25).

Conclusions

With CRP cut-off points <5, <10 and <15 mg / L, similar results are obtained (in %), being the CRP point <10 with which we obtain the best results (90.3% of negative PCT).

When the CRP value increases (<15, <20 and <25), the data gets worst, which, in our opinion, we do not recommend to base the filter on CRP values higher than 10 mg/L.

We believe that the lowest impact for patients (9.7% of PCT> 0.5 ng / mL) is achieved using a CRP value <10 with a substantial annual saving (direct cost 38.688 euros), since the number of determinations that are saved is much higher than the cut-off point CRP <5 and that difference is not maintained with the CRP cut <15.

We must remark that this protocol would be a base to start working and to which other parameters such as the number of leukocytes could be added and always recommending the determination when there is a high clinical suspicion.

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M331

Performance evaluating of Abbott 25-OH-vitamin D assay: comparison with HPLC and LC-MS/MS systems

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Background-aim

Vitamin D deficiency is a worldwide health problem caused mainly by insufficient exposure to sunlight and dietary intake. Vitamin D deficiency represents several clinical findings such as muscle weakness, orthostatic hypotension, eczema etc. Liquid

chromatography-tandem mass spectrometry (LC-MS/MS) as the best method for quantifying vitamin D metabolites due to improved sensitivity, accuracy, and reproducibility. High-Pressure Liquid Chromatography (HPLC) can effectively separate 25-hydroxyvitamin D3 [25(OH) D3], D2 [25(OH) D2], and other Vitamin D metabolites. Abbott diagnostic claimed, their 25- OH Vitamin D assay could determine 25(OH) Vitamin D metabolites, with excellent accuracy and sensitivity. In the present study, we aim to investigate the performance of Abbott 25-OH-Vitamin D assay in contrast to HPLC and LC-MS/MS.

Methods

We randomly have chosen 80 serum specimens from the patients' samples pool during four days period. Serum specimen aliquoted into three parts and analyzed with immunoassay [Abbott Architect i-2000 (Abbott Park, IL, USA)], HPLC and LC-MS/MS systems [Zivak HPLC and Zivak Tandem Gold Triple quadrupole (Istanbul, Turkey)]. Continuous variables were expressed as mean ± standard deviation (SD), median (minimum-maximum values) and categorical variables as number and percent. Shapiro–Wilk tests were used for testing normality. We used kappa analysis to evaluate agreement between gold standard and HPLC and IA measurements. Sensitivity, Specificity, Negative and Positive predictive values were used f to analyze the performance of HPLC and IA measurements. Wilcoxon signed rank test was used for determining the difference between gold standard values and other technics. Venn diagrams were used to examine consistency between 3 methods. All statistical analyses analysed by SPSS, 24.0 and p-value less than 0.05 was considered statistically significant.

Results

We accepted deficiency/insufficiency/sufficiency/toxic levels respectively 0-10& 10-20& 20-70&>70 (ng/ml) those were defined by World Health Organization (WHO). Patients' age means value was the 50.2±17.69 year. D vitamin mean values 21.2±14.49 nmol/L, HPLC was 22.72±14.83 nmol/L and IA 19.45±14.73 nmol/L. There was strong accordance among three-assay method. As a gold standard method LC-MS/MS, sensitivity, specificity, positive and negative predictive values for HPLC and IA were respectively 88.9-93.3%, 94.3-82.9%, 95.2-87.5%, and 86.8-90.6%.

Conclusions

In deficiency clinic, IA more compatible then HPLC with the gold standard. HPLC was successful in insufficiency than the IA method. In the present study Abbott 25-OH-Vitamin D assay is appropriate for determining Vitamin D status.

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M332

Point-of-care (POC) deployment and management of blood gas analyzers following an international organization for standardization (ISO) 22870 quality framework

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Background-aim

CHU de Bordeaux is a large teaching hospital in France with a robust, decentralized POC testing (POCT) program. Management of decentralized blood gas testing across a network of acute care settings and a vast number of operators (more than 800) requires a rigorous quality framework, close partnership between the lab and clinical areas and reliable technology to ensure success.

This analysis describes the management of 12 GEM® Premier™ 4000 and implementation of 7 new GEM Premier 5000 blood gas analyzers networked to GEMweb® Plus 500 Custom Connectivity (Instrumentation Laboratory) in acute care settings across two hospital sites using ISO 22870 framework.

Methods

Three dedicated lab technicians supported the roll-out of the new blood gas analyzers using ISO 22870 framework to meet the clinical and quality requirements of each area throughout the pre-installation, validation and go-live phases. The process required a close and constant partnership between the laboratory, clinical care services, biomedical staff, material management, suppliers and many other stakeholders. Pre-planning included: definition of requirements, compliance, connectivity, patient records, method validations, document management, competency training, and consumables, among others. All phases of the roll-out examined key quality indicators to measure success.

Results

The 7 new GEM Premier 5000 analyzers were added to the network in less than 6 months, with a carefully executed quality plan. Over 495 care staff in 10 sectors were trained as a part of the program. Management and implementation of the new systems were facilitated by the built-in risk management features of the GEM Premier 5000 with iQM2 and GEMweb Plus, specifically as it pertained to quality management (including COFRAC reports), error detection, device management and operator competency training.

Conclusions

Implementation and management of a broad blood gas program requires rigorous quality standards, processes and technology. Active collaboration of the main clinical and laboratory stakeholders in a decentralized roll-out is fundamental. GEM Premier analyzers tied into GEMweb Plus can be effective tools to facilitate accreditation compliance and decentralized testing management, particularly as it pertains to risk-management requirements.

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