

The importance of quality control (QC) to quality blood gasting

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Test results, essential for quality healthcare, constitute more than 70% of patients' health records. Because quality results are so important, governments around the world mandate a series of laboratory practices to ensure quality. All laboratories in the United States follow the Clinical Laboratory Improvement Amendments (CLIA) requirements. Many laboratories worldwide either follow the International Organization for Standardization (ISO) standards 15189 and 22870 (requirements for quality and competence) or local adaptations of these two standards. Both CLIA and ISO are based on a quality management system approach that includes essential elements to ensure quality in each phase of the testing process. One of the essential elements in the analytical phase is the daily measurement and evaluation of QC materials on different levels. QC is especially important for blood gas testing because the results are needed for acute treatment of critically ill patients. In addition to the extra cost and delay associated with retesting, erroneous results may lead to wrong diagnosis and mistreatment of the patient.

WHAT IS QUALITY?

Quality evokes many mental images, depending on one's background and experiences. The true meaning of "quality" is often diminished because it is continually used and associated with so many different products and services. Consequently, in all aspects of our lives, we not only expect quality but demand it, even when we are unsure of the exact definition.

J. M. Juran, who is referred to as the "father" of quality, added a total quality management dimension to the definition and talks about quality in terms of "fitness for intended use" [1]. This definition basically says that quality is "meeting or exceeding customer expectations". W. E. Deming, considered the "founder" of the modern industrial quality movement, stated that the customer's definition of quality is the only one that matters! [2].

When quality is defined as meeting the requirements or needs of "customers" and satisfying their expectations, the customers and their expectations must be stated. In laboratory testing, our primary customers are patients and their physicians. Both expect quality information for timely diagnosis and the appropriate treatment that leads to good patient outcome. Other customers,

such as those who ultimately pay for the testing, seem to focus only on cost reduction. But these customers also should be concerned with quality since quality test results eliminate costs associated with retesting (analyst's time, additional reagents, new patient sample, and delay in the result) and potentially the wrong diagnosis and treatment (poor patient outcome, increased hospital stay) due to an erroneous result.

For optimum patient care, all test results depend on a series of corrects throughout the three phases of the testing process – pre-analytical, analytical, and post-analytical [3]:

1. Correct patient identified for specimen collection
2. Correct time for specimen collection
3. Correct specimen collected and processed
4. Correct (accurate) test result generated
5. Correct patient result recorded in correct patient record

The above series begins with the clinician ordering the correct tests and ends with the clinician correctly interpreting the data for timely and appropriate treatment. Wherever a wrong replaces any one of the corrects, the quality of the test result, and ultimately the patient's treatment and safety, may be compromised. Consequently appropriate policies and procedures must be in place and followed for all three phases of testing.

WHY ARE QUALITY TEST RESULTS SO IMPORTANT TO QUALITY PATIENT CARE AND PATIENT SAFETY?

Patient safety is the cornerstone of high-quality patient healthcare and can be described as freedom from unintentional or preventable harm due to avoidable, adverse events (medical errors) that directly impact the quality of care [4]. We all know that errors, even under the best circumstances, do happen. Regardless of the source, errors can affect the quality of care and jeopardize patients' safety. This is even truer for critically ill patients requiring rapid interventions based on multiple blood gas and critical care measurements. It has been stated that "Blood gas and pH analysis has more immediacy and potential impact on the patient care than any other laboratory determination ... In blood gas analysis, an incorrect result can often be worse for the patient than no result at all" [5].

In the U.S. more than 10 billion laboratory tests are performed each year and test results constitute more than 70% of patients' health records [6, 7]. The Institute of Medicine reported that anywhere between 44,000 and 98,000 hospitalized patients in the U.S. die each year due to medical errors, and additional reports on medical errors continue to be reported [8, 9, 10]. While poor-quality test results are not attributed directly to medical errors, laboratory results certainly are part of the problem. It is estimated that as many as three-quarters of clinician decisions are based on laboratory tests [7]. The key words in these reports are "mistakes" and "preventable", which means that solutions can be found and practices implemented to check and ensure quality.

FOLLOWING ESTABLISHED STANDARDS TO ENSURE QUALITY THROUGHOUT THE TESTING PROCESS

Because quality test results are such an important component of healthcare, many governments and professional laboratory organizations around the world specify a series of good laboratory

practices to ensure quality laboratory results. In the United States, the government mandates all laboratory testing sites to adhere to the quality requirements specified in the Clinical Laboratory Improvement Amendments (CLIA) [11]. Many laboratories worldwide follow the standards developed by the International Organization for Standardization (ISO). Especially two ISO standards are relevant: 1) ISO 15189:2007, Medical laboratories – particular requirements for quality and competence, and 2) ISO 22870:2006, Point-of-care testing - requirements for quality and competence [12, 13]. Some countries even have made local adaptations of these two standards mandatory for test sites to follow. The ISO standards were developed by experts from 33 countries and reflect worldwide opinion on what is essential to ensure quality specifically for clinical laboratory testing. The CLIA and ISO standards are based on a quality management system (QMS) approach that includes widely accepted good laboratory and error-prevention practices and incorporate “Essential Elements” (Table I) for management, technical guidance, and structure of the entire testing process [14].

TABEL I: Quality Essential Elements to build the QMS

1. Documents and records
2. Organization
3. Personnel
4. Equipment
5. Purchasing and inventory
6. Process control
7. Information management
8. Occurrence management
9. Internal and external assessment
10. Process improvement
11. Customer service/ satisfaction
12. Facilities and safety

QC AS PART OF ENSURING ANALYTICAL QUALITY

The characteristics of useful, accurate, precise, reliable, and timely apply to all quality test results including blood gas and critical care results. Ultimately for laboratories to meet all these demands, QC assessment for ongoing quality assurance is essential! A recent essay by Dr. Westgard discusses how laboratories often operate on false assumptions [15]. Despite their desire for the perfect, error-proof instrument that always yields perfect results, such an instrument does not exist! If laboratories do not evaluate their analytical processes or use insufficient QC practices that do not detect critical analytical errors, they will not be aware of potential “analytical hazards” and poor quality test results. What follows focuses on the importance of routine QC to ensure the quality of the analytical phase of testing (#9 of the essential elements in Table I) for blood gas and critical care measurements.

The CLIA and ISO standards require the analysis of different levels of QC materials at specified intervals to evaluate the quality of the measurement system. Typically laboratories statistically evaluate QC data to determine whether instrument performance is within the expected variation

[16]. While QC is essential for all laboratory measurements, QC assessments for blood gas and critical care measurements are particularly important because patients requiring these measurements are critically ill and in need of immediate treatment based on these test results. Wrong results can be fatal! Consequently QC is absolutely necessary and should prequalify the instrument to ensure proper performance before the patient sample is analyzed.

The CLIA regulations, in section §493.1256, require each laboratory to implement “control procedures that monitor the accuracy and precision of the complete analytic process and . . . detect errors that occur due to test system failure, adverse environmental conditions, and operator performance” [11]. For most quantitative tests, CLIA requires the analysis of at least two different concentrations of QC materials on days when patient testing is conducted. CLIA’s section §493.1267 specifies additional and more stringent requirements for blood gas measurements and directs testing sites to analyze at least one sample of QC material each 8 hours of testing and three levels (low, normal, and high) each day (24 hours) of testing. CLIA also requires analysts to review the QC results before reporting patient results to ensure that only patient results within quality specifications are reported. All unacceptable QC results must be investigated and appropriate corrective actions taken before reanalyzing samples and reporting patient results. As part of a laboratory’s ongoing quality assurance activities, CLIA mandates a retrospective review of cumulative QC data so that potential analytical problems can be identified and corrected before test result quality is affected.

ISO 15189:2007, in section 5.6, states that a “laboratory shall design internal QC systems that verify the attainment of the intended quality of results” [12]. The intended quality of results is based on the laboratory’s quality goal or acceptable error tolerance for test results. Test sites must design QC practices to ensure that all patient results meet the stated quality goal. ISO 22870:2006 states that the “quality manager is responsible for the design, implementation, and operation of QC that ensures POCT conforms to the quality standards of the central laboratory” [13]. Both ISO standards require corrective actions when QC results are unacceptable and mandate the review of QC data as part of ongoing quality assurance activities to detect and prevent potential errors.

QC VERIFIES THE VALIDITY OF THE CALIBRATION CURVE

Both CLIA and ISO standards make clear distinctions between calibration activities and analyzing QC samples. The calibration process uses calibrators of known concentrations to position the instrument’s calibration curves to yield correct test results. CLIA, in section §493.1267, directs test sites performing blood gases to: 1) calibrate or verify calibration according to the manufacturer’s specifications and frequency, and 2) test one sample of control material each 8 hours of testing using a combination of control materials that include both low and high values on each day of testing, and 3) test one QC sample each time patient samples are tested unless calibration is automatically verified every 30 minutes [11]. ISO 15189, in section 5.6.3, requires test sites to perform QC in addition to calibration to ensure that patient results are traceable to specified reference materials [12]. The analysis of three levels of QC verifies the position of the calibration curves across the measurement ranges. Because these QC and calibration practices are requirements and reflect recognized good laboratory practices, several manufacturers now design

instruments to automatically perform calibration at specified intervals and analyze, typically, three levels of QC each day [17-20]

QC MANDATES AND COUNTRY SPECIFIC AND PROFESSIONAL ACCREDITATION REQUIREMENTS

While all laboratories in the U.S. adhere to the CLIA requirements and laboratories throughout the world follow ISO 15189 and ISO 22870 standards, countries such as Germany, Australia, and France have adapted the ISO requirements to meet local needs. In addition to following the ISO requirements, RiliBÄK, the German guidelines, mandate the analysis of at least two QC samples on days that patient samples are measured and require specific evaluation of the QC data at the time of measurement as well as a retrospective analysis of the QC data at least every three months [21, 22]. The Australian National Association of Testing Authorities (NATA) specifies that “The minimum requirement for blood gas and CO-oximetry QC is a daily assay of control material at two or more control levels, performed concurrently” [23]. Cofrac, the French Notified Body for Laboratories Accreditation, directs laboratories to follow ISO 15189 (and ISO 22870 for POCT) standards [24]. Accreditation will be mandatory by the end of 2016. The French standards mandate each laboratory to implement an internal quality program (section 5.6.1) and participate in a peer group comparison (section 5.6.4). The analysis of QC materials is mandatory for blood gas testing and two levels per day are recommended. An accompanying document, “Les contrôles de qualité analytique en Biologie Médicale, LAB GTA 06”, emphasizes that the calibration solutions cannot be used as QC (section 9.2.2) [25].

Additionally, many laboratories throughout the world voluntarily seek formal accreditation from professional organizations for further recognition of their ability to provide quality testing. The accreditation process, conducted by independent parties, is a systematic and uniform assessment of a laboratory’s competence in complying with accepted testing standards producing quality test results [26]. As part of the process, surveyors audit laboratories’ facilities, equipment, personnel, methodologies, and record-keeping systems to ensure that an adequate QMS is in place. The regular ongoing analysis of QC materials is an essential component of the QMS.

“I would never accept test results to be used to treat patients if regular QC was not performed on the analyzer. The QC frequency depends on the type of instrumentation, for example in my hospital, we have five blood gas analyzers and we measure QC on three levels, three measurements per day.”

Dr. Pierre Bouchelouche, MD, Medical Director of the Department of Clinical Biochemistry, Koege Hospital, University of Copenhagen, Denmark [27].

QC PROVIDES ESSENTIAL INFORMATION

An example of the importance of QC, but not using the information, is the Maryland General Hospital (Baltimore, Maryland USA) case [28]. Over a 14 month period, up to 460 questionable HIV and hepatitis test results were reported despite QC results indicting analytical errors. The safety of all these patients was jeopardized. Many of the patients tested during this period were misdiagnosed based on the erroneous results and all of these patients required reassessment. As a consequence for not following testing requirements, numerous personnel were prosecuted and

sanctions were placed on the hospital.

CONCLUSION

Quality – useful, accurate, precise, reliable, and timely tests results – is essential for providing patients with the best possible healthcare. However, even under the best conditions, errors can and do happen! Consequently, laboratories must plan for quality. Testing standards, such as those mandated by CLIA, ISO, Rilibæk, Cofrac and NATA, assist in the planning process. Each are based on a QMS containing Essential Elements (Table I) to direct test sites to systematically plan and manage the entire testing process to ensure that “corrects” (quality results) are achieved. All of these standards mandate ongoing QC measurements to evaluate analytical quality. Quality test results are not automatic. To deliver quality healthcare and ensure patients’ safety, laboratories cannot assume that simply following manufacturers’ directions and trusting the instrument automatically will ensure that quality test results are generated. Because of the criticality of blood gas and critical care measurements, QC must prequalify the instrument before patient samples are analyzed to avoid delays due to instrument problems, reporting incorrect results, and collecting additional patient samples for reanalysis.

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译文（非专业人士翻译仅供参考）

质控在血气检测中的重要性

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对于基本的优质医疗，测试结果占 70% 以上的患者“健康记录。因为质量是如此重要，世界各地的政府强制一系列的实验室工作，以确保质量。所有在美国的实验室按照临床实验室改进修正案（CLIA）的要求。世界各地的许多实验室按照国际组织标准化组织（ISO）（15189 和 22870 的质量要求和标准这两个标准的能力）或根据当地的条款执行。CLIA 和 ISO 是基于在质量管理体系的方法，包括基本的要素，以确保在测试过程中的每个阶段的质量。其中的重要元素之一是分析阶段每天的测量和评价在不同的 QC 材料的水平上。QC 血气测试，的结果对需要治疗急性临界危重病人是特别重要的。除了额外的成本和延迟与复验，错误的结果可能会导致错误的诊断和病人的死亡。

什么是质量？

许多精神图像质量的唤起，取决于人的背景和经历。真正的“质量”的意义就会被削弱，因为它是不断地使用和许多不同的产品和服务。因此，在我们生活的各个方面，我们不仅期待质量需求，甚至当我们不知道如何确切的定义。

J. M. Juran，谁被称为质量方针之父，增加了一个全面质量管理定义和讨论质量方面的“适合用途”[1]。这定义基本上说，质量是“满足或超越客户的期望”。W. E.戴明，认为是现代产业的质量运动的“创始人”，客户对质量的定义是唯一一个事情！ [2]。



当质量被定义为“客户”的要求或需要的满足和满足他们的的期望，客户和他们的期望必须加以说明。在实验室测试中，我们主要客户是病人和他们的医生。都期待高品质的信息，以便得到及时诊断和适当的治疗，给予患者良好的预后。其他客户，如最终支付的测试，似乎只注重降低成本。但这些客户也应该关注质量，因为质量测试结果消除成本与复验（分析师的

时间，额外的试剂，新的患者样本和延迟增加的结果），由于一个错误的结果导致错误的诊断和治疗（患者的预后较差，住院）。

为获得最佳病人护理，所有的测试结果取决于三个阶段分析前，分析中和分析后阶段的测试过程 - [3]：

- 1、确定正确的病人标本采集
- 2、标本采集的正确时间
- 3、正确的标本收集和处理
- 4、正确（准确）的测试结果
- 5、正确的患者结果记录在正确的病人记录

上述系列开始正确的测试和最终临床医生正确解释的数据进行及时和适当的治疗。在一个错误的替换中任一项的校正，都会对测试结果的质量产生影响，并最终对病人的治疗和安全受到影响。因此，在所有这三个阶段的测试适当的政策和程序必须到位，并随访。

质量检测结果，为什么对病人提供优质的护理服务和病人的安全如此重要？

病人安全的基石是高品质的病人的医疗和可以被描述为自由从无意或预防的伤害是可以避免的，不良事件（医疗错误），直接影响到护理质量[4]。我们都知道，错误，即使在最好的的情况下，确实发生了。不管是什么原因，错误可能会影响医疗质量和危害病人的安全。这是尤其如此危重病人，需要快速干预基于多血气和重症监护测量。已经指出，“血气和 pH 值分析有更多的直接和潜在的影响比其他任何对病人的护理实验室测定血气分析，不正确的结果往往比没有结果是更糟”[5]。

在美国，超过 10 亿的实验室进行测试，每年测试的结果构成 70% 以上的病人的健康记录[6,7]。医学研究所的报告 44,000 和 98,000 之间的任何住院的患者在美国每年死于因医疗差错和额外的医疗差错报告继续报道[8, 9, 10]。而质量较差的测试结果不直接归因于医疗差错，化验结果肯定是问题的一部分。据估计，多达四分之三的临床医生决定基于实验室测试[7]。在这些报告中的关键词是“错误”和“预防”，这意味着解决方案可以被发现和实施，检查并确保质量。

按照既定的标准，以确保质量贯穿于测试过程中由于质量测试的结果是这样一个重要组成部分，医疗保健，许多国家的政府在世界各地指定的专业实验室组织了一系列良好的实验室做法，以确保高质量的实验室结果。在美国，政府要求所有实验室进行符合规定的质量要求临床实验室改进修正案（CLIA）[11]。世界各地的许多实验室遵循的标准由国际标准化组织（ISO）开发的。尤其是两个 ISO 标准是相关的：1）ISO15189:2007 医学实验室 - 特殊要求。质量要求的素质和能力，2）ISO22870:2006，照顾测试点 - 能力[12, 13]。一些国家甚至在本地做出了适应这两个考点遵循的标准作为强制性标准执行。ISO 标准制定的专家 33 个国家和反映意见什么是必要的，以确保质量，专门为世界各地的临床实验室测试。CLIA 和 ISO 标准的质量管理的基础上，系统（QMS）的方法，包括广为接受的良好实验室和错误预防的做法，并纳入“基本要素”（表 I）的管理，技术指导，和结构的整个测试过程[14]。

表一：基本要素：质量，建立质量管理体系

- 1、文件和记录
- 2、组织
- 3、人员
- 4、设备
- 5、采购与库存
- 6、过程控制
- 7、信息管理
- 8、发生管理
- 9、内部和外部评估
- 10、工艺改进
- 11、客户服务/满意
- 12、设施和安全

QC 确保分析质量的一部分，

有用的，准确的，精确的，可靠的，及时的特点，适用于所有的质量检测结果包括血气和重症监护结果。最终的实验室，以满足所有这些要求，持续的质量保证 QC 评估是必不可少的！最近的一篇文章 Westgard 讨论，实验室经常操作错误的假设[15]。尽管他们的欲望完美的，总是能产生完美的效果，这样的文书不存在！如果实验室没有评估他们的分析过程或使用不足 QC 做法没有检测到关键的分析错误，他们不知道潜在的“分析危害”质量较差的测试结果。以下着重于常规 QC 的重要性，以确保血气分析阶段的测试（排名第 9 的表 I 中的基本要素）的质量和重症监护的测量。

CLIA 和 ISO 标准需要不同程度的 QC 材料的分析，在指定的的时间间隔，以评估的测量系统的质量。通常实验室统计 QC 数据进行评估，以确定仪器性能是否在预期的变化 [16]。虽然所有实验室测量血气，QC 评估和质量控制是至关重要的重症监护测量尤为重要，因为病人需要这些测量危重，需要立即治疗的基础上，这些测试结果。错误的结果可能是致命的！因此，QC 是绝对必要的，并应参加资格预审仪器前，病人样本，以确保适当的性能进行了分析。

CLIA 法规，在第§493.1256，要求每个实验室实行“控制”程序监控的完整分析过程的准确度和精密度和检测由于测试系统故障时，不利的环境条件下，和操作者的所发生的错误表现“[11]。对于大多数的定量测试，CLIA 需要在至少两个不同的分析浓度的 QC 材料的日子，当患者进行测试。CLIA 的部分§493.1267 指定更多和更严格的要求，血气分析，检测点的定向分析至少一个样品的 QC 材料每 8 小时的测试和三个级别（低，中，高），每天（24 小时）的测试。CLIA 还需要分析师审查 QC 成果报告之前，病人的结果，以确保病人的结果只有在品质规格的报道。所有不可接受的 QC 成果，必须予以追究和采取适当的纠正措施之前重新分析样品和报告病人的结果。如一个实验室的持续的质量保证活动，CLIA 授权的回顾性的一部分累计 QC 数据，使潜在问题的分析，可以发现和纠正前测试结果的质量的影响。

ISO15189:2007，第 5.6 节，“实验室内部质量控制系统设计验证实现预期结果的质量”[12]。预期的结果是质量根据实验室的质量目标还是可以接受的误差容限测试结果。测试网站

必须设计质量控制措施，以确保所有患者的结果满足规定的质量目标。ISO22870:2006“质量经理负责设计，实施操作的质量控制，以确保 POCT 符合质量标准的中央实验室”[13]。这两个 ISO 标准要求的纠正行动 QC 结果是不可接受的和强制审查的 QC 数据的持续的质量保证活动的一部分，检测和防止潜在的错误。

QC 验证其有效性的校准曲线

CLIA 和 ISO 标准之间做出明确的区分校准活动和分析 QC 样品。校准过程中使用的已知浓度的校准器，以定位仪器的校准曲线，以得到正确的测试结果。在第§493.1267，CLIA，指示测试地点进行血液气体：1) 校准或验证校准，根据制造商的规格和频率，以及 2) 测试样品的对照材料每 8 小时的测试，使用相结合的控制材料，包括低和高值每一天的测试，以及 3) 测试一个 QC 样品每次患者样本进行测试，除非校准自动验证每 30 分钟[11]。

ISO15189 第 5.6.3 要求考点进行 QC 除校准，以确保病人的结果是可追溯至指定的参考材料[12]。分析了三个层次的 QC 验证的位置的整个测量范围内的校准曲线。由于这些质量控制和校准方法的要求，体现了公认的良好实验室操作规范，一些制造商设计工具，以自动地在指定的时间间隔上进行校准，通常三个 QC 水平的每一天分析[17-20]。

QC 授权及具体国家，专业评审要求

虽然所有的实验室在美国坚持 CLIA 的要求和实验室的整个世界遵循 ISO15189 和 ISO22870 标准的国家，如德国，澳大利亚，法国已经适应了 ISO 的要求，以满足当地的需求。除了按照 ISO 要求，RiliBÄK，德国指引，强制 QC 样品的分析中的至少每天两个，患者样本进行测量，并要求在具体评价的 QC 数据时间测量以及回顾性分析 QC 数据至少每三个月[21, 22]。澳大利亚国家测试机构协会 (NATA) 规定，“血气和血氧饱和度测定 CO-QC 的最低要求是每天检测控制材料在两个或两个以上的控制水平同时进行”[23]。COFRAC，法国认证机构实验室认可，指导实验室按照 ISO15189 (ISO22870 POCT) 标准[24]。认证将被强制要求到 2016 年底。法国标准规定每个实验室实施内部质量程序 (第 5.6.1 节)，并参与在对等体组的比较 (第 5.6.4 节)。QC 材料的分析是强制性的血气体检测和每天两个层面的建议。附随文件，以“lescontrôles 质量 analytique BiologieMédicale, LAB GTA06”，强调的校准解决方案不能作为 QC (第 9.2.2 节) [25]。

此外，许多实验室在世界各地主动寻求正式认可为进一步确认他们有能力提供质量检测的专业机构。“评审过程中，由独立人士进行，是一个系统的，统一的评估在遵守国际公认的检测标准，生产质量测试的一个实验室的能力结果[26]。作为这一进程的一部分，测量师审计实验室的设施，设备，人员，方法和记录保存系统，以确保有足够的质量管理体系是在地方。“定期进行的分析，QC 材料是质量管理体系的一个重要组成部分。

“我绝不会接受使用经常不执行 QC 测试结果的分析仪被用来治疗病人。QC 频率取决于类型的仪器，例如在我的医院，我们有五个血气分析仪和每天进行 QC 三个层次的测量。“博士皮埃尔 Bouchelouche，医学博士，医学临床生物化学系的主任，KOEGE;医院，大学，丹麦哥本哈根[27]。

QC 提供必要的信息

QC 的重要性一个例子，是马里兰医院（马里兰州的巴尔的摩，美国）的情况下[28]。超过 14 个月期间，多达 460 可疑尽管 QC 成果起诉误差艾滋病毒和肝炎测试结果的报告。“所有这些患者的安全受到威胁。很多的测试，在此期间患者误诊基于错误的结果，所有这些病人需要重新评估。如不按照测试要求的结果，大量的人员被起诉。

结论

质量 - 有用的，准确的，精确的，可靠的，及时的测试结果 - 是必不可少的提供患者提供尽可能最好的医疗保健。然而，即使在最好的条件下，错误可以而且确实发生了！因此，实验室的质量计划。测试标准，如 CLIA, ISO, Rilibäk, COFRAC 和 NATA 授权的，在规划过程中协助。每一个都是基于对质量管理体系的系统规划和含有人体必需的元素（表一）直接测试网站管理整个测试过程，以确保实现“纠正”（质量结果）。所有这些标准要求持续的 QC 测量，以评估分析质量。质量测试结果是不是自动的。为了提供高质量的医疗保健，并确保病人的安全，实验室不能想当然地认为只要按照制造商的指示和信任的仪器将自动确保质量测试结果产生。由于血液的临界气体和重症监护测量，QC 仪器前必须参加资格预审的患者样本进行分析，以避免延误，由于仪器的问题，报告不正确的结果，收集其他病人的样本进行重新分析。

文献概述：质控在血气检测中的重要性，准确、精确可靠及时的质控是必不可少的，如若没有质控，即使在最好的条件下也有可能发生错误，并列举了在马里兰医院（马里兰州的巴尔的摩，美国）460 例患者检测错误的一个例子，大量结果错误，致使样本需要重新采集，医务人员被投诉。

关键词：质量控制、质量控制管理体系