Competency Assessment in Andrology Laboratory

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Erma Z. Drobnis

1 Introduction to Competency Assessment

One of the most important components of quality management in an andrology laboratory is competent performance of the complex tasks leading to accurate results. This relies on having competent personnel, starting with the laboratory director and including all supervisory and testing personnel involved in testing, processing sperm, and quality control procedures. There are a number of recent chapters and reviews that cover this subject [1–3] as well as guidelines from societies, including the European Society of Human Reproduction and Embryology (ESHRE) [4] and the American Society of Reproductive Medicine (ASRM) [5, 6], and guidelines from organizations, including the World Health Organization (WHO) [7] and International Organization for Standardization (ISO) [8]. Governmental and accreditation agencies often include personnel requirements for clinical laboratories. This chapter will focus on assessment of personnel performing testing in the andrology laboratory with examples from the author's facility.

Andrology testing is high complexity and requires highly qualified personnel. In most cases, a 2- or 4-year college/university degree in a laboratory science or the equivalent is required. Significant training and evaluation of personnel is also necessary, and, in the USA, a year of conducting clinical testing under direct supervision is required before testing personnel can work independently in a clinical laboratory [9]. The personnel file of each laboratory staff member should contain:

- Documentation of qualifications
- References
- Health records (e.g., vaccinations)
- Training
- Performance evaluations
- Continuing education

If the laboratory is part of a hospital or clinic, some of the personnel policies will be provided by the institution, which may have a human resources (HR) department; nevertheless, the laboratory requires its own personnel policies that may refer to those of the managing organization when applicable. Independent andrology laboratories must have complete, written personnel policies, without the benefit of an organizational framework. A clear description of each employee's responsibilities is key to laboratory quality. Job satisfaction and employee retention require that each staff member understands what is required of them and what is provided for them by the employer.

2 Attributes of Laboratory Testing Personnel

The laboratory requires enough personnel, having the necessary education, training, and experience, to conduct all of the management, supervision, and testing being performed. Due to the increase in quality management procedures and the increasing complexity of testing methodology, the time required to perform and IVF cycle has more than doubled [10] in recent years, and, for similar reasons, andrology testing has also become more labor intensive. In general, the laboratory requires a director, supervisor(s), and testing personnel. This could be a single individual for a small laboratory, provided there is a backup person available with the required training, qualifications, and accreditation (if applicable) to conduct andrology testing without direct supervision. An individual may act as the laboratory director for multiple laboratories, but a qualified supervisor must be onsite during all hours of testing and should review all results within a day of testing.

The laboratory standard operating procedures (SOPs) should include descriptions of the personnel needs, titles,

E.Z. Drobnis, PhD (✉)
Department of Obstetrics, Gynecology and Women's Health, Reproductive Medicine and Fertility, School of Medicine, University of Missouri, 500 N Keene Street, Suite 203, Columbia, MO 65201, USA
e-mail: drobnise@health.missouri.edu

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responsibilities, and duties of testing personnel. In many countries and regions, the qualifications and responsibilities of clinical laboratory personnel are included in governmental regulations, standards of accreditation organizations, and guidelines of scientific societies. In the latter case, the practice committees of scientific societies may have more stringent requirements than those of governmental regulations and provide guidance on the standard of care for clinical practice.

The requirements for clinical testing personnel have evolved over time and now require persons capable of analytical thinking [11]. Although there are SOPs that define the steps required for testing and a supervisor available to answer questions that arise, modern clinical testing involves the ability to understand the SOP, recognize unusual circumstances, determine when assistance is required, and document any deviations from the SOP during testing.

In addition to the technical and cognitive abilities of laboratory staff, it is important that there is a culture of teamwork, integrity, confidence, and motivation in the laboratory [12]. Accurate results require personnel who take ownership of their position and have confidence in their work arising from universal participation in quality management. Good teamwork requires trust, respect, and cooperation among coworkers [1]. One person with undesirable character can easily poison the working environment in the laboratory, inevitably resulting in poorer quality of the laboratory's results. These "soft" aspects of an applicant's character can be challenging to assess during the hiring process, and it may be advisable to consult with an HR professional if the laboratory lacks access to an HR department.

3 Training Laboratory Testing Personnel

The laboratory director is responsible for defining the training needs for testing personnel. This includes initial training, on-the-job training and continuing education. Even if the new technician has worked in another andrology laboratory, it is important that new personnel are trained in all SOPs. In fact, retraining of experienced andrologists can be challenging in that changes in cherished methodology used in the past may be necessary. Training will be most effective if the trainee understands the reason why a specific procedure is important. Take the time to explain the principles and encourage questions from the trainee. Notes can be added to the SOP to address some of these questions, providing early reinforcement of the trainee's importance to the team.

3.1 Initial Training

Initial training will generally include considerable instruction in background information before the trainee works in the laboratory. Although the institution may provide some of this training, there should be SOPs in place to cover initial training in policies specific to the individual andrology laboratory. Regardless of the prior experience of a new staff member, the basics should be covered to insure his or her understanding and commitment to quality performance in the new position. This includes:

- Code of conduct
- Personnel policies
- Chain of command
- Culture of quality
- Laboratory safety
- National, state, local, institutional regulations
- Materials and reagents
- Use of SOPs
- Daily QC

After this background training, the new staff member can work side-by-side with a supervisor to begin learning the basics of facilities management, equipment operation, and laboratory supplies. This will involve many of the regular QC activities described in the preceding chapter. It is advisable that the trainee have a firm grasp of these aspects of laboratory quality before proceeding to actual testing.

Finally, the new employee learns specimen receipt and testing procedures, by:

1. Observation of testing personnel
2. For semen analysis: side-by-side analysis of semen with approved testing personnel
3. For sperm processing: practice with donor specimens or semen remaining after completion of semen analysis

Ideally, the laboratory has benchmarks that indicate when a trainee can be considered for patient testing; examples are given by Björndahl et al. [2], including recovery of motile sperm after sperm preparation or cryopreservation. These authors also suggest that these benchmarks be achieved on three consecutive events followed by a determined number of successful procedures under close supervision.

During training, a supervisor coaches the trainee and (1) provides critical assessment of the trainee's work, (2) provides positive feedback for desirable performance, and (3) acts as a role model for teamwork, integrity, confidence, and motivation. During this stage of training, the employee will learn the importance of faithful adherence to the SOPs and accurate documentation of all activities, including

deviations from the SOPs. It is particularly important that transparency is emphasized, reporting of errors is encouraged, and the trainee knows the steps to take if an error occurs.

As the staff member learns the testing procedures, the foundation material can be reinforced and put into context. For example, a technician approved to receive and accession specimens into the laboratory should also know the regulatory requirements for that activity. Encourage questions and instill quality performance among technologists and leading by example. The supervisor should always be available and willing to answer questions, for example, looking at an unusual specimen when the testing person is unsure of how to measure or record results.

When the testing person is judged competent to perform a task, documentation is required to authorize him or her for clinical testing. Table 3.1 shows an example of a form used by the author to document training. In the early stages of a new andrologist's testing, it is advisable to perform more frequent evaluation of inter-technician QC until stable QC results are routinely obtained. Note that training records should be maintained after termination of an employee for a time determined by the laboratory and applicable regulations.

3.2 Ongoing Training and New SOPs

Training is an ongoing process occurring for all employees over time. Informal training will occur whenever the technician is working in the lab under supervision, but formal training must also be documented. Whenever an SOP changes within the scope of an employee's work duties, the technician must (1) be trained in the changes, (2) read the new SOP, and (3) document that they have reviewed the new SOP. In addition, each employee should regularly review (e.g., annually) all SOPs relevant to the testing he or she is approved to perform, including the associated policies and procedures for personnel, facilities, equipment, QC, quality assurance (QA), and laboratory safety. Annual refresher training should also be offered, covering code of conduct, safety, and laboratory compliance with regulations (government and institutional if applicable).

3.3 Continuing Education

An important part of a technician's training is continuing education. Medical knowledge is increasing and clinical testing is no small part of the resulting changes in patient care. Technicians should be exposed to new techniques and better understanding of the principles underlying current methodology. Regulations and safety methods also change over time. Ongoing improvement of the technician's knowledge base will help maintain excellence of the andrology laboratory. There are multiple formats for continuing education.

- Scientific conferences, local meetings, and/or workshops—a highly effective method because technicians benefit from formal lectures as well as direct communication with their peers.
- Online courses and webinars offered through scientific societies and accreditation agencies—in some cases, these are free or low cost to members.
- Lectures from the clinicians who are clients of the laboratory service.
- Reading material provided by the laboratory director in the form of manuals, book chapters, and scientific papers—subsequent evaluation of the technician's comprehension is advised.
- Directed literature review—technicians can assist the laboratory by researching methodology.

One method of training documentation is having the technician write a summary of what they learned.

In the process of continuing education, personnel are exposed to information from outside the laboratory in which they work. This can lead to stimulating discussions among laboratory workers. Ideas for improvements proposed by personnel should be entertained if possible, ideally allowing the technician to conduct small studies or literature reviews to compare proposed innovations with the laboratory's current methodology.

4 Process of Personnel Assessment

Once an employee is approved to perform testing, his or her performance must be monitored and this evaluation documented.

4.1 Routine Monitoring

Routine evaluation of personnel by the supervisor includes:

- Observing routine patient testing
- Observing instrument maintenance and function checks
- Monitoring the recording and reporting of results
- Reviewing test results and test QC

Providing the staff member with regular, constructive feedback during the performance of laboratory tasks and acknowledging improvement can give the employee confidence in his or her personal performance and pride in the quality of the laboratory's results. A proven teaching method is asking the learner questions, including what the technician

Table 3.1 Sample training form documentation for andrology laboratory personnel

Laboratory procedure	Date approved	Supervisor initials	Comments
Laboratory code of conduct, accreditation, and applicable regulations (required before testing activities)			
Code of conduct			
Personnel policies			
Overview of quality management, culture of quality			
Laboratory organization and chain of command			
Services performed by the laboratory			
Job description and responsibilities			
Guidelines (AATB and ASRM)			
CLIA regulations			
FDA regulations			
HIPAA			
Hospital policies			
Proficiency testing policies			
PT remedial action			
Overview of QC and remediation			
Computer security			
Laboratory safety and security (required before testing activities)			
Laboratory security			
Emergency action plan			
University environmental health and safety policies			
Electrical safety			
Personal apparel and PPE			
Unattended operations			
Chemical hazard identification			
Chemical inventory			
Safety data sheets (SDS)			
Disposal of chemicals			
Chemical spill and emergency response			
Blood-borne pathogens standard			
Hand hygiene			
Biohazardous waste disposal			
Biohazard spills and emergency response			
Fire safety			
Use of fire extinguishers			
Fire emergency response			
Severe weather emergency response			
Hospital emergency response regulations and codes			
Laboratory ergonomics			
Handling liquid nitrogen			
Standard laboratory procedures (required for all testing)			
Entering the lab, equipment function checks, sanitization			
Laboratory cleanup after testing			
Centrifugation			
Microscopy			
Using the biosafety hood			
Andrology testing (required for all testing)			
Andrology QC before testing			
Collection room sanitation			
Requisitions for tests			
Accessioning semen specimens			
Rejection of semen specimens			
Notification of referring physician or nurse if Special Action Values are obtained for an IUI or cryopreservation specimen			

(continued)

Table 3.1 (continued)

Laboratory procedure	Date approved	Supervisor initials	Comments
Maintaining integrity of sperm samples—cross contamination			
Extraction of data from requisition and specimen information sheet for report form			
Determining liquefaction time			
Determining macroscopic characteristics			
Determining specimen volume			
Treatment of non-liquefying or hyperviscous semen			
Determining sperm concentration and daily QC			
Determining sperm motility and daily QC			
Determining round cell density			
Stain determination of WBC density and daily QC			
Record keeping for cryopreserved specimens			
Thawing semen specimens			
Completion and approval of andrology report forms			
Disposition of andrology report forms			
Data entry into the electronic medical record (EMR)			
Sperm wash IUI			
Determination of whether 2-step or 1-step gradient			
Sperm wash			
Preparation of wash-only specimen			
Gradient sperm preparation			
Packaging of IUI specimen			
Timing of thaw for IUI with cryopreserved semen			
Preparation of thawed specimens			
Process controls for IUI preparation			
Semen analysis			
Determination of agglutination			
Preparation of morphology slides and daily QC			
Determination of morphology and daily QC			
Viability determination			
Preparation of ASA controls			
Performing and scoring the ASA test			
Preparation of semen collected by retrograde ejaculation or electroejaculation			
Andrology QC materials and media			
Receipt of materials (shipments)			
Preparation of leukocyte staining controls			
Changing morphology stains			
Preparation of gradient solutions			
Preparation of control slides for staining QC			
Toxicity testing of contact materials			
Microbial monitoring			
Tissue bank and semen cryopreservation			
Receipt of specimens for cryopreservation			
Labeling vials for cryopreserved semen			
Cryopreservation of semen			
Storage of cryopreserved semen in the sperm bank			
Process controls for semen cryopreservation			
Donor semen policies			
Transferring cryopreserved specimens between tanks			
Shipment of cryopreserved semen			
Receiving a shipment of cryopreserved semen			

(continued)

Table 3.1 (continued)

Laboratory procedure	Date approved	Supervisor initials	Comments
Maintenance and QC activities			
Supply inventory and ordering			
Receipt of shipments, logging, labeling, and storage of supplies			
Contact materials log and toxicity testing			
Testing for microbial contamination			
Centrifuge maintenance and QC			
Dewar maintenance and QC			
CO_2 incubator maintenance and QC			
Biosafety hood maintenance and QC			
Microscope maintenance and QC			
Pipettor maintenance and QC			
Refrigerators and freezer maintenance and QC			
Thermometer maintenance and QC			
Weekly, monthly, biannual, annual QC			
Review of SOPs			
Storage of laboratory records			
The event record			
Communications and complaints			
Detection and reporting of incidents—incident response			

CLIA Clinical Laboratory Improvement Amendment, *AATB* American Association of Tissue Banks, *HIPPA* Health Insurance Portability and Accountability Act, *PPE* personal protective equipment, *ASA* antisperm antibody

would do in hypothetical situations, what regulations govern his or her current activity, and the performance specifications for the test being conducted. Encouraging both questions and suggestions from the technician can establish the sense of teamwork and will gradually allow the staff member to answer questions from clinic staff and clients on behalf of the andrology laboratory.

4.2 Inter-technician QC

In addition to formal performance review, the inter-technician (intra-laboratory) variation should be monitored for each test. In particular, split sample testing should be conducted for sperm concentration, motility, and morphology. Multiple evaluations, involving splitting a single donor specimen for analysis by all technicians, can indicate if updated training is required. In fact, the process of side-by-side testing lends itself to on the spot training. For documentation purposes, note that there will be some random variation, and statistical analysis should be used to detect significant differences in the values obtained by different testing personnel.

Inter-technician differences can be detected over the long term by comparing results for patient samples, including replicate counts. Figure 3.1 shows the comparison of two technicians for determination of progressive motility and sperm concentration over a year of testing. The differences in values and in precision differed significantly between the technicians, and remedial action is required to determine the cause(s). Tables 7.2, 7.3, 7.4, and 7.5 in the WHO laboratory manual for the examination and processing of human semen [7] gives a list of sources of variation in assessing and proposed solutions for determination of sperm concentration, morphology, motility, and viability. Remedial action, including any training activities, should be documented with demonstration of the technician's competence before he or she resumes patient testing.

Another method for tracking consistent performance by technicians is regular evaluation of daily QC activities, such as bead counts, sperm motility from videotapes, and sperm morphology counts, to detect inter-technician variation. If QC data are maintained in a database, this practice can be a routine analysis. For example, the inter-technician difference from the expected value and variation (SD; CV) can be calculated monthly. Values for counting latex beads are shown in Fig. 3.2 for two technicians that differ in the median counts.

4.3 Formal Performance Evaluations

Each laboratory requires SOPs for formal performance evaluation of personnel and documentation of this activity. Ensure that policies and procedures are established for monitoring the expertise of individuals who conduct testing and to identify needs for remedial training or continuing education to improve skills if needed. Formal evaluations should be more frequent for new employees and be conducted at least annually for all staff.

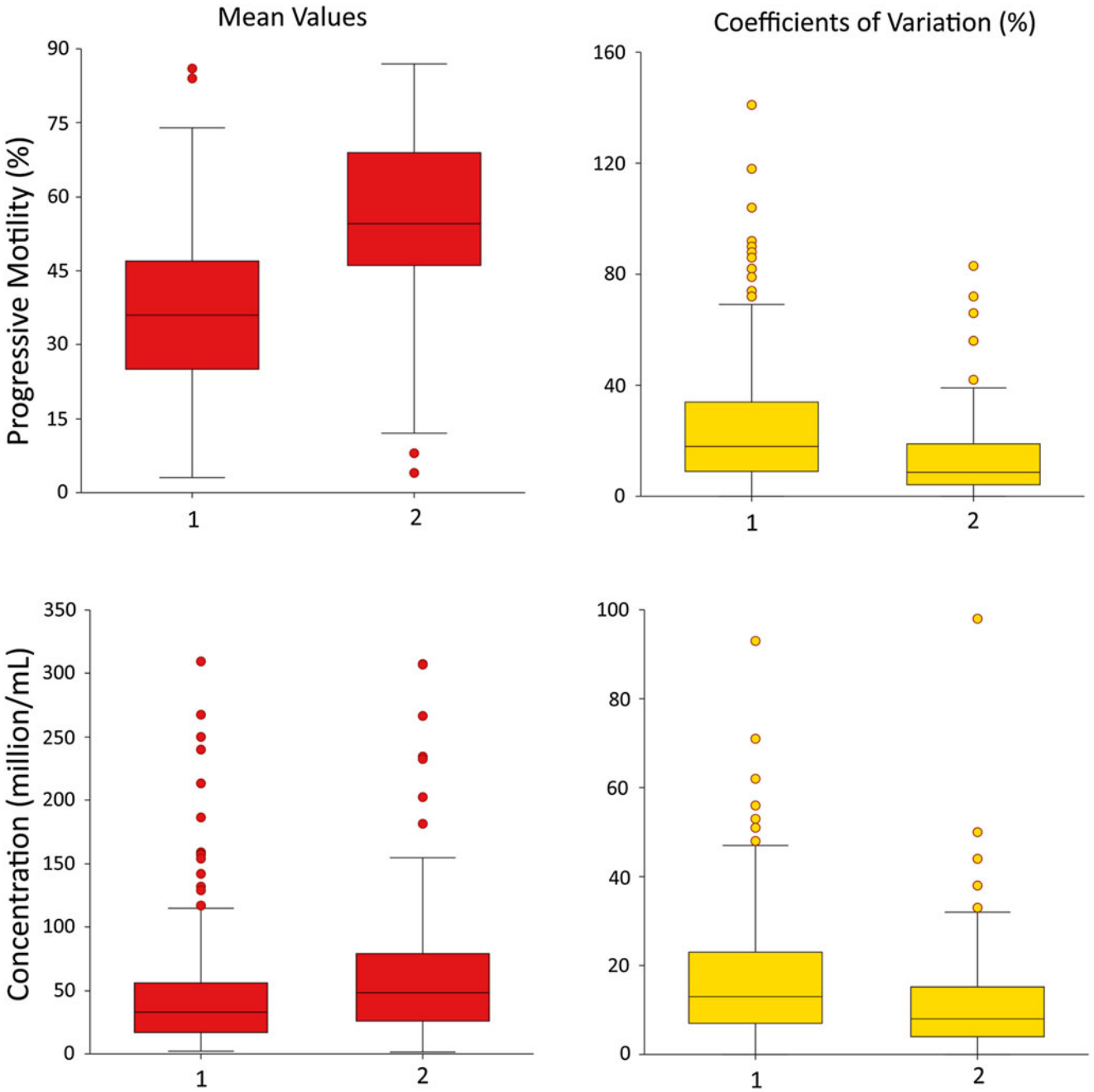

Fig. 3.1 Comparison between two technicians in values for sperm concentration and motility for 1 year. The left-hand columns (*red*) show box plots for the sperm measures and the right-hand columns (*gold*) show the coefficients of variation (CV) for the replicates each day. The figures include 367 patient specimens evaluated by technician 1 and 130 different patient specimens evaluated by technician 2. In all four plots, the difference between the 2 technicians was highly significant ($p<0.001$; Kruskal-Wallis ANOVA on ranks). Technician 2 counted higher concentration and progressive motility with greater precision than technician 1

The annual performance evaluation should involve the employee, his or her supervisor, and the laboratory director. The criteria should sum up the routine process of personnel assessment, including the worker's growth and progress. It should be consistent and supportive of other documentation used to describe employee performance. Table 3.2 is the form used in the author's laboratory.

Producing quality results with satisfied clients and patients is impossible without competent laboratory staff. Ensuring the competency of andrology laboratory personnel is an active, ongoing process that includes the entire laboratory team. Establishing and maintaining a culture of quality that involves each staff member will improve pride in the laboratory, job satisfaction, and retention of competent employees.

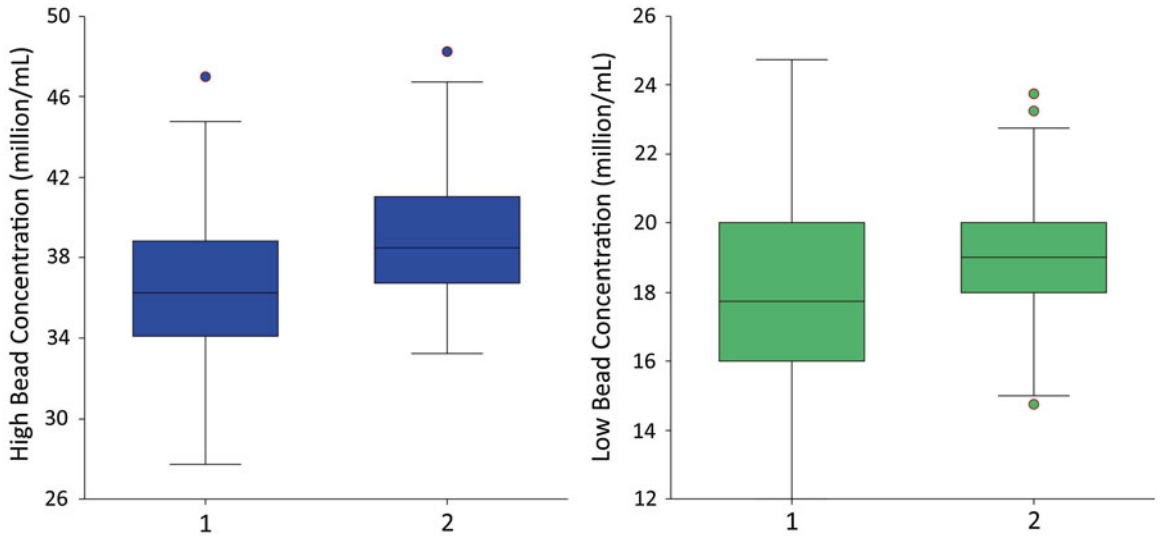

Fig. 3.2 Comparison between two technicians in values obtained for daily counts of latex beads for 1 year. Counts are for the same Makler chamber and the same lot of beads. Technician 1 counted beads on 146 days and technician 2 on 127 days. Technician 2 obtained significantly higher values for both high (*blue*) and low (*green*) bead suspensions ($p < 0.001$; Kruskal-Wallis ANOVA on ranks)

Table 3.2 Sample annual employee competency evaluation form

Name of employee:						
Title:						
CLIA qualification title(s):						
Facility or functional area:						
Reports to:						
Review period:						
Part A. Organizational standards						
Criteria: (1) unacceptable, (2) improvement expected, (3) successful, (4) exceeds expectations, (5) role model	**1**	**2**	**3**	**4**	**5**	**N/A**
1. Commitment to coworkers/teamwork: does the employee perform tasks and duties and behave in a way that shows they work well with coworkers, are available to the department and others when needed, and are willing to assist with tasks and assignments outside their normal job duties? Does the employee offer to or find ways to assist coworkers and others?						
2. Attendance: does the employee follow university and department policies on the use of time off, which includes vacation, sick, and personal days? Does the employee try to avoid tardiness and taking unscheduled time off and provide enough notice for time off requests?						
3. Quality customer care/communication: does the employee show positive customer service skills to patients, staff, and visitors, including greeting customers in a friendly and timely manner; trying to personalize service (i.e., using customer name) when possible; updating customers on delays; using appropriate verbal and nonverbal communication etc?						
4. Work environment: does the employee act as an "owner" of the work place by keeping the work area neat and clean and showing respect for the space of others, such as patients, visitors, and staff? Does the employee follow safety policies and report safety hazards if needed?						
5. Efficiency and resource management: does the employee appropriately use university and hospital resources, including time, property, equipment, educational materials, and other items? Does the employee try to reserve resources, recycle, and reuse materials and avoid waste? Does the employee suggest ways to improve quality of processes and procedures?						
6. Diversity and respect: does the employee accept and respect the diverse mix of patients, staff, and visitors and provide steady and standard service to all customers without regard to race, age, gender, national origin, sexual orientation, religion, and socioeconomic status?						
7. Pride in self: does the employee demonstrate pride in themselves and the organization through their attitude and the way they appear, dress, and behave? Does the employee represent the organization well within the community (if applicable)?						

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8. Participation: does the employee participate in departmental meetings, in-services, staff forums, and training? Does the employee take part in hospital or organization-wide committees and work teams (if applicable)?						
9. Flexibility: does the employee have the ability to alter actions and behaviors based on the changing needs of the organization? Does the employee accept and learn new tasks and duties? If asked, does the employee accept transfer to other areas of the department?						
10. Professional growth: does the employee seek to learn, grow, and advance skills and abilities? Do they take advantage of chances to learn, seminars, and workshops if/when offered? Do they target and improve performance of job-related goals and objectives which can be measured?						
11. Critical thinking and judgment: does the employee show good judgment? Does the employee recognize and react in a proper manner to problems and challenges and work with others to solve as necessary?						
12. Privacy: does the employee respect and adhere to the confidentiality (privacy) policy designed to protect confidential (private) information, including, but not limited to, patients, employees, visitors, students, and volunteers, as well as business/proprietary and third-party information?						
Part B. Position responsibilities: individual job duties/competencies						
Criteria: (1) unacceptable, (2) improvement expected, (3) successful, (4) exceeds expectations, (5) Role model	**1**	**2**	**3**	**4**	**5**	**N/A**
1. Supervise and perform chemical, bacteriological, serological, or microscopic laboratory test procedures on specimens. Recognize instrument malfunctions and abnormal test results and take corrective action, including communications with manufacturer as required by CLIA						
2. Validate, review, and report results of tests performed. Ensure that patient test results are not reported until all corrective actions have been taken and the test system is properly functioning						
3. Communicate effectively with technicians, clinical staff, support staff, and patients						
4. Assure that all remedial actions are taken whenever test systems deviate from the laboratory's established performance specifications						
5. Calibrate, standardize, and maintain instruments following established procedures						
6. Prepare reagents, standards, and controls according to prescribed procedures						
7. Review for accuracy and update standard operating procedures as assigned						
8. Perform quality control to ensure proper functioning of instrumentation, reagents, and procedures						
9. Research and develop new medical laboratory procedures as assigned						
10. Dispose of or properly handle biological, radioactive, and/or hazardous waste in a manner that is consistent with laboratory, university, state, and federal government policy						
11. Participate in the ordering activities for supplies, materials, and equipment as needed						
Overall comments/performance plan:						
Goals for next rating period:						
Employee comments:						
Plan to improve	**Measure of success**			**Must improve by**		
The above evaluation has been explained to me, and any questions I had were answered						
Employee: _____ Date:_____						
Supervisor: _____ Date:_____						

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