# Semen Evaluations in the Clinical Laboratory

## *How Well Are They Being Performed?*

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*Because semen analysis is the primary diagnostic tool in male fertility investigations, we assessed its performance in clinical laboratories. We randomly surveyed United States hospital laboratories to determine the factors that predict demand for semen analysis and to assess the technical caliber and quality of semen testing performed. Hospital size, presence of a fertility center in the hospital, reproductive care physicians ordering the test, and quality of testing are factors that predict semen analysis demand. Our study also revealed that, in spite of increased demand for semen analysis, testing is not comprehensive, technology is minimal, and quality is compromised. Most clinical laboratories do not offer a quality semen analysis sufficient for diagnosing infertility.*

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Public and professional awareness of the problem of infertility, a condition that affects approximately 10% to 20% of couples of childbearing age in the United States, is increasing.[1] Approximately 50% of the cases investigated implicate a male factor as the cause.[1–3] Heightened awareness of the male role in infertility has prompted a significant increase in requests for semen analysis (SA), which is considered the most important tool in the evaluation of male fertility.[2,4]

Although many semen tests are performed in andrology labs associated with a growing number of fertility centers (medical centers that perform artificial reproductive technology procedures such as in vitro fertilization [IVF] and gamete intrafallopian transfer [GIFT]), hospital clinical laboratories also report an increase in requests for conventional semen analysis.[1,5]

Even though demand for SA is increasing, many believe the test is not well performed in the hospital clinical laboratory.[6,7] Most hospital clinical laboratories do not yet have the technology for interpreting semen parameters that is routine in many andrology laboratories.[8,9] In addition, the testing that is performed in the hospital laboratory is often of questionable diagnostic value, particularly for the purpose of a fertility work-up.[6]

We conducted this study to determine factors that predict the demand for the SA in the clinical laboratory and to assess the technical caliber and quality of testing that is being performed.

## Materials and Methods

### *Sample*

We selected a random sample of 500 acute care community hospitals from the American Hospital Association file of member hospitals in the United States. We mailed questionnaires to the chief laboratory technologist in each hospital. The response rate after follow-up was 129 (26%), which is an expected rate for a mailed survey.[10] We used all responses and did not impute missing responses.

### *Questionnaire*

Clinical laboratory scientists and medical technologists with expertise in laboratory management and academic education, along with a reproductive biologist certified in medical technology developed the questionnaire (Fig 1). A health policy analyst with expertise in statistical analysis evaluated the data.

Questions were targeted to determine predictors that explained SA

**Semen Analyses in the Clinical Laboratory Survey**

Title:_____

Instituion:_____

Directions: This questionnaire is designed to elicit information regarding the number and types of semen analyses performed in the clinical laboratory. This information is needed as an integral part of a research effort. If data are unavailable, please indicate by marking "NA" (not available) in the appropriate space. If data are not known, please indicate by marking "U" (unknown) in the appropriate space. The data collected will be used only in the aggregate and all responses will be confidential. Return the survey in the enclosed stamped envelope by January 15, 1993. Only numbers recorded and hospital bed-size will become part of the statistical data.

1. Size of institution:

A. Your hospital has **168** beds. **mean**

B. Your laboratory employs **18 = mean** technologist level FTE.

2. How many semen analyses does your laboratory perform per month? **mean = 4**

3. Check which clinical laboratory or laboratory section performs routine semen analyses?
**32.6%** urinalysis
**40.3%** hematology
**11.6%** other (specify)_____

4. *,† What Is the education/certification level of personnel performing routine semen analysis?

A. Certified Laboratory Personnel (level or equivalent)

**5.4%** CLA/MA **44.2%** MLT/CLT **73.6%** MT/CLS

B. Noncertified Personnel
**10.1%** AA/AS or BA/BS degree

C. **14.7%** other

5.* Is the semen analysis automated? (eg, CASA)
**1.6%** yes **98.4%** no

A. If yes, please specify_____
B. If no, check the counting chamber used

**76.0%** Hemacytometer **3.1%** Makler chamber
**20.9%** N/A

6. List number of semen analyses per month ordered for the following diagnoses. Mean

| | | | |
|---|---|---|---|
| **2.43** | infertility testing | **1.69** | postvasectomy evaluation |
| **0.01** | forensic medicine | **0.16** | assessment of vasovasotomy |
| **0.11** | other | | |

7. Rate (1–7) in order of frequency of tests ordered by each specialist: **(Mean)**

| | | | |
|---|---|---|---|
| **0.78** | Infertility specialist | **1.10** | Ob/Gyn |
| **1.03** | Urologist | **1.22** | Family practitioner |
| **0.92** | Endocrinologist | **1.12** | Oncologist |
| **N/S** | Other | | |

8. Does the hospital have a fertility center?
**4.7%** yes **95.3%** no
If no, the nearest fertility center is:
**39.5%** less than 50 miles away **38.8%** more than 50 miles away

9. Check the semen parameters evaluated as part of the routine semen analysis. = yes = %

a. **79.1** semen volume
b. **53.5** pH
c. **51.9** viscosity
d. **46.5** sperm concentration/ml
e. **69.0** total sperm count
f. **80.6** % motility
g. **39.5** progression of motility
h. **17.8** rate of motility
i. **24.0** viability
j. **77.5** morphology
k. **4.7** size measurements

10. If morphologies are stained, please list the stain or stains used.
**53.6% reported using a stain including Papanicolaou's, Wright's,hematoxylin-eosin, prestained Testsimplets, Gram's stain, new methylene blue, crystal violet, and eosin**

Fig 1.—Results of survey of semen analyses in the clinical laboratory.

demand, assess technology and semen testing caliber, and determine testing quality.

A cover letter explained the purpose of the study, encouraged the laboratory practitioner to complete the questionnaire, and assured confidentiality with respect to individual sources and location.

*Analytical Methods*

We hypothesized that the number of SAs performed in hospital clinical laboratories would depend on the size of the hospital, the facility's distance from a fertility center, the presence of reproductive care physicians (gynecologists, obstetricians/gynecologists, and urologists) ordering the analysis, and level of technology and quality of testing. Both level of technology and quality of testing were determined from selected survey questions that were incorporated to assess these areas.

To determine the functional relationship between variables, one question, representative of technology, was selected as an indicator and used in the statistical analysis. We chose use of stage micrometers as this indicator because determination of sperm dimension and strict criteria (referred to as Kruger morphology in the questionnaire; Fig 2) require micrometers.[11]

Morphology requires a significant time commitment by the technologist for preparation, analysis, and interpretation. We therefore selected it as an indicator for quality of testing. We assumed that laboratories performing morphologies included a standard quantitative differential denoting structural defects, obvious abnormal sizes, and amorphous forms in their examination.[8] Since survey respondents were chief technologists, we were confident that they would be unlikely to report morphology as part of the SA unless the standard assessment had been performed.

The assessments for both technology and quality of testing included certification of personnel performing the SA. Semen analysis is considered to be a "moderate to complex" test requiring interpretive skills.[12] We used personnel certification as a predictor for SA demand because quality may reflect demand for the SA.

The variables of interest were descriptively analyzed (see Figure 1). To explain the variance in the number of SAs done in the hospital laboratory, we estimated a regression model (table) as follows. The

11.† Do you run controls for semen analysis?
**2.3%** yes **97.7%** no

If yes, please describe

12A. Is the Kruger sperm morphology run as part of the semen analysis?
**1.6%** yes **98.4%** no

12B. If no, are you familiar with the Kruger morphology?

**4.7%** yes **95.3%** no

13.* Are your microscopes equipped with stage micrometers?
**31.8%** yes **68.2%** no

14.† Does your laboratory note spherical cells on the semen morphology?.
A. **31.8%** yes **68.2%** no

B. If yes, does your laboratory distinguish between sperm precursors and white blood cells

**17.8%** yes **82.2%** no
C. If yes, what method or stain is used?

**21.9% reported method** including Papanicolaou's, Wright's, prestained Testsimplets, safranin, eosin, methylene blue, hematoxylin-eosin, Wright's/Giemsa, Gram's, periodic acid–Schiff, eosin-nigrosin, crystal violet, and carbofuchsin stains; and phase microscopy. One reported that the morphology was read by a pathologist but did not list the method.

15.* Check which of the following tests does your laboratory perform on semen? = **Do perform = %**

| | |
|---|---|
| **14.0** fructose | **0.8** zinc |
| **13.2** aerobic cultures | **7.0** anaerobic cultures |
| **5.4** *Chlamydia* screens/cultures | **3.1** *Mycoplasma/Ureaplasma* cultures |
| **0.8** immunology testing | 0 other enzymes—specify_____ |
| **0.8** blood group/secretor status | |

16. List any other tests performed on semen:

The following questions deal with your opinions on semen analysis performed at your laboratory:

17.† Semen analyses run in this laboratory are always accurate?

**43.4%** yes **56.6%** no

18.† The results of the semen analysis varies with the technologist performing the tests?

**54.3%** yes **45.7%** no

19.† The semen analyses performed in this laboratory are sufficient for infertility diagnosis? %
**42.6%** yes **57.4%** no

20. Would your laboratory benefit from continuing education materials on the semen analysis?
**71.3%** yes **28.7%** no

21. Would a videocasette on sperm motility be helpful as a training tool?
**67.4%** yes **32.6%** no

22. Would your laboratory technologists be interested in reviewing training materials on the semen analysis?
**69.0%** yes **31.0%** no

Thank you for helping with this research project. The results will be submitted to a national professional journal for publication. If you would like a copy of the results, please include your request when you return the survey.

If you have any questions about this survey or the results, please contact us. Janice M. Klaassen, MS, MT(ASCP)SM; Doris J. Baker, PhD, MT(ASCP); Janis M. Glatzel, MS, MT(ASCP); Department of Clinical Laboratory Sciences / Bigelow Health Sciences Bldg., Room 335, University of Nevada, Las Vegas / 4505 Maryland Pkwy/ Las Vegas, NV 89154-3021 Department phone: (702) 895-3788 FAX: (702) 895-3872

***Level of Technology,** response #13 was used as **indicator** for statistical analysis
†**Quality of Testing**, response #9k was used as **indicator** for statistical analysis

functional relationship between the variables is

Number of SAs are a function of: intercept + #beds + hospital fertility center + reproductive care physicians ordering + region + certified med tech + morphology + stage micrometer + population + error.

## Results

### *Sample*

We analyzed the responses for bias. Respondents generally represented the overall distribution of US hospitals. A slight bias toward small and midwestern hospitals existed, however (Fig 3).

### *Analytical Results*

Regression results are presented in the table. The model was significant at $P$=.01 and predicted 28% of the variance in this cross-sectional data. No significant correlations were found among the independent variables used in the model, thus no correction was done for colinearity. Residual plot examination showed random distribution of residuals. A post-hoc analysis was done, and the sample had a power of .99 ($\alpha$ = .05; $\beta$ = .002). The sample size, therefore, was adequate for the analysis performed.

### *Predictors for Demand for Semen Analysis Requests*

Regression analysis (see table) showed that, within the model, the significant predictors for the SA requests were number of hospital beds, presence of a fertility center at the hospital, presence of reproductive care physicians ordering the test, and quality of SA as indicated by including morphology as part of the test.

Marginal analysis showed that, although number of beds is a predictor of testing ordered, it does not add greatly to test volume. The addition of 100 beds adds 0.6 tests per month, while the addition of a fertility center adds 8.51 tests per month; presence of a reproductive care specialist ordering tests adds 3.02 tests per month.

Technology level did not predict demand for the SA, but quality of testing, as measured by morphology, was a significant predictor and added 4.41 tests per month.

We hypothesized that clinical labs would perform fewer SAs if the hospital had a fertility center or if a center was located nearby. Results showed that when a fertility center was associated with the hospital, the number of SAs requested through the clinical lab actually increased. When a fertility center was not associated with the hospital, distance to the nearest center was not a factor in predicting the request for SA.

Because the certification level of personnel performing the analysis should

**Regression Results***

**Dependent variable**
#Semen Analyses Performed

| Independent variables | Parameter Estimates | Standard Error | Marginal Effect |
|---|---|---|---|
| Intercept: | -3.332 | 1.866† | (# additional tests) |
| # Beds | 0.006 | 0.003‡ | 0.6/100 beds |
| Fertility center at hospital | 8.512 | 2.286§ | 8.51 if yes |
| Reproductive care physician orders tests | 3.021 | 1.083§ | 3.02 if yes |
| Medical technologist analyzes | -2.387 | 1.393† | -2.38 if yes |
| Morpology done | 4.411 | 1.539§ | 4.41 if yes |
| Stage micrometer | -0.538 | 1.024 | NS |
| Population (control) | 0.132 | 0.093 | NS |
| Region (control) | -0.265 | 0.468 | NS |

**Model Statistics**

| Source | *df* | Sum of Sq. | Mean Sq. | F-Value |
|---|---|---|---|---|
| Model | 8.000 | 1574.750 | 196.843 | 7.340§ |
| Error | 120.000 | 3218.261 | 26.819 | |
| C Total | 128.000 | 4793.006 | | |

* $R^2$=.329; adjusted $R^2$=.284; NS indicates not significant; *df*, degrees of freedom.
† Significant at *P*=.10.
‡ Significant at *P*=.05.
§ Significant at *P*=.01.

reflect both the level of technology and quality of testing, we hypothesized that the number of requests would increase when certified medical technologists performed the tests. On the contrary, our results showed a decrease in the demand for SA in labs in which testing was performed by certified medical technologists.

*Technology of Testing*

We based our evaluation of technical caliber of testing on descriptive analysis, including certification of personnel performing the SA, laboratory automation and types of counting chambers used, parameters included in SA, and associated testing performed on semen (see Fig 1). The survey found that the "moderate to complex" SA[12] was being performed by all levels of certified personnel and in some cases (10.1%) by noncertified personnel (response 4).

The survey further showed that hospital clinical laboratories tended to use conventional methods for SA evaluations, including hemacytometer sperm counts and visual motilities. Only 1.6% (response 5) ran an automated SA and only 3.1% used a specialized Makler counting chamber (Sefi-Medical Instruments, Haifa, Israel).[14,15] The majority (98.4%) of hospital laboratories did not perform a strict criteria evaluation (response 12A), and only 4.7% were familiar with this morphology (response 12B), which may be useful as a predictor of sperm-fertilizing capability.[11]

Parameters included in the routine SA varied (response 9). Although most labs (77.5%) did a sperm morphology (response 9j) and 31.8% of microscopes are equipped with a stage micrometer (response 13), only 4.7% (response 9k) measured sizes, a determination that should be a component of a routine SA.[8,16] Other associated laboratory tests performed on semen were minimal (response 15). The majority did not run various biochemical markers of accessory

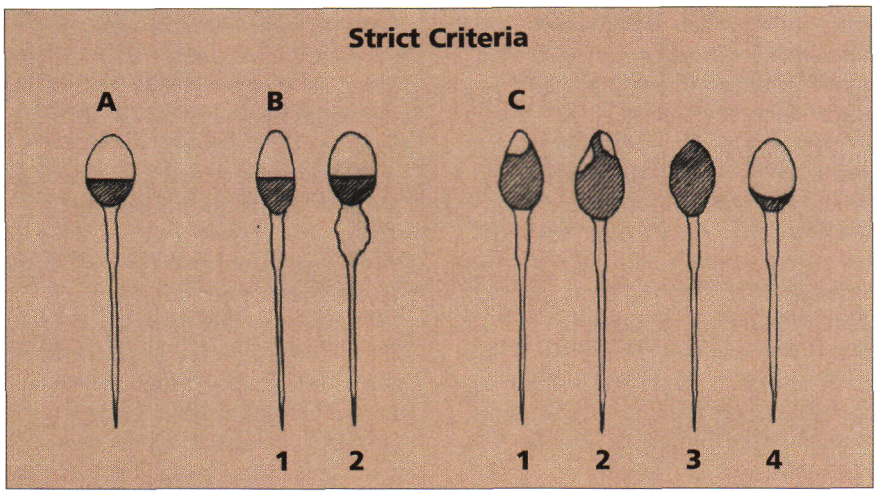


Fig 2.—Quick-stained spermatozoa. **A,** normal form: head, oval shape, smooth configuration, acrosome 40% to 70%, no neck, midpiece, or tail defects. Head length: 5 to 6 μm, diameter 2.5 to 3.5 μm. **B1,** slightly amorphous head; slightly elongated, loss of oval shape, acrosome 40% to 70%, diameter 2 to 2.5 μm. **B2,** slightly amorphous neck defect; thick neck but normal-shaped head. **C 1,2** abnormally small acrosome. **C3,** no acrosome. **C4,** acrosome >70% of head. **To be considered normal by strict criteria, the sperm must fall in the defined range (A). A reading of more than 14% normal sperm represents fertility (threshold for assisted reproduction); 5% to 14% indicates subfertile/fertile (good prognosis pattern); and 0% to 4% represents subfertile (poor prognosis pattern).** (From *Fertil Steril.* 1988;49:113. ©1988 by the American Fertility Society. Used by permission.)

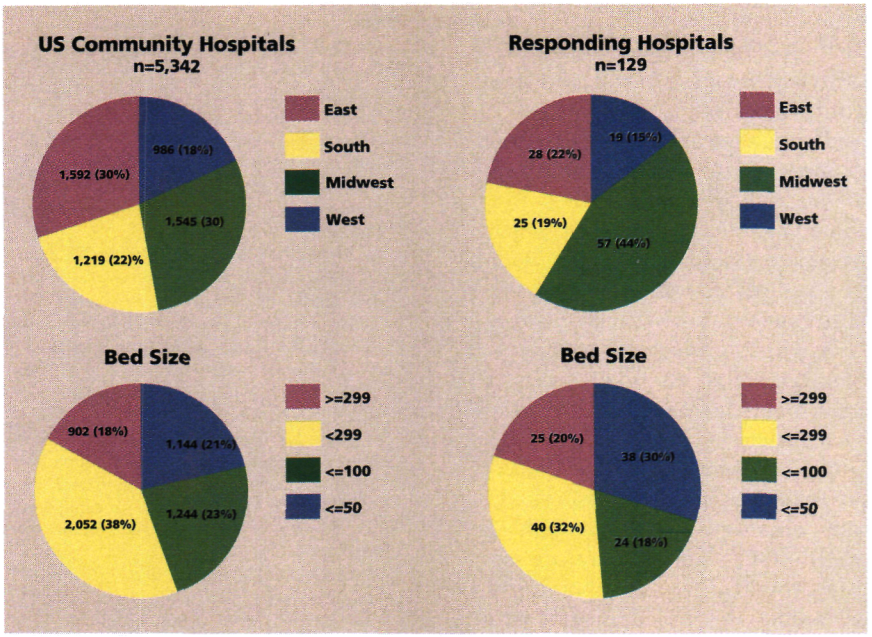


Fig 3.—Population-to-sample comparison of hospitals performing semen analyses.

gland function (eg, fructose, zinc, enzymes).[8]

Immunology testing on semen was almost nonexistent, and most labs did not culture for aerobic and anaerobic microorganisms. The questionnaire specifically addressed screens and cultures for *Chlamydia, Mycoplasma,* and *Ureaplasma*—organisms associated with infertility.[17,18] The majority of respondents did not assay for *Chlamydia,* but four of nine labs responding to the question did culture semen for *Mycoplasma* and *Ureaplasma.*

*Quality of Testing*

Evaluation of testing quality was based on descriptive analysis, including certification of personnel performing the test, overall quality of the test as indicated by performance of a stained morphology and morphology differential, use of controls, and the opinion of the respondent regarding accuracy and quality (see Fig 1). Although 77.5% of the respondents included a morphology as part of the SA (response 9j), 68.2% did not distinguish spherical cells (response 14A) and 82.2% did not attempt to distinguish white blood cells from sperm precursors (response 14B).

The questionnaire asked labs performing morphology to report staining procedures used (responses 10 and 14C), but only 56.7% of those reporting morphologies as part of the SA listed a staining procedure. Although the Papanicolaou's and Wright's stains were reported most frequently (28.8%), other reported stains included hematoxylin-eosin, new methylene blue, safranin, gram stain, periodic acid–Schiff, crystal violet, carbolfuchsin, and Testsimplets (Boehringer-Mannheim, Mannheim, Germany). Two respondents sent the morphology component of the SA to a reference laboratory. More important in the assessment of overall testing quality, 97.7% did not use controls for the SA (response 11).

Based on the confidential personal opinion of the respondents (response 17), only 43.4% felt that SA done in their lab was accurate, and 54.3% (response 18) felt that the accuracy of SA results varied with the technologist performing the test. The majority, 57.4%, felt that SAs performed in their labs were not sufficient for an infertility diagnosis (response 19).

## Comments

We were particularly interested in two of the study's findings. First, we were suprised to find that more SAs were done in hospitals associated with a fertility center.

Increased demand for semen testing in hospitals with fertility centers could be explained by overflow testing by the hospital lab to the fertility center. This is unlikely, though, because most physicians ordering the SA were not fertility specialists (response 7). Our descriptive data furthermore show that the technical caliber and quality of the SA in the clinical lab is not at an acceptable level to explain such an arrangement.

Another explanation for increased demand for semen testing in hospitals with fertility centers is the increased awareness of infertility services by physicians practicing in the hospital. This explanation seems likely because the ordering of tests by reproductive care physicians is a significant predictor of demand.

The second finding that surprised us was that the demand for the test actually decreased when certified medical technologists performed the SA. It is interesting to speculate about this seemingly paradoxical finding. Perhaps well-trained medical technologists influence the laboratory director not to perform the SA because they feel the test is not being adequately performed.

Technology for performing the SA, a low-profile test, in the nonspecialized hospital lab is at an expected level; most testing used classical methods including hemacytometric determinations of sperm concentration and observation of sperm motility.

Most clinical laboratorians were concerned with the overall quality of semen evaluations. The majority of respondents did not feel that the SA in their lab was sufficient for an infertility investigation (response 19), although most SAs were ordered for that diagnosis (response 6).

In 1983, Chong referred to the SA as the "neglected laboratory test."[6] This survey shows that because lack of specific controls for the SA and a perceived lack of confidence in test quality exist, SA is still not receiving proper attention in many clinical labs.

## Conclusion

Physicians influence demand for SA. The literature shows that the demand for the test is increasing,

and newly enacted laws and regulations may spur even more demand for the SA in the future. Public Law 102-493, the Fertility Clinic Success Rate and Certification Act of 1992, requires states to develop, through the Centers for Disease Control and Prevention, and carry out a certification program for fertility laboratories. The program was to be in place no later than 2 years after the date of enactment (November 1992).[19]

The American Fertility Society (AFS) and the College of American Pathologists (CAP) have joined to form the AFS/CAP Reproductive Laboratory Accreditation Program and will seek deemed status for inspection of fertility labs. The increased cost of maintaining andrology laboratories for accreditation according to the standards set by AFS and CAP may be prohibitive for some fertility centers and may result in the closing of those centers and their associated labs.[20,21] If there is a decline in available testing at fertility labs, hospital clinical labs may realize an increase in testing volume for the diagnosis of infertility. Legislation introduced by Representative Stark (D-CA) addressing physician ownership and referral arrangements, may ultimately affect testing offered in labs that are part of fertility centers.[22]

In the future, some andrology labs associated with fertility centers may not be able to run testing for physicians outside the center, and hospital laboratories may have to assume this overflow testing. In light of the increasing demand for semen evaluations in the clinical lab and increasing Clinical Laboratory Improvement Amendments of 1988 (CLIA '88) requirements for standardization, accuracy, and precision, it seems timely for hospital clinical laboratories to reevaluate the conventional SA.

A quality SA, sufficient for a fertility diagnosis, can be achieved within the constraints of the hospital clinical laboratory.[4,23] Classical methods for performing the SA, including hemacytometric determinations of sperm concentration, visual sperm motility assessment, and stained morphologies, may have high levels of repeatability provided certain criteria are met. Qualified technologists[12,24] must be thoroughly trained; procedures, including semen collection and transport protocols, must be standardized[8]; and internal[25,26] and external[27] quality control must be established.

Standardized SA procedures should include all significant semen parameters (response 9) along with a protocol for stained morphology, morphometric assessment of sperm cells, and an evaluation of white blood cells and sperm precursors.[5,8] As demand dictates, associated tests, such as determination of fertilizing ability of sperm in vitro and culturing semen for infertility-associated microorganisms, could reasonably be added in the clinical laboratory setting. Now that fertility laboratories are becoming certified, quality assurance programs must be developed for reproductive biology laboratories.[28] The Reproductive Biology Resource Committee of the College of American Pathologists has sponsored two pilot surveys for proficiency testing of SA in reproductive biology labs.[29]

In the future, pathologists and chief technologists will be able to refer to programs developed for andrology labs when establishing internal and external quality control for SA and associated semen testing in the hospital clinical laboratory.❑

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