

NBSIR 73-162

Executive Summary of A Proficiency Test Assessment of Clinical Laboratory Capability in the United States

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National Bureau of Standards
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Final Report

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Prepared for
Division of Health Evaluation
Office of the Assistant Secretary for Planning and Evaluation
Department of Health, Education, and Welfare
Washington, D. C. 20201

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U. S. DEPARTMENT OF COMMERCE, Frederick B. Dent, Secretary
NATIONAL BUREAU OF STANDARDS, Richard W. Roberts, Director

Background

The primary objective of this study was to obtain performance capability measures for various classes of clinical laboratories in the United States and to determine if there are significant differences in analytical accuracy which would warrant remedial action by public agencies or the private sector.

The procedure utilized was to: (1) establish a Scientific Advisory Committee of governmental and health industry representatives, (2) develop a survey design, (3) contact professional and regulatory groups to solicit laboratory participation, (4) procure and distribute two sets of laboratory samples in clinical chemistry, hematology and bacteriology to laboratories participating in the study, and (5) statistically analyze the results reported by the laboratories.

Participants

Six types or groups of clinical laboratories participated in the study:

1. Interstate—laboratories engaged in interstate commerce and licensed by the Center for Disease Control, Health Services and Mental Health Administration, under the Clinical Laboratory Improvement Act of 1967 (CLIA '67) in one or more of the specialties under consideration in this study.
2. American Academy of Family Physicians—private physician laboratories, generally small, which are currently affiliated with AAFP.
3. American Society of Internal Medicine—laboratories operated in conjunction with a private physician's practice which, like AAFP affiliated laboratories, are presently exempt from any Federal licensure program.
4. Joint Commission on Accreditation of Hospitals—laboratories within hospitals which are accredited under JCAH.
5. Medicare Certified Hospitals—laboratories in hospitals which are Medicare providers under Title XVIII, Health Insurance for the Aged. Hospitals and laboratories accredited under JCAH were excluded from this category.
6. Medicare Certified Independent—private and commercial laboratories which are reimbursed for certain laboratory procedures under Medicare, but which are not normally licensed under CLIA '67 or accredited by JCAH.

Approximately 1,000 laboratories participated in the study. The number within a category ranged from 43 (AAFP) to 231 (Interstate). A seventh category of 18 reference laboratories served as a control group.

Methodology

Separate proficiency test specimens were prepared for clinical chemistry, hematology and microbiology. Criteria for selection of the clinical chemistry and hematology constituents to be analyzed were that laboratory analysis should be routine, and that fairly well developed analytical procedures exist. Each clinical chemistry shipment included normal and abnormal samples. The laboratories were asked to determine the concentration of eight constituents: glucose, urea nitrogen, calcium, total bilirubin, cholesterol, uric acid, sodium, and total protein. Each hematology shipment required analysis of red blood count, white blood count, hemoglobin, hematocrit, and mean corpuscular volume levels in both normal and abnormal specimens. Five pure cultures of ordinary bacteria were used as sample cultures for identification in the microbiological portion of the study.

Two shipments of specimens and/or cultures were sent to each participating laboratory. All analytic results were reported by the laboratory on forms shipped with the test specimens.

Results - Clinical Chemistry

There were no significant differences (at the 90% confidence level) among the average laboratory results obtained by the groups participating in the study. The interlaboratory consistency ("interlaboratory precision") of the laboratory groups can be exhibited as follows, where groups joined by the same line did not exhibit significantly different precision at the 90% confidence level.

<u>Rank Order</u>	<u>Laboratory Group</u>
Most Precise	Medicare Independent Interstate JCAH
Least Precise	AAFP/ASIM Medicare Hospital

The techniques used had a considerable effect on the accuracy and precision of reported analyses. Table 1 lists the techniques which were most satisfactorily applied and the percentage of the participating laboratories which applied each technique. In most instances, automated methods were applied with equal or better average accuracy and considerably better precision than the corresponding manual methods. Results reported by laboratories using diagnostic kits were consistently less precise than other determinations.

Table 1. Clinical Chemistry - Referee Methods and Best Applied Techniques

Constituent	Referee Method	% Using	Best Applied Techniques	% Using
Glucose	Hexokinase	1.5	Ferricyanide AutoAnalyzer	12.9
Urea Nitrogen	Diacetyl monoxime	63.2	Diacetyl monoxime Automated	34.0
Calcium	Atomic Absorption	4.0	Atomic Absorption Cresolphthalein Complexone Automated	4.0 33.4
Bilirubin	Diazo-Other Coupling (Jendrassik & Grof)	43.6	Diazo-Other Coupling (J & G) Automated	24.9
Cholesterol	Abell Kendall	0.6	FeCl ₃ -H ₂ SO ₄ with Prior Extraction Manual or Automated	5.9
Uric Acid	Uricase	2.2	Uricase Phosphotungstate Automated	2.2 24.2
Sodium	Flame Photometer	96.7	Flame Photometer Automated	12.6
Total Protein	Biuret	78.4	Biuret Automated Refractometer	34.5 15.7

Insufficient information was available to assess the medical usefulness of the total bilirubin determinations. Of the remaining seven constituents, only cholesterol was analyzed by the study participants with sufficient precision to permit the interlaboratory monitoring over time of the variation in an individual patient's constituent concentrations. In contrast, reference laboratory analyses of cholesterol, uric acid, urea nitrogen, sodium and total protein were all sufficiently precise to permit interlaboratory monitoring of individual variation. Those participating laboratories using the best applied techniques also achieved acceptable interlaboratory precision in analyses of these five constituents.

Results - Hematology

As with clinical chemistry, the average laboratory results obtained by the participating groups did not differ significantly at the 95% confidence level. The interlaboratory precision of the laboratory groups can be exhibited as follows where groups joined by the same line did not exhibit significant differences at the 90% confidence level.

<u>Rank Order</u>	<u>Laboratory Group</u>
Most Precise	Medicare Independent JCAH
	Interstate
	Medicare Hospital
Least Precise	AAFP/ASIM

Table 2 shows the best applied techniques and the percentages of participating laboratories using these techniques.

Results - Microbiology

The performance of the Interstate group was significantly better than the performance of the other groups at the 95% confidence level; 7.6% of the Interstate laboratory determinations were incorrect while 19.9% of all other determinations were incorrect. However, even a 7.6% mis-identification rate is not satisfactory. Most troublesome are such mis-identifications as Neisseria NOS, N. gonorrhoeae or N. meningitidis for the pure culture of Streptococcus faecalis.

The relative performance of the laboratory groups can be portrayed as shown, where the lines join groups whose performance did not differ significantly at the 95% confidence level.

Table 2. Hematology - Best Applied Techniques

Constituent	Best Applied Techniques	% Using
Red Cell Count	All Coulter Models Kits	43.3
White Cell Count	All Coulter Models Kits	45.7
Hematocrit	Microhematocrit	75.9
Hemoglobin	All techniques applied equally well	100.0
Mean Corpuscular Volume	Impossible to judge	---

<u>Rank Order</u>	<u>Laboratory Group</u>
Best Performance	Interstate JCAH
Worst Performance	Medicare Independent AAFP/ASIM Medicare Hospital

Conclusions

The data indicate that high volume laboratories may be more proficient than smaller laboratories, such as those which serve Doctors' Offices and Medicare Certified Hospitals. In microbiology, 7.6% of the Interstate laboratory determinations were incorrect, while 16.5% of the determinations by other large laboratories (JCAH and Medicare Independents) were incorrect. Thus, it would appear that the CDC proficiency testing program has considerably improved the microbiology performance of the enrolled laboratories. Conversely, clinical chemistry and hematology analyses by the Interstate laboratories were no better than comparable analyses by other large laboratories, many of whom do not engage in routine proficiency testing programs. This seems to indicate that the CDC proficiency testing programs in clinical chemistry and hematology have had relatively little effect upon the performance of laboratories participating in the program. This conclusion is further substantiated in a companion report.* It is particularly important to improve the effectiveness of these programs because the interlaboratory consistency of study participants with respect to clinical chemistry and hematology was too often insufficient to support monitoring of an individual's constituent concentrations over time. It appears that poor selection of techniques is an important factor in the low rate of acceptability of laboratory determinations.

Limitations

It must be clearly understood that the results of this survey are limited by four important considerations:

1. Because all of the laboratories participated on a purely voluntary basis, no straightforward extrapolation can be made to the larger universe of unsampled clinical laboratories.

2. It is probable that the results of this study do not represent routine laboratory performance for two reasons: (a) a laboratory probably would not volunteer if its management felt that to do so would be disadvantageous, and (b) the sample materials probably received special attention in many of the smaller laboratories which were unfamiliar with analyzing proficiency test samples.

*Clinical Laboratory Performance Analysis Using Proficiency Test Statistics, NBS Report, NBSIR 73 197, 1973 (to be published).

3. The clinical chemistry test specimens were prepared by a dialyzation process which removes naturally occurring reducing agents and other substances. As a result, the accuracy of some methods, as applied to the test specimens, might differ from their accuracy in analyses of human serum.

4. The true constituent concentrations of cholesterol and the hematology constituents could not be exactly determined. For these constituents accuracy was assessed relative to the mean reference laboratory assays.

Recommendations

Satisfactory performance in a microbiology proficiency testing program conducted under the auspices of either Federal or other approved authorities should be a legislative requirement for all clinical laboratories analyzing microbiological specimens.

A Technical Advisory Committee consisting of government and professional society representatives should be established to identify the most accurate and precise analytical methods available and encourage their use by the largest possible number of clinical laboratories. Zones of acceptable performance for proficiency testing should be constructed in a manner which reflects the variability associated with the more accurate and precise methods and systems. In this way, failure to accept the recommended procedures would increase the risk of unacceptable performance ratings.

An experimental study should be undertaken to determine a better design for proficiency testing programs in clinical chemistry and hematology. An empirical description of the causes of inadequate laboratory work should be used in defining alternative testing strategies for consideration. This study should deal with such questions as frequency of sampling; feedback to participants; number of levels at which to test; long-term monitoring of intralaboratory variability; follow-up procedures on outlier values; and the criteria for scoring, ranking or rating laboratory performance and its medical usefulness. Until the results of this recommended study become available, it does not appear justified (or warranted) to alter the frequency of CDC proficiency testing in clinical chemistry and hematology.

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16. ABSTRACT (A 200-word or less factual summary of most significant information. If document includes a significant bibliography or literature survey, mention it here.) Executive summary of a report abstracted as follows: The proficiency of a selected sample of physician, hospital and independent laboratories was assessed with respect to their ability to analyze clinical chemistry and hematology samples and to identify microbiological organisms. For the assessment of clinical chemistry and hematology proficiency, the laboratories were grouped and determinations of group accuracy and group precision were made. Further analyses were performed to determine relative accuracy and precision of the techniques presently applied by these groups. There was no significant difference at the 95% confidence level in the accuracy achieved by the various laboratory groups involved in clinical chemistry and hematology analysis. In clinical chemistry, the Medicare-Certified Independent Laboratories, CDC Tested Laboratories and JCAH-Members generally proved more precise than Physicians' Office and Medicare-Certified Hospital Laboratories. However, none of the laboratory groups were sufficiently accurate to permit the monitoring over time of variation in an individual patient's constituent concentrations. It would appear that poor selection of techniques was an important contributor to this low performance level. In hematology the Physicians' Office Laboratories proved to be the least precise of the groups. There was no noticeable difference in precision between participants in the CDC proficiency testing program and non-participants. With respect to microbiology, 7.6% of the identifications by laboratories participating in the CDC testing program were incorrect, while 19.4% of all other identifications were incorrect.			
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