Commercial and Reference Laboratories*

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It occurred to me in thinking over the area to be covered that the title, although in general use today, refers to generic terminology. I thought it might be wise to define the two terms in relationship to the term "laboratory." Webster defines "commercial" for our purposes as "having financial profit as the primary aim" and "reference" as "any person or thing referred to for information, recommendations, etc." In my own mind in the strictest sense of the word, a reference laboratory is one where materials tested by stringent techniques are forwarded to participant laboratories throughout the country. These tests are analyzed and the results returned to the reference laboratory for comparison with their results. These results are then made available to the participants to compare with their own and others in the program; in short, a quality control program. The two best examples I have are the College of American Pathologists’ Proficiency Testing Service and Dr. F. William Sunderman. A step further down the line is a combination of commercial and reference laboratories. Here, exotic tests or tests not ordinarily performed in a laboratory are referred to a laboratory for testing. This, of course, is done for a profit. The third step is the situation where all types of tests referred to a laboratory are performed for a profit. A good example of the commercial-reference laboratory is Bio-Science Laboratories in California. The third step involves a myriad of laboratories—state, interstate, and national—with which by now all physicians are familiar.

A physician who is practicing away from an area where diagnostic procedures are immediately available, and even in areas where good laboratory medicine is practiced, has to decide what laboratory or laboratories he will use. What steps should be taken to make certain of good quality service from the many laboratories that are at his disposal? The first thing to remember is that the performance of any medical laboratory test is not a simple procedure. It is a technique of medical practice which should be as important to the physician as the delivery of a baby is to the obstetrician. The determination of a simple hemoglobin can present many difficulties which can be compounded by time and delay of transportation. A physician must examine his conscience and determine firstly that he must demand quality to ensure good patient care. Once this has been settled in the individual’s mind, he should analyze the speed of performance, the quality of performance, the amount of quality control, how the laboratory is operated and equally important, the cost to the patient.

The speed of performance in some instances is important but in other areas need not be a factor. In office practice where a patient will not return to the office for ten to fourteen days, practically all laboratories will have returned the test results. This is even true of some of the more exotic tests such as aldosterone, estrogen levels, etc. In Virginia at the present time, a number of laboratories are performing daily pickup service, with the return results reported on routine procedures the following day. This might pose some minor delays in rural areas but speed must not overshadow quality of work performed.

Quality and quality control are tied so closely together that they can be discussed together. A laboratory performing good quality laboratory medicine should provide you with well-trained technical
personnel who are under well-trained supervisors directing and reviewing the test procedures being performed. Some laboratories operate on a twenty-four-hour basis with night-shift personnel who may not be adequately trained or if they are, are working a second shift and so will not be working at peak efficiency. Quality control charts of the laboratory operator should be made available to you at regular intervals to assure you that tests are performing within acceptable standard deviation variations (usually not over 2 SD from mean).

I wish to point out at this time why results from a commercial laboratory may differ from your hospital laboratory. The point to emphasize is that different methodologies between one automated piece of equipment and another, and between automated equipment and standard wet-bench-chemistry methods may have different normal values. This has caused considerable furor in laboratory circles but is a fact of life that must be accepted. In addition, one should remember that enzyme tests, CPK, SCOT, LDH, are very difficult to reproduce on automated equipment. Of these three, the CPK is the most difficult to reproduce in terms of uniform levels within a given laboratory and between different laboratories. This is especially true of the ultraviolet light (UV) determinations of CPK with conversion to international units.

The delivery of good quality and good quality care are dependent on how the laboratory is operated. The question to be raised here is: "What are the professional qualifications of the people you select to do your laboratory diagnosis?" Is the head of the laboratory one who has been trained in laboratory medicine, a pathologist or otherwise, and most important is this person a physician? It is quite important that you as a physician know the director, his background and education, his staff and the facilities from which the laboratory operates. This is coming under much better control today at both the federal and state levels. I feel that knowing your consultant in laboratory medicine is just as important as knowing other physicians with whom you consult. This, of course, is not always possible but the closer to home the commercial laboratory you use, the closer the contact and knowledge you can have of its operation and staffing. There are many companies sponsoring commercial laboratories today. All of the larger companies, such as Dow Chemical, Damon, Smith, Kline and French and Upjohn have a pathologist as director. All of these you can be assured are turning out quality assurance work. There are others in this vicinity, pathologist directed, with excellent staffing, not associated with a major company that are also turning out quality work with good quality control.

One of the problems with the number of commercial laboratories in this country has led to some of the other smaller units bringing to light the "symptom of what is going on in many practices." Competition has made some of the laboratories lower the quality of work to stay in business, and in some instances has caused price reductions at the cost of good quality assurance. This seems to occur because some physicians care very little about the quality of the tests performed on their patients, but prefer more tests for the cheapest price. In the final analysis, the cost to the patient remains a major factor. Here also have arisen many of the problems to which we as physicians must direct ourselves. I think it ridiculous for a physician to change laboratories in order to have a test done for twenty-five cents less. This has actually occurred recently here in Richmond. Whether there was a difference of quality one can only speculate. The bigger problem which we as physicians must face is that in using any laboratory, the price to the patient must be fair for the work rendered. It is ironic to realize that most physicians are marking-up tests done by outside laboratories by three-to-four to even ten times the amount charged by the laboratory. This has caused an understandably adverse reaction by the American Medical Association and the Blue Plans. This has also stirred reaction in our own state and has caused action by the Medical Society of Virginia. It is apparent from many studies that some differential is needed between hospital and doctor's office charges such as is now in effect in California. My point in raising this issue is that as physicians, the high volume, low cost of tests performed by commercial laboratories should still carry only a reasonable increase to the patient and not the marked increase which is much more prevalent than many physicians admit.

I have not covered the area of advertising in the material presented here, because there is mixed emotion by even those within the commercial laboratory field as to how this can best be accomplished. I would be wary of the laboratory which advertises by price cutting, for prices are now close to an all time low level. I would insist on quality of work with evidence of quality control. I might point out here that one of the problems in mailing long dis-
tance is that of deterioration and hemolysis of specimens. I know of one instance where material was sent to a western laboratory for platelet counts and where an observer noted all specimens which were being counted by phase were hemolyzed. I am sure the referring physicians were unaware of the method used and that using any method platelets will have dis-integrated within six-to-eight hours. Such specimens reaching the west coast from nearly anywhere would be useless for evaluation of platelets. This should re-emphasize the need for knowing your referring laboratory and its staff.

Remember that the cost to the patient is the important factor and the price passed on to him should be a reasonable one and in line with the cost for operating your practice. As I said earlier, every doctor today, in the face of mounting pressures, must examine his conscience and determine what quality he will insist on for good patient care.

In summary, there are now in existence many good commercial and reference laboratories. I would use those laboratories with which you are most familiar, where you know the staff, those which can demonstrate reasonable speed in testing and can assure good quality testing and control at what you feel is a reasonable cost to the patient.