In recent months, there has been much discussion regarding the increasing needs of the insurance industry for laboratory testing. As such, many analyses have been initiated by both insurance companies and laboratory companies investigating the critical value of the components of the blood profile and the urine profile in the evaluation of an applicant for life insurance. A key component in that investigation by insurance companies is the review of the capabilities of the laboratory company that performs the testing and its position on technical, service, and quality assurance issues as they relate to the insurance testing. Alternately, the challenge for the large, full service clinical laboratory is to deliver its experience and service philosophies built over many years to the insurance industry and providing additional flexibility and customization to enhance value to the insurance company. In recent years, the insurance industry has augmented test criteria for applicants. In coming years it is predicted that the number of tests, as well as the number of applicants, will increase as the value of the test components continues to assist risk assessment.

How does the full service clinical lab approach this "new" market? Let's look at the perceptions about a clinical laboratory. Some think clinical labs only know the medical testing business. Actually, many clinical labs perform testing for many non-medical clients, including pharmaceutical studies, test methodology evaluation, environmental testing, employee health screening programs, and sports medicine testing, to name a few. If we look at the definitions of "clinic" we find the following:

"A group meeting devoted to the analysis and solution of concrete problems or to be acquiring of specific skills or knowledge in a particular field." That's exactly the approach that's taken. An extensive analysis is made of the current needs of the industry, an indepth accounting of existing available resources, and the assessment of additional resources required. Most importantly, the full service laboratory has the ability to properly service the industry and reporting of testing results in the timely manner required, while maintaining existing service levels of turnaround time.

Let us broadly address the perspective of the clinical laboratory in three (3) areas of importance to the insurance industry.

TECHNICAL CONSIDERATIONS: Research, development and evaluation of new biotechnologies are an important aspect of any laboratory business. A company must have dedicated resources to consistently evaluate new equipment and testing methodologies to ascertain their utility for their respective marketplaces. Too often, new biotechnologies are introduced only to fail in delivering the anticipated benefits because of inadequate evaluation or inappropriate application to the market. Research and evaluation cannot be done on a "part-time" basis.

An example of one such technical issue is the testing parameters predicting and/or indicating coronary heart disease. There are several relatively new pharmaceuticals available which can be used in conjunction with diet to lower cholesterol levels, reduce and stabilize blood pressure, etc. Additionally, new classifications of the results of such tests impact the assessment of a condition of an individual. Knowledge and communication of these changing factors are a key to the service provided by a laboratory facility.

An example of such changes in a laboratory report is as follows:

<table>
<thead>
<tr>
<th>CARDIOVASCULAR RISK REPORT</th>
</tr>
</thead>
<tbody>
<tr>
<td>BASED ON LDL, HDL &amp; TOTAL CHOLESTEROL</td>
</tr>
<tr>
<td>TEST</td>
</tr>
<tr>
<td>LABORATORY FINDINGS:</td>
</tr>
<tr>
<td>Triglycerides</td>
</tr>
<tr>
<td>Cholesterol</td>
</tr>
<tr>
<td>HDL Cholesterol</td>
</tr>
<tr>
<td>LDL Cholesterol</td>
</tr>
<tr>
<td>Cholesterol/HDL Ratio</td>
</tr>
<tr>
<td>LDL Chol/HDL Chol</td>
</tr>
</tbody>
</table>

NOTE: THIS INDIVIDUAL'S AGE WAS NOT GIVEN; WE ASSUMED, THEREFORE, 40 YEARS OF AGE. THIS EVALUATION MAY BE INCORRECT IF THIS PERSON'S AGE IS SIGNIFICANTLY DIFFERENT FROM 40. THIS INDIVIDUAL'S SEX WAS NOT GIVEN; ASSUMED FEMALE.

CONSULTING PHYSICIAN'S REPORT: This individual has hypercholesterolemia with a marked elevation of LDL cholesterol for an individual of this age and sex. Based on these findings, this individual is considered at high risk for cardiovascular disease and dietary therapy with, if necessary, drug therapy has been recommended to lower the cholesterol. In the clinical assessment of risk for cardiovascular disease, other risk factors such as family history, smoking history, obesity, hypertension, diabetes, etc., should also be considered.

IMPRESSION: HYPERLIPROTEINEMIA, AT HIGH RISK FOR CARDIOVASCULAR DISEASE.
Studies relating to current trends may be provided. For example:

Additional studies have been published demonstrating the value of the blood profile components as an indication of risk relating to heart disease, liver disease and diabetes. The total blood profile continues to prove itself as the essential component supporting the total health assessment of an individual.

In the future, advances in HIV testing, genetic marker testing and tumor marker testing will be of value to insurance companies as they become more sophisticated in risk assessment procedures. The advantage of access to a laboratory that serves a broad market of clinical testing in these areas, in addition to specialized testing of drugs for hypertensive, diabetic and other cardiovascular conditions, will provide an insurance company with a more comprehensive picture of a person’s condition. This allows the development of diverse insurance products to protect the market share and profitability of the insurance company.

Consultations by medical and technical staff with key industry advisors are key support factors in technical issues. Affiliation and participation in medical industrial trade groups is also vital in the constant assessment of appropriate test methodologies.

SERVICE CAPABILITY: Service begins with the laboratory staff. Careful selection, training and supervision of a competent staff of registered technologists and technicians, in conjunction with review of technical staff and procedures in quality assurance programs by doctorate level scientists and board certified pathologists, are the first steps in the provision of accurate and dependable results. Specimen processing on an around-the-clock basis with direct report delivery by telecommunications and CRT inquiry is standard within the full service clinical laboratory environment. This capability is supported by the utilization of state-of-the-art automation in test equipment and communication systems which are provided by commercial manufacturers with long standing, high quality service records in the industry.

Obviously, computerization is vital in the laboratory service industry, not only for the rapid processing and communication of results, but also for flexibility in customized reporting, data retrieval and analysis and servicing of clients for special consultation reports. The report of results on a real time basis as they become available, rather than on a batched basis according to some pre-established criteria, provides for the servicing of all clients with test reporting within a 24-hour basis in most cases. Only in cases when an abnormal result is detected and must be confirmed by an alternate procedure or extensive reflex test criteria (additional tests required subject to the value of one particular test) should the report time exceed 24 hours.

Today, many clinical laboratories perform as much testing from its clients (insurance, industrial and medical) in three months as an insurance laboratory performs in one year. Importantly, the mission of the laboratory computer system in the clinical lab is to provide all test results to all clients within 24 hours. (As previously mentioned, the exception of abnormal result verification and esoteric testing may involve longer turnaround time. In such cases notification to the client of the report status and provision of partially completed reports is a standard operating procedure.) Therefore, a computerized system that has demonstrated flexibility in serving diverse markets is a critical factor in the assessment of laboratory service. Every test result must be processed equally in an accurate and efficient manner in order for all clients to efficiently service their customers.

An experienced client services department is the support function to an efficient communications system. These individuals must be highly trained to assure that questions and concerns are promptly and courteously handled or channeled to the appropriate technical professional personnel for assistance. This staff must have direct access to current laboratory information via computer terminals.

Additionally, client relations specialists may be available for personal contact with clients. These specialists act as a liaison...
between the laboratory and the client and may be made available for in-service education, specific questions and other educational needs.

QUALITY ASSURANCE: In addition to mandatory compliance with state and federal guidelines, the laboratory can voluntarily participate in internal and external programs to assure its quality. Some of these programs should include:

1. Standardization in specimen identification throughout the laboratory, from specimen and test order entry to result reporting;
2. Standardization in test procedures;
3. Standardization in automated test equipment;
4. Utilization of commercial quality control programs at standardized intervals during test procedures;
5. Utilization of equipment specific commercial control programs;
6. Participation in proficiency testing programs, including, but not limited to, the College of American Pathologists (CAP) and state health departments' programs;
7. Participation in external proficiency testing programs by commercial manufacturers;
8. Licensure and certification by the Center of Disease Control (CDC) and the U.S. Department of Health and Human Services;
9. Voluntary submission to inspection and accreditation program of College of American Pathologists (CAP) (the highest designation of quality, safety and service that a clinical laboratory can achieve). Only a small minority of reference labs hold the "Fully Accredited" distinction from the College of American Pathologists;
10. Abnormal result review by doctoral level scientists and/or board certified pathologists;
11. Random checks of the results of daily instrument calibration and controls;
12. Mock inspections by an internal quality assurance manager (under the guidance of the medical director);
13. Periodic blind samples circulated internally in the laboratory for internal proficiency testing;
14. Review of technical procedure and quality assurance programs by doctorate level scientists and/or board certified pathologists, including documentation of inspection reports, corrective action reports, personnel training and quality control records.

Additionally, to monitor the service and quality levels of the laboratory, a quality assurance committee should be utilized. This committee, made up of employees from all areas of the laboratory, including marketing, client services, technical operations, and data processing, meets periodically to review and discuss current operations as well as improvements to current operations.

Sound extensive, complex and supportive? It is! Whether processing one hundred specimens per day or ten thousand specimens per day, these quality assurance procedures must be in place to assure the quality and accuracy of test procedures. After all, we are dealing with the health assessment of an individual. Therefore, quality and accuracy cannot be compromised.

GROWTH CONSIDERATIONS

Due to the anticipated growth in testing from the insurance industry, it is critical that a laboratory be well positioned to grow at a rate faster than the market growth. This capability is directly related to how well suited the laboratory is to the previously mentioned considerations. Experience in planning and expansion, as well as the availability of duplicate facilities can assure the industry of uninterrupted service levels. These capabilities provide viable alternatives to other testing facilities utilized by the industry.

Integrating the service capabilities of the clinical laboratory for the existing and potential needs of the insurance industry is an ongoing process. From this perspective, input from insurance clients, input from paramedical companies, participation in insurance association meetings and expansion of current legislative involvement in the laboratory industry to include the insurance industry are the basic essentials utilized in designing new programs to service the insurance industry. Acquiring the industry knowledge through these avenues will propel the clinical laboratory in delivering its expertise and skills to the insurance company.

What does this mean to the insurance company in today's changing environment? It means the provision of additional vital resources for both medical directors and underwriters for technical information and test methodologies directly affecting underwriting policies. An examination of methodologies for disease detection can be examined and incorporated appropriately utilizing a broader base of information from different populations. As new drug treatments and tests for monitoring those drug treatments evolve, insurance companies can more accurately assess risks for acceptance or denial of an application.

The services provided by the clinical laboratory must enhance the effectiveness and thoroughness of decision making for the medical director and the underwriter. As such, the challenge is "on" for the clinical laboratory industry to provide its total range of services to the insurance industry!

References