

The Contemporary Laboratory in Today's Underwriting Environment

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The modern reference laboratory has assumed critical importance in the objective evaluation of the morbidity and mortality risk posed by an insurance applicant. The insurance industry is increasingly turning to urinalysis and blood profile tests as cost effective tools in the risk selection process. Testing as a protective underwriting instrument is being driven by the expanding need for information concerning a wide range of health concerns. Although nondiagnostic in nature, specialized insurance-oriented laboratory tests provide client companies with specific information indicative of liver and kidney disorders, diabetes, cardiovascular disease risk, bacterial and viral infections and other health risks.

In addition, testing is performed to detect the presence of nicotine, and certain medications associated with medical conditions that may not be revealed by a physical examination. Laboratory testing also can detect the presence of cocaine, other drugs of abuse, and the antibody to HIV, the viral agent responsible for AIDS.

The high rates of mortality associated with the rapidly growing number of AIDS cases has contributed to the increased use of testing services. The result of this demand has been a substantial increase in the number of blood and urine tests performed on behalf of insurance companies.

According to a recent study, of the approximately 20 million individual life, health and disability policies issued in 1987, it is estimated that less than three million had some type of laboratory tests performed, and less than one million required blood, HIV antibody, or cocaine tests for underwriting purposes. While the growth rate of testing performed for the industry increased substantially in 1987, there are indications that even greater use of laboratory testing services will be required by insurance companies in the future.

As a result of the growing demand for these services, the number of new entrants in the insurance laboratory testing industry has increased. These new players include local small-scale physician laboratories, start-up insurance-oriented laboratories and large clinical or general testing laboratories expanding into the insurance field. Consequently, insurance companies seeking testing services have a variety of laboratory options from which to choose. The variations in the quality of service offered by each type of laboratory must be carefully evaluated by insurance companies seeking these services.

Today's laboratory should hold a federal clinical laboratory license, as administered by the U.S. Department of Health and Human Services. The laboratory must meet or exceed several states' regulatory requirements and the stringent requirements of independent laboratory proficiency testing organizations in order to maintain the federal license. These proficiency organizations, approved by the Centers for Disease Control (CDC), include the College of American Pathologists (CAP), the American Association of Bioanalysts (AAB) and others.

The laboratory should follow the protocol for HIV testing and Western Blot confirmations recommended by the Food and Drug Administration (FDA) or CDC. Correlation of cholesterol testing standards and procedures with the National Bureau of Standards, and participation in other voluntary proficiency survey systems are also hallmarks of a quality laboratory.

Finally, all external and internal proficiency testing records should be available for client inspection on a continuous basis. For the client companies' understanding of the inner workings of the laboratory, complete inspections of laboratory testing facilities should be easily arranged.

Specimens for insurance testing are normally collected by independent paramedical personnel using custom-designed kits and containers. These kits and containers are delivered to the laboratory via overnight delivery services or the U.S. Postal System.

Most laboratories concerned with quality test results request that paramedics utilize overnight delivery services for specimen transport. Faster delivery yields better test results, especially during the seasonal extremes.

Upon receipt of the kit at the laboratory, the specimens are coded for internal identification. Depending on the volume of specimens handled at a particular laboratory, identification may be as sophisticated as barcode scanners and computer touchscreens, or as simple as manual numbering. Specimens being processed through any laboratory, however, must be handled on a confidential basis, especially with today's testing in the sensitive areas of HIV-antibody determination or detection of controlled substances.

In progressive laboratories, specimens are inspected upon receipt for evidence of tampering, and full documentation

of modified chain-of-custody considerations are standard procedure. After internal coding, specimens are then processed according to each client's specifications.

Because the risk selection process can vary from company to company, data processing systems which can customize several different profiles based on pre-selected parameters are integral components of the modern laboratory. This data processing and information management is also extremely important in the transmission of results to the client's underwriting department.

With the lack of standardization of data processing hardware and software within the insurance industry, today's laboratory must offer extensive communication options. These may include CPU to CPU transmissions, third-party mailbox networks, direct transmission to data terminals and PCs, overnight mail, facsimile transmission and others. Additional customized methods of transmission should be available depending upon the specific needs of client companies.

Insurance-oriented blood chemistry profiles provide data for insurance companies in risk assessment. While blood chemistries and other types of tests can be performed by many types of laboratories, a quality insurance laboratory will establish specialized test parameters directly geared to morbidity and mortality risk. This perspective constitutes a significant advantage over general clinical laboratories in underwriting interpretations and decisions.

A comprehensive range of testing services is available to client insurance companies, depending on which laboratory is chosen. The following profiles and testing areas should be available in the contemporary laboratory serving the insurance industry:

- **LIPID PROFILE** — A lipid profile assesses the risk of cardiovascular disease. It should provide data on total cholesterol, triglyceride and high-density lipoprotein cholesterol (HDL cholesterol) levels, low-density lipoprotein cholesterol (LDL cholesterol) levels, the ratio of total cholesterol to HDL cholesterol, and the ratio of LDL cholesterol to HDL cholesterol. Additional testing, such as apolipoprotein determinations as supplementary information for elevated cholesterol readings and other abnormal lipid findings, adds significantly to the total understanding of a particular applicant's risk factors.

The challenge facing many laboratories today is to communicate to paramedics and insurance agents the importance of requesting fasting applicant specimens. Quality laboratories must often ultracentrifuge nonfasting specimens in order to reduce lipemic interference in testing procedures. This is a time-consuming, labor-intensive process.

- **BLOOD GLUCOSE PROFILE** — designed to assess diabetic risk. A blood glucose/urine glucose profile should provide information on glucose levels, including a

follow up test to measure hemoglobin A_{1c} levels to confirm an elevated glucose reading. In addition, if a urine specimen is determined to be glucose positive, the corresponding preserved plasma sample should be tested for repeat glucose and hemoglobin A_{1c} levels.

- **HEPATIC PROFILE** — utilizes GGTP, ALT, AST, alkaline phosphatase and total bilirubin measurement to screen for liver disorders. GGTP is 80% sensitive in detecting fatty liver due to alcohol-induced liver disorders. Total bilirubin, including direct bilirubin, can be used to separate liver disorders into pre, post and intrahepatic disorders.
- **RENAL PROFILE** — designed to measure blood urea nitrogen, creatinine and uric acid. A renal profile provides data as a means to assess possible kidney dysfunctions.
- **ACQUIRED IMMUNODEFICIENCY SYNDROME TESTING** — designed to detect the presence of antibodies to HIV-1, the etiological agent responsible for acquired immunodeficiency syndrome (AIDS).

The emergence of AIDS as a growing concern in 1981 presented new problems to the insurance testing laboratory. Since the first diagnostic test kit was introduced in 1985, laboratories testing for the antibody to HIV have had to contend with complex issues, unrelated to actual laboratory testing.

Considerations related to HIV-antibody testing include test result confidentiality, legislative limitations on direct HIV testing, informed consent of the person being tested, and notification of state health departments of positive results in some states. In addition, increased attention to laboratory worker protection and biohazardous waste disposal have necessitated changes in laboratory management practices.

On the technical side, problems range from differences in the performance of the numerous diagnostic kits on the market, to confusion over the interpretation of Western Blots. The most difficult issue, however, is the stubborn problem of indeterminate test results and the desire for clarification of HIV antibody status in individuals with indeterminate findings.

Progressive laboratories recognize the need for better indeterminate testing, and recent improvements in HIV antibody detection by the use of recombinant DNA technology and radioimmunoprecipitation assays (RIPA) offer solutions to this difficult problem. Direct HIV antigen testing as an adjunct to HIV antibody determination could be a future remedy to the indeterminate problem, although the scientific justification for this assay is not, at present, clearly defined. The insurance laboratory must maintain a fine balance in providing useful information to insurance underwriters, while assuring that scientific methodologies used in the laboratory are thoroughly proven for accuracy and applicability.

- **DRUGS OF ABUSE PROFILE** — designed to detect both legally prescribable medication and illegal substances, the so-called "street" or "recreational" drugs. Progressive insurance laboratories should offer controlled substance tests, primarily cocaine, in response to the serious mortality, health, and accident risk posed by the usage of controlled substances.

These tests are designed to detect the use of cocaine, marijuana, and other drugs of abuse. As a means of ensuring quality control and to provide litigious protection, all positive drug screens should be confirmed by the FDA-approved gas chromatography/mass spectrometry methods.

Although controlled substance tests have become a vital underwriting tool, drug testing, like HIV antibody testing, requires procedures in addition to the laboratory technology. These include attention to applicant confidentiality, informed consent, and chain-of-custody issues.

- **URINALYSIS PROFILE** — designed to test for levels of glucose, protein, red blood cells, white blood cells, and formed elements. The presence in the urine of these analytes may indicate disease, infection or organ dysfunction. Specific gravity tests should be performed on specimens with excessive urinary proteins to assess the kidney's concentration function.

Immunoassays using urine can detect the presence of certain prescription drugs. These include antihypertensive medications, oral diabetic medications and cardiovascular disease medications ("beta blockers"). These tests are of particular importance to insurers, since certain prescription drugs can mask disorders that may not be revealed by a physical examination. Historically, urinalyses have always been an important component of insurance laboratory testing.

- **NICOTINE SCREEN** — designed to measure the amount of nicotine present in a urine specimen. This test is particularly important to the insurance industry since most companies offer substantial premium discounts for nonsmokers. The nicotine screen is included in over 80 percent of urinalyses submitted for testing by the insurance industry.

While this article is not intended as advertisement for any open laboratory, the authors believe that the insurance

industry is best served by laboratories devoted exclusively to insurance testing, offering at least the services described in the preceding paragraphs. The perspective offered by an insurance reference laboratory is elaborated in a variety of details, some of which are discussed above. The establishment of normal ranges, the particular tests offered, and the attention to customer service from an insurance perspective are some significant benefits offered by the progressive insurance laboratory.

Home Office Reference Laboratory, Inc. (HORL) is the nation's leading provider of laboratory testing services to the insurance industry and serves over 800 insurance companies in the United States and Canada. During its 16-year history, HORL has established an industry reputation for promptly delivering accurate test results on a basis that is cost-effective to its clients.

With the aforementioned increase in the demand for insurance testing, HORL has continued to demonstrate adaptability in the face of a changing industry. As an example, the installation of sophisticated high-volume laboratory instrumentation at HORL has been fueled directly by the increasing specimen volume processed. HORL has the distinction of accommodating a greater than 500% increase in insurance testing volume in the last year, while continuing to lower its net delivery time of test results. In addition, expanded customer service capabilities, back-up laboratory instruments and facilities, and uninterruptable power sources have been adopted at HORL, again in response to the needs of our clients.

As an example of the integral role the insurance industry plays in the HORL's continuing success, the HORL Advisory Board, comprised of insurance industry medical directors and underwriting officers was established in 1984. This group affords a forum for review of strategic business decisions by a broad range of industry experts.

In summary, the contemporary insurance laboratory must provide its clients with reliable and accurate laboratory testing on a timely, cost-effective basis. Realizing this goal requires a unique mixture of technical sophistication, insurance perspective and adaptability to a changing environment. Because insurance companies have expanded choices in today's environment, careful consideration of the many factors involved in quality laboratory testing is required.