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Search Archives

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Signs of a Reliable Reference Laboratory

The search for a reliable reference lab doesn't have to be trial and error; there are many evaluation techniques to help you in your quest.

By Susan Hopkins

Reference laboratories provide specialized testing that requires rare or complex assays and specially trained staff, which hospital labs may not be able to provide. Thus, with reference labs having such an important role in the operation of clinical labs, it is crucial that clinical labs carefully weigh their options and consider all aspects before choosing with which reference lab to work.

Knowing Your Lab

Before meeting with reference lab representatives, you should gather some information about your own lab. Your lab's patient populations, test mix and resource allocations should be determined before the selection process even begins.[1]

Greg Stelzer, PhD, senior vice president and chief scientific officer, Esoterix, Brentwood, TN, says lab administrators should consider their lab's breadth of testing menu—can the reference lab meet the majority of needs as far as testing is concerned? Esoterix is a laboratory service that offers approximately 2,500 assays and profiles through its centers in the United States and Western Europe. Esoterix's client base includes hospitals, physicians, pharmaceutical and biotechnology companies, reference laboratories and managed care organizations.

"You want to select the reference lab that most meets your needs," adds Irina Lutinger, MPH, MT(ASCP)DLM, senior administrative director, Clinical Laboratories, New York University Medical Center (NY), who also feels labs should consider their own population mix, test menu and resource allocations during the selection process.

Aspects to Compare

There are numerous aspects to weigh of the reference labs themselves. The quality of reference laboratory services is a broad topic that could include everything from the courier's attitude to telephone response time.[1] Reference labs must provide a menu of tests and services that allows the hospital lab to be both fiscally sound and competitive in their market segement.[2] However, the quality of the test performance seems to be the most

important factor that lab managers want to know.

Ronald L. Weiss, MD, MBA, is president and chief operating officer of ARUP Laboratories and professor of Pathology, University of Utah School of Medicine, Salt Lake City. ARUP is a national, full-service reference laboratory that provides clinical and anatomic pathology services to hospitals and independent laboratories around the country. Dr. Weiss believes there are three broad categories of critical attributes to consider when selecting reference laboratories (Table):

1. service quality,

2. service effectiveness and

3. result communication.

But, when narrowing down the categories, Dr. Weiss says lab managers should evaluate reference labs based on analytical quality, competitive price for the quality of the services provided (value), turnaround time (TAT), client services support and problem resolution, and effective reporting mechanisms.

Dr. Stelzer feels the top five topics to compare between reference labs are test menu, TAT, information technology (IT) capability, customer service and QA parameters.

"TIQ [test in question], QNS [quantity not sufficient], lost specimen rates and other aspects of QA metrics for the selected lab also should be considered" Dr. Stelzer says. A TIQ is any specimen submitted which has a technical problem that prevents it from being run. QNS is when not enough specimen is submitted to run the test.

Lutinger offers similar recommendations. She advises clinical lab managers to evaluate the reference lab's quality of testing, reputation, test offering, TAT, customer service and location (East versus West coast) relative to your facility.

Genzyme Genetics, Westborough, MA, performs about 1 million esoteric tests per year and also sends tests to reference labs. "We do send outs for a lot of clients for rare diseases that they see once a year or maybe once in a career," explain David Lockwood, PhD, senior vice president of Operations, and Bernice Allitto, PhD, director of Molecular Diagnostics at Genzyme Genetics.

When looking for a reference lab, they review the lab's licensure, insurance, quality programs, overall reputation, diversity of menus, pricing, billing procedures (e.g., will they bill Genzyme, the client directly or a third party?) and overall service levels. "How they interact with us and how they emulate our client service levels are very important," Dr. Lockwood says.

Dr. Allitto adds that they want the TAT to be reasonable, and they want to be able to get in touch with the reference lab and have someone call Genzyme when there are concerns about samples.

Other important features they look for are adaptability or creativity—can the reference lab customize to fit their needs?

"We also audit all of our reference labs, and we get audited a lot ourselves. Sometimes they are paper audits and sometimes site visits," Dr. Lockwood explains. "We have to be sure the reference labs are covered by all the regulatory agencies. Since Genzyme is a national lab, they have to have all the state and federal licensure and all the proficiency exams. If they say they are New York State licensed, we want the documentation to show it.

"Since a lot of what we do is esoteric testing, the outcomes are around making pregnancy decisions and treating cancer patients—it's very critical for us that those answers are correct," he continues. "If we reference out, we are as liable as that reference lab is. We have to make sure that they have the credentials and the standards—that they do the things that need to be done to produce accurate results."

Leonard H. Kellner, MS, president and chief scientific officer, Lenetix, a genetic testing reference lab in Franklin Square, NY, explains that his lab provides testing for hospitals, university medical centers and reference labs both small and large. When selecting a lab to work with, Kellner recommends looking at the lab's ease of use, cost, test menu (does the lab have experience dealing with a specific type of specimen or are they a more general lab?), customer support, if their reports are readable (do they make sense at first read or does the physician or receiving lab have to hunt for the results?), and ensuring they have permits or licenses to perform the tests.

Customer Service

Customer service is of course crucial when working with reference labs. Reference labs must provide high-quality information and support for clinical decision making.[2] Lab managers should expect to be able to get quick responses regarding disposition of samples or reports, Dr. Stelzer explains. There should also be a quick connection to appropriate scientific professionals for interpretation questions and quick resolution to logistic problems.

The critical elements of effective customer service support, Dr. Weiss feels, should be:

ready availability and access to a client services representative (low hold times),

professionalism,

effective problem resolution (timely and complete),

access to technical consultants when necessary and

complete, accurate and timely answers.

Lutinger says labs should be sure the reference lab follows up about problem samples, and their response time and flexibility with requests should also be taken into consideration.

Dr. Lockwood agrees. "We look for how responsive they are and what kind of connection we form with that lab. Whenever there's a problem we want to make sure we know who to go to, that they are going to be responsive and we know we are going to get the answers," he says.

"A lot of it depends on if I'm the client or I'm letting this reference lab interact directly with my customer. How easily accessible they are, how quickly I can reach their professionals, how quickly they respond to and resolve billing problems, how understandable their bills are—these are things we consider," Dr. Lockwood adds. "Even when you're a good laboratory or a good provider, you can drop the ball by not doing quality billing."

"You ought to be able to access [a reference lab's] professionals who can handle questions about difficult samples," Dr. Allitto adds. "A reference lab is typically getting the difficult or rare samples, so you need to make sure you have ready access to their expertise when you need it. It is also good to know how good they are at responding in, and recovering from, emergencies such as a blizzard or a phone line being cut," Dr. Lockwood says.

Kellner believes it is important to know if, when calling the reference lab, you only get an automated call center, or you get directed to a person who is responsive and technically trained or knows how to route calls. "Their customer support should have basic information for the caller such as hours of draw stations and accessibility of TATsthings that they can just look up on their screen," he adds.

Customer support, however, doesn't just involve responding to phone calls or e-mails. Another issue to consider is transition support. A reference lab that makes the process of changing laboratories as easy and seamless as possible can reduce errors and support staff introduction to new systems.[1] Some things to consider:

Does the reference lab have a transition plan and a transition support team?

Will it train the primary lab's personnel on any new procedures, support customization of IT products and establish dedicated channels for two-way communication during the transition?[1]

Specimen Delivery

In addition to having very clear specimen collection and transport instructions, the reference laboratory should take great care in the transportation of specimens so as to preserve specimen integrity. Of course, transport should be timely, says Dr. Weiss. "But, when unforeseen events intervene (e.g., natural disasters, including severe weather), the reference laboratory should have contingency plans in place to adapt to these events to minimize transportation delays and compromised specimens."

Once the specimens are received, the reference lab should have the necessary specimen processing and analytical infrastructure in place to meet or exceed published TATs. "The referring laboratory should consider the use of financial penalties for transport and/or TAT failures (e.g., for delays, lost specimens, compromised specimens, etc.)," Dr. Weiss adds. "The contract should have some provisions for handling these occurrences. The reference laboratory should also comply with all hazardous materials shipping requirements and should provide the referring lab with the necessary instructions to ensure such compliance."

Tracking capabilities of a lab and being able to know where samples are at all times are two things that Dr. Lockwood feels are important. "We want to make sure the lab knows the sample is coming, and if it doesn't arrive they should know to look for it. Samples get lost—but how good is that lab at knowing when that happens and finding that sample?"

Dr. Lockwood recommends checking what specimen delivery options are available—will they do overnight, AirNet direct, postal, couriers, what shipping materials they'll provide you and how easy the materials are to use. He also checks to see if the reference lab's TAT compares to the statistics they publish. "How consistent are they in that actual performance? For example, a lab may say they have a seven day TAT in literature, but the range actually is from one day to two weeks, or they don't consistently hit seven—that's another way I really look at reference labs."

Kellner reminds us that TAT depends on the type of test being ordered. "They can range from within hours for stat testing to 24 hours for our sequential tests or first trimester screen," he says. "Or they can take up to one to two weeks for certain genetic tests like familial dysautonomia or Gaucher's disease in which chromosome analysis is performed. And testing for fragile X could take up to 20 to 30 days."

TAT is a critical factor that can make or break your decision to work with a lab. Dr. Stelzer recommends that lab managers look for data to support published TATs and claims around logistics of specimen pickup and delivery. And Lutinger looks for how frequent specimen delivery takes place as well as TATs. "Also, it is based on the needs of your facility, i.e., some tests could be more critical for you than for someone else because of your service," she says, adding that result reporting has now taken on a more sophisticated and reliable approach in many labs—electronically.

Electronically Speaking

Electronic test ordering and result reporting can reduce transcription errors and improve TAT. Ease of use, time/labor involved in system installation, compatibility with the facility's LIS and ongoing product support are all key factors to be explored when choosing a reference lab with result reporting.[1]

"EDI [electronic data interface] is our most frequent laboratory connection for referral workWeb-enabled is not really being used here," Dr. Stelzer says of his lab. EDI is a direct computer connection between the customer lab and the reference lab that allows test ordering and resulting directly between the two.

Electronic order entry and result reporting are the norm for reference laboratories, explains Dr. Weiss. "The means for doing so vary from computer-to-computer interfaces to PC-based workstations. The value of this mode of communication is timeliness and accuracy of orders and results. These systems should be designed to be easy to use," he says. "Some systems, particularly those that communicate through PC workstations, may have additional functionality, such as the ability to generate a variety of management reports that can track reference laboratory utilization and TAT statistics. Use of the Internet for both order entry and result inquiry is also being developed and used."

However, many of the larger reference labs are using electronic reporting systems, but they may not perform some esoteric tests, Kellner explains. "There are smaller esoteric testing labs that don't have the electronic test ordering and result reporting ability yet, but they should certainly be considered because they have the specialty testing," he says.

"Electronic test ordering and result reporting are extremely important," Lutinger says. "Electronic ordering saves time, reduces error rate of ordering and improves results availability. By having an electronic interface, facilities can also look up the necessary information regarding testing, updates, etc."

Dr. Lockwood adds, "Electronic test ordering and result reporting is getting to be more important. It isn't a 'have

to have' right now, but it's getting close. We're in an industry where it's all about service, efficiency, rapid response and minimizing the labor work (entering information, tracking samples, understanding where the reports are and when the results are going to be complete). Electronic interfaces help with the front end of test ordering.

"Another thing we ask from our reference labs, and we produce ourselves as well, is reporting characteristics—what our utilization rate is, how we compare to their other clients; we want a lot of performance metrics from them," he says. "We want them to tell us not only how they are doing but also how we are doing in comparison to their other clients. So, if we have problems we can identify, approve upon and solve them; we don't wait for a problem, we try to anticipate one. For example, if our TAT to a reference lab is a day behind everyone else's, I want to know why."

Planning Ahead

Ultimately, the optimum choice of a reference lab is the one that best meets the current needs and supports the long-term goals of the primary lab over time.[1] "As testing gets to be more complicated and more esoteric, primary/reference lab relationships become more important. In addition, therapeutic/diagnostic relationships are expanding. Labs and reference labs need to focus on making this business successful. The two labs need to have a relationship, a partnership," Dr. Lockwood says.

Susan Hopkins is an assistant editor.

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