

clients. The Centers for Medicare & Medicaid Services, or CMS, establishes procedures and continuously evaluates and implements changes to the reimbursement process.

We believe that most of our bad debt expense, which was 4.2% of our net revenues in 2005, is primarily the result of missing or incorrect billing information on requisitions received from healthcare providers and the failure of patients to pay the portion of the receivable that is their responsibility rather than credit related issues. In general, we perform the requested tests and report test results regardless of whether the billing information is incorrect or missing. We subsequently attempt to contact the healthcare provider or patient to obtain any missing information and rectify incorrect billing information. Missing or incorrect information on requisitions adds complexity to and slows the billing process, creates backlogs of unbilled requisitions, and generally increases the aging of accounts receivable and bad debt expense (see “Regulation of Reimbursement for Clinical Laboratory Services”).

## **Competition**

While there has been significant consolidation in the clinical laboratory testing industry in recent years, our industry remains fragmented and highly competitive. We primarily compete with three types of laboratory providers: hospital-affiliated laboratories, other commercial clinical laboratories and physician-office laboratories. We are the leading clinical laboratory testing provider in the United States, with net revenues of \$5.5 billion during 2005, and facilities in substantially all of the country’s major metropolitan areas. Our largest competitor is Laboratory Corporation of America Holdings, Inc. In addition, we compete with many smaller regional and local commercial clinical laboratories, specialized esoteric labs, as well as laboratories owned by physicians and hospitals (see “Payers and Customers”).

We believe that healthcare providers consider a number of factors when selecting a laboratory, including:

- service capability and quality;
- accuracy, timeliness and consistency in reporting test results;
- number and type of tests performed by the laboratory;
- number, convenience and geographic coverage of patient service centers;
- reputation in the medical community; and
- pricing.

We believe that we compete favorably in each of these areas.

We believe that large commercial clinical laboratories may be able to increase their share of the overall clinical laboratory testing market due to their large service networks and lower cost structures. These advantages should enable larger clinical laboratories to more effectively serve large customers and members of large healthcare plans. In addition, we believe that consolidation in the clinical laboratory testing industry will continue. However, a majority of the clinical laboratory testing is likely to continue to be performed by hospitals, which generally have affiliations with community physicians that refer testing to us (see “Payers and Customers – Hospitals”). As a result of these affiliations, we compete against hospital-affiliated laboratories primarily on the basis of service capability and quality as well as other non-pricing factors. Our failure to provide service superior to hospital-affiliated laboratories and other laboratories could have a material adverse effect on our net revenues and profitability.

The diagnostic testing industry is faced with changing technology and new product introductions. Advances in technology may lead to the development of more cost-effective tests that can be performed outside of a commercial clinical laboratory such as (1) point-of-care tests that can be performed by physicians in their offices; (2) esoteric tests that can be performed by hospitals in their own laboratories; and (3) home testing that can be carried out without requiring the services of clinical laboratories. Development of such technology and its use by our customers and patients would reduce the demand for our laboratory testing services and negatively impact our net revenues (see “Regulation of Clinical Laboratory Operations”).

## **Quality Assurance**

Our goal is to continually improve the processes for collection, storage and transportation of patient specimens, as well as the precision and accuracy of analysis and result reporting. Our quality assurance efforts

focus on proficiency testing, process audits, statistical process control and personnel training for all of our laboratories and patient service centers. We continue to implement our Six Sigma and standardization initiatives to help achieve our goal of becoming recognized as the undisputed quality leader in the healthcare services industry. Our Nichols Institute facility in San Juan Capistrano was the first clinical laboratory in North America to achieve ISO certification. Two of our clinical trials laboratories, our diagnostic kits facility and two of our routine laboratories are also ISO certified. These certifications are international standards for quality management systems.

**Internal Proficiency Testing, Quality Control and Audits.** Quality control samples are processed in parallel with the analysis of patient specimens. The results of tests on quality control samples are monitored to identify trends, biases or imprecision in our analytical processes. We also perform internal process audits as part of our comprehensive Quality Assurance program.

**External Proficiency Testing and Accreditation.** All of our laboratories participate in various external quality surveillance programs. They include, but are not limited to, proficiency testing programs administered by the College of American Pathologists, or CAP, as well as some state agencies.

CAP is an independent, non-governmental organization of board certified pathologists. CAP is approved by CMS to inspect clinical laboratories to determine compliance with the standards required by the Clinical Laboratory Improvement Amendments of 1988, or CLIA. CAP offers an accreditation program to which laboratories may voluntarily subscribe. All of our major regional laboratories are accredited by CAP. Accreditation includes on-site inspections and participation in the CAP (or equivalent) proficiency testing program. “CAP whistle blower” hotline posters, which are used to escalate unresolved quality and laboratory safety concerns to CAP, are posted in all of our CAP accredited laboratories.

## **Regulation of Clinical Laboratory Operations**

The clinical laboratory industry is subject to significant federal and state regulation, including inspections and audits by governmental agencies. Governmental authorities may impose fines or criminal penalties or take other actions to enforce laws and regulations, including revoking a clinical laboratory’s federal certification, which is required to operate a clinical laboratory operation. Changes in regulations may (i) increase our operating costs including, but not limited to, those costs associated with performing clinical laboratory tests, and administrative requirements related to billing or (ii) decrease the amount of reimbursement related to testing services performed.

**CLIA and State Regulation.** All of our laboratories and (where applicable) patient service centers are licensed and accredited by the appropriate federal and state agencies. CLIA regulates virtually all clinical laboratories by requiring they be certified by the federal government and comply with various operational, personnel and quality requirements intended to ensure that their clinical laboratory testing services are accurate, reliable and timely. CLIA does not preempt state laws that are more stringent than federal law. For example, state laws may require additional personnel qualifications, quality control, record maintenance and/or proficiency testing. The cost of compliance with CLIA makes it cost prohibitive for many physicians to operate clinical laboratories in their offices. However, manufacturers of laboratory equipment and test kits could seek to increase their sales by marketing point-of-care laboratory equipment to physicians and by selling to both physicians and patients test kits approved by the FDA for home use. Diagnostic tests approved or cleared by the FDA for home use are automatically deemed to be “waived” tests under CLIA and may be performed in physician office laboratories with minimal regulatory oversight under CLIA as well as by patients in their homes.

**Drug Testing.** The Substance Abuse and Mental Health Services Administration, or SAMHSA, regulates drug testing for public sector employees and employees of certain federally regulated businesses. SAMHSA has established detailed performance and quality standards that laboratories must meet to perform drug testing on these employees. All laboratories that perform such testing must be certified as meeting SAMHSA standards. All of our laboratories that perform such testing are certified as meeting SAMHSA standards.

**Controlled Substances.** The federal Drug Enforcement Administration, or DEA, regulates access to controlled substances used to perform drugs of abuse testing. To obtain access to controlled substances, laboratories must be licensed by the DEA. All of our laboratories that use controlled substances are licensed by the DEA.