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 and two of our esoteric 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 ("CLIA"). CAP offers an accreditation program to which laboratories may voluntarily subscribe. All of our major regional and esoteric laboratories and most of our rapid response 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. In May 2000, the CDC published a notice of intent to create a genetic specialty under CLIA; however, in September 2006, CMS publicly announced that it did not intend to promulgate a rule creating a genetic specialty. 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.

Medical Waste, Hazardous Waste and Radioactive Materials. Clinical laboratories are subject to federal, state and local regulations relating to the handling and disposal of regulated medical waste, hazardous waste and radioactive materials. We generally use outside vendors to dispose of such waste and contractually require them to comply with applicable laws and regulations.

FDA. The FDA has regulatory responsibility over instruments, test kits, reagents and other devices used to perform diagnostic testing by clinical laboratories. In the past, the FDA also has claimed regulatory authority over laboratory-developed tests, but it has stated that it is exercising enforcement discretion in not regulating most laboratory-developed tests performed by high complexity CLIA-certified laboratories. On September 7, 2006, the FDA published two draft guidance documents that could impact us if finalized. The first draft guidance document describes various manufacturer practices and products that the FDA believes would take certain reagent products out of the Class I (exempt) Analyte Specific Reagent (ASR) category. The ASR draft guidance, if adopted as proposed, could restrict laboratory access to certain products now available, if in response to its adoption, manufacturers voluntarily withdraw their products from the market. The other draft guidance document describes certain laboratory-developed tests that the FDA intends to regulate as *in vitro* diagnostic test systems (i.e., as medical devices). The FDA calls this category of laboratory-developed tests "In Vitro Diagnostic Multivariate Index Assays" (IVDMIAs). The IVDMIA draft guidance, if adopted as published, would extend FDA oversight over laboratories that offer certain laboratory-developed tests. Many of the esoteric tests that we develop internally are first offered as laboratory-developed tests. FDA regulation of laboratory-developed tests or increased regulation of the various medical devices used in laboratory-developed testing would lead to increased regulatory burden and additional costs and delays in introducing new tests, including genetic tests. Representatives of clinical laboratories (including us) and the American Clinical Laboratory Association (our industry trade association), or ACLA, have communicated industry concerns to representatives of the FDA about potential FDA regulation of laboratory-developed testing and issues with regard to the continued availability of certain analyte specific reagents. FDA has extended to March 5, 2007 its original deadline for public response to the draft guidance documents.

The diagnostic products business conducted by our *in vitro* diagnostic product manufacturing subsidiaries is subject to regulation by the FDA, as well as by foreign governmental agencies, including countries within the European Union who have adopted the Directive on In Vitro Diagnostic Medical Devices ("IVDD"). These agencies enforce laws and regulations that govern the development, testing, manufacturing, labeling, advertising, marketing and distribution, and market surveillance of diagnostics products. Prior to marketing or selling most diagnostic products, we must secure approval from the FDA and (when appropriate) counterpart non-U.S. regulatory agencies, although the IVDD allows us to market in Europe many products using a process in which the manufacturer certifies that the device conforms to the regulatory and quality requirements for the device. Following the introduction of a diagnostic product into the market, the FDA and non-U.S. agencies engage in periodic reviews of the manufacturing processes and product performance. Compliance with these regulatory controls can affect the time and cost associated with the development, introduction and continued availability of new products. These agencies possess the authority to take various administrative and legal actions against us, such as product suspensions, recalls, product seizures and other civil and criminal sanctions. Where appropriate, voluntary compliance actions, such as voluntary recalls, may be undertaken.

Occupational Safety. The federal Occupational Safety and Health Administration, or OSHA, has established extensive requirements relating specifically to workplace safety for healthcare employers. This includes requirements to develop and implement multi-faceted programs to protect workers from exposure to blood-borne pathogens, such as HIV and hepatitis B and C, including preventing or minimizing any exposure through sharps or needle stick injuries.

Specimen Transportation. Transportation of most clinical laboratory specimens and some laboratory supplies are considered hazardous materials subject to regulation by the Department of Transportation, the Public Health Service, the United States Postal Service and the International Air Transport Association.

Corporate Practice of Medicine. Many states, including some in which our principal laboratories are located, prohibit corporations from engaging in the practice of medicine. The corporate practice of medicine doctrine has been interpreted in certain states to prohibit corporations from employing licensed healthcare professionals to provide services on behalf of a corporation. The scope of the doctrine, and how it applies, varies from state to state. In certain states these restrictions affect our ability to directly provide anatomic pathology services and/or to provide clinical laboratory services directly to consumers.