

Company's billing policies and practices. In addition, we are involved in various legal proceedings arising in the ordinary course of business. Some of the proceedings against us involve claims that are substantial in amount.

During the fourth quarter of 2004, the Company and NID each received a subpoena from the United States Attorney's Office for the Eastern District of New York. The subpoenas request a wide range of business records, including documents regarding testing and test kits related to parathyroid hormone ("PTH") testing. The Company is cooperating with the United States Attorney's Office. The Company has voluntarily provided information, witnesses and business records of NID and the Company, including documents related to testing and various test kits other than PTH tests, which were not requested in the initial subpoenas. During the third quarter of 2006, the government issued two additional subpoenas, one to NID and one to the Company. The subpoenas cover various records, including records related to test kits in addition to PTH. The government may issue additional subpoenas in the course of its investigation. This investigation could lead to civil and criminal damages, fines and penalties and additional liabilities from third party claims. In the second and third quarters of 2005, the FDA conducted an inspection of NID and issued a Form 483 listing the observations made by the FDA during the course of the inspection. NID responded to the Form 483. Noncompliance with the FDA regulatory requirements or failure to take adequate and timely corrective action could lead to regulatory or enforcement action against NID and/or the Company, including, but not limited to, a warning letter, injunction, fines or penalties, recommendation against award of governmental contracts and criminal prosecution. On April 19, 2006, the Company decided to discontinue the operations of NID. See Note 15 to the Consolidated Financial Statements for further details.

During the second quarter of 2005, the Company received a subpoena from the United States Attorney's Office for the District of New Jersey. The subpoena seeks the production of business and financial records regarding capitation and risk sharing arrangements with government and private payers for the years 1993 through 1999. Also, during the third quarter of 2005, the Company received a subpoena from the U.S. Department of Health and Human Services, Office of the Inspector General. The subpoena seeks the production of various business records including records regarding our relationship with health maintenance organizations, independent physician associations, group purchasing organizations, and preferred provider organizations from 1995 to the present. The Company is cooperating with the United States Attorney's Office and the Office of the Inspector General.

During the second quarter of 2006, the Company received a subpoena from the California Attorney General's Office. The subpoena seeks various documents including documents relating to billings to MediCal, the California Medicaid program. The subpoena seeks documents from various time frames ranging from three to ten years. The Company is cooperating with the California Attorney General's Office.

Several of the proceedings discussed above are in their early stages of development and involve responding to and cooperating with various government investigations and related subpoenas. While the Company believes that at least a reasonable possibility exists that losses may have been incurred, based on the nature and status of the investigations, the losses are either currently not probable or cannot be reasonably estimated.

Although management cannot predict the outcome of such matters, management does not anticipate that the ultimate outcome of such matters will have a material adverse effect on our financial condition, but may be material to our results of operations and cash flows in the period in which the impact of such matters is determined or paid.

As an integral part of our compliance program discussed below, we investigate all reported or suspected failures to comply with federal and state healthcare reimbursement requirements. Any non-compliance that results in Medicare or Medicaid overpayments is reported to the government and reimbursed by us. As a result of these efforts, we have periodically identified and reported overpayments. While we have reimbursed these overpayments and have taken corrective action where appropriate, we cannot assure investors that in each instance the government will necessarily accept these actions as sufficient.

## **Compliance Program**

Compliance with all government rules and regulations is a significant concern throughout the clinical laboratory industry because of evolving interpretations of regulations and the emerging changes in laboratory science and healthcare technology. We established a compliance program early in 1993.

We emphasize the development of training programs intended to ensure the strict implementation and observance of all applicable laws, regulations and Company policies. Further, we conduct in-depth reviews of procedures, personnel and facilities to assure regulatory compliance throughout our operations. The Quality, Safety & Compliance Committee of the Board of Directors requires periodic reporting of compliance operations from management.

We seek to conduct our business in compliance with all statutes and regulations applicable to our operations. Many of these statutes and regulations have not been interpreted by the courts. We cannot assure investors that applicable statutes or regulations will not be interpreted or applied by a prosecutorial, regulatory or judicial authority in a manner that would adversely affect us. Potential sanctions for violation of these statutes include significant damages, penalties and fines, exclusion from participation in governmental healthcare programs and the loss of various licenses, certificates and authorization necessary to operate some or all of our business, which could have a material adverse effect on our business.

### **Intellectual Property Rights**

Our success in remaining a leading innovator in the diagnostic testing industry by continuing to introduce new tests, technology and services will depend, in part, on our ability to license new and improved technologies on favorable terms. Other companies or individuals, including our competitors, may obtain patents or other property rights that would prevent, limit or interfere with our ability to develop, perform or sell our tests or operate our business. As a result, we may be involved in intellectual property litigation and we may be found to infringe on the proprietary rights of others, which could force us to do one or more of the following:

- cease developing, performing or selling products or services that incorporate the challenged intellectual property;
- obtain and pay for licenses from the holder of the infringed intellectual property right;
- redesign or reengineer our tests;
- change our business processes; or
- pay substantial damages, court costs and attorneys' fees, including potentially increased damages for any infringement held to be willful.

Patents generally are not issued until several years after an application is filed. The possibility that, before a patent is issued to a third party, we may be performing a test or other activity covered by the patent is not a defense to an infringement claim. Thus, even tests that we develop could become the subject of infringement claims if a third party obtains a patent covering those tests.

Infringement and other intellectual property claims, regardless of their merit, can be expensive and time-consuming to litigate. In addition, any requirement to reengineer our tests or change our business processes could substantially increase our costs, force us to interrupt product sales or delay new test releases. In the past, we have settled several disputes regarding our alleged infringement of intellectual property rights of third parties. We are currently involved in settling several additional disputes. We do not believe that resolution of these disputes will have a material adverse effect on our results of operations, cash flows or financial condition. However, infringement claims could arise in the future as patents could be issued on tests or processes that we may be performing, particularly in such emerging areas as gene-based testing and other specialty testing.

### **Insurance**

As a general matter, providers of clinical laboratory testing services may be subject to lawsuits alleging negligence or other similar legal claims. Some of these suits involve claims for substantial damages. Any professional liability litigation could also have an adverse impact on our client base and reputation. We maintain various liability insurance coverages for claims that could result from providing or failing to provide clinical laboratory testing services, including inaccurate testing results and other exposures. Our insurance coverage limits our maximum exposure on individual claims; however, we are essentially self-insured for a significant portion of these claims. The basis for claims reserves considers actuarially determined losses based upon our historical and projected loss experience. Management believes that present insurance coverage and reserves are sufficient to cover currently estimated exposures. Although management cannot predict the outcome of any claims made against the Company, management does not anticipate that the ultimate outcome of any such proceedings or claims will have a material adverse effect on our financial condition but may be material to our results of operations and cash flows in the period in which the impact of such claims is determined or paid. Similarly, although we believe that we will be able to obtain adequate insurance coverage in the future at acceptable costs, we cannot assure you that we will be able to do so.

### **Employees**

At December 31, 2006, we employed approximately 41,000 people. This total excludes employees of the joint ventures where we do not have a majority interest. We have no collective bargaining agreements with any unions covering any employees in the United States, and we believe that our overall relations with our employees are good.