

CAUTIONARY FACTORS THAT MAY AFFECT FUTURE RESULTS

Some statements and disclosures in this document are forward-looking statements. Forward-looking statements include all statements that do not relate solely to historical or current facts and can be identified by the use of words such as “may”, “believe”, “will”, “expect”, “project”, “estimate”, “anticipate”, “plan” or “continue.” These forward-looking statements are based on our current plans and expectations and are subject to a number of risks and uncertainties that could cause our plans and expectations, including actual results, to differ materially from the forward-looking statements. Investors are cautioned not to unduly rely on such forward-looking statements when evaluating the information presented in this document. The following important factors could cause our actual financial results to differ materially from those projected, forecasted or estimated by us in forward-looking statements:

- (a) Heightened competition from independent clinical testing companies, and from hospitals with respect to testing for non-patients and from physicians.
- (b) Increased pricing pressure from customers and payers.
- (c) Impact of changes in payer mix, including any shift from fee-for-service to discounted or capitated fee arrangements.
- (d) Adverse actions by government or other third-party payers, including unilateral reduction of fee schedules payable to us, competitive bidding, and an increase in the practice of negotiating for exclusive arrangements that involve aggressively priced capitated or fee for service payments by health insurers or other payers.
- (e) The impact upon our testing volume and collected revenue or general or administrative expenses resulting from our compliance with Medicare and Medicaid administrative policies and requirements of third party payers. These include:
 - (1) the requirements of Medicare carriers to provide diagnosis codes for many commonly ordered tests and the possibility that third party payers will increasingly adopt similar requirements;
 - (2) the policy of CMS to limit Medicare reimbursement for tests contained in automated chemistry panels to the amount that would have been paid if only the covered tests, determined on the basis of demonstrable “medical necessity,” had been ordered;
 - (3) continued inconsistent practices among the different local carriers administering Medicare;
 - (4) inability to obtain from patients an advance beneficiary notice form for tests that cannot be billed without prior receipt of the form; and
 - (5) increased challenges in operating as a non-contracted provider with respect to healthcare insurers.
- (f) Adverse results from pending or future government investigations, lawsuits or private actions. These include, in particular, monetary damages, loss or suspension of licenses, and/or suspension or exclusion from the Medicare and Medicaid programs and/or criminal penalties.
- (g) Failure to efficiently integrate acquired businesses, and to manage the costs related to any such integration, or to retain key technical, professional or management personnel.
- (h) Denial of CLIA certification or other licenses for any of our clinical laboratories under the CLIA standards, revocation or suspension of the right to bill the Medicare and Medicaid programs or other adverse regulatory actions by federal, state and local agencies.
- (i) Changes in federal, state or local laws or regulations, including changes that result in new or increased federal or state regulation of commercial clinical laboratories or tests developed by commercial clinical laboratories, including regulation by the FDA.
- (j) Inability to achieve expected benefits from our acquisitions of other businesses.
- (k) Inability to achieve additional benefits from our Six Sigma and efficiency initiatives.
- (l) Adverse publicity and news coverage about the clinical testing industry or us.
- (m) Computer or other IT system failures that affect our ability to perform tests, report test results or properly bill customers, including potential failures resulting from the standardization of our IT systems and other system conversions, telecommunications failures, malicious human acts (such as electronic break-ins or computer viruses) or natural disasters.
- (n) Development of technologies that substantially alter the practice of clinical test medicine, including technology changes that lead to the development of more cost-effective tests 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 or (3) home testing that can be carried out without requiring the services of clinical laboratories.

- (o) Issuance of patents or other property rights to our competitors or others that could prevent, limit or interfere with our ability to develop, perform or sell our tests or operate our business.
- (p) Development of tests by our competitors or others which we may not be able to license, or usage of our technology or similar technologies or our trade secrets by competitors, any of which could negatively affect our competitive position.
- (q) Regulatory delay or inability to commercialize newly licensed tests or technologies or to obtain appropriate reimbursements for such tests.
- (r) Inability to obtain or maintain adequate patent and other proprietary rights protections of our products and services or to successfully enforce our proprietary rights.
- (s) Impact of any national healthcare information network and the adoption of standards for health information technology interoperability that are incompatible with existing software and hardware infrastructure requiring widespread replacement of systems and/or software.
- (t) Inability to promptly or properly bill for our services or to obtain appropriate payments for services that we do bill.
- (u) Changes in interest rates and changes in our credit ratings from Standard & Poor's and Moody's Investor Services causing an unfavorable impact on our cost of and access to capital.
- (v) Inability to hire and retain qualified personnel or the loss of the services of one or more of our key senior management personnel.
- (w) Terrorist and other criminal activities, hurricanes, earthquakes or other natural disasters, which could affect our customers, transportation or systems, or our facilities, and for which insurance may not adequately reimburse us.

Item 1B. Unresolved Staff Comments

There are no unresolved SEC comments that require disclosure.