WhitePaper

Cleaning Up Your Medical Laboratory's FOB Testing Program:

An Opportunity to Improve Patient Care

By: Stephen Kincaid

Editor: Karen Appold

DARK Daily Laboratory and Pathology News @ darkdaily.com

DARK Daily
Clinical Laboratory and Pathology News/Trends

Table of Contents

Preface

Colorectal cancer (CRC) is the third most common cancer diagnosed in both men and women in the United States.[1] CRC is preventable through regular screening. However, unlike many other types of cancer, CRC is easily curable if found early.

The fecal occult blood test (FOBT) is one of the most commonly recommended CRC screening methods.

The fecal occult blood test (FOBT) is one of the most commonly recommended CRC screening methods by the National Cancer Institute, National Institute of Health, and the American Cancer Society.[2] The FOBT has widely been used as an effective screening tool for CRC by Medical Laboratories.

Studies have shown that FOBT, when performed every one to two years in people aged 50 to 80, can help reduce the number of deaths due to CRC by 15 to 33 percent.[3,4,5]

Introduction

In the United States, the third most common cancer diagnosed in both men and women is CRC. As of 2012, The American Cancer Society estimates 101,700 new cases of colon cancer and 39,510 new cases of rectal cancer. CRC is expected to cause about 49,380 deaths during 2012.[1]

Unlike many other types of cancer, CRC is easily curable if found early and can be prevented by removing precancerous polyps.

CRC is preventable through regular screening by Clinical and Medical Laboratories. Unlike many other types of cancer, CRC is easily curable if found early and can be prevented by removing precancerous polyps. Both polyps and early-stage cancers are usually asymptomatic. Compared with these lesions, cancers that have grown large enough to cause symptoms have a much worse prognosis.

This contrast highlights the need for screening in asymptomatic persons. In fact, if everyone aged 50 or older had regular screening tests, at least one-third of deaths from CRC could be avoided.

Risk Factors for CRC

The lifetime risk of developing CRC is about one in 20 (5.1 percent). This risk is slightly lower in women than in men.[1] The exact causes of CRC are unknown. However, studies have shown that certain factors are linked to an increased chance of developing this disease.[7-16] They include having polyps; a personal history of CRC, ulcerative colitis or Crohn colitis, or ovarian, uterine, or breast cancer; a family history, i.e., having immediate relatives that have had CRC; and being over age 50.[17]

In addition, some evidence suggests that the development of CRC may be associated with a sedentary lifestyle; cigarette smoking; and high dietary consumption of red and processed meats and low consumption of whole grains, fruits, and vegetables.[17]

Chapter 1.

FOBT Market Summary

This white paper will discuss advantages of the iFOBT compared to the CFOBT for Medical laboratories, physicians, and patients, and why it is critical that all laboratories adopt iFOBT techniques.

Currently, there are two types of FOBT available. A chemical-based FOBT (CFOBT) uses the chemical guaiac to detect heme in stool. Heme is the iron-containing component of the blood protein hemoglobin. The other type, called immunochemical FOBT (iFOBT), uses antibodies to detect human hemoglobin protein in stool.

In comparing the two test types, the iFOBT has some significant advantages.

The iFOBT is designed to detect human hemoglobin and is also specific for blood in the lower G.I. tract rather than blood originating from other sources higher up in the gastrointestinal tract.[6]

The CFOBTs exhibit false positive results due to the presence of plant and animal materials. In order to get more accurate test results, the test requires that patients avoid certain foods, drugs, vitamins, and many other substances three to seven days before testing. In spite of this, pseudo-positive results remain as high as 30 percent.

In addition, a major drawback to guaiac-based FOBTs as a screening technique is poor compliance. Only about 38 percent of patients in large trials completed all planned tests. The complexity includes patient preparation, inconvenience, facilities and equipment needed, as well as patient discomfort.

This white paper will discuss advantages of the iFOBT compared to the CFOBT for Medical laboratories, physicians, and patients, and why it is critical that all Clinical laboratories adopt iFOBT techniques.

Chapter 2.

Diagnosis of CRC: Traditional Testing Practices

In addition to the FOBT, other tests for CRC screening include colonscopy, virtual colonoscopy, sigmoidoscopy, double contrast barium enema, and digital rectal exam.

The Pros and Cons of Traditional CFOBT as used by Clinical Laboratories

In addition to the FOBT, other tests for CRC screening include colonscopy, virtual colonoscopy, sigmoidoscopy, double contrast barium enema, and digital rectal exam. To determine which test to perform, several factors are considered, including:

- the patient's age, medical history, family history, and general health;
- the accuracy of the test;
- the potential harms of the test;
- the preparation required for the test;
- whether sedation is necessary during the test;
- the follow-up care after the test;
- the convenience of the test; and
- the cost of the test and availability of insurance coverage.[17]

Advantages of using the FOBT include:

- No cleansing of the colon is necessary.
- Samples can be collected at home.
- Low cost compared to other CRC screening tests.
- Does not cause bleeding or tearing/perforation of the colon's lining.[17]

Disadvantages of using CFOBT include:

- This test fails to detect most polyps and some cancers.[10,3]
- False-positive results are possible.[3,5]
- Dietary restrictions and changes, such as avoiding meat, certain vegetables, vitamin C, iron supplements, and aspirin, and increasing fiber consumption, are often recommended for several days before a CFOBT. These restrictions and changes are not required for iFOBT.

Chapter 3.

Immunoassay Test Opens the Door to Improved CRC Diagnostics

Doctors can easily, quickly, and accurately read Hemosure's test results in 5 to 10 minutes.

Compared to traditional testing, Hemosure's one-step product is the latest technological breakthrough in iFOBT. Approved by the U.S. Food & Drug Administration (FDA) and CLIA waived, Hemosure employs a unique combination of monoclonal and polyclonal antibodies to detect only human blood in stool.

In addition to the inherent specificity and sensitivity, the Hemosure test can be performed by health care providers in hospitals, Medical laboratories, and private practices. It is not necessary to send fecal samples to the laboratory.

Hemosure's clear accurate reading of one or two bands is comparable to interpreting a pregnancy test. Doctors can easily, quickly, and accurately read Hemosure's test results in 5 to 10 minutes. Guaiac tests, conversely, show a blue color that is often difficult to interpret.

This new technology has greatly improved specificity, sensitivity, accuracy, and cost-effectiveness of FOBTs. Hemosure's test provides greater than 96 percent lower gastro-intestinal tract specificity, which is much higher than guaiac-based testing. This is due to Hemosure's unique combination of monoclonal and polyclonal antibodies that are specific to hemoglobin. A traditional guaiac test reacts with the peroxidase activity of heme protein in blood and is non-specific for human hemoglobin. Therefore, certain foods and medications can interefere with the results

of a guaiac test and cause false positive results. Hemosure's iFOBT is not affected by food or medication. Therefore, patients can perform the test immediately and don't forget to do it.

Regarding sensitivity, Hemosure's tests has greater than 87 percent sensitivity. It detects as low as 50 ng HB/ml and is human hemoglobin specific. In comparison, Guaiac tests offer only 50 percent sensitivity and detect 90,000 ng HB/ml or higher of non-specific hemoglobin.

Another benefit of Hemosure's test is that it provides greater than 97 percent accuracy; traditional tests are less than 86 percent accurate.

Another benefit of Hemosure's test is that it provides greater than 97 percent accuracy; traditional tests are less than 86 percent accurate.

Study: Hemosure iFOBT Test Has Increased Sensitivity and Specificity

A multicenter Laboratory study compared Hemosure Inc.'s new iFOBT to the guaiac-based test for CRC detection in Chinese patients. A hypothetical sequential method (SFOBT), in which iFOBT was used only as a confirmatory test for CFOBT, was also evaluated.[18]

A total of 324 patients were recruited from five major hospitals in Beijing, China. For each patient, three consecutive stool samples were collected for simultaneous CFOBT and iFOBT tests, followed by colonoscopic examination. The study compared the sensitivity and specificity of the three methods (CFOBT, iFOBT, and SFOBT) in two settings, with the first two consecutive samples versus all three samples.[18]

The sensitivity for the detection of cancer and large (>20 mm) or multiple adenoma was similar for all three methods in the three-sample setting. However, in the two-sample setting iFOBT had higher sensitivity than SFOBT for detecting cancer (87.8 percent vs. 75.5 percent, respectively, $p<0.05$) and large (>20 mm) or multiple

adenomas (65.4 percent vs. 42.3 percent, respectively, $p<0.05$). The iFOBT also had a higher specificity than the CFOBT (89.2 percent vs. 75.5 percent, respectively, $p<0.01$) in "normal" individuals defined by colonoscopy in the three-sample setting.[18]

Comparing the two-sample setting to the three-sample setting, both CFOBT and SFOBT showed significant loss of sensitivity for the detection of cancer as well as adenoma, whereas the sensitivity for iFOBT did not change significantly.[18]

The study concluded that Hemosure's iFOBT with two consecutive stool samples appeared to be the most cost-effective approach for CRC screening.

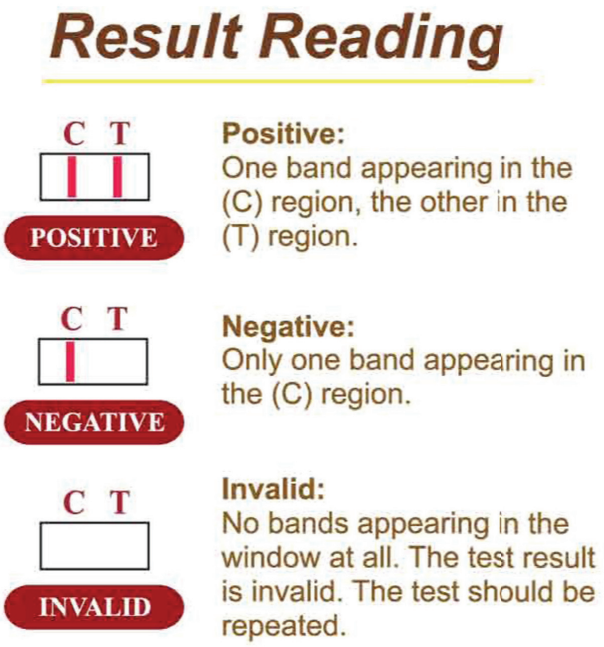
Overall, iFOBT with two-sample testing showed compatible sensitivity and specificity to the three-sample testing, and had a lower relative cost per cancer detected than the three-sample testing. The study concluded that Hemosure's iFOBT with two consecutive stool samples appeared to be the most cost-effective approach for CRC screening.[18]

Hemosure's Laboratory Test Kit: Quick, Easy, and Less Mess

Obtaining a sample for Hemosure's iFOBT is quick and easy. To get a sample, the patient lifts the toilet seat and positions the sample collection paper across the rim of the toilet bowl. Adhesive tabs should be secured to the sides of the toilet seat before it is lowered. Then, the patient makes a bowel movement onto the collection paper.

Next, the patient unscrews the purple cap from the sample collection tube and pokes the spiral applicator into the stool at six different sites. Only enough fecal material to cover the tip of the applicator is needed; the patient shouldn't clump, scoop, or fill the tube. Then the applicator is screwed back into the tube and is tightly secured. The patient then mails or returns the sample in a provided pouch to his doctor or Medical laboratory.

Hemosure's test is then easily performed in a physician office or Clinical laboratory. The technician performing the test shakes the sample in the collection tube, unscrews the tip cover, and then squeezes the tube to dispense three drops into the sample well. The result should be read in five minutes. If two bands appear in the testing window, the result is positive. One band indicates a negative test.



Chapter 4.

Implications for the Medical Laboratory

Because specimen collection methods are easier, faster and less messy, there is greater laboratory staff buy-in (which ultimately increases morale).

Benefits of Hemosure's iFOBT to the medical laboratory abound. For instance, the specimen collection process is simple and requires less sample (no scooping or smearing is necessary). Additionally, only one Hemosure sample is required compared to three samples required by traditional methods.

CFOBTs require three to four days for the patient to complete, while Hemosure offers a clear, interpretive result in a matter of minutes. Results are easy to read and are conveyed via a single or double line. Previously, diagnosis was based on color, which could be difficult to interpret.

Because specimen collection methods are easier, faster and less messy, there is greater medical laboratory staff buy-in (which ultimately increases morale).

Hemosure's test also has a higher Medicare reimbursement rate than traditional tests. Using diagnostic code 82274QW and screening code G0328QW, Hemosure's test is reimbursed at $21.86 each while traditional tests are only reimbursed at $4.54 per test. At an average list price of $216 for 30 Hemosure kits, a medical laboratory's profit margin would be 209 percent.

Other advantages of Hemosure's test include:

- CLIA waived and FDA approved.
- Heightened analytical performance.
- Greatly reduces false positive results.
- Increased early detection results in reduced costs for medical care.
- Increased specificity reduces the number of unneeded colonoscopies and in turn reduces hospital expenditures on unnecessary procedures.
- No dietary or drug restrictions increases patient compliance; other tests require multiple days of restrictions. (Time value)

Chapter 5.

Assessing the Opportunity

By switching from a traditional guaiac test to Hemosure's test, the laboratory reduced the number of colonoscopies it performs to one-quarter of the previous amount.

Hemosure's test offers a practical solution to delivering more accurate, timely results for CRC screening. Medical laboratories can positively impact their financial performance and reputation with clinicians as well as improve patient care in a cost-efficient manner.

Consider these statistics from the medical laboratory at Jacobson Memorial Hospital in Elgin, ND. By switching from a traditional guaiac test to Hemosure's test, the medical laboratory reduced the number of colonoscopies it performs to one-quarter of the previous amount. Under the previous methodology, the medical laboratory performed about 100 colonoscopies in-house per year and sent out between 300 to 400 per year. By using Hemosure's test, the medical laboratory now performs only 30 to 40 colonoscopies in-house per year and sends out less than 100.

Hemosure's iFOBT has enabled the medical laboratory at Jacobson Memorial Hospital to save money in the area of CRC screening because fewer false positive results are obtained. An additional benefit is that the medical laboratory doesn't have to refer as many patients to other providers for further testing.

Hemosure is cost effective, simple to use and has a high reimbursement rate which can add to your bottom line. Hemosure's shelf life is 24 months in a room temperature of 35.6°F to 86°F. Patient samples can last up to 14 days at temperatures up to 98.6°F. If kept at 39.2°F, the samples can last up to six months.

According to clinical laboratory supervisor Jane Cote, MLT(AMT), "Longer shelf life means that I can order a larger quantity for less price per test. Patients always do the Hemosure test correctly (*instructions are written on the pouch*) and are much more likely to complete the test."

Because more samples are being returned for testing and Hemosure's reimbursement rate is significantly higher, reimbursement has significantly improved.

Cote continues on to say that Hemosure's samples are much easier for patients to collect than guaiac samples. As a result, fewer kits need to be ordered, which is a cost savings, since more samples are being returned for testing and Hemosure has a significantly higher reimbursement rate.

Cote and her associates have had many patients open the guaiac testing kit incorrectly, then because of the difficult, unpleasant collection process patients oftentimes didn't complete the guaiac test upon their physician's first request. As a result, patients wouldn't do the test until receiving a second kit. Consequently, additional kits were required at a cost.

Note: The laboratory charged insurance companies $70 for Hemosure's test and $14 for a guaiac test. Currently, the national average for Medicare reimbursement is $21.86 for Hemosure and $4.54 for guaiac screenings.

Cote continued, "Providers are more apt to order a test if they are confident in the results" and because of that trust she believes her laboratory colleagues can add to the overall FOBT volume in their facilities.

The addition of Hemosure iFOBT to the array of diagnostics in Cote's lab led her to an unexpected, pleasing conclusion: "We feel more confident in reporting the results."

Chapter 6.

Case Study: Phoenix Indian Medical Center

"I thought that it would be almost impossible for patients to improperly collect a sample or put it in the wrong place for the Hemosure test," Beach says.

The medical laboratory at Phoenix Indian Medical Center in Phoenix, AZ, was not completely satisfied with using 2 traditional guaiac cards to perform CRC screening due to the low specificity and sensitivity of the test and patient dietary restrictions. Additionally, many patients were improperly collecting specimen samples.

Consequently, the medical laboratory evaluated different testing methodologies from multiple vendors, including Hemosure's iFOBT. Monica Beach, MT, supervisory medical technologist, Microbiology, Phoenix Indian Medical Center, based her decision upon a fullproof collection methodology and ease of patient compliance.

Beach rejected one product because its collection tubes could confuse patients because it has two openings. Conversely, the Hemosure product only has one place to open the vial. "I thought that it would be almost impossible for patients to improperly collect a sample or put it in the wrong place for the Hemosure test," Beach says. Additionally, the price of Hemosure's test was either consistent with other methods or even lower. Subsequently, Beach chose Hemosure's product.

Like the medical laboratory's previous testing method, Hemosure's patient samples last up to six months when refrigerated and test kits have a shelf life of 24 months. The amount of training to perform Hemosure's test is minimal, the same as before. Both have easy methodology with built-in internal quality control to read the test.

Turnaround Time Decreases; Cost Effectiveness Increases

While Phoenix Indian Medical Center's previous CRC screening method required three tests, Hemosure's offering only requires one test. Regarding the previous method, if a patient submitted three samples during a three-day period, the results would take four days to obtain. For the Hemosure test, results are received the same day as the laboratory receives the specimen. To clarify, the actual time to perform the test on each individual sample isn't less, but since testing is performed on one sample instead of three the turnaround time is reduced. Subsequently, the provider gets results faster. If the patient needs a colonoscopy, it can be scheduled more quickly.

Because Hemosure's test requires only one test instead of three, the number of tests are now fewer, but the total number of patients being tested are higher due to compliance.

Because Hemosure's test requires only one test instead of three, the number of tests are now fewer, but the total number of patients being tested are higher due to compliance. The testing process begins with the specimen arriving at the medical laboratory and receiving a laboratory identification number. The test is accessioned, labeled, and performed. Testing time takes approximately 10 minutes.

Because it is more sensitive and detects early CRC at a higher percentage than guaiac methodology, the return on investment is better patient care.

The cost for each Hemosure test, including the collection kit and mailer is reasonably priced. "But the cost is not the primary focus, rather, it is detecting CRC earlier so it can be effectively treated," Beach maintains. In addition, there are less false positives due to cross reactions with organic chemicals or animal blood.

Happier Staff, Happier Patients

Hemosure's iFOBT has increased staff morale at Phoenix Indian Medical Center's clinical laboratory because the workload has decreased as a result of fewer tests and tests that must be repeated.

Hemosure's test is also easier for patients because they only have to collect one sample and can mail it instead of bringing it to the lab.

Beach believes that patients are more satisfied because they no longer have dietary restrictions when performing Hemosure's test. "(Previously), we had a fair amount of false positives because some patients would continue to eat red meat before they collected a sample or they would have some kind of peroxidase due to eating cauliflower, broccoli, or carrots." Less false positives result in fewer patients having to redo the testing process. Hemosure's test is also easier for patients because they only have to collect one sample and can mail it instead of bringing it to the lab.

Chapter 7.

Conclusion

Increased specificity reduces the number of unneeded colonoscopies and in turn reduces hospital expenditures on unnecessary procedures.

iFOBT has significant advantages over CFOBT. iFOBTs deliver more accurate, timely results for CRC screening. Clinical laboratories can positively impact their financial performance by using iFOBT, enhance their professional reputations with clinicians, and can improve patient care in a cost-efficient manner.

Compared to other FOBT offerings, Hemosure's one-step product has greatly improved specificity, sensitivity, accuracy, and cost-effectiveness. Increased early detection results in reduced costs for medical care. Increased specificity reduces the number of unneeded colonoscopies and in turn reduces hospital expenditures on unnecessary procedures.

Clinical laboratories that are seeking to improve patient care, upgrade FOBT technology and maximize profitability would do well to make use of the top-selling iFOBT in the U.S. marketplace, Hemosure's iFOBT.

References

1. Colorectal Cancer. The American Cancer Society. Available at: http://www.cancer.org/cancer/colonandrectumcancer/detailedguide/colorectal-cancer-key-statistics. Accessed June 3, 2011.

2. Smith RA, Mettlin CJ, Davis KJ, et al. American Cancer Society guidelines for the early detection of cancer. *CA Cancer J Clin.* 2000; 50:34-49.

3. Burch JA, Soares-Weiser K, St John DJ, et al. Diagnostic accuracy of faecal occult blood tests used in screening for colorectal cancer: A systematic review. *Journal of Medical Screening.* 2007;14(3):132–137.

4. PDQ® Cancer Information Summary. National Cancer Institute; Bethesda, Maryland. *Colorectal Cancer Screening—Health Professional*. Date last modified: 08/26/2008. Available at http://www.cancer.gov/cancertopics/pdq/screening/colorectal/healthprofessional. Accessed 10/3/2008.

5. Ouyang DL, Chen JJ, Getzenberg RH, et al. Noninvasive testing for colorectal cancer: A review. *American Journal of Gastroenterology*. 2005;100(6):1393-1403.

6. Young GP, St. John DJ, Winawer SJ, Rozen P, et al. Choice of fecal occult blood tests for colorectal cancer screening: Recommendations based on performance characteristics in population studies: A WHO (World Health Organization) and OMED (World Organization for Digestive Endoscopy) report. *Am J Gastroenterol*. 2002;97:2499–507.

7. Hill LB, O'Connell JB, Ko CY. Colorectal cancer: Epidemiology and health services research. *Surgical Oncology Clinics of North America*. 2006;15(1):21-37.

8. Schatzkin A, Mouw T, Park Y, et al. Dietary fiber and whole-grain consumption in relation to colorectal cancer in the NIH-AARP Diet and Health Study. *The American Journal of Clinical Nutrition*. 2007;85(5):1353-1360.

9. Koushik A, Hunter DJ, Spiegelman D, et al. Fruits, vegetables, and colon cancer risk in a pooled analysis of 14 cohort studies. *Journal of the National Cancer Institute*. 2007;99(19):1471-1483.

10. Gonzalez CA. The European Prospective Investigation into Cancer and Nutrition (EPIC). *Public Health Nutrition*. 2006;9(1A):124–126.

11. Norat T, Bingham S, Ferrari P, et al. Meat, fish, and colorectal cancer risk: The European Prospective Investigation into Cancer and Nutrition. *Journal of the National Cancer Institute*. 2005;97(12):906-916.

12. Howard RA, Freedman DM, Park Y, et al. Physical activity, sedentary behavior, and the risk of colon and rectal cancer in the NIH-AARP Diet and Health Study. *Cancer Causes and Control*. 2008;19(9):939–953.

13. Friedenreich C, Norat T, Steindorf K, et al. Physical activity and risk of colon and rectal cancers: The European Prospective Investigation into Cancer and Nutrition. *Cancer Epidemiology, Biomarkers and Prevention*. 2006;15(12):2398-2407.

14. Samad AK, Taylor RS, Marshall T, et al. A meta-analysis of the association of physical activity with reduced risk of colorectal cancer. *Colorectal Disease*. 2005;7(3):204–213.

15. Paskett ED, Reeves KW, Rohan TE, et al. Association between cigarette smoking and colorectal cancer in the Women's Health Initiative. *Journal of the National Cancer Institute*. 2007;99(22):1729–1735.

16. Chao A, Thun MJ, et al. Cigarette smoking and colorectal cancer mortality in the Cancer Prevention Study II. *Journal of the National Cancer Institute*. 2000;92(23):1888-1896.

17. Colorectal Cancer Screening. National Cancer Institute at the National Institute of Health. Available at: http://www.cancer.gov/cancertopics/factsheet/detection/colorectal-screening. Accessed June 8, 2011.

18. Li S, Wang H, Hu J, et al. New immunochemical fecal occult blood test with two-consecutive stool sample testing is a cost-effective approach for colon cancer screening: Results of a prospective multicenter study in Chinese patients. *Int. J. Cancer.* 118,3078-3083(2006).

Appendices

A-1
About Stephen Kincaid

Stephen Kincaid owns and operates SDK Instruments, Inc., a medical consultation company in North Carolina. He has more than 40 years experience in the clinical laboratory field. After graduating with honors from the U.S. Air Force School of Medical Technology, he served at Malcolm Grow Hospital, Andrews AFB in Washington, DC. Kincaid later attended the University of North Carolina at Greensboro (UNC-G) where he received a B.A. in biology with a minor in English literature. He served as a laboratory supervisor at a local hospital during his years at UNC-G.

Kincaid began his laboratory sales career with Curtin-Matheson Scientific, Inc., where he was awarded "Sales Representative of the Year" and the "President's Club Award" during his time there. In 1981 he founded Landmark Scientific, Inc., a regional laboratory supply company. Later he started LSI Instruments, Inc., a manufacturer of small bench top chemistry analyzers. After selling both companies in the late 1990s, he co-founded Select Diagnostics Laboratory, a regional clinical lab that serves North and South Carolina. He also currently serves on the board of directors of Cell Solutions, Inc., and Select Laboratory Partners. Both companies have clinical laboratory involvements.

He has served as an FDA consultant to Mindray Electronics, Inc., which over the past several years has introduced lines of hematology and chemistry analyzers into the U.S. market. Presently, he serves as a technical resource and eastern regional manager for Hemosure, Inc.

Kincaid resides in Greensboro, NC, with his wife and two children.

Contact: skincaid@hemosure.com

A-2
About Hemosure

Hemosure has continuously researched, developed, and produced high quality rapid test systems that have not only revolutionized the medical industry, but have also set new industry standards and guidelines. With extensive marketing and through close interaction with end-users, Hemosure is able to continually improve upon its products and packaging to fit an array of needs for its customers. By using Hemosure products, doctors, hospitals, and laboratories are able to provide quick, easy, accurate testing to help improve the lives of their patients. The company's current product leader is Hemosure®, a trade name recognized worldwide in Immunological Fecal Occult Blood Testing (iFOBT).

A-3
About DARK Daily

"Dark Daily is a concise e-news/management briefing on timely topics in clinical laboratory and anatomic pathology group management. It is a solution to the dilemma facing anyone in the laboratory profession.

DARK Daily is a concise e-news/management briefing on timely topics in clinical laboratory and anatomic pathology group management. It is a solution to the dilemma facing anyone in the laboratory profession. New developments, new technology, and changing healthcare trends make it imperative to stay informed to be successful. At the same time, the Internet, cell phones, blackberries, laptop computers and wireless devices are overwhelming any one individual's ability to absorb this crushing Tsunami of data.

DARK Daily is a quick-to-read, easy-to-understand alert on some key development in laboratory medicine and laboratory management. It has no counterpart in the lab world. Why? Because it is produced and written by the experts at THE DARK REPORT and The Dark Intelligence Group, who know your world, understand your needs and provide you with concise, processed intelligence on only those topics that are most important to you!

You will find DARK Daily to also be an exceptionally valuable resource in laboratory and pathology management. Some of the lab industry's keenest minds and most effective experts will be offering their knowledge, their insights and their recommendations on winning strategies and management methods. Many of these experts are unknown to most lab directors. As has proven true with THE DARK REPORT for more than a decade, DARK Daily will be your invaluable— and unmatched—resource, giving you access to the knowledge and experience of these accomplished lab industry professionals.

A-4
About The Dark Intelligence Group, Inc. and THE DARK REPORT

"Membership is highly-prized by the lab industry's leaders and early adopters. It allows them to share innovations and new knowledge in a confidential, non-competitive manner.

The Dark Intelligence Group, Inc., is a unique intelligence service, dedicated to providing high-level business, management and market trend analysis to laboratory CEOs, COOs, CFOs, pathologists and senior-level lab industry executives. Membership is highly-prized by the lab industry's leaders and early adopters. It allows them to share innovations and new knowledge in a confidential, non-competitive manner. This gives them first access to new knowledge, along with the expertise they can tap to keep their laboratory or pathology organization at the razor's edge of top performance.

It offers qualified lab executives, pathologists and industry vendors a rich store of knowledge, expertise and resources that are unavailable elsewhere. Since its founding in 1996, The Dark Intelligence Group and THE DARK REPORT have played in instrumental roles in supporting the success of some of the nation's best-performing, most profitable laboratory organizations.

The Dark Intelligence Group (TDIG) is headquartered in Austin, Texas. This location makes it very accessible for any laboratory organization seeking input, insight and support in developing their business operations, creating effective business strategies and crafting effective sales and marketing programs that consistently generate new volumes of specimens and increasing new profits. The Dark Intelligence Group, Inc. owns and operates two Web sites in the TDIG Website network:

THE DARK REPORT

http://www.DarkReport.com

DARK Daily
Clinical Laboratory and Pathology News/Trends

http://www.DarkDaily.com

A-5
About the *Executive War College on Laboratory and Pathology Management*

Every spring since 1996, the lab industry's best and brightest gather at the *Executive War College on Laboratory and Pathology Management* to learn, to share and to network. Many consider it to be the premier source of innovation and excellence in laboratory and pathology management.

Each year, a carefully selected line-up of laboratory leaders and innovators tell the story of how their laboratories are solving problems, tackling the toughest challenges in lab medicine and seizing opportunities to improve clinical care and boost financial performance. The *Executive War College* is the place to get practical advice and solutions for the toughest lab management challenges. A unique case study format brings participants face-to-face with their most successful peers. They tell, first hand, how their laboratory solved intractable problems and successfully used new technology.

Many lab management secrets are shared, along with specific "what-not-to-do's" gained from hard-won experience! It's not pie-in-the-sky theory, but useful knowledge that can be put to use in any lab. The *Executive War College* offers superlative networking, with lab administrators and pathologists attending from countries as far away as the United Kingdom, Germany, Brazil and Australia. It makes the *Executive War College* a melting pot for all the best ideas, new lab technologies and management strategies now reshaping the laboratory industry. It's also become a recruiting ground used by headhunters and major lab organizations.

In the United Kingdom, The Dark Intelligence Group and the Association of Clinical Biochemists (ACB) have co-produced a meeting every February since 2003. Known at *Frontiers in Laboratory Medicine* (FiLM), it attracts laboratory leaders and innovators in the United Kingdom. Also featuring a case study format, this meeting pioneered the international laboratory side-by-side case study, where a North American laboratory and a United Kingdom laboratory prepare a comparison of best practices and an operational assessment of their two organizations.

In September 2005, a laboratory management meeting called *Executive Edge* was conducted in Toronto, Ontario, Canada, by The Dark Intelligence Group and QSE Consulting. It provided pathologists and lab directors in Canada with a customized meeting devoted to the strategic and operational issues of laboratory management in Canada.

A-6
About Karen Appold

Karen Appold is the owner of Write Now Services, which offers professional writing and editing services. She has extensive experience working in the clinical laboratory industry. In addition to The Dark Intelligence Group, Inc., clientele includes COLA, American Medical Technologists, American Association for Clinical Chemistry, American Society of Clinical Pathology, Clinical Laboratory Standards Institute and ADVANCE Newsmagazines. Ms. Appold has worked on editorial projects with Siemens Healthcare Diagnostics, McKesson Corp., Xifin Inc., Integrated Laboratory Automation Solutions, Aurora Interactive and more.

Ms. Appold is also published in many other health-care/medical publications. She has a B.A. in English (writing) from Pennsylvania State University and resides in Limerick, PA.

Contact: KarenAppold@comcast.net or 610-948-1961.
Visit www.WriteNowServies.com.

Terms of Use:

Contact Information

The Dark Intelligence Group, Inc.
Customer Service
800-560-6363
21806 Briarcliff Drive
Spicewood, Texas 78669

Legal Notices