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COMMUNIQUÉ

IMPROVING PATIENT CARE THROUGH ESOTERIC LABORATORY TESTING

VOLUME 31, NO. 9

Overuse of Serological Testing for Inflammatory Bowel Disease

Introduction

In recent years, health care providers have placed increasing emphasis on evidence-based medicine—clinical practices developed and validated through peer-reviewed clinical research. In the clinical laboratory, recommendations for evidence-based testing rely upon identifying how frequently definitive test results can be expected in specific populations of patients with particular signs and symptoms of disease. Mayo Medical Laboratories (MML) used the principles of evidence-based medicine to perform a retrospective audit of results obtained for the #81443 Inflammatory Bowel Disease Serology Panel, Serum, which includes the following assays:

- *Saccharomyces cerevisiae* antibodies, IgA
- *Saccharomyces cerevisiae* antibodies, IgG
- Neutrophil specific antibodies (perinuclear anti-neutrophilic cytoplasmic antibody—pANCA)

The results of the audit and recommendations for using the test panel in clinical practice are discussed in the following paragraphs.

Background—Inflammatory Bowel Disease

Inflammatory bowel disease (IBD) is a term applied to Crohn's disease (CD) and ulcerative colitis (UC). Both diseases are characterized by inflammation of the digestive tract lining. The American College of Gastroenterology Practice Parameters Committee recommends a combination of clinical, endoscopic, histologic, radiographic, and surgical findings to differentiate between UC and CD.[1,2] In a minority of cases (approximately 20%), overlapping symptomatology and nonclassic histologic and radiographic findings make differential diagnosis difficult. It is medically important to differentiate CD and UC as these diseases have different prognoses and treatments.

Patients with UC are at increased risk of developing colon cancer; and, when medications fail to control the inflammatory process, surgical removal of the colon is indicated as a curative therapy. In contrast, surgery is not curative and can lead to further complications in patients with CD. Nevertheless, surgery may be required to treat complications of CD, including obstruction of the intestine, strictures, and fistulae. Additionally, CD patients are more

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likely to require antibiotics and may benefit from treatment with infliximab, an antitumor necrosis factor agent.

Serological IBD Markers

The best studied serological markers of IBD are neutrophil cytoplasmic antibody (pANCA), also called neutrophil-specific antibody (NSA), which is more prevalent in UC patients, and IgG and IgA antibodies to *Saccharomyces cerevisiae* (ASCA), which are more prevalent in CD patients. Wide variation in reported test sensitivity and specificity has fueled the controversy over the use of these serologic markers. Additionally, a recent Mayo study reported the detection of IgA and IgG ASCA, as well as IgA endomysial antibodies, in patients who were diagnosed with gluten-sensitive enteropathy (celiac disease).[3]

- Positive pANCA is found in 30% to 83% of UC patients[1,4–7]; yet 2% to 40% of CD patients also test positive for pANCA.[1,5,7] Additionally, approximately 33% of patients have low-titer antinuclear antibodies, which may interfere with testing and make it impossible to distinguish the presence or absence of pANCA.
- Positive ASCA are found in 35% to 76% of CD patients; but, 5% to 15% of UC patients also test positive for ASCA.[4,6–8]
- Positive ASCA are not specific for CD, but can occur in patients with other diffuse intestinal diseases, such as celiac disease.[3]
- When IBD patients are tested for both pANCA and ASCA the reported predictive values range from 63.6% to 93% for UC and 80% to 96% for CD.[1,3–5,7]

Yet another serologic marker, Omp C, is touted as providing additional differentiation between cases of UC and CD in cases of ASCA-negative patients. In fact, among ASCA-negative patients, a positive Omp C result can be associated with either disease. Therefore, Omp C fails to improve the sensitivity of IBD panels for CD, and may result in additional confusion in the diagnosis.[9]

Based on these test performance parameters, the American College of Gastroenterology Practice Parameters Committee published the following statement defining the appropriate patient population to be tested using IBD serological markers:

> *"While pANCA and ASCA assays at this stage of knowledge are neither a first step nor a definitive step in differential diagnosis or clinical decision-making, they may be useful in the patient in whom all other clinical features do not allow a distinction between UC and Crohn's colitis."*[1]

Adhering to the committee's guidelines, Mayo Medical Laboratories has published the following guidelines for determining whether #81443 Inflammatory Bowel Disease Serology Panel, Serum is appropriate for your patient.

Not Useful For:

An IBD serology panel is **not recommended** in the following situations:

- Screening for IBD in patients with nonspecific gastrointestinal symptoms. The relatively low sensitivity of individual test components combined with the low prevalence of IBD in the general population makes IBD serology tests cost-prohibitive for general screening and would generate large numbers of false-positive and false-negative test results.[2,6–7]

- Screening patients who are strongly suspected of having IBD. Patients with negative results would still need to undergo standard diagnostic testing to rule out the diagnosis of IBD. Patients with positive results would also need to undergo standard diagnostic testing to confirm the differential diagnosis of CD or UC.

- Distinguishing between CD and UC in patients who have not undergone standard diagnostic tests. Some patients with CD have detectable

pANCA levels, and some patients with UC have elevated levels of ASCA. Standard diagnostic testing must be performed to confirm a differential diagnosis of UC or CD.

- Determining the extent of disease in patients with IBD, and monitoring response to disease-specific therapy. There is insufficient clinical evidence that pANCA and ASCA levels are linked with disease severity or that they change in response to specific medical treatments for IBD.[5,7]

Useful For:

An IBD serology panel is **recommended** only for a very specific patient population.

As indicated in the practice parameter mentioned above, the MML panel is useful as an adjunct test to differentiate CD and UC in patients with a clinical diagnosis of IBD and nondiagnostic histology and X-ray findings. The positive predictive values of pANCA and ASCA test results are high enough (>90%) to be useful for this specific purpose only.

Audit Background

Based on published studies, the tests included in #81443 Inflammatory Bowel Disease Serology Panel, Serum are useful only under limited circumstances.[1,2,4–8] However, some commercial proponents have advocated a much wider application than is currently supported by the peer-reviewed clinical literature. For this reason, we performed a test audit comparing the preintroduction performance of the test panel with its postintroduction performance (auditing service is available through MML by special request).

Results Of The MML Test Audit

MML test validation studies have shown that serological markers of IBD can be expected to provide definitive diagnostic results in approximately 40% of patients with IBD who have overlapping symptomatology for UC and CD.[10] The results of a retrospective audit of 2,754 consecutive IBD panels performed on sera submitted to MML revealed definitive results for CD or UC in only 18% of tests.[10] Panel test results were considered definitive if the predictive values of positive results were >90% for either UC or CD.[10] These data indicate that more than 80% of requests for this panel of tests were not accompanied by results that could be relied upon with a high degree of confidence to make a clinical diagnosis. Of the numerous institutions that ordered this test panel, only 2 had results consistent with expectations (for definitive test results), indicating that they had identified the appropriate patient population for testing.

The results of the audit identified a substantial percentage of test orders that produced results that were not definitive and not likely to be medically useful. This suggests that serologic testing is being ordered prior to or without the recommended clinical review and histologic, endoscopic, and radiographic studies. This finding points to the need for physicians to use particular care when ordering this test panel to insure that testing is only performed in an appropriate clinical situation, as recommended in the American College of Gastroenterology Practice Parameters Committee's guidelines.

Summary

An estimated 1 million Americans have UC and CD. Three fourths of CD patients will require at least 1 surgery, and 25% to 40% of UC patients also will require surgery. Tests that would provide

accelerated diagnosis and improve the monitoring of treatment strategies might improve IBD treatment and could even delay or eliminate the need for costly surgeries. While serological IBD markers hold promise, the currently available IBD serological marker panels lack the necessary sensitivity and specificity to definitively diagnose CD and UC, or monitor IBD status.

Unless care is used in selecting the appropriate patients for testing, serological IBD marker panel tests can provide both false-positive and false-negative results, leading to misdiagnosis and incorrect treatment. Since the standard testing modalities (endoscopy, histology, and radiology) are required to establish a definitive diagnosis of UC or CD, ordering the serological tests prior to traditional testing adds unnecessary costs and increases the possibility of an incorrect diagnosis. Mayo recommends adherence to the American College of Gastroenterology Practice Parameters Committee recommendations for diagnosis of CD and UC, which will reduce unnecessary testing, misdiagnosis, and misuse of limited health care resources.

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Prostate-Specific Antigen Doubling Time and Velocity

Prostate Cancer

The second most common malignancy in American men,[1] prostate cancer is also the second leading cause of death in this group.[2] African American men have a significantly higher incidence of the disease, and their mortality rates from prostate cancer are nearly double that of other racial and ethnic groups.[2] While the incidence and mortality rates for prostate cancer have declined from the highs of the early 1990s, the cost of the disease continues to grow. In 2004-adjusted dollars, it is estimated that treatment costs reached $8 billion a year. National Cancer Institute funding for prostate cancer research in 2005 was estimated at $310 million.

Once prostate cancer has been identified, many patients find that their physician recommends "watchful waiting" (observation), as the disease usually grows very slowly. In fact, most patients identified with low-grade, early prostate cancer will not die from the disease.[1] Watchful waiting can include the 2 most common tests for prostate cancer: digital rectal examination (DRE) and testing for the prostate-specific antigen (PSA) level.

Prostate-Specific Antigen Testing

PSA levels have been used for many years to aid in diagnosing and monitoring prostate cancer. In fact, PSA is not specific for prostate cancer; it is produced by both normal and malignant cells of the prostate gland. PSA level is, therefore, an imperfect tumor marker and elevated serum PSA levels may be seen in patients with benign prostate disease (eg, benign prostatic hypertrophy [BPH], prostatitis) as well as those with prostate cancer. Conversely, some patients with prostate cancer may have PSA levels that fall within the range seen in normal patients.

Treatment options for prostate cancer range from watchful waiting to radical prostatectomy, which carries the risks of impotence and incontinence.

Because fewer than 3% of men with prostate cancer will die of their disease, the ability to distinguish between those patients who are at greatest risk of progressing to fatal disease and those who are at lower risk could improve treatment decision making.

The limitations of the PSA test, as well as studies that suggest that PSA testing has not decreased prostate cancer mortality, have caused some to question whether PSA testing should be offered. These limitations have also spurred the development of variations of PSA monitoring to improve the utility of PSA measurements, including:

- Use of age-specific reference intervals.
  As men age, the prostate gland often enlarges (BPH) and the enlarged prostate produces more PSA. The use of age-specific reference intervals provides a better indication of abnormal PSA concentration than relying on a single upper limit of normal for all age groups. For example, Mayo-performed normal value studies, using serum from over 500 men from Olmsted County, Minnesota, the location of Mayo Clinic Rochester, who had no evidence of prostate cancer, showed that the upper limit of normal for men increased, as follows[3]:

PSA*	Age
2.0	40
3.0	52
4.0	61
5.0	68.5
6.0	74
7.0	79

**includes men with BPH*

This test is available from Mayo Medical Laboratories (MML) as #9284 Prostate-Specific Antigen (PSA), Serum.

- Free PSA, complexed PSA, and PSA ratio.
  PSA exists in serum in unbound (free) and bound (complexed to alpha-1-antichymotrypsin and enveloped by alpha-2-macroglobulin) forms. For reasons that are not clear, lower percentages of free PSA are associated with higher risks of prostate cancer. This is expressed as the PSA ratio (free PSA/total PSA). The relative risk of prostate cancer is approximately doubled when the free PSA/total PSA ratio is <0.10. Conversely, the relative risk is approximately halved when the ratio is >0.24.

  This test is available from MML as #81944 Prostate-Specific Antigen (PSA), Total and Free, Serum.

- PSA density.
  Larger prostates produce more PSA than smaller prostates produce. The PSA density calculation (PSA concentration/prostate volume) adjusts for this. Prostate gland volume is estimated by transrectal ultrasonography. However, because of difficulties obtaining accurate measurements of prostate volume, PSA density is not often used.

- Rate of PSA increase.
  Changes in PSA are determined as either the rate of PSA increase over time (ie, PSA velocity) or how quickly PSA levels double (ie, PSA doubling time [PSADT]). Both parameters are determined using multiple PSA levels obtained over time (#9284 Prostate-Specific Antigen [PSA], Serum).

Figure 1 describes 2 patients with different PSA doubling times and velocities.

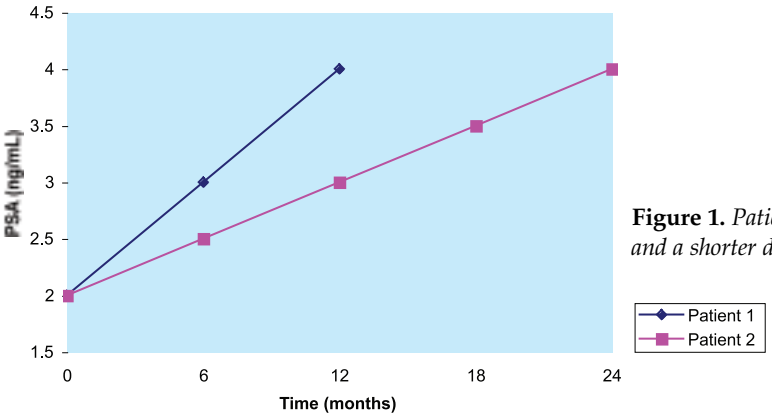

Figure 1. *Patient 1 has a more rapid PSA velocity, and a shorter doubling time than patient 2.*

How are PSA Doubling Time and PSA Velocity Calculated?

Both parameters are best determined using multiple PSA levels obtained over time. At a minimum, 2 measurements taken at least 3 months apart should be used. Ideally, all specimens from a patient should be analyzed using the same method and laboratory each time. Tools (eg, linear regression curves, Web-based calculators) are available to calculate PSA velocity and doubling times. One such tool is found at http://www.mskcc.org/mskcc/html/10088.cfm. Alternatively, they can be calculated utilizing the basic formulas shown below.

PSA velocity, in ng/mL/year =
$0.5\{[(PSA2 - PSA1)/(t)]+[(PSA3 - PSA2)/(t)]\}$
Where PSA1, 2, and 3 are the first, second, and third PSA measurements, respectively, and t is the elapsed time, in years, between 2 measurements.[4]

PSA doubling time =
[log (2) x t]/[log (final PSA)-log (initial PSA)]
Where t is the time interval from initial to final PSA determination.[5]

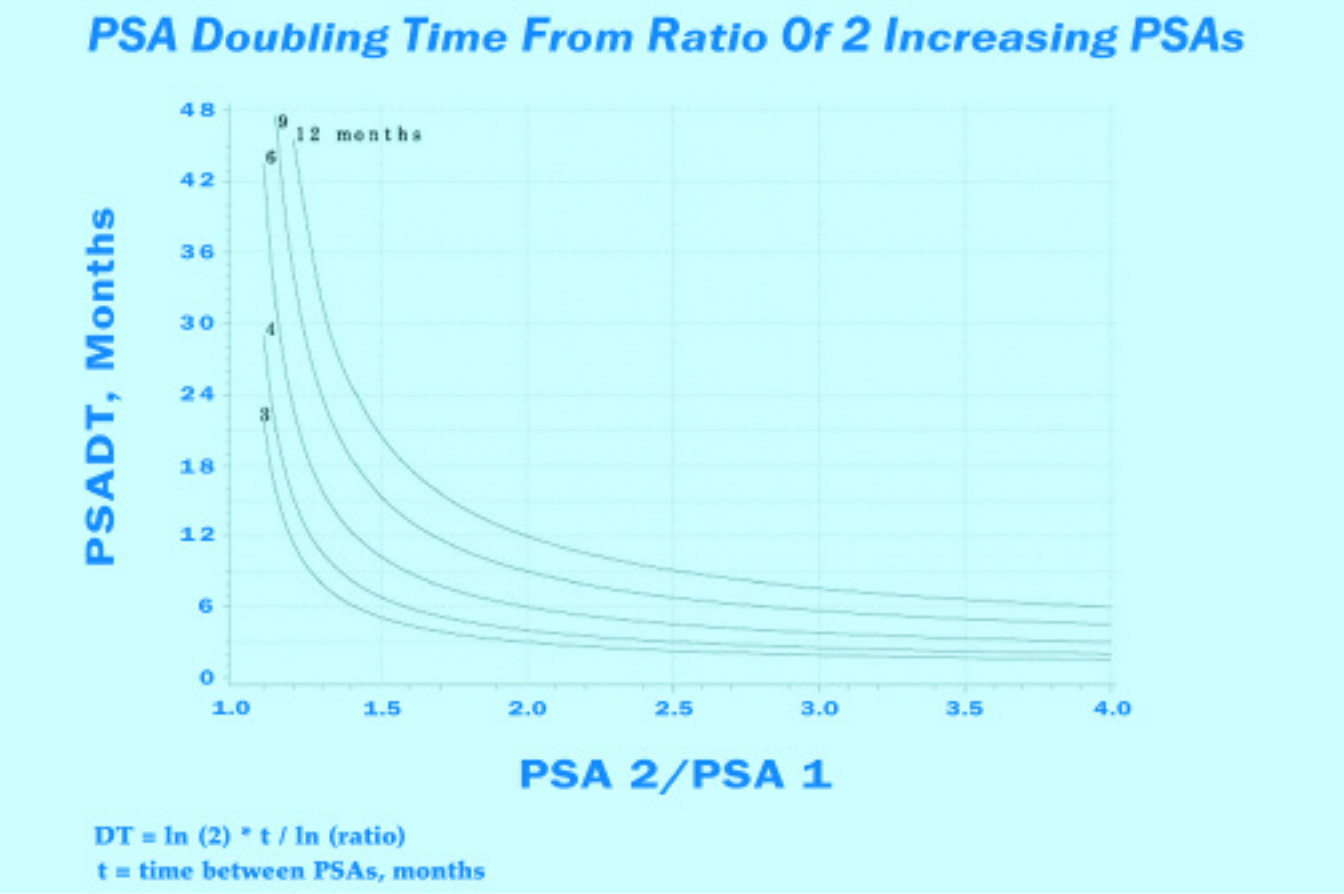

Figure 2. *Prostate-specific antigen doubling time (PSADT) as function of ratio between 2 increasing PSA measurements, stratified by number of months (t) between measurements. For ratios of 1.1 or less, PSADT is greater than 21 months for all values of t of 3 months or longer.*
Reprinted with permission from Sengupta S, et al: Simple graphic method for estimation of prostate-specific antigen doubling time. Urology 2005;67(2):409

A graphical method of evaluating PSA doubling time was recently developed at Mayo Clinic (Figure 2).[6]

What is the difference between these measures?

PSA velocity assumes a linear rate of PSA increase (ie, the rate of change is constant over time) and is calculated as the change in PSA ÷ elapsed time between measurements (eg, ng/mL/year). PSA doubling time assumes that PSA increases exponentially over time. Doubling time is calculated using the slope from the log linear regression of PSA (y) vs elapsed time (x) and is expressed as months or years. Some believe that PSA doubling time better reflects prostate cancer growth.

What is the value of determining the rate of PSA increase?

Recently, a Mayo study of PSA velocity and doubling time showed that these 2 variables are strong and independent predictors of outcome.[7] This study followed over 2,200 men who underwent prostatectomy. Preoperative PSA levels were compared with follow-up levels over, on average, a 7-year period. High (rapid) PSA velocities (>3.4 ng/mL yearly) and short doubling times (<18 months) were associated with increased likelihood of death. This study suggests that PSA velocity and PSA doubling time may provide physicians with information that could help them make treatment decisions.

Summary

Despite questions about its clinical utility, PSA testing has become common practice. Additional studies are needed to determine the optimal use of PSA tests. Until research identifies better methods for identifying and monitoring prostate cancer, PSA will remain the primary blood test of choice. Calculation of PSA velocity and doubling times provide additional tools to assist the physicians in selecting the optimal treatment for their patients.

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2006 Reader Survey

Dear Reader,

We would appreciate your opinion. The goal of the Communiqué is to provide the information that is most relevant to you about Mayo Medical Laboratories testing. Therefore, we would appreciate your taking a few minutes of your time to fill out and return the enclosed postage-paid survey. Alternatively, you may fill out the survey online at www.mayoreferenceservices.org/communique/. When we have reviewed the survey results, we will share them with you in a future issue.

Please accept our thanks for your time.

Sincerely,

Denise Masoner

Denise Masoner
Managing Editor, Communiqué

Focus on Education Conferences—Spaces Still Available

Practical Surgical Pathology
September 14–16, 2006

Designed for practicing surgical pathologists, the *Practical Surgical Pathology* conference addresses common but difficult diagnostic problems encountered by the pathologist in everyday practice. Every effort is made to present cases of common practical value. Participants and faculty will review case histories, examine case images, and formulate the diagnosis. The unique subtleties and differentiating characteristics of each diagnosis are then highlighted. Faculty and participants will also discuss the patient management strategy used in each case. Images of all cases presented are provided on a DVD to be viewed by virtual microscopy following the program.

The program format features multiple specialty areas each day. Throughout the 2½ days of the conference, 32 cases are presented and discussed. Audience participation is strongly encouraged.

The following specialty areas are selected for discussion:

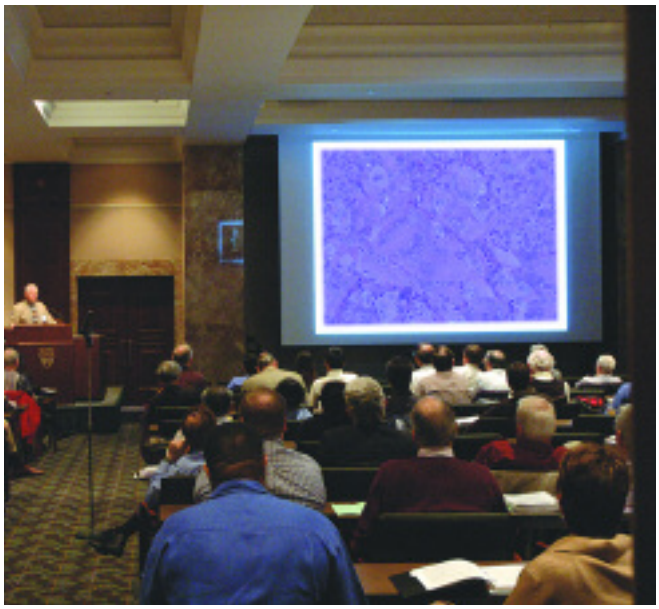
Bone
Breast
Cardiovascular
Cytology
Cytopathology
Dermatopathology
Head and Neck
Endocrine
Forensics
Gastrointestinal
Genitourinary
Gynecology
Hematopathology
Neuropathology
Pulmonary
Soft Tissue

Upon completion of the conference participants should be able to:

- Identify common diagnostic problems of pathologies selected for study
- Interpret appropriate ancillary tests for study cases
- Classify each case according to pathology type
- Enumerate the treatment options of each case diagnosis
- Integrate diagnostic, clinical, and pathological challenges in pathologist-clinician communication methods

Mayo Clinic College of Medicine designates this educational activity for a maximum of *16 AMA PRA Category 1 credit*™. Physicians should only claim credit commensurate with the extent of their participation in the activity.

The *Practical Surgical Pathology* conference will be held September 14–16, 2006. Course headquarters are located in the Leighton Auditorium foyer on the second floor of the Siebens Medical Education Building, Mayo Clinic, 100 Second Avenue SW, Rochester, Minnesota.



State-of-the-Art Thrombophilia
September 21–23, 2006

This course is designed for practicing clinicians, primary care providers, hematologists, cardiologists, hospitalists, neurologists, and vascular medicine specialists whose practices and interests include clinical aspects of thrombotic disorders.

The objective of this first Mayo Clinic continuing medical education course on thrombophilia is to provide both clinically applicable and cutting-edge material focused on the evaluation of patients who have arterial or venous thrombotic disorders. The course will refresh the basics and provide the latest information and philosophy on the evaluation and treatment of common thrombotic disorders, and also review specific aspects of uncommon thrombotic diseases. There will be an emphasis on clinically applicable scenarios and ample opportunity to ask questions and discuss difficult diagnostic or management issues.

At the conclusion of the program, the participant will be able to:

- Recognize the optimal diagnostic strategy of venous thromboembolism
- Employ the latest data for contemporary venous thromboembolism treatment
- Outline recent developments in stroke prevention and treatment
- Assess current management of patent foramen ovale (PFO)
- Review controversies of PFO closure in the stroke patient
- Describe optimal bridging therapy with low molecular weight heparin in the high-risk thrombosis patient
- Determine the role resistance plays in currently available platelet antagonists

Mayo Clinic College of Medicine designates this educational activity for a maximum of *15 AMA PRA Category 1 Credits*™. Physicians should only claim credit commensurate with the extent of their participation in the activity.

This activity has been reviewed and is acceptable for up to 15 elective credits by the American Academy of Family Physicians.

Mayo Reference Services is approved as a provider of continuing education programs in the clinical laboratory sciences by the ASCLS P.A.C.E.® Program. This program has been approved for 15 P.A.C.E. contact hours. Level of instruction for this program is intermediate.

This program has been approved for 15 credit hours towards State of California and State of Florida credit.

State-of-the-Art Thrombophilia will be held September 21–23, 2006. Course headquarters will be in Phillips Hall on the first floor of the Siebens Medical Education Building, Mayo Clinic, 100 Second Avenue SW, Rochester, Minnesota. Meeting facilities are easily accessible by skyway and pedestrian subway, which connect Mayo Clinic to shops, restaurants, and hotels.

Registration

Conference brochures are available online at www.mayoreferenceservices.org/education. To register, fill out the registration form in the brochure and fax it to 507-284-8016. Questions may be directed to the MML Education Department at 800-533-1710.

2006 Education Calendar

Upcoming Education Conferences . . .

Practical Surgical Pathology
September 14–16, 2006
Siebens Building • Mayo Clinic, Rochester, MN

State-of-the-Art Thrombophilia
September 21–23, 2006
Siebens Building • Mayo Clinic, Rochester, MN

Quality Phlebotomy: Back to the Basics
October 2, 2006
Hilton Dallas/Park Cities • Dallas, TX

Practical Spirometry
October 12–13, 2006
Radisson Hotel & Suites • Chicago, IL

Real-Time PCR for the Clinical Microbiology Laboratory
October 26–27, 2006
Siebens Building • Mayo Clinic, Rochester, MN

Practical Spirometry
November 14–15, 2006
Siebens Building • Mayo Clinic, Rochester, MN

Biomarkers of Cardiovascular Risk: State of the Art
November 16–17, 2006
Siebens Building • Mayo Clinic, Rochester, MN

Interactive Satellite Programs . . .

Genomics and Proteomics: An Update
September 12, 2006
Presenter: *David B. Schowalter, MD, PhD*

An Approach to Evaluation of Bleeding Disorders
October 3, 2006
Presenter: *Rajiv K. Pruthi, MBBS*

Update on Contemporary Pain Management of the Patient with Cancer
November 14, 2006
Presenters: *Marc A. Huntoon, MD*
Toby N. Weingarten, MD

Update on Cardiovascular Markers
December 12, 2006
Presenter: *Allan S. Jaffe, MD*

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