

Avera Laboratory Network  
*Lab News* is published  
every other month to provide  
the latest updates on  
services from labs of the  
Avera Laboratory Network.

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## D-Dimer Test Receives FDA Clearance

Biosite Incorporated received clearance from the Food and Drug Administration (FDA) to market the Triage D-Dimer Test. This diagnostic tests intended use is as an aid in the assessment and evaluation of patients suspected of having thromboembolic events, such as pulmonary embolism. This point-of-care diagnostic test can be used in the emergency department or at the patients' bedside.

Pulmonary embolism, or PE, is a blockage of one or more of the pulmonary arteries by blood clot, which is a common and highly fatal condition that is a leading cause of death in all age groups. Currently, more cases of PE are missed than are actually diagnosed because of vague and non-specific symptoms. PE is the third most common cause of death in the United States, with at least 650,000 cases occurring annually. It is the first or second most common cause of unexpected death in most age groups. The highest incidence of unrecognized PE occurs in hospitalized patients. Autopsy results show as many as 60 percent of patients dying in the hospital have had a PE, but the diagnosis has been missed in about 70 percent of the cases.

*ASCP news 12-3-04*

Mark your  
Calendars  
Annual ALN Spring  
Symposium  
Wednesday,  
March 16, 2005

# lab net news

*Reginal* response. *Personal* results.

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JANUARY/FEBRUARY 2005

## Thompson's Resignation Yields Uncertainty At CMS

Department of Health & Human Services Secretary Tommy Thompson announced his resignation December 10, 2004. He is the eighth member of President Bush's 15-member Cabinet to step down since the November elections.

At a news conference, Thompson said he initially wanted to resign shortly after the Medicare Modernization Act was enacted at the beginning of 2004. But the White House persuaded him to serve out the rest of President Bush's first term, he said.

This resignation comes as the agency gears up to overhaul Medicare in 2006. Thompson also suggested HHS would move to improve the Food and Drug Administration, calling for "an independent office of safety to look at drugs."

According to the *New York Times*, CMS Administrator Mark McClellan is "widely expected" to take the helm at HHS. However, losing its second administrator in less than a year could be a heavy drain on CMS, which has yet to complete implementation of the MMA. Claude Allen, Newt Gingrich, Tony Fauci, Elias Zerhouni and Julie Gerberding are also named as possible replacements. Thompson's resignation is slated for Feb. 4, 2005 unless a new secretary is named earlier.

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## Standardizing Employee and Customer Interactions

More and more facilities are moving toward standardizing or "scripting" proper language to use when employees are addressing patients, particularly in situations like specimen collection. This ensures that all patients are being addressed pleasantly and respectfully, and all receive a polished, professional and uniform interaction. An additional benefit to scripting is that it assures the most important components of the process are being followed. In the specimen collection procedure this would include such items as patient identification, inquiries about fainting, and explanation of the phlebotomy process. This standardized language also eliminates variables such as attitudes, people skills, and varying degrees of professionalism.

A properly prepared script includes these elements:

1. Introduction
2. Statement of Purpose
3. Gather patient information
4. Cue the patient to the process or procedure being performed
5. Thank the patient

Under each of these elements, carefully prepare the language that you wish to have your employees follow. When gathering the patient information, be sure to use open-ended questions so as to accurately identify the patient. Do not ask, "Are you John Doe?" Your question should state something such as "Could you please tell me your name?"

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## CASE STUDY

A 30-year old Caucasian woman in her 36<sup>th</sup> week of pregnancy experienced a sudden onset of lower abdominal pain and profuse vaginal bleeding. She was taken to the Emergency Department where upon examination she was found to be hypotensive and had marked tachycardia. Large ecchymoses and continuous oozing from venipuncture sites were observed. A fetal heart tone was barely audible. The woman's prior pregnancies and births were unremarkable.

Data from her initial lab work follows:

PT=26 seconds	(11-13 seconds)
PTT=84 seconds	(24-30 seconds)
Platelets=20,000/microliter	(140,000-400,000/ microliter)
Fibrinogen=85 mg/dl	(145-350 mg/dl)
FDP's=>40 micrograms/ml	(<10 micrograms/ml)
Protamine sulfate=positive	(negative)

Peripheral smear showed presence of numerous RBC fragments

This case is illustrative of acute disseminated intravascular coagulation (DIC) triggered by placental abruption. With delivery and removal of the placenta, the triggering mechanism was removed and the bleeding stopped. Normal hemostatic parameters were restored within hours of delivery.

DIC is the term used to describe a condition in which the clotting cascade is activated throughout the body, instead of being restricted to an area of local injury. The clotting factors are eventually used up, which is why the condition is sometimes referred to as "consumptive coagulopathy". The fibrinolytic system is also activated as a result of thrombosis formation. DIC can cause bleeding, which is more common, or a thrombotic episode. It can occur in acute and chronic forms.

Acute DIC is characterized by generalized bleeding which can range from petechiae to exsanguinating hemorrhage, or microcirculatory and macrocirculatory thrombosis. Chronic DIC is characterized by subacute bleeding and diffuse thrombosis.

Patients with DIC can show any of the following physical symptoms: various degrees of bleeding, diffuse or local thrombosis, hypotension, tachycardia, respiratory distress, hematemesis, azotemia, renal failure, hematuria, oliguria, petechiae, purpura, skin necrosis, infection, wound bleeding, or deep subcutaneous hematomas. Acute DIC can be triggered by infectious processes, malignancy, obstetric complications, trauma, burns, snake venom, transfusion, hemolytic reactions, liver disease, prosthetic devices, shunts, or ventricular assist devices. Chronic DIC can be caused by malignancy, obstetric complications (retained dead fetus/products of conception), myeloproliferative syndromes, paroxysmal nocturnal hemoglobinuria, rheumatoid arthritis, myocardial infarction, and inflammatory states (colitis, Crohn's disease, sarcoidosis).

Laboratory studies used to diagnose DIC include:

- D-dimer: the presence of this fibrin-degradation product verifies the presence of thrombin and has the greatest specificity for the diagnosis of DIC
- Antithrombin III: functional ATIII levels decrease in DIC
- Fibrinogen and FDP's: this test alone is not diagnostic of DIC, yet its presence indicates fibrinolytic activity
- Fibrinopeptide A: FPA is a breakdown product of fibrinogen, and is increased in DIC
- Platelet count: platelet counts are decreased and functional deficits are often present
- Prothrombin time: may be shortened, normal, or prolonged therefore is an unreliable test for the diagnosis of DIC
- Activated partial thromboplastin time: the results may be variable and so is unreliable for the diagnosis of DIC
- Thrombin time: prolonged in DIC
- Protamine test: detects fibrin monomers in plasma and should be positive in DIC
- Decreased coagulation factors: V, VIII, X, XIII, and Protein C

No single diagnostic test exists for DIC. DIC is initially suggested by the following hallmarks: a clinical condition consistent with DIC, thrombocytopenia, prolonged PT/APTT, and the presence of FDP, and positive D-dimer.

Complications which can occur from DIC include acute renal failure, life-threatening thrombosis/hemorrhage, fluid accumulation around the heart (cardiac tamponade), hemothorax, intracerebral hematoma, gangrene and loss of digits, and death. Prognosis depends on the severity of the DIC and the underlying cause.

Therapy should be based on treating the underlying cause and treatments include anticoagulants, blood components, and antifibrinolytics. Anticoagulants are used in the presence of intravascular thrombosis when the patient continues to bleed or clot 4-6 hours after initiation primary and supportive therapy. Heparin augments antithrombin III and prevents the conversion of fibrinogen to fibrin. It does not actively lyse the clots but inhibits further thrombogenesis and it prevents reaccumulation of a clot after fibrinolysis. Blood components are used to correct abnormal hemostatic parameters. Packed cells and platelets are considered safe for use in DIC, but FFP and cryoprecipitate may interfere with or improve DIC. Antifibrinolytic agents are used as a last resort after all other treatments have been found to be unsuccessful. They inhibit fibrinolysis by displacing plasminogen from fibrin. Antifibrinolytic agents may be useful in cases of DIC secondary to hyperfibrinolysis associated with acute promyelocytic leukemia and other forms of cancer.

SOURCES: [www.emedicine.com/emerg/topic150](http://www.emedicine.com/emerg/topic150)  
[www.nlm.nih.gov/medlineplus](http://www.nlm.nih.gov/medlineplus)

## ADVANCES IN CERVICAL CANCER SCREENING

By Dr. Henry P. Travers

Since the late 1940s, the mainstay of cervical cancer screening has been the Pap smear developed by Dr. George Papanicolaou. Simple to perform, though often difficult to interpret, this simple screening method has been credited with reducing the mortality from cervical cancer by 75%. Nonetheless, even today approximately 15,000 women in the United States develop invasive cervical cancer and 5,000 die.

Significant technical and interpretative improvements in the Pap smear have been introduced in the last 10 years. These include monolayer technology, computer-aided screening and testing for human papilloma virus (HPV virus). HPV virus typing has emerged as an element in screening strategy because most, if not all, cases of cervical cancer are due to infection by this virus.

Beginning two and one half years ago, Physician's Laboratory (PL) introduced the ThinPrep® method of monolayer Pap smear collection and preparation based on solid and accumulating evidence of its effectiveness. The technique has improved the detection of dysplasias and, together with HPV determinations, provided prognostic and therapeutic information required by new diagnostic and treatment algorithms developed by professional societies.

In all excellent laboratories there is a small fraction of truly abnormal Pap smears that are classified as "normal". Minimizing this "false negative fraction" is important and has been the goal of quality improvement activities in cytology nationwide as well as at PL for years. With the introduction of computer imaging technology from Cytoc Corporation ThinPrep® Imaging System for initial screening, followed by reviews by our cytotechnology and pathology staff, we expect to decrease our false negative fraction by 50 per cent.

Through a partnership with Access Genetics, Physician's Laboratory has changed its HPV testing method from one providing "high risk" and "low risk" categories to one that will provide specific viral phenotypes. The change was based on evolving information regarding risk stratification by type. Because development of this information is dynamic, we expect to continuously refine our risk stratification over the coming years.

HPV type 16, for example, is strongly associated with cervical cancer (about 60% of women with squamous cervical cancer have this type) and is classified as high risk. HPV type 53 occurs in only 0.2% of women with squamous cervical cancer and is probably low risk, although it was recently classified as of unknown risk.

About 70% of ASCUS cases and 52% of LGSIL are either HPV negative or have HPV types rarely isolated from HGSIL or cancer. While colposcopy is routinely performed for HGSIL, the finding of a low-grade cytologic abnormality with an HPV type associated with HGSIL/cancer less than 1 % of the time may render colposcopy unnecessary.

Munoz and colleagues' used odds ratios of the association of HPV type with cervical cancer. High risk types were those with odds ratios of at least 5; low risk types were defined as odds ratios of less than 3. The odds ratios for types 16 and 18 were 434 and 248 respectively, indicating the substantial risk of cervical cancer with infection by these types. Known viral types not detected in the population studied were classified as unknown risk. These authors were able to reclassify several types from the low-risk group to the high-risk group. Our previous testing method (hybrid capture) did not allow us to provide up-to-date risk stratification advice to medical professionals in the dynamic way changes in our knowledge demand.

*Note: Monolayer technology is available through all ALN Service Centers*