IRL INFORMS...newsletter

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CLOSTRIDIUM DIFFICILE UPDATE

Clostridium difficile is an anaerobic, spore forming, enterotoxin producing, gram positive bacilli and the most common cause of antibiotic-associated diarrhea and pseudomembranous colitis in the hospital setting. Two types of toxins are produced; an enterotoxin (toxin A) and a cytotoxin (toxin B). Both enterotoxins represent major virulence factors for this organism. C. difficile is found as part of the normal gastrointestinal flora of many people, however, following extensive antimicrobial therapy, normal bacteria are killed allowing this pathogen to multiply and cause disease. Spores of C. difficile are frequently transmitted among hospitalized patients and survive for prolonged periods within the hospital environment. Nosocomial infections in hospitals and nursing homes are common.

Recently the rate, severity and mortality associated with C. difficile infections have increased in the US and Canada. C. difficile strain NAP1/027 has been implicated as a new epidemic strain that produces increased levels of toxins A and B. It also produces a binary toxin which may act synergistically with toxins A and B resulting in very severe colitis. The new strain has also demonstrated resistance to fluoroquinolones.

Prudent selection of antibiotics, particularly of broad spectrum agents and avoidance of their use when possible are important steps toward prevention of C. difficile infections. Decontamination of environmental surfaces, better hand hygiene and barrier precautions are effective means of controlling transmission. A combination of approaches is likely required to control transmission in the healthcare setting.

C. DIFFICILE LABORATORY DIAGNOSIS DO'S AND DON'T'S

C. difficile-associated disease should be suspected in **patients with diarrhea** who have received antibiotics within the previous 2 months or whose diarrhea begins **72 hours** after hospitalization.

Do not request testing on patients with formed stools. Testing is not recommended for asymptomatic patients, unless ileus is suspected. There is a high probability of obtaining false-positive result s when testing patients without diarrhea.

Do not request C. difficile as a "test of cure." A positive test result at the end of therapy does not predict who will develop a recurrence or relapse.

Do not conduct repeat testing for C. difficile if a patient has had a stool sample **positive** for C. difficile, unless symptoms resolved with treatment and then returned. Repeated C. difficile testing does not provide any useful clinical information.

WHAT IS ANA TESTING?

As part of IRL's commitment to provide high quality, standardized laboratory results, we perform ANA testing using a new microbead technology. The AtheNA Multi-Lyte ANA test system employs a fluorescence-based microparticle immunoassay. This test system provides more objective, higher quality results than traditional methodologies. The system provides the following 10 test results from a single patient sample: ANA screen, dsDNA, Sm, RNP, SSA, SSB, Scl-70, Jo-1, Centromere B and Histone. The Athena Multi-Lyte is a significant improvement over the ANA indirect fluorescent assay (IFA) which is labor intensive and subject to interpretation.

Today IFA patterns are used primarily to guide the physician on which reflex tests to order. These reflex tests are performed simultaneously with the ANA screen as part of the AtheNA Multi-Lyte panel. To assist the physician in making a more rapid diagnosis, IRL offers an ANA screen with reflex to the 9 ENAs (order code 75191). The ANA screen (order code 60000) may also be ordered by itself without reflex. In this instance the ENA results are archived and may be retrieved at a later date if requested by the physician.

The Athena Multi-Lyte technology has resulted in a significantly improved turnaround time for ANA and ENA results. IRL uses innovative technology and highly trained staff to get the right information, in the right hands, at the right time, every time.

DID YOU KNOW?

Copies of our State license, and Federal & CAP certificates can be found on our website: irlfl.com. Just click the link, "Licenses/ Certifications" on left navigation bar.

It's about time.

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APRIL National Health Observances

Autism Awareness Month
Donate Life Month
EARTH DAY, April 22nd

MODIFICATION OF LUPUS ANTICOAGULANT TESTING PROCEDURE

Lupus anticoagulants (LA) are associated with numerous clinical states such as systemic lupus erythematosus, recurrent spontaneous abortions, thromboses, and infections. Their presence may be persistent or transitory. The diagnosis of LA is often difficult because of variable reagent sensitivity and the intrinsic heterogeneity of LA.

Specifically, lupus anticoagulants are antibodies directed against phospholipid/protein complexes. They have the ability to prolong the clotting times of the phospholipid dependent tests. In practice, factor deficient plasma are easily identified, since the addition of normal citrated plasma restores normal *invitro* APTT clotting time. However, the APTT test alone cannot provide clear-cut differentiation between LA antibody-containing plasmas and those that contain anti-factor antibodies and/or heparin.

There is no gold standard assay for lupus anticoagulant. Detection of lupus anticoagulant is based purely on different laboratory assays. According to the ISTH, (International Society for Hemostasis and Thrombosis), the criteria for confirming the presence of lupus anticoagulant are the following: (1) prolongation of a phospholipid-dependent clotting assay, (2) evidence of an inhibitor demonstrated by mixing studies, (3) confirmation of the phospholipid-dependent nature of the inhibitor, and (4) lack of specific inhibition of any one coagulation factor. Because of the heterogeneity of lupus anticoagulants, some tests are more sensitive than other tests. Therefore, the use of at least 2 types of confirmation assays (contact activation and tissue factor pathways) for lupus anticoagulant are recommended according to the ISHT.

As such, IRL has modified its existing LA testing scheme to meet the ISHTA recommendations for LA testing. LA testing will occur in two phases. Phase 1 consists of a Thrombin Time, PT, aPTT and a Dilute Russell Viper Venom test (DRVVT). If the Thrombin Time is increased above normal, a test for Heparin will be conducted. If Heparin is determined to be present, no other testing will occur and the recommendation made that heparin be discontinued and LA testing repeated. If all phase 1 tests are normal, no further testing will occur with the conclusion that LA is not present.

If any of the Phase 1 tests are abnormal, Phase 2 testing will occur and will consist of aPTT mixing study, Hexagonal Phospholipid confirmatory assay and DRVVT confirmatory assay including a DRVVT mixing study if warranted based on the initial confirmatory test. Patient results will then be determined based on the confirmatory results of each of the Phase 2 tests.

LA testing is performed daily.

CPT Information for the Lupus Anticoagulant Test:

Always performed:

TEST	CPT
LA1	85613
LA2	85613
PT (LUPUS)	85610
THROMBIN TIME	85670
APTT	85730

Potential reflex tests:

TEST	CPT
LA 1 1:1:P	85613
LA 2 1:1 P	85613
HEP TROMBIN TIME	85670
HEXAGONAL PHOSPHOLIPID	85597
APPT 1:5 1 HOUR INCUBATION	85730
APTT 1:1 NP	85730
APTT 1:1 SALINE	85730

NEW TESTING BROUGHT IN-HOUSE JANUARY 2009

1. Cyclic Citrullinated Peptide (CCP)

The CCP test is a semi-quantitative/qualitative assay for the detection of human autoantibodies specific to CCP. The assay is intended to aid in the diagnosis of Rheumatoid Arthritis (RA). The CCP test will be performed weekly on Thursdays.

2. HIV Western Blot Analysis

The HIV Western Blot tests for antibodies to particular proteins specific for HIV infection. The assay is intended as a confirmation assay for HIV screening procedures for the diagnosis HIV. HIV Western Blot Assays will be performed on Wednesdays and Saturdays.