IRL INFORMS...newsletter

Volume 2, Issue 3

INTEGRATED REGIONAL LABORATORIES IRL

ANA TESTING

The presence of one or more auto antibodies that react with a patient's various nuclear and cytoplasmic proteins characterizes the rheumatic diseases. The term antinuclear antibody, or ANA, is routinely used to describe these antibodies, regardless of the components to which they bind. When certain auto antibodies are present at levels above a defined threshold, particular disease states may be indicated:

Table 1: Autoantibodies in the Rheumatic Diseases

Autoantibody	Disease Associations, Condition	Frequency
dsDNA (double-stranded DNA)	Systemic lupus erythematosus (SLE)	40% – 60%
SSA (anti-Sjögren A, Ro)	Neonatal lupus, Sjögren syndrome SLE	~100% 40% – 70% 25% – 35%
SSB (anti-Sjögren B, La)	Sjögren syndrome SLE	30%2 10%
SM (anti-Smith)	SLE	15% – 30%
RNP (U1 nRNP, antiribonucleoprotein)	Mixed connective tissue disease SLE Polymyositis and/or dermatomyositis	~95% 30% – 50% 20%
Scl-70 (anti-DNA topoisomerase)	Scleroderma (diffuse) CREST	20% – 35% 13%
Jo-1	Polymyositis and/or dermatomyositis	20% – 40%
Centromere B	CREST (limited systemic sclerosis)	80%
Histones	Drug-induced SLE SLE	~90%2,5 50% – 70%

At present, IRL uses multiplex-bead flow cytometry to screen for antinuclear antibodies (ANA). This methodology allows for the simultaneous identification of all nine (9) of the above auto antigens from a single detection well. Each analysis is performed with 10 distinct immunoassay microspheres, one of which measures a patient's antibody response to a HEp-2 cell nuclear antigen preparation (ANA screen). Additionally, the assay also detects the presence of antibodies to nine other antigens (dsDNA, SSA, SSB, Sm, RNP, Scl-70, Jo-1, centromere B,and histones) to improve the accuracy and utility of the ANA result. It has been demonstrated that the detection of specific ANAs is more sensitive than ANA-IFA (qualitative immunofluorescent screen which relates fluorescent staining patterns to the specific autoantibody identified above) and that a significant number of patients with rheumatic connective tissue disease could potentially go undetected if ANA-IFA were used.

As such IRL will only perform Test No. 075191, ANA with reflex to 9 ENAs, for all ANA screening and confirmations.

IRL ANA testing options

Test number	Test Name	CPT	Description	Remarks
075191	ANA with reflex to 9 ENA's	86038 If positive 86225, 86235(x8) at additional charge	ANA screen with reflex to confirmation of ENA's	If ANA screen is negative, reported as negative; if ANA screen is positive, test will reflex to all 9 ENA's and positive ENA's reported

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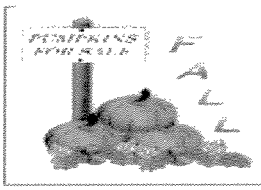


OCTOBER National Health Observances
Breast Cancer Awareness Month
Domestic Violence Awareness Month

DISCONTINUATION OF RAPID URINE SCREEN

Annually, our Microbiology Laboratory tests approximately 117,000 urine specimens submitted for urine culture and sensitivity. Until recently, the Coral UTI automated analyzer manufactured by Coral Biotechnology was routinely used by our laboratory for screening urine culture specimens. The instrument allows for same day reporting of final negative results, while positive Coral UTI screen results must be reflexed to a traditional plated urine culture. Unfortunately, the manufacturer has not provided the level of technical support and manufacturing depth to enable us to consistently offer urine screening. There is no other equivalent technology available today that could be considered in lieu of the traditional plating method. **Therefore, effective November 2nd, 2009, IRL will discontinue the use of the Coral UTI screen instrument. All requests for urine C&S will be performed by traditional plated urine culture.**

In general, screening methods such as the Coral UTI screen compare well with urine culture for specimens containing 10^5 CFU of bacteria per ml or greater, but do not perform as well when colony counts are lower. The Coral UTI screen has an overall sensitivity of 86%, a specificity of 75% and a positive and negative predictive value of 45% and 95%, respectively. In pediatric patients, the sensitivity of the Coral UTI screen is only 72% due to UTIs with low bacterial count. Such low sensitivity values limit the performance of the Coral UTI screen and may result in falsely negative screen results.

We have now completed a TAT study of over 30,000 urine C&S samples received in our laboratory between 1/1/09 and 8/31/09, including 14,183 specimens tested by the Coral UTI screen and 16,224 plated urine cultures. We found that for urine cultures yielding clinically relevant organisms, there is no difference in the average time to final results between plated urine cultures and Coral UTI screens (both tests average 42 hrs). Importantly, preliminary results from traditional plated urine cultures are reported as soon as results become available during our 24/7 laboratory operation (usually in 12 to 24 hours).

Our study demonstrates that the TAT between the two testing methods (plated urine culture vs. Coral UTI screen) is equivalent for clinically significant UTI and that the discontinuation of the use of the Coral instrument will not compromise our result TAT.

If you have any questions about this information please contact us at 954-777-0018.

References:
Evaluation of the Coral UTI screen system for rapid automated screening of significant bacteriuria in a regional centralized laboratory. H. Semeniuk, J. Noonano, H. Gill and D. Church. Diagnostic Microbiology and Infectious Disease 44; pp 7-10 (2002).
Evaluation of the Coral UTI screen system for rapid automated detection of significant bacteriuria in children. Calgary Laboratory Services, Microbiology Newsletter; Volume 12, 2003.

PATIENT SAFETY

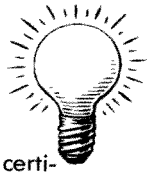
The 1999 Institute of Medicine's report, *To err is Human: Building a Safer Health System*, brought to light the importance of patient safety in healthcare[1]. As such, Clinical Laboratory testing is essential for the delivery of quality health care and provides physicians with objective data needed to promptly diagnose and effectively treat and monitor disease. It is estimated that lab testing has an impact on over 70 percent of medical decisions, yet laboratory services account for only three percent of health care spending (and two percent of Medicare expenditures).[2] In this context the laboratory plays an essential and vital role in influencing patient safety in the healthcare setting.

From a clinical lab perspective, addressing patient safety encompasses three distinct areas: 1) pre-analytical errors (46-68%) or errors associated with ordering, collection and delivery of the sample to the laboratory; 2) analytical errors (less than 15%) or errors associated with the analytical testing process; and 3) post-analytical errors (18-47%) or errors associated with the delivery, receipt and interpretation of testing results.[3] The relatively high pre-analytical error rate is generally associated with variability in communication among physicians, nurses, phlebotomists, etc., poorly designed processes, failure to pay attention to detail and other non-laboratory factors outside of the laboratory's control. The most common pre-analytical error categories are patient identification, phlebotomy techniques, test collection procedures, specimen transport and specimen processing. Of these categories, the five most common, specific pre-analytical errors (in general order of frequency) are hemolyzed specimen, insufficient sample, incorrect sample, clotted sample and mis-identification of the patient.[4] As such, it is imperative that proper patient identification and collection procedures are in place, and followed, in order to obtain accurate laboratory results and ensure optimum patient safety.

References:
1. Kohn KT, et al, To err Is Human: building a safer health system. Washington, DC: National Academy Press, 1999.
2. http://www.clinical-labs.org/issues/value/index.shtml accessed 7 Oct 2009
3. Plebani, M, Errors in clinical laboratories or errors in laboratory medicine, Clin Chem Lab Med 2006; 44(6) 750-759
4. Bonini, P, et al, Errors in Laboratory Medicine, Clin Chem 48:5, 691-698 (2002).

DID YOU KNOW?

Copies of our State license, Federal and CAP certifications can be found on our website: www.irlfl.com
Just click on the link, "LICENSES/CERTIFICATIONS" on the left navigation bar



24/7 CUSTOMER SERVICE SUPPORT

IRL is pleased to announce that the Internal Customer Services department has expanded hours of operations to provide enhanced service to our customers. Our customer service representatives will provide you with personalized service, answering your questions and ensuring a seamless working relationship. The department has transitioned to a 24/5 environment Sunday through Thursday nights, with plans to expand to a complete 24/7 environment in the near future. Understanding the needs of our customers, we measure and maintain a hold time of less than 20 seconds on average to reach a customer service representative.

ICS representatives can provide our customers with the following support services:

- STAT phlebotomy requests.
- Test code and specimen inquiries.
- Test results and test TAT.
- Additional test requests (test add ons).
- Critical results notifications.
- Problem specimen resolution.

Additional support is available for IT and technical inquiries as well. To reach an Internal Customer Service representative, please call 954-777-0018, and dial extension 501.