

LABSCOPE

The AMA Laboratory Newsletter

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Routine HIV Testing Recommended for Almost All Americans

In a multi-center study published recently in the "New England Journal of Medicine" (2/10/05), two large, federally funded studies found that the cost of routinely testing and treating nearly all adults would be outweighed by a reduction in new infections and the opportunity to start patients on drug cocktails early, when they are most efficacious.

The journal's editorial stated that "given the availability of effective therapy and preventive measures, it is possible to improve care and perhaps influence the course of the epidemic through

widespread, effective and cost-effective screening." The editorial further added that "a failure to institute such screening at doctors' offices and clinics would be a critical disservice to patients with the AIDS virus and the future health of the nation."

In light of these recommendations, Dr. Robert Janssen, Director of HIV-AIDS prevention at the Centers for Disease Control and Prevention, said CDC will re-evaluate its guidelines over the next two years, and will consider the study's findings as well as the availability of new, rapid HIV tests that produce results in a half-hour instead of the usual week or two.

Early Alzheimer's Test in Development

Currently, the only way to definitively test for Alzheimer's Disease is through the autopsy study of brain tissue. However, if a test is available to detect the onset of Alzheimer's early in the course of the disease, then this could lead to earlier treatment and evaluation of experimental treatment protocols.

In a recent issue of "Proceedings of the National Academy of Sciences" (2/1/2005, a new test methodology for Alzheimer's and other diseases was reported as effective in

measuring the level of amyloid-beta-derived diffusible ligand (ADDL), a small soluble protein that appears to increase in the Alzheimer's patients.

The method needs to be repeated and tested on more patients in order to confirm that ADDL does increase in the presence of Alzheimer's according to some experts. If a relationship is established, the testing could lead to earlier detection and treatment and also allow physicians to follow the effectiveness of treatment.

Collection Tube Alert

1. Adjusted BD Vacutainer SST glass and plastic Tubes Available Now

On February 4, 2005, we sent out a Technical Bulletin to all our clients informing them that the adjusted BD vacutainer SST glass and Plus plastic and SST II blood collection tubes are now available. These adjusted tubes can be used for all chemistry, immunochemistry and other assays requiring serum samples. The new tubes have an **alpha character after the lot number** printed on the label of the tube (example: 430919A). The alpha character can be A, B, C, D, or E. The old serum separator tubes do not have the alpha character after the lot number.

The new tubes should have been delivered to all clients' facility. Therefore, if you still do not have them, please call our Supply Department and request for them.

Please use the adjusted tubes and discard the old tubes for all tests requiring serum separator tubes.

2. For ABO-Rh testing, please submit a lavender tube and/or a pink tube. DO NOT submit red tubes.

REGULATORY REMINDERS

In order to comply with laboratory regulations, the following reminders are being provided to all our valued clients and their respective office staff.

1. Write the ICD-9-CM or Family PACT specific "S" Code.

We continue to receive some requisitions without the ICD-9-CM or Family PACT specific "S" code. Remember that we need the diagnostic code to the highest degree of certainty to process specimens. If we don't have the diagnostic code on the requisition form, we have to call the client to obtain the diagnosis code.

2. Indicate the name of the licensed practitioner ordering the test/s.

By federal and state regulations, only a licensed practitioner may order clinical laboratory tests. The name of the ordering licensed practitioner is required on every test order.

3. Use only the Medicare-approved Organ/Disease Panels.

These are the Basic, Comprehensive, Lipid, Prenatal/Ob-Gyn, Renal and Electrolyte Panels. The components are indicated in the AMA requisition form. Any other panel established for any client is considered customized and must be documented with a medical necessity statement. You may order any component of the panels separately if you don't need to order the entire panel. Ordering tests for screening purposes is not allowed by Medicare.

4. A signed Advanced Beneficiary Notice (ABN) is required for some patients.

If you think that a test may not be covered by Medicare, the patient must be notified that he/she may have to pay for the test you are ordering. The patient has to sign the ABN in this case.

5. Label all specimen containers properly with the patient's full name.

We occasionally receive specimens with incomplete or illegible name, incorrect or not matching the requisition form, or in some cases, containers without any name at all. All these specimens undergo delay in testing because establishing positive identification, correcting names or, in some cases, outright rejection of the specimen has to be done. To avoid this situation, label the containers properly with the correct full name of the patient that matches what is in the submitted requisition form.

BILLING BITS!

Note: This column will appear from time to time to update our clients of any billing changes or information important in properly processing the billing claims for all patients. This will hopefully help our clients and us facilitate better reimbursement claims.

1. Just a reminder to all licensed health care practitioners that Medi-Cal will reimburse for **Chorionic Gonadotropin (beta hCG)** testing only when it is ordered with a diagnosis of Malignant Neoplasm (site specific), Hydatidiform Mole, Ectopic Pregnancy, or supervision of a normal pregnancy (V22.0-V22.1). It is specifically not reimbursable with a diagnosis of V22.2 (normal pregnancy). The Presumptive Eligibility (PE) Program will pay for Beta hCG only if an ectopic pregnancy is established.

Beta hCG's ordered for Medi-Cal patients without the proper diagnosis will be billed either to the patient directly or the physician ordering the test.

If you have any questions, please feel free to call our billing department, or check your Medi-Cal Provider Manual, Section 2, pages path chem. 5 and presum 18.

2. Please attach a copy of the patient's current Medi-Cal card to each requisition. The patient's Medi-Cal number can change and we need the most current date of issue as well as the date of birth. A few extra minutes in preparing the requisition and attaching the necessary copies can save all of us from phone calls and faxes.

LABORATORY UPDATE

1. C-reactive Protein (CRP) Testing

We occasionally get inquiries about high sensitivity CRP (hs-CRP) testing and its difference from wide range CRP (wrCRP) testing. When CRP level measurement for cardiac testing was first introduced, most IVD companies offered a separate CRP test for cardiac testing (so-called cardiac CRP) such that the assay could measure low levels of CRP down to about 0.0 – 0.25 mg/dL, usually using latex particle-enhanced turbidimetric methods. A separate assay for CRP measurement due to inflammation (so-called regular or inflammation CRP) is also available which can measure down to about 0.0- 0.8 mg/dL, usually using immunoassay methods. It is obvious that the lowest level of CRP measurement is very similar for both types of assays. In time, some IVD manufacturers introduced the so-called wide-range CRP using the more sensitive particle-enhanced turbidimetric method with an analytical range starting from 0.012 mg/dL up to the level of the highest calibrator of the assay. With this method, both the “cardiac” and “inflammation” levels are covered.

We currently offer both the high sensitivity and wide-range CRP testing methods.

2. Coagulation and Hemostasis Testing

We are currently validating a new instrument from Dade Diagnostics that will enhance our coagulation testing menu. In addition to the PT, PTT, and INR measurements, the new instrument can assay for D-dimers, Extrinsic Factor, Intrinsic Factor, Thrombin, Fibrinogen, Protein C, Protein S, Lupus anticoagulant, Factor VIII and von Willebrandt factor. The introduction of these assays will reduce the turn-around time for these tests since they will now be run in-house.

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