

**ALLINA MEDICAL LABORATORIES
OCTOBER 2004
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ALLINA MEDICAL LABORATORIES OCTOBER 2004

BLOOD BANK / TRANSFUSION SERVICES

❖ NEW BLOOD BANK COMPUTER SOFTWARE IMPLEMENTED

On October 2, 2004, Allina Medical Laboratories completed the transition to our new Blood Bank computer software, SafeTrace Tx. All Allina Medical Laboratories' metro laboratories at Abbott Northwestern, Mercy, Unity, and United Hospital are now using SafeTrace Tx. SafeTrace Tx has many safety enhancements built into the system that assure accurate result reporting, reducing clerical errors and report corrections.

We're hoping this transition will be fairly transparent to our clients, but there will be a few changes.

REPORTS

Blood Bank reports from SafeTrace Tx will no longer be sent separately. Blood Bank reports will now come out of our LIS, ULTRA, appearing with your other clinical reports. Blood Bank results will also be available for review in the Horizon Ambulatory Care system as well as the Excellian Electronic Medical Record. The actual results will look the same, with the exception of the Rh type for Rh negative individuals and Antibody Titers as explained below.

RESULTS FOR WEAK D TESTING and ANTIBODY TITERS HAVE CHANGED

WEAK D TESTING

Prior to SafeTrace Tx implementation, weak-D neg individuals were resultated as Rh neg and weak-D pos individuals were resultated as Rh pos.

With SafeTrace Tx, individuals requiring weak-D testing will be resultated as follows:

ABO and Rh screen: O, see weak-D

The results of the weak-D test will be reported separately as:

Weak D: Negative OR Weak D: Positive

Brief Background/Principles:

Red blood cells that appear to be D (Rh) negative by direct test methods may be further tested to detect weaker expressions of the D (Rh) antigen by the weak-D test. Red cells demonstrating the weak-D antigen with this additional testing are described as "weak-D" (in the past called Du-positive) and are considered D (Rh) positive. The Blood Bank currently performs weak-D testing on our reference lab client specimens to determine if pregnant patients are candidates for Rh immune globulin (Rhlg). The following women are NOT Rhlg candidates:

1. D-positive women
2. D-negative women who deliver D-neg or weak-D neg infants
3. D-negative women who are actively immunized to the D antigen

Bottom Line:

Anytime you see "see weak D", see the separately issued weak-D result to determine if the patient is Rh positive or Rh negative.

ANTIBODY TITER

Antibody titers will now be resulted in whole numbers.

We have made this change at this time to ensure uniformity between institutions and to comply with American Association of Blood Banks recommendations.

Rationale:

The definition of antibody titer is the reciprocal of the highest dilution of plasma/serum that gives a 1+ reaction. For example, an antibody that reacts up to a dilution of 1:16 has a titer of 16. An antibody that reacts only in straight serum (undiluted) will have a titer of 1.

If you have any questions regarding these changes, please feel free to contact Marisa Peterson, Allina Medical Laboratories Technical Consultant for Blood Bank at 612-863-4382.

CHEMISTRY

❖ BNP CHANGES

Effective *immediately*, Allina Medical Laboratories will discontinue performing proBNP testing and replace it with the Biosite BNP (Brain Natriuretic Peptide) test. This change is being made in response to numerous requests by staff physicians to switch back to the BNP assay. This change will affect all Allina Metro Hospitals (Mercy, Unity, United, and Abbott-Northwestern) and Reference Laboratory. The Biosite BNP assay will be available 24 hours / day, 7 day's per week and may be ordered on a STAT basis.

BNP (Brain Type Natruietic Peptide) is used as an aid in the diagnosis of congestive heart failure. BNP is stored in and secreted predominantly from membrane granules in the heart ventricles, and is continuously released from the heart in response to both ventricle expansion and pressure overload.

TEST INFORMATION:

Test Name: BNP
Test #/Code: 5531/BNP
Specimen Type: EDTA Purple Top
Specimen Handling: BNP must be performed within 4 hours of collection. If unable to perform the test within 4 hours, spin, separate, and freeze plasma at -20 degrees C.
Day / Time performed: 24 / 7, May be ordered STAT
Reference Range: 0 - 100 pg/ml

Please contact Jorge Ferreiro, M.D. in the pathology department at Abbott Northwestern (612-863-4685), or Tom Massmann, Chemistry Technical Consultant if you have any questions (612-863-4223).

❖ TSH REFERENCE RANGE CHANGE

Effective immediately, Allina Medical Laboratories has changed the upper reference interval for TSH from 5.6 μ IU/ml to 2.5 μ IU/ml. The lower reference interval will remain unchanged at 0.34 μ IU/ml (New Reference Interval: 0.34 μ IU/ml - 2.50 μ IU/ml). This change will affect all Allina Metro Hospitals (Mercy, Unity, United, and Abbott-Northwestern) as well as the Reference Laboratory. The National Academy of Clinical Biochemistry has recommended that laboratories adopt the new upper reference interval for TSH. The reasons for this include:

1. Improved sensitivity and specificity of monoclonal antibody assays for TSH.
2. Recognition that rigorously screened normal "euthyroid" patients have a lower upper reference interval.
3. Increased TSH values increase the odds ratio of developing hypothyroidism in the future, especially if thyroid antibodies are elevated.

Patients with sub-clinical thyroid disease may or may not require further treatment and physicians are urged to consult an endocrinologist or the medical literature (JAMA 2004;291:228-238) for help in making this decision.

This is a change in Reference Range ONLY. This is not a change in methodology.

Please contact Jorge Ferreiro, M.D. in the pathology department at Abbott Northwestern (612-863-4685), or Tom Massmann, Chemistry Technical Consultant if you have any questions (612-863-4223).

❖ SWEAT CHLORIDE TESTING

Effective immediately, Sweat Chloride testing will be done only at the Mercy Hospital laboratory. Testing is performed at either 10:15am or 1:15pm and must be scheduled ahead of time. Please direct your patients to call 763-236-8158 to schedule an appointment for Sweat Chloride testing.

❖ BD VACUTAINER (SST TUBE) IMMUNOASSAY INTERFERENCE

Allina Medical Laboratories has been notified by BD Diagnostics of the possible over-recovery of Total T3, Total T4, Serum Folate, Vitamin B12, FSH, CA 27.29, and an increased false positive rate for Hepatitis B Surface Antigen when specimens are collected in BD Vacutainer® SST glass and Plus plastic tubes. This over-recovery has been identified when testing for the assays listed above was performed on the Beckman Coulter Access®, Bayer ADVIA Centaur® and ACS:180® systems, and the DPC IMMULITE® systems. An increased initial and/or repeat reactive rate was found when using the Abbott Diagnostics AUSZYME Monoclonal Assay.

Allina Medical Laboratories uses the Roche Elecsys Modular Analytics E170 analyzer to perform Total T3, Total T4, Serum Folate, Vitamin B12, and FSH testing. We have been notified by Roche Diagnostics that all of the listed analytes have been evaluated with specimens collected in BD Vacutainer® SST tubes and exhibited no significant effect on recovery for any of the assays listed. Specimens for these tests can continue to be submitted in BD Vacutainer® SST tubes

AML sends all Hepatitis B Surface Antigen tests to Memorial Blood Center; Memorial Blood Center does not use the Abbott Diagnostics AUSZYME Monoclonal Assay. Specimens for these tests can continue to be submitted in BD Vacutainer® SST tubes.

Allina Medical Laboratories sends all CA 27.29 tests to Quest Diagnostics. Quest does perform CA 27.29 testing on the Bayer Centaur® and recently notified AML of the issue of over-recovery of CA 27.29 with their method. **Due to this over-recovery, Quest Laboratories recommends that specimens for CA 27.29 be collected in a plain red top tube. Specimens received in an SST will be rejected.**

BILLING AND COMPLIANCE

❖ XIFIN IMPLEMENTED 10/1/04

On October 1, Allina Medical Laboratories implemented a new billing system, Xifin, which will be used for all reference lab client and third party billing. Beginning with your November invoices, you will see a new format to the invoice. Additionally, you may receive invoices from both the old and new systems for a couple of months if you have an outstanding balance from prior to October 1, 2004. If you have any questions regarding the new invoices, please contact your AML Account Representative or call lab billing customer service at 612-775-9300 or email LabBilling@allina.com

❖ CHANGES IN DAILY BILLING SHEETS

In response to client feedback, the font of the daily billing sheets has been increased to make them more readable.

With the implementation of the new billing system, we needed to remove pricing from our LIS system which is used to generate the daily billing sheets that some clients receive. For all samples collected on or after 10/1/04, daily billing sheets will no longer contain prices but will instead display with a \$0.01 charge. This change was made to eliminate the need to try to maintain accurate pricing in two systems. Going forward, all AML reference lab pricing will be maintained and updated in Xifin only. All clients should have access to their fee schedule in order to obtain AML pricing for specific tests. For pricing or CPT information on tests not listed in your fee schedule, please use the CPT/Client Fee Request Form.

❖ NEW INVOICES WILL ARRIVE IN NOVEMBER

With the new billing system comes a new invoice format (please see attached example of blank invoice form). We've added a column for accession number (this number will be the key when referencing charges to be corrected going forward) as well as separate columns for charge versus credit to help you clearly distinguish between the two. You will also notice that under the account number there will now be a four letter alpha code (the same as your client collection center code) rather than your former twelve digit numeric account number. Hopefully this will make things easier when requesting billing adjustments.

Additionally, please see the attached revised Billing Correction Form. Please begin using this new form immediately. For those customers preferring an electronic version, it is also available on the AML website. The former SSN field has been replaced with an Accession Number field. The accession number can currently be found on your invoices and lab reports (on your Xifin invoices it will begin with XO4...during 2004, and on your lab reports it will display as 04...). We are investigating the feasibility of having the accession number added to the client daily billing sheets as well.

HISTOLOGY

❖ DIRECT IMMUNOFLUORESCENCE ASSAY NOW AVAILABLE

AML and HPA (Hospital Pathology Associates PA) are pleased to announce that our new Direct Immunofluorescence (DIF) assay for skin biopsies is now available!

Skin biopsies for DIF should be submitted in Zeus transport media along with a completed AML Immunofluorescence Request. The media and request forms are available in our electronic Supply Catalog at www.allina.com/medicallaboratories, or by calling the AML Supplies Department at 612-863-4678, Option 2.

Specimens submitted for DIF are treated with fluoresceinated antibodies and analyzed with a fluorescent microscope. Our HPA Board-Certified Dermatopathologists have abundant experience in interpreting DIF specimens, which can be critical in establishing several diagnoses. The conditions include autoimmune bullous diseases (e.g. Pemphigus, Bullous Pemphigoid and Dermatitis Herpetiformis), connective tissue diseases (e.g. Lupus Erythematosus and Dermatomyositis) and some forms of vasculitis (e.g. Henoch-Schonlein Purpura).

If you need assistance in obtaining supplies for this testing, please contact your AML Account Representative. Technical questions may be directed to Dr Rob Werling (651-241-5236) or Dr Pam Sakkinen (651-241-8779).

MICROBIOLOGY

❖ CLOSTRIDIUM DIFFICILE TOXIN A/B CONTAINER CHANGE

In order to make submittal of specimens easier, the enzyme immunoassay kit for testing for *Clostridium difficile* toxins A and B (6588/CDT) has been changed to allow transport of the stool specimen in Cary Blair (C&S) Transport vials, refrigerated or room temperature, within 5 days. Unpreserved stool specimens must be submitted refrigerated within 48 hours.

Information regarding this change is included in the Collection Manual update attachment at the end of this newsletter.

SENDOUTS

❖ SCREENING FOR SYPHILIS

When screening for syphilis, the most appropriate test to order is the RPR Syphilis Screen (714/RPR). If the result of this screening test is reactive, per Minnesota law, the specimen will be forwarded to the MN Board of Health for the FTA-ABS confirmatory testing.

The FTA-ABS test will be performed only if the RPR is reactive, or if the physician indicates possible neural syphilis. Once a patient has a reactive FTA-ABS, it will remain active for life.

❖ SPECIMEN QUANTITY PROBLEMS

The AML Send Outs Department has seen an increase in specimens identified as insufficient specimen quantities when Vitamin D, 25 Hydroxy (113/VTD) and Vitamin D1, 25 Dihydroxy (293/VD1) are submitted together. Clients submitting both tests have not been sending enough serum for both tests to be completed.

In order to assure adequate specimen volume to perform both tests, specimen quantity for each of these tests is now 2ml of frozen serum. If you are submitting both of these tests on a patient, a total of 4mls of frozen serum must be sent in order for both tests to be completed.

The on line Collection Manual has been updated to reflect these changes.

❖ RAPAMYCIN RESULTING CHANGES

The University of Minnesota Physician's Outreach Laboratories has informed AML that due to instrumentation changes in their laboratory, they will be temporarily be reporting out two results for Rapamycin. They will be reporting out both the result from their current instrument, as well as the result from their new instrument.

Rapamycin (5134/RAP) will have both results reported out for approximately two months. An example of how the results will appear on your report from AML follows:

Rapamycin	L	4.5 ug/L	(5.0-15.0)
		New Method Result:	7.4 ug/L
Date of Last Dose		XX/XX/XXXX	
Time of Last Dose		XX:XX	

Testing Performed By
University of Minnesota
Physicians Outreach Laboratories
Minneapolis, MN

CYTOLOGY

❖ THIN PREP PAP COLLECTION REMINDERS

When collecting thin prep pap smears, once the brush/broom has been thoroughly rinsed in the vial liquid, the brush/broom should be removed and discarded. **Please do not leave the apparatus in the vial, as this causes major instrument malfunctions during the specimen processing and slide preparation.**

More detailed instructions for collection of the thin prep pap smear can be found on our web site at www.allina.com/medicallaboratories. The collection instructions are located under the "Collection Details" link under the Collection Manual header in the left hand NavBar.

ANDROLOGY

❖ ANTISPERM ANTIBODIES

Effective October 15, the Andrology laboratory discontinued performing the Kibrick assay as a part of the anti-sperm antibody assay panel on semen and serum samples.

The Kibrick assay is an indirect assay which detects the presence of some forms of anti-sperm antibodies, but nonspecific factors can result in false positive results. The direct and indirect Immunobead assays are more specific, with a lower false positive rate, and have generally replaced the formerly used Kibrick and Isojima assays.

Direct and indirect Immunobead assays will be performed on semen samples, while the indirect Immunobead assay will be used for serum. The Immunobead assays quantify the level of IgG, IgM, and IgA antibodies, and specify the region of antibody binding to the sperm, resulting in more clinically useful information.

❖ DONOR SPERM CONSENT PROCESS

Effective November 15TH, the Andrology laboratory will launch a more streamlined consenting process for patients using donor sperm. There will be 3 short documents for the physician to review with the patient prior to obtaining donor sperm from the Andrology Laboratory. These documents may be faxed directly to the laboratory or photocopied and delivered by the patient prior to obtaining sperm. A copy of these documents along with an instruction sheet listing the requirements for each will be mailed to you in October. Please contact the Andrology laboratory at 612-863-4115 with additional questions.

HELP US HELP YOU

❖ MOLECULAR DIAGNOSTICS 101: CURRENT AND FUTURE APPLICATIONS

AML Continuing Education is pleased to announce our first continuing education seminar.

On October 27, 2004, Dr John Mendiola, Virginia Piper Cancer Institute will be presenting *Molecular Diagnostics 101: Current and Future Applications*.

Molecular assays are increasingly playing a role in clinical diagnostics. The theory, techniques and clinical utility of these molecular assays are frequently not well understood by laboratory, clinical and hospital personnel. This continuing education seminar will:

- Introduce/review basic DNA structure and function
- Provide several examples of current molecular diagnostics assays including the clinical utility of these assays
- Discuss future directions in molecular diagnostic testing including the concept of "Personalized Medicine"

Tuition for this seminar includes conference materials, parking and a light supper. Pre-registration by October 20, 2004, is encouraged. Brochures and registration materials have been mailed. You can also find registration materials on our AML website at www.allina.com/medicallaboratories.

❖ BILINGUAL HPA/AML CUSTOMER PADS

When histology and cytology specimens are submitted to AML with a request to bill the patient's insurance for the work, it is possible that the patient may receive two bills, one from Allina, and the second from Hospital Pathology Associates.

In order to help you explain this to your patients, we have created a bilingual (English-Spanish) information sheet for your use. This sheet comes in pads of 50 sheets, and is available in the Forms-Information Pads section of our electronic Supply Catalog. The catalog can be accessed at www.allina.com/medicallaboratories. You may also order a supply by calling the AML Supply department at 612-863-4678, Option 2.

❖ ADDITIONAL INFORMATION ADDED TO AML HOME PAGE

In order to serve our clients better we continue to add new information and client resources to our AML homepage. If you visit our home page at www.allina.com/medicallaboratories you will find that we have added two new features to our site.

In the left hand NavBar, you will find a link to 'Continuing Education'. Information on upcoming CE events, as well as registration forms can be accessed via this link.

We have also added a section in the main body of the page where you can locate information regarding Collection Manual updates. The section title is 'Collection Manual Changes' and there are links under the title for each month. If you click on the month, a

listing of tests updated will appear, and clicking on the test name itself will take you to the collection detail page for the test so that you can view the information

❖ **CUSTOMER SERVICE FOLLOW-UP PHONE CALLS**

Have you received a follow-up phone call in response to a call that you placed to AML Customer Service?

In order to serve you better, we have initiated a program where we will place occasional follow up phone calls to clients who have contacted our AML Customer Service department. We will be asking a few brief questions in order to obtain feedback from our clients. We will use the information obtained to improve on our service and if necessary, make changes in our processes to serve our clients better.

❖ **COMMUNICATION OF TEST RESULTS**

The results for any testing that you submit to AML can be called to your office if requested. Tests ordered with a STAT priority will be called ONLY if "Call To" is also indicated. When a 'Call To' is indicated, the results will be called to your clinic number unless an alternate number is indicated with the request. If you would like the results called to an alternate number (e.g. pager), please include the number along with your request.

Critical results will always be called to your office. Critical results are flagged on the report as LL (Critical Low/Panic) or HH (Critical High/Panic). A result flagged as H or L (outside of the AML reference range) or # (abnormal non-numeric result) will not be called unless a "Call To" has been requested. Please remember that if you have network or fax reporting, you may receive the hard copy of the critical result before you receive the phone call, as critical results print upon completion and verification.

❖ **COLLECTION MANUAL UPDATES**

An attachment has been included at the end of this newsletter listing updates for your AML Collection Manual. The AML on line Collection Manual has been revised to reflect these changes.

THANK YOU FOR CHOOSING ALLINA MEDICAL LABORATORIES! WE VALUE YOUR BUSINESS!

www.allina.com/medicallaboratories