



## **ALLINA MEDICAL LABORATORIES DECEMBER 2005 UPDATE**

- UPCOMING TUBE LABELING REQUIREMENT CHANGE REMINDER**
  
- BILLING AND COMPLIANCE**
  - National Coverage Determinations (NCD) Update
  - Standing Orders
  - Consult Specimens and Release of Information
  - 2006 CPT Code Changes
  - 2006 Fee Increases
  
- CHEMISTRY**
  - Vancomycin Critical Value Change
  
- CYTOLOGY**
  - Updated Sample Collection Information for ThinPrep Pap Tests
  
- HEMATOLOGY/COAGULATION**
  - Platelet Function Test Update
  - Morphology Reminder
  
- MICROBIOLOGY**
  - GC and Chlamydia Testing Update
  - Collection Manual Change
  - Transport of Urine Culture Specimens
  
- SUPPLIES**
  - New Viral Transport Media
  - Rotation of Stock and Review of Expiration Dates

# ALLINA MEDICAL LABORATORIES UPDATE DECEMBER 2005

## ❖ REMINDER: Tube Labeling Requirements Change Effective 1/1/2006

To ensure quality laboratory results it is essential that all laboratory specimens received by the Allina Medical Laboratories be accurately and legibly labeled. Patient identification on request forms must exactly match patient identification on the specimens.

As shared in our October Update newsletter, effective **January 1, 2006**, Allina Medical Laboratories will require that ***all non-blood bank specimens submitted for testing be labeled with, at a minimum, two identifiers: Patient's full name and one additional unique identifier***, either Date of Birth (DOB) or Social Security Number (SSN). To accommodate the heightened sensitivity to revealing SSN's, the preferred second identifier is the DOB. Specimens received with only a single identifier will be considered mislabeled.

There is no change in the current labeling requirements for Blood Bank testing.

### **Optimal Labeling for Non-Blood Bank Reference Lab Specimens**

- Patient's complete name (First, Middle Initial if available, Last)
- Second unique identifier, either Social Security number (SSN) or Date of Birth (DOB)
- Date of Collection

### **Minimal Labeling for Non-Blood Bank specimens:**

- Patient's first and last name
- Second unique identifier, either Date of Birth (DOB) Social Security number (SSN)

### **Mandatory Labeling for Blood Bank Reference Lab Specimens:**

If any of the following components are missing, the specimen is considered mislabeled and will be rejected.

- Patient's complete name (First and Last)
- Patient's Social Security Number or Epic Number
- Date of Birth if Social Security Number or Epic Number is unavailable
- Date of Collection
- Identity of phlebotomist

## **BILLING AND COMPLIANCE**

### ❖ NATIONAL COVERAGE DETERMINATIONS (NCD) UPDATE

The Centers for Medicare and Medicaid Services (CMS) requires Medicare carriers to establish policies to ensure that the medical necessity of services being paid for the Medicare program. CMS itself established national policies and effective 11-25-2002 implemented National Coverage Determinations (NCD's). Carriers will approve payment only for those particular test procedures when they have determined them to be medically necessary for the patient. As a result, a claim submitted for payment without a specific diagnosis (ICD-9) code that indicates medical necessity will result in a denial of payment for those services. This policy applies to all Medicare part B providers of clinical laboratory services.

To help with this process, effective January 2006, AML will begin to send out request faxes asking for additional supporting diagnosis (ICD-9) codes if a supporting diagnosis code is not received with the test order. The supporting diagnosis (ICD-9) codes will be listed on the sheet to help expedite the process. These will follow just like the other additional information letters that your clinic currently receives. If you should have any questions on this please contact your AML Account Representative.

### ❖ **STANDING ORDERS**

To assure that standing orders used within Allina Medical Laboratories meet the established guideline to allow accurate billing by the laboratory, the following data elements are required:

- Patient Name and Address
- Patient's DOB
- Patient's SS#
- Billing preference (bill insurance or bill client)
- Patient's insurance information (if AML to bill insurance)
- Effective start date and end date (can not exceed 12 months)
- Tests requested
- Testing Frequency (Weekly, monthly, etc.) PRN is not an acceptable frequency
- Diagnosis codes to support medical necessity
- Physician's Full name

If required information is missing, AML will contact your facility to obtain the necessary information.

### ❖ **CONSULT SPECIMENS AND RELEASE OF INFORMATION**

When requesting Allina Medical Laboratories Consult Center to acquire slides for your patient from a non-Allina facility, a Release of Information form must be completed by the patient granting permission. Minnesota State law **requires** that a consent be given for release of information, unless it is an emergency or within a related health care entity for current treatment.

Outside facilities will not release the specimens/slides until such form is sent indicating patient approval. To expedite the process, please forward a Release of Information form with your request for specimen/slide retrieval.

### ❖ **2006 CPT CODE CHANGES**

Due to Technical Consultant review and changes in AMA CPT codes, effective January 1<sup>st</sup>, several CPT code changes will occur. For your convenience, a spreadsheet containing the affected tests along with their old and new CPT codes has been included at the end of this newsletter.

### ❖ **2006 FEE INCREASES**

Due to increases in vendor pricing for some testing and services referred by AML to outside laboratories, effective February 1, 2006, pricing for select tests will be increasing. A listing of these tests, along with the new price, has been included at the end of this newsletter.

## CHEMISTRY

### ❖ VANCOMYCIN CRITICAL VALUE CHANGE

Effective December 1, 2005 the Critical Value /Toxic Value for Vancomycin Trough (963/VNT) will change. In response to a concern from several Infectious Disease Doctors and Pharmacists the toxic value for Vancomycin Trough will be raised to 20 µg/ml (from 15 µg/ml).

This change was necessary for 2 reasons:

1. Many times, the Doctor and Pharmacist want the Vancomycin trough level to be > 15 µg/ml in order to provide the appropriate dose level for their patient.
2. This will also place Allina Medical Laboratories more in agreement with other local and national Reference Laboratories for the reporting of Vancomycin Levels.

When the Vancomycin Trough Level is >20 µg/ml it is considered toxic by laboratory standards. While the result is considered toxic, the patient is in *NO IMMEDIATE DANGER*. DO NOT STOP TREATMENT without checking with the provider.

## CYTOLOGY

### ❖ UPDATED SAMPLE COLLECTION INFORMATION FOR THINPREP PAP TESTS

Cytec Corporation has evaluated a variety of popular lubricants and found that those containing an ingredient known as "carbomers" or "carbopol polymers" are prone to interfere with the ThinPrep Pap test. Cytec does not recommend the use of lubricants, since the ingredients within the lubricant may not be listed. However, if a lubricant must be used due to patient discomfort or use of a plastic speculum, it should be done sparingly, with care to avoid the tip of the speculum.

Usage of lubricant is not recommended by published guidelines (NCCLS Document GP15-A, ACOG Practice Bulletin, No. 45, August 2003). Its use can adversely affect the cervical cytology collection process in many ways, including the following:

- Abundant lubricant on the cervical face will require removal with swabbing of the cervix, which theoretically could remove exfoliated diagnostic cells.
- Residual lubricant could interfere with the endocervical brush and spatula or cervical broom in the acquisition of cervical cells.
- Residual lubricant may create a potential immiscible interface in alcohol-based liquid Pap solutions, leading to potential agglutination and cellular loss.

For those situations identified above in which a lubricant may be used, the following table lists lubricants that do not contain the interfering substance, and medical supply distributors known to us. Please note that this list is not exhaustive and is merely a starting point provided for your reference.

K-Y Jelly®	<ul style="list-style-type: none"> <li>➤ PSS World Medical</li> <li>➤ www.drugstore.com</li> </ul>
Surgilube®	<ul style="list-style-type: none"> <li>➤ PSS World Medical</li> <li>➤ Cardinal Health</li> </ul>
Astroglide®	<ul style="list-style-type: none"> <li>➤ PSS World Medical</li> <li>➤ www.drugstore.com</li> </ul>
Crystelle®	Check with local distributors

If you have any questions, please contact Cytec's Technical Support Department at 1-800-442-9892, option 6.

K-Y Jelly is a registered trademark of Johnson & Johnson.  
Surgilube is a registered trademark of E. Fougera & Co.  
Astroglide is a registered trademark of Biofilm, Inc.  
Crystelle is a registered trademark of Deltex Pharmaceuticals

## HEMATOLOGY/COAGULATION

### ❖ PLATELET FUNCTION TEST ( 6950/PFT) UPDATE

The Platelet Function Test is a very time sensitive assay, and testing must be COMPLETED within four hours of specimen collection. AML has been having difficulty receiving these specimens in a timely enough manner that the specimen can be processed and testing completed within the time limitations.

In order to allow AML staff adequate time to process and test these specimens, the following changes have been made to the Transport/Stability and Collection and Processing Details in the AML online Collection Manual. Please make note of these changes in your hard copy of the Collection Manual.

#### **Transport/Stability:**

Previous: Ambient \*\*\*TIME SENSITIVE \*\*\*

**NEW:** Send by STAT Courier: Ambient: (Room Temperature) \*\*\*TIME SENSITIVE \*\*\*

#### **Collection/Processing Details:**

Previous: Draw with 21G needle. "DO NOT SPIN". It is best if specimens are collected at a testing site. If not - specimen MUST arrive at an AML (ANW, Mercy, Unity, or United) testing lab in time to be processed and run within four (4) hours of collection.

**NEW:** PFT MUST be ordered STAT. Draw with 21G needle. DO NOT SPIN. Best if specimen is collected at a testing facility (ANW, MERCY, Unity, United). If not sample MUST be placed in a STAT bag and STAT couriered to the closest testing facility. MUST arrive at testing facility within 3 hours of collection.

## ❖ MORPHOLOGY REMINDER

With each Morphology specimen/request submitted to AML (470/MOR), a Morphology Form must be completed and submitted to AML before the testing will be completed.

Information that must be included on the form includes:

- Patient Name and second identifier
- Brief pertinent clinical information
- Current or recent therapeutic regimens
- What specific question does the provider wish to have answered in the pathologists report
- Name of ordering provider (printed)
- Date

Pads of Morphology Forms can be ordered on our website at [www.allina.com/medicallaboratories](http://www.allina.com/medicallaboratories), or by calling Customer Service at 612-863-4678. If you have immediate needs for a form, PDF files are also available to print from our website under the *Forms* link.

## MICROBIOLOGY

### ❖ GC AND CHLAMYDIA TESTING UPDATE

Since our September conversion to the Gen-Probe Aptima GC and Chlamydia transport/testing, AML has had to reject a significant number of specimens due to improper specimen collection.

#### ***Please Note:***

Transport swab containers must contain one blue shafted swab for both male and female patients

Containers with the large white swab will be rejected. The white swab is used to clean the cervical os and then should be discarded. This is an important step in order to obtain cells containing organisms.

#### **Female Endocervical Swab Specimens:**

1. Remove excess mucus from cervical os and surrounding mucosa using cleaning swab (white shaft swab in package with red printing). **Discard the swab.**
2. Insert specimen collection swab (blue shaft swab in package with green printing) into endocervical canal.
3. Gently rotate swab clockwise for 10 to 30 seconds in endocervical canal to ensure adequate sampling.
4. Withdraw swab carefully; avoid any contact with vaginal mucosa.
5. Remove cap from swab specimen transport tube and immediately place specimen collection swab into specimen transport tube.
6. Carefully break swab shaft at scoreline; use care to avoid splashing contents.
7. Re-cap swab specimen transport tube tightly.

## **Hysterectomy Patients: GC and Chlamydia Testing**

GC and Chlamydia Probe testing can be performed on urine specimens from hysterectomy patients, since vaginal specimens are unacceptable.

For hysterectomy patients, this provides an easier collection alternative to Chlamydia trachomatis Culture and GC Culture which require two different transport systems, M4 transport tube and a charcoal swab, respectively. Probe testing of urine also provides a faster turnaround time of one day, Monday – Friday, versus 3-4 days for cultures.

Please submit the urine specimen in a Gen-Probe Aptima Urine Transport tube, filled within the “Fill Area”. *Patient should not have urinated for at least 1 hour prior to specimen collection and should not cleanse the labial area prior to urine collection.*

The only specimens that are currently FDA-approved for GC and Chlamydia Probe testing are:

*Female blue-shafted endocervical swab or urine  
Male blue-shafted urethral swab or urine*

*Specimens not received in the appropriate container, or not containing the appropriate swab will be rejected.*

<b>Chlamydia trachomatis Probe vs Patient Infected Status</b>		
<b>Specimen</b>	<b>Sensitivity (%)</b>	<b>Specificity (%)</b>
Female endocervical swab	94.2	97.6
Female urine	94.7	98.9
Male urethral swab	95.9	97.5
Male urine	97.9	98.5
Overall	95.9	98.2

<b>Neisseria gonorrhoeae Probe vs Patient Infected Status</b>		
<b>Specimen</b>	<b>Sensitivity (%)</b>	<b>Specificity (%)</b>
Female endocervical swab	99.2	98.7
Female urine	91.3	99.3
Male urethral swab	99.1	97.8
Male urine	98.5	99.6
Overall	97.8	98.9

### **❖ COLLECTION MANUAL CHANGE**

Please note that the transport temperature for the following test has been changed in the AML online Collection Manual:

**Test Name:** Vaginal/Rectal Strep Culture  
**Test Code:** 6568/VRS  
**Transport:** Ambient (previously indicated refrigerated)

Please make this update to your hard copy of the AML Collection Manual.

### **❖ TRANSPORT OF URINE CULTURE SPECIMENS**

The AML Microbiology department would like to remind all clients to please submit all urine specimens for Urine Culture or Urine Culture, Additional Workup (6564/UC or 6680/UCA) in grey top urine culture preservative tubes. Preservation of the urine specimens reduces

overgrowth of pathogens by contaminants and decreases the number of unsatisfactory urine cultures due to contaminants.

Urine culture preservative tubes can be ordered using our online supply catalog at [www.allina.com/medicallaboratories](http://www.allina.com/medicallaboratories), or by contacting AML Customer Service at 612-863-4678.

## SUPPLIES

### ❖ NEW VIRAL TRANSPORT MEDIA

AML has been notified by ViroMed that they will be transitioning from their current red cap M4-RT and blue capped M4 Transport Media (Mycoplasma/Ureaplasma) to one Universal Transport Media (UTM-RT) that can be used for collection of Virus, Chlamydia, Mycoplasma and Ureaplasma culture specimens. As our current supplies of the room temperature M4-RT and refrigerated M4 are exhausted, we will begin to issue the new product. UTM-RT comes in a purple capped tube and can be stored at *room temperature prior to use*.  
Specimen Collection and Handling:

**Swabs:** Place swab into medium and break off shaft

**Tissue/Scrapings:** Place a small portion into the medium

*Once the medium has been inoculated with specimen, it should be stored and transported at refrigerated temperatures.*

The AML on-line Supply Catalog and the AML Microbiology & Virology Resource are being updated to reflect these changes.

If you have any question about this new product, please contact your AML Account Representative.

### ❖ ROTATION OF STOCK AND REVIEW OF EXPIRATION DATES

In order to ensure stability of specimens during transport, it is necessary that they be sent in the proper containers and in transport media that has not exceeded its expiration date.

Recently AML has received specimens in transport media that expired in 2004. Suppliers and manufacturers imprint expiration dates in different formats. It is very important to make sure that stock is rotated and expiration dates reviewed so that the oldest stock is used first, and prior to expiration.

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

[www.allina.com/medicallaboratories](http://www.allina.com/medicallaboratories)