



**ALLINA MEDICAL LABORATORIES
APRIL 2007
UPDATE**

❑ BILLING AND COMPLIANCE

- CPT/Fee Request Form Updated

❑ CHEMISTRY

- Serum/Urine ELP Reflex Testing Change
- Hepatitis and HIV Testing Brought In-House
- SJA Testing Brought In-House
- ENA Testing Brought In-House
- Vancomycin Reference Range Change

❑ CYTOLOGY

- Reporting of HPV Results

❑ HISTOLOGY

- Diagnosis of Onychomycosis (Fungal Infection of Finger and/or Toe Nails)

❑ MICROBIOLOGY

- Improve Your Diagnosis Of Vaginitis With The Vaginal Trichomonas, Gardnerella, Candida DNA Probe Test
- Antimicrobial Susceptibilities Card

❑ SENDOUTS

- Kappa & Lambda Light Chain Testing Update
- Lead, Blood (147/PB) Alternate Collection Available
- Histoplasma Antigen Reference Range Changes
- Phenolphthalein, Feces Testing Discontinued

❑ HELP US HELP YOU

- Keeping Your Physician List Current
- Packaging Specimens for Courier Transport

ALLINA MEDICAL LABORATORIES UPDATE

APRIL 2007

BILLING AND COMPLIANCE

❖ CPT/FEE REQUEST FORM UPDATED

The AML CPT/Fee Request Form has been updated to include patient specific requests. When requesting CPT/Fee information, please include the patient information. This will help the Billing staff define the tests more accurately.

The updated form is available on our website at www.allina.com/medicallaboratories as either a PDF that can be printed, completed and faxed in, or as an interactive Word document that can be completed on line, saved and emailed in to billing. Click on the Forms link in the left hand column and then on CPT-Fee Request.

AML Billing Fax Number: 612-262-5965
AML Billing email address: LabBilling@allina.com

CHEMISTRY

❖ SERUM/URINE ELP REFLEX TESTING CHANGE

Allina Medical Laboratories has changed the way Serum and Urine ELP's are ordered and reflexed. This change will give the ordering physician the ability to state whether they would like the Serum or Urine Immunofixation test added to an ELP with an identified monoclonal peak. There are three tests that will be affected by this change:

- ❖ Protein ELP, Serum 216/SER
- ❖ Protein ELP, 24 Hr Urine 218/UEP
- ❖ Protein ELP, Random Urine 3218/REP

In the Excellian, Horizon, and STAR computer systems, when any of these tests is ordered, the physician will be required to answer Yes or No to the question "Reflex to IFIX if Monoclonal Peak present?" Based on the answer to this question, the appropriate IFIX will be performed if a Monoclonal Peak is observed. If you are submitting testing on a manual requisition, and you would like to order the reflex test, please indicate "Reflex to IFIX if Monoclonal Peak present".

❖ HEPATITIS AND HIV TESTING BROUGHT IN-HOUSE

We are pleased to announce that on AML has brought Hepatitis and HIV testing in-house. The tests included are:

HAV: Hepatitis A Total (Anti HAV)

- A Reactive result will auto-reflex to HAV IgM

HAM: Hepatitis A IgM (IGM Anti-HAV)

AHB: Hepatitis B Antibody (Immune Status)

HBS: HBsAg (Hepatitis B Surface Antigen)

- An Equivocal or Reactive result will auto-reflex to HBsAg Neutralization

HBC: Hepatitis B Core (Anti-HBC)

HBM: Hepatitis B Core IgM (IgM Anti-HBC)

HCV: Hepatitis C Antibody (Anti-HCV)

- An Equivocal or Reactive result will auto reflex to HCV RIBA
- A Reactive result that exceeds a Signal to Cutoff Ratio of 11.0 (high positive) will be resulted as Reactive, no confirmation required.

AHP: Acute Hepatitis Panel (Includes HAM, HBS, HBM, and HCV)

H12: *Anti-HIV 1 & 2*

We will also be offering a new second Anti HCV test, Hepatitis C Antibody with Quantitation (HCQ).

Changes for the above tests, as well as complete information for the new HCQ are as follows:

TEST NAME	HAV ANTIBODY IGG / IGM
Test #/ Ultra Code	693 / HAV
Collect	1 mL Serum
Performing Lab	AML
Days Set up	Monday – Saturday
Expected TAT	1 Day
Reference Range	Non-reactive
Collection & Processing Details	This test detects both IgG and IgM antibody fractions. “Reactive” results REFLEX to HAV IgM
List Price	\$15.30

TEST NAME	HAV IGM ANTIBODY
Test #/ Ultra Code	1172 / HAM
Collect	1 mL Serum
Performing Lab	AML
Days Set up	Monday – Saturday
Expected TAT	1 Day
List Price	\$19.80

TEST NAME	HBS ANTIBODY	
Test #/ Ultra Code	689 / AHB	
Collect	1 mL Serum	
Performing Lab	AML	
Days Set up	Monday – Saturday	
Expected TAT	1 Day	
Reference Range	Accepted criteria for immunity to HBV, in	accordance with CDC
Guidelines, is an	Anti-HBs Index Value of ≥ 1.00 . An Index	Value of 1.00 is
equivalent to 10 mIU/ml.		
List Price	\$11.70	

TEST NAME	HBS ANTIGEN	
Test #/ Ultra Code	686 / HBS	
Collect	1 mL Serum	
Performing Lab	AML	
Days Set up	Monday – Saturday	
Expected TAT	1 Day	
Collection &		
Processing Details	“Reactive” results will REFLEX to HBsAg	Neutralization test
(CPT Code 87341 –	List Price \$31.50)	
List Price	\$11.20	

TEST NAME	HBV CORE ANTIBODY, TOTAL (IGG &	IGM)
Test #/ Ultra Code	688 / HBC	
Collect	1 mL Serum	
Performing Lab	AML	
Days Set up	Monday – Saturday	
Expected TAT	1 Day	
List Price	\$11.20	

TEST NAME	HBV CORE IGM ANTIBODY
Test #/ Ultra Code	655 / HBM
Collect	1 mL Serum
Performing Lab	AML
Days Set up	Monday – Saturday
Expected TAT	1 Day
List Price	\$21.60

TEST NAME	HCV ANTIBODY WITH RIBA REFLEX
Test #/ Ultra Code	527 / HCV
Collect	1 mL Serum
Performing Lab	AML
Days Set up	Monday – Saturday
Expected TAT	1 Day
Reference Range	Non-reactive
Collection &	
Processing Details	If result is Equivocal or Reactive, RIBA Confirmation will be performed at additional charge. If result is Reactive with S/CO Ratio ≥ 11.0 , RIBA confirmation <u>WILL NOT</u> be performed (>95% positive rate).
List Price	\$13.50

TEST NAME **ACUTE HEPATITIS PANEL**
Test #/ Ultra Code 696 / AHP
Collect 2 mL Serum
Performing Lab AML
Days Set up Monday – Saturday
Expected TAT 1 Day
List Price \$66.10

TEST NAME **HIV 1 / 2 ANTIBODY**
Test #/ Ultra Code 533 / H12
Collect 1 mL Serum
Performing Lab AML
Days Set up Monday – Saturday
Expected TAT 1 Day
List Price \$12.60

*****NEW*****

TEST NAME **HCV ANTIBODY WITH QUANTITATION**
Test #/ Ultra Code 7789 / HCQ
Collect 2 - Serum Aliquots 1.0 mL each
Container False Bottom transfer vial
Processing Spin, Separate, Freeze
Transport/Stability Frozen: Stable 30 days frozen
Alternate Names Hepatitis C, Anti-HCV
Performing Lab AML
Days Set up Monday – Saturday
Expected TAT 1 Day
Reference Range Non-reactive
Collection & Processing Details Separate serum from cells within 2 hours of collection. Freeze 2 separate aliquots.
If HCV result is Equivocal or Reactive, an HCV RNA and Genotype will be performed at additional cost.
Methodology ICMA
CPT Code 86803
List Price \$13.50

Along with these testing changes, the following tests will ***no longer be available:***

7259/CNR HCV without RIBA Reflex

700/HIV HIV-1 Antibody

If you have any questions regarding the contents of this message, please contact your AML Account Representative.

❖ SJA TESTING BROUGHT IN-HOUSE

Allina Medical Laboratories is now performing **Sjogren's Antibodies (SJA)** testing in-house.

Sjogren's Antibodies SS-A (Ro) and SS-B (La) are used to aid in the differentiation of autoimmune diseases. Antibodies to SS-A (RO) are observed in 70 - 75% of Sjogren's Syndrome and 30 - 40% of SLE cases. Antibodies to SS-B (LA) are observed in 50 - 60% of Sjogren's cases and is specific if it is the only ENA Antibody present. SS-B is also found in 15 - 25% of patients with SLE.

Specimen requirements and test information are included below.

Test Name	SJA (Sjogren's Antibodies)
Test Number/ Ultra Code	648 / SJA
Collect	1.0 ml Serum
Container	Serum Separator Tube (SST)
Processing	Spin, Refrigerate
Transport	Refrigerated
Stability	7 Days when stored at 2° – 8°C
Alternate Names	SS-A, SS-B, Anti-Ro, Anti-La
Performing Lab	AML
Days Set up	Tuesday, Friday
Expected TAT	3 - 4 Days
Reference Range	< 10 u/ml
Methodology	EIA
Critical Values	None
CPT Code	86235 x 2
List Price	\$39.60

If you have any questions in regards to this information, please contact your AML Account Representative,

❖ ENA TESTING BROUGHT IN-HOUSE

On Monday March 5, 2007, Allina Medical Laboratories began performing ENA (Extractable Nuclear Antigen Antibodies) testing in-house.

The Extractable Nuclear Antigen Antibodies, Smith (Sm) and Ribonucleic Protein (RNP) are used to aid in the differentiation of autoimmune diseases. Sm (Smith) Antibody is very specific for Systemic Lupus Erythematosus (SLE) but only occurs in 30 - 35% of SLE cases. Smith antibodies are often associated with renal disease. RNP Antibody is seen in 95 - 100% of mixed connective tissue disease cases. The presence of RNP Antibody and the absence of Sm and dsDNA Antibody is considered specific for Mixed Connective Tissue Disease (MCTD). RNP Antibody is also present in 20 - 30% of SLE and 15 - 25% of Progressive Systemic Sclerosis cases.

Specimen requirements and test information are included below.

Test Name	ENA (Extractable Nuclear Antigen	Antibodies)
Test Number/ Ultra Code	651 / ENA	
Collect	1.0 ml Serum	
Container	Serum Separator Tube (SST)	
Processing	Spin, Refrigerate	
Transport	Refrigerated	
Stability	7 Days when stored at 2° – 8°C	
Alternate Names	Anti-Sm/RNP, ENA Antibody	
Performing Lab	AML	
Days Set up	Tuesday, Friday	
Expected TAT	3 - 4 Days	
Reference Range	< 10 u/ml	
Methodology	EIA	
Critical Values	None	
CPT Code	86235 x 2	
List Price	\$44.20	

If you have any questions in regards to this information, please contact your Allina Medical Laboratories Account Representative,

❖ **VANCOMYCIN REFERENCE RANGE CHANGE**

Effective **Thursday April 19, 2007** the Reference Ranges for Vancomycin Peak (964/VNP) and Vancomycin Trough (963/VNT) will be changing in an effort to align AML Vancomycin Peak and Trough Reference Ranges with the Allina Pharmacy and Therapeutics Committee Dosing Guidelines. The new Reference Ranges are:

Vancomycin Peak:	Current:	20 - 40 µg/mL
	New:	35 - 45 µg/mL
Vancomycin Trough:	Current:	5 - 10 µg/mL
	New:	7 - 20 µg/mL

Please direct any questions to your AML Account Representative.

CYTOLOGY

❖ REPORTING OF HPV RESULTS

The reporting of the ThinPrep® Pap test with HPV testing has undergone a significant change. In the past, reports for Pap tests with HPV (reflex or otherwise) were held until HPV testing was completed and the results available for inclusion into the report. Clinics and health care providers told us that incorporation of HPV results into the Pap test report, while beneficial, is of secondary importance when compared to turnaround times. In addition, providers often received HPV results before the Pap report, leading to an incomplete clinical impression which could cause confusion when planning patient management.

Therefore, effective immediately, the Pap test interpretation will be reported immediately following screening of the slide, and the HPV results (when ordered as a reflex test or concurrently with the Pap test using the ThinPrep® vial) will be reported independently when they become available. HPV results will no longer appear in the cytologic report.

In addition, if you wish to collect a specimen for HPV testing **only** (no pap collected) be sure to use the Digene® collection vial (see the AML Collection Manual or contact your Account Representative for instructions/supplies) not the ThinPrep® vial. Order the Human Papillomavirus Test (High Risk Panel Only), test 6595/HPV; do not order under the pap test.

On another note, the Cytology laboratory has recently seen an increase in the number of vials being submitted with a cytobrush or broom left in the vial. The presence of the cytobrush or broom can easily damage our ThinPrep® processor. Please make sure to vigorously work the cytobrush or broom against the ThinPrep® vial walls to dislodge cellular material, and then discard the cytobrush or broom.

Please direct any questions regarding this issue to the Cytology laboratory at 612-863-4668.

HISTOLOGY

❖ **DIAGNOSIS OF ONYCHOMYCOSIS (FUNGAL INFECTION OF FINGER AND/OR TOE NAILS)**

Diagnosis of Onychomycosis (fungal infection of finger and/or toe nails) can be confirmed by three different laboratory tests. Confirmation of infection by one of these methods is often required by insurance payors to justify systemic antifungal therapy.

➤ ***KOH Prep, Skin, Hair & Nails (4348/KOS)***

The quickest and easiest is the **KOH Prep**.

This test can be performed in the clinician office or in the laboratory. AML offers this test in Microbiology and can be ordered on an AML Clinical (Blue) requisition.

A specimen is obtained by simply scraping (with a #15 scalpel or curet) the undersurface of an infected nail, after clipping and cleaning it. The scrapings are deposited in a sterile container and transported to AML Microbiology.

The specimen is mounted on a glass slide in a solution of 10% KOH for 30-60 minutes and then examined with a microscope, usually by a Microbiology technologist. The test requires about one hour.

➤ ***Fungus Culture, Skin, Hair & Nails (888/FUH)***

The most time-consuming but most informative test is **Fungus Culture**. AML offers this test in Microbiology and it can be ordered on a Clinical (Blue) requisition.

Specimen collection and transport are identical to KOH prep. Culture may require up to 4 weeks for a result. This test provides information regarding fungal speciation, which is not provided by KOH prep or histology. Most anti-fungal therapies, however, do not depend on speciation.

➤ ***Histology with PAS Stain***

Finally, **histology with PAS** stain is a sensitive and specific test for onychomycosis.

This test is performed in Histology. The specimen consists of nail clippings and/or skin from the nail bed. The specimen should be submitted in formalin with a **Histology Requisition Slip**, labeled with anatomic site (i.e. which nail) **Fungal Stain** marked in the Special Instructions box on the requisition.

This test requires overnight processing and a special histochemical stain; it is interpreted by a pathologist. Results are usually reported within two business days.

A copy of the AML Histology Requisition has been included at the end of this newsletter for your reference. If you do not have a Histology Requisition Slip and would like to obtain a supply, please contact your AML Account Representative

MICROBIOLOGY

❖ IMPROVE YOUR DIAGNOSIS OF VAGINITIS WITH THE VAGINAL TRICHOMONAS, GARDNERELLA, CANDIDA DNA PROBE TEST

The Wet Prep is only 50-75% sensitive. While the Vaginal Trichomonas, Gardnerella, Candida DNA Probe cannot be performed during the patient visit, it has higher sensitivity and specificity for more accurate diagnosis and treatment.

Organism	Sensitivity	Specificity	Overall Accuracy
<i>Gardnerella vaginalis</i>	95%	100%	98.5%
<i>Trichomonas vaginalis</i>	92%	100%	95.3%
<i>Candida species</i>	82%	98%	95.2%

OTHER ADVANTAGES:

- With the DNA Probe there is no loss of *Trichomonas* due to greater than 1 hr. delays as in wet prep testing. The DNA Probe transport media maintains the DNA for up to 72 hr after collection.
- Mixed infections occur in up to 25% of patients. A patient with a positive wet prep for *Trichomonas* may also have bacterial vaginosis. *Gardnerella* is the sentinel indicator for bacterial vaginosis on the DNA probe.
- Wet preps have both false positives and false negatives. The DNA probe only detects clinically relevant levels of *Gardnerella* and *Candida*, minimizing false positives.
- Unlike the Wet Prep, with the DNA Probe test, there is no interference with vaginal lubricants or menstruation.
- The DNA Probe test is performed 7 days/week, 24 hr/day.

Test Name: VAGINAL TRICHOMONAS, GARDNERELLA, CANDIDA DNA PROBE

Test Code/#: TGC/7763

Performing Lab: AML

Days Performed: 7 days/week, 24 hr/day

TAT: Stat - 2 hr after receipt
Routine - 8 hr after receipt

Specimen Type: Vaginal only

Container: BD Affirm VPIII Ambient Temperature Transport System (includes collection swab, transport reagent, and transport tube). Collection swab included must be used. These transport systems can be ordered via our on-line Supply Catalog at www.allina.com/medicallaboratories

Unacceptable:

- Swabs other than the Affirm VPIII swab.
- No swab in the transport tube.
- Urethral and other non-vaginal sources.

Transport: Ambient temperature or refrigerated within 72 hr of collection

**Reference
Range:**

Trichomonas Probe - Negative
Gardnerella Probe - Negative
Candida Probe - Negative

CPT Codes: Trichomonas Probe 87660
Gardnerella Probe 87510
Candida Probe 87480

List Price: \$102.60

Specimen collection instruction guides are available to you and can be obtained by contacting your AML Account Representative.

❖ ANTIMICROBIAL SUSCEPTIBILITES CARD

Enclosed with this newsletter is a card with the summary of the 2006 antimicrobial susceptibilities of the major pathogens isolated from patients from Allina Medical Laboratories Reference Lab, outpatient clinics, and emergency departments of Abbott Northwestern, Mercy, United, and Unity Hospitals. This information is also available on the AML website, www.allina.com/medicallaboratories.com. Contact your AML Account Representative for additional cards.

The intent of this card is to provide a preliminary guide to susceptibilities. This information should be used together with the specific susceptibility results of the isolated organism and guidelines from current publications.

For further information, contact Jo-Ellen Abraham, Microbiology Technical Consultant, JoEllen.Abraham@allina.com, 612-863-8396, or James Strom, M.D., Medical Director of the Microbiology Laboratories, 612-863-4636.

SENDOUTS

❖ KAPPA & LAMBDA LIGHT CHAIN TESTING UPDATE

Effective April 23, 2007 Mayo Medical Laboratories (MML) will no longer offer Kappa & Lambda Light Chain Urine Tests, MML test #'s 91436 (24 Hr) and 91315 (Quant).

There is one new test that will be replacing both; MML #87934, Immunoglobulin Total Light Chains, Urine.

The discontinued tests were going to Focus Diagnostics for testing and the new test will be performed at MML.

At this time, there will be no change in the price or CPT codes, only the location where the testing will be performed.

The Reference Values for the new test, Immunoglobulin Total Light Chains, Urine, will be slightly different:

Kappa Total Light Chain, Urine

Current: 1.5 mg/dl
New: <0.68 mg/dl

Lambda Total Light Chain, Urine

Current <2.0 mg/dl
New: <0.40 mg/dl

The new test also provides a ratio:

Kappa/Lambda TLC Ratio, Urine = 0.7 - 6.2

The AML Collection Manual will be updated to reflect these changes at the appropriate time.

❖ LEAD, BLOOD (147/PB) ALTERNATE COLLECTION AVAILABLE

Please note that there is a new alternate collection available for Lead, Blood (147/PB). Although the preferred container is still the Tan Lead Free Tube, Clients can now collect either the tan or a Royal (Navy) Blue EDTA.

Test Name: LEAD, BLOOD
Test Number: 147/PB
Collect: 3 ml Whole Blood
Alternate Collect: Royal (Navy) Blue EDTA
Container: Tan - Lead Free Tube
Processing: Do Not Spin
Transport/Stability: Refrigerated

❖ HISTOPLASMA ANTIGEN REFERENCE RANGE CHANGES

Effective immediately, Mayo Medical Laboratories (MML) has revised the reference ranges for the Histoplasma Antigen, Blood and Urine.

Test Name: *Histoplasma Antigen, Blood*

Test #/Code: 2342/HSB

Ref Ranges: None Detected = Negative
<0.6-3.9 ng/ml = Low Positive
4.0-19.9 ng/ml = Mod Positive
20.0->39 ng/ml = High Positive

Test Name: *Histoplasma Antigen, Urine*

Test #/Code: 2343/HSU

Ref Ranges: None Detected = Negative
<0.6-3.9 ng/ml = Low Positive
4.0-19.9 ng/ml = Mod Positive
20.0->39 ng/ml = High Positive

❖ PHENOLPHTHALEIN, FECES TESTING DISCONTINUED

Mayo Medical Laboratories (MML) has discontinued the Phenolphthalein, Feces (4780/PEF) test. This test was originally designed to look for laxative abuse by testing for phenolphthalein in feces. Phenolphthalein was found to be a carcinogen and was banned from use in laxatives in 1999. Old laxatives that contained the product are now out of circulation; therefore, the test is being discontinued.

HELP US HELP YOU

❖ KEEPING YOUR PHYSICIAN LIST CURRENT

Please review your AML requisitions on a regular basis to make sure that we are maintaining a complete and accurate physician listing for your clinic. If any updates (removals or additions) are needed, please contact your Account Representative.

❖ PACKAGING SPECIMENS FOR COURIER TRANSPORT

To aid in proper storage temperature during transport, and the most efficient delivery of specimens to the appropriate laboratory, please package each of the following specimen types in their own individual courier bag:

- Clinical Refrigerated
- Clinical Room Temperature
- Cytology
- Anatomic Pathology/Histology

If you have any questions about this, please contact your AML Account Representative.

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