



# 2010 Catalog and Information Guide for Proficiency Testing

Improving Quality Care Through Accurate Diagnostic Testing



A Service of **ACP**  
AMERICAN COLLEGE OF PHYSICIANS  
INTERNAL MEDICINE | Doctors for Adults

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### Attention: Renewing MLE Participants! Save \$75 on your 2010 enrollment!

Enroll your colleagues in the MLE Program. You AND your colleagues will save \$75. For details, see page 20.

# At a Glance

## Customer Service Hours and Contact Information

Monday through Friday from 9:00 a.m. to 5:00 p.m. ET

**Telephone:** 1-800-338-2746, option 5

**E-mail:** [mle@acponline.org](mailto:mle@acponline.org)

**Fax:** 202-835-0440

**Web:** [www.acponline.org/mle](http://www.acponline.org/mle)

## Event Dates

MLE ships 3 times per year. Enroll anytime of the year.

After the first event, module pricing is pro-rated.

**M1: February 1 • M2: May 10 • M3: September 13**

## Enrollment/Renewal of Proficiency Testing

Whichever method of enrollment you select, once we process your order, you will be mailed an order verification for your review and signature.

**Online Order Form:** Visit [www.acponline.org/mle](http://www.acponline.org/mle). Click on the "Enrollment Info" link. Complete the appropriate electronic order form to automatically calculate pricing, and you will receive an order summary page.

**MLE PT Order Form:** Detach the order form, complete it and fax it. (If submitting a purchase order, please fax.)

**Fax:** 202-835-0440.

### Mail:

Mailing Form with Payment	Mailing Form w/o Payment
RO800 ACP/MLE PO Box 7777 Philadelphia, PA 19175-0800	MLE/ACP Suite 700 25 Massachusetts Ave. NW Washington, DC 20001-7401

## Method of Payment

Enroll now to ensure the availability of specimens for the 2010 program year. We will not bill you until November. Subsequent enrollments will be billed within 1 week after activation and are payable within 30 days. Payment options include credit card (Mastercard or Visa), purchase order, or check.

## Off-Schedule Proficiency Testing

Provides laboratories with an option for immediate, on-demand proficiency testing, a complement to the regular scheduled proficiency testing. For more details on this service, see page 16.

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# Overview

An essential tool for quality improvement, Proficiency Testing (PT) was originally developed as an educational tool to help laboratories investigate internal procedural problems and take corrective action to minimize the effect on patient results. Today, PT is the standard of competency most heavily weighed by regulatory inspectors. MLE's Proficiency Testing (PT) program is designed for easy access, simple performance, and clear reporting.

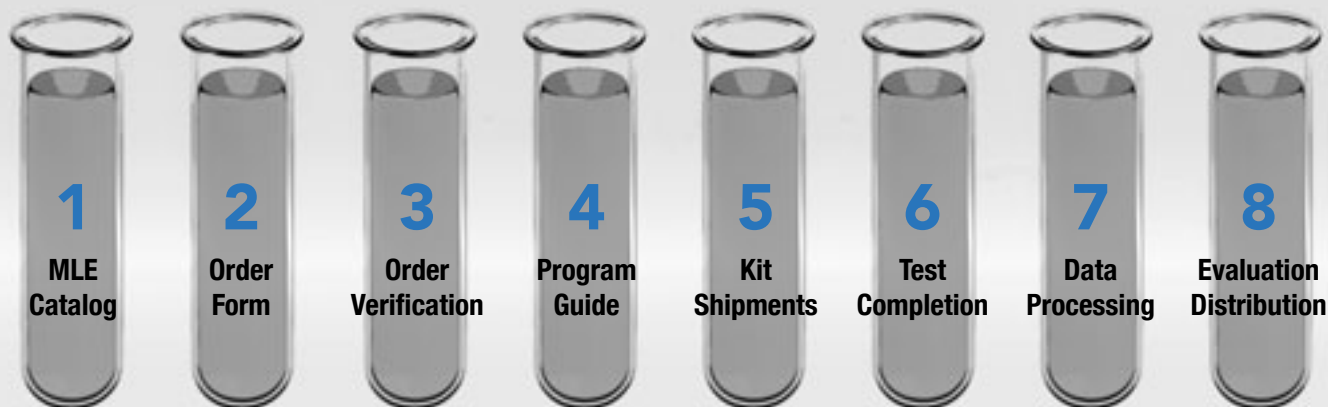
PT is the practice of testing specimens of unknown values sent from an outside source. After submitting your test results, you receive data that compare your laboratory's performance with that of other labs that did the same procedures on the same specimens.

All tests in the MLE Program are included in the same shipment.

## Our Guarantee

If a specimen is missing, leaking, broken, not labeled, hemolyzed, or crushed, and you contact us within three (3) working days of receipt of your kit, we will provide a replacement for the specimen(s) FREE of charge (limited to material availability) or your lab will receive a grading exception for that test.

## How MLE Works



**1** MLE sends you a catalog to review program options.

**2** You complete an online or hard copy order form (page 24) and return it to MLE for processing.

**3** MLE processes your order and sends you an Order Verification for your review and approval.

**4** Approximately two weeks prior to the upcoming shipment, MLE sends you a program guide to prepare for your first testing event.

**5** MLE sends you scheduled shipments of test kits which include specimens to analyze in the same way that you regularly test patient specimens.

**6** Upon completion of the testing, you submit your results via online or by mail to MLE for evaluation.

**7** MLE performs statistical compilation of all participants' results.

**8** MLE mails or e-mails you an evaluation report, graded according to regulatory requirements, that compares your performance with that of other laboratories that used similar methods and instruments.

**832 i-STAT Chemistry—Waived . . . . . \$138**

For i-STAT analyzer. Waived cartridges only.

**Two challenges each.**

<i>Chloride</i>	<i>Glucose</i>	<i>Ionized Calcium</i>
<i>Creatinine</i>	<i>Hematocrit</i>	<i>Potassium</i>
<i>CO<sub>2</sub></i>	<i>Hemoglobin</i>	<i>Sodium</i>
		<i>Urea Nitrogen</i>

**850 Glycohemoglobin . . . . . \$138**

For waived and non-waived methods.

**Two challenges.****871 Whole Blood Glucose—Waived . . . . . \$132**

For waived methods only. Designed to allow the reporting and evaluation of results for as many as five different glucose analyzers.

**Two challenges.****215 Hemoglobin/Glucose . . . . . \$126**

For HemoCue only.

**Two challenges each.****Provider-Performed Microscopy (PPM)****532 Urine Sediment Identification . . . . . \$87****Two challenges consisting of color photographs.****534 Provider-Performed Microscopy (PPM) . . . . . \$90**

Color photographs depicting microscopic fields for the examination of Vaginal Wet Mount Preparations, Vaginal KOH Preparations, Nasal Eosinophils, Fecal Leukocytes, Pinworms, Sperm, and FERN testing.

Urine sediment identification not included.

**Six challenges.****538 KOH Slides . . . . . \$114**

Two fixed glass slides for determining the presence or absence of fungal elements in skin scrapings.

**Two challenges.**

## Lab Supplies & Services

### Supplies

**121 Pipette—1 mL . . . . . \$20**

For use with 320, 321, 845. Reusable Class A volumetric pipette required for reconstitution of lyophilized proficiency testing specimens.

**126 Pipette Pump . . . . . \$24**

For use with product 121 above.

### Services

**107 Hard Copy of Participant Summary for the Year . . \$15****108 Additional Program Binder . . . . . \$15****116 Automatic Program Renewal . . . . . FREE**

Free yourself from re-enrollment/re-ordering hassles. We'll do it for you! See next page for details.

### "E-Notify"

**Notification of newly waived tests and FDA Recalls delivered to your e-mail account . . . . . FREE**

To sign up for "E-Notify," send an e-mail to [mle@acponline.org](mailto:mle@acponline.org).

### Web Data Entry System (WDES)

**Online Result Reporting Program . . . . . FREE**

To register or receive more information, send an e-mail to [ptwebsupport@acponline.org](mailto:ptwebsupport@acponline.org). See next page.

### Off-Schedule Proficiency Testing

**Starts at . . . . . \$200**

Off-schedule proficiency testing (PT) provides laboratories with immediate, on-demand, customized proficiency testing for reinstatement or remedial purposes; a complement to the regularly scheduled PT program.

#### Who Needs Off-Schedule Testing?

- Laboratories with unsuccessful performance (score of less than 80%) for two out of three regular testing events may be required to perform off-schedule PT to lift a "cease-testing" order from their regulatory or accrediting agency. In these cases, two acceptable proficiency performances (score of 80% or better) may be required for the lab to resume testing patients.
- Some laboratories use off-schedule PT to verify that corrective actions were effective.

This service is available to every laboratory, regardless of MLE enrollment status.

For information on cost and availability, contact MLE Customer Service at 800-338-2746, option 5, or e-mail us at [mle@acponline.org](mailto:mle@acponline.org).

# Get more with WDES

- more user-friendly
- more intuitive
- more time savings



MLE's Online Result Entry Program. You will LOVE the significantly enhanced, "user-friendly," intuitive program, complete with:

- Evaluation results (access current and past reports)
- Links to the Participant Summaries, Test Result Form Booklet, and other valuable information.
- It retains your method codes!

## What are you waiting for?

Register for the next event by sending an e-mail request to [ptwebsupport@acponline.org](mailto:ptwebsupport@acponline.org)

## Sign Up NOW for "Automatic Renewal!"

Simple.  
Easy.

Best of all, it's one important management detail that you never have to worry about again!

*We automatically:*

- Renew your enrollment.
- Reorder the modules in which you participated in the previous year.
- Send you a 2010 catalog to see if you would like to make changes to your order and an order verification for your review.
- Send an order change form should you wish to add or delete modules from your renewed order.

You even have time to cancel your order without penalty if you choose by **December 18th!**

To enroll in Automatic Renewal, check the automatic renewal box on the PT order form or the 2010 renewal form.

# How To Order

If you would like assistance with designing the most economical order or have questions about our service or your order, contact MLE for assistance at 1-800-338-2746, option 5, or send us an e-mail at [mle@acponline.org](mailto:mle@acponline.org).

## Order Online with Ease!

[www.acponline.org/mle](http://www.acponline.org/mle)

- Click on the “Enrollment info” link.
- Click on the “2010 MLE PT Order Form” link.
- Complete the electronic form. It will calculate pricing for you. Once you submit the form, it will provide you with a summary of your order to print for your records. That’s it!

If you are ordering an educational resource, click on the Educational Resources link.

## Order By Fax

Complete the PT order form insert (or the Educational Resources order form). Fax your completed order form to MLE: 202-835-0440. If using a PO, please fax a copy of it with the order form.

## Order By Mail

Complete the PT order form according to these instructions and mail it to the address printed on the form.

Note: Purchase Orders (PO) must be accompanied by a renewal form or order form. POs by themselves will not be accepted.

# PT Order Form Instructions

Enroll in MLE by **December 18, 2009**, to ensure you receive shipments for the entire year. You may enroll any time after the first event at a prorated cost depending on the availability of specimens.

## Using the PT Order Form

### Formulate Your Order

Review the catalog to determine the products which best meet your proficiency testing (PT) needs.

Note any instructions that refer to specific regulatory requirements or instrument/method compatibility. Choose the product most appropriate for your testing needs. **Please pay close attention to instrument compatibility notes when selecting hematology modules and coagulation modules.**

### Top Section

Complete the PT order form (last page of catalog).

1. Indicate whether you are new to the MLE program or renewing your enrollment.
2. Print the address of the location where the invoice statement should be mailed (“BILL TO”).
3. Print the name of the laboratory director.

4. Enter the laboratory’s CLIA identification number. If you do not know your CLIA identification number, contact your CMS Regional Office.
5. Print the address of the location where the proficiency testing specimens and program paperwork should be shipped (if different from the “BILL TO” address). We will send the PT specimens via one-day express delivery to the “SHIP TO” address. For this reason, we cannot deliver specimens to a PO Box, so please provide a complete street address.
6. Designate the regulatory agency(ies) or lab consultant(s) to receive a copy of your PT results by checking the appropriate box. Don’t forget to include the COLA or state agency number assigned to you, if applicable, and the name, address, and phone number of any other persons who should receive a copy of your results.  
Indicate “Auto Renewal”.  
Indicate “Express Evaluation Reports”.
7. Indicate a module number, description, quantity, and price. Quantity of “1” includes a full year of shipments.

## Method of Payment

8. Specify the method of payment by checking the corresponding box.

Enroll now to ensure the availability of specimens for the 2010 program year. We will not bill you until November. Subsequent enrollments will be billed within 1 week after activation and are payable within 30 days.

**Invoice Option:** FAX (202-835-0440) the order form or MAIL it to the Washington, DC, address listed on the form. Billing terms are normally net 30 days from the date of invoice.

**Credit Card Option:** FAX (202-835-0440) the order form or MAIL it to the Washington, DC, address listed on the form. Check VISA or MasterCard, indicate the card bearer’s name, card number, and signature and the expiration date.

**Check Option:** MAIL the order form and check to the Philadelphia address listed on the form.

**Purchase Order (PO) Option:** FAX (202-835-0440) the order form or MAIL the order form and a copy of the PO to the Washington, DC, address listed on the form.

Billing terms are net 30 days from the date of invoice.

## Amount Due/Discounts

9. Add the cost of all the items you checked to the annual administration fee of \$75.

Enter the total amount in the box. If you qualify for an MLE ADVANTAGE discount, please check the appropriate box and provide the appropriate information.

## Next Step

- Photocopy the order form for your records.
- Within two weeks, you should receive an “Order Verification” confirming receipt of this order. **If you do not receive the order verification within two weeks, please contact us immediately.**

The MLE products you order may contain pathogenic material. By returning the order form, you assume all risk and responsibility in connection with the receipt, handling, storage, use, and disposal of the products.

# Frequently Asked Questions

## **1. Automatic Renewal Option: I do not want to worry about whether we are enrolled from year to year. Do you have an automatic renewal option?**

We sure do! By checking the Automatic Renewal box on the PT order form or your renewal form, you will never again have to worry about proficiency testing enrollment or placing your order for a new program year. We will automatically re-order the modules in which you participated the previous year, generate an order verification for your review, and send an order change form should you wish to add or delete modules from your renewed order. Simple. Easy. And best of all, one important management detail that you never have to worry about again! See the "Cancelling an Automatic Renewal Order" section for more information.

## **2. When to Order: When does my order have to be submitted to ensure availability of the modules I ordered?**

We encourage you to enroll in MLE as soon as you can to guarantee product availability. Enrolling by December 18, 2009, will ensure that you receive shipments for the entire year. Remember, payment is not due until 30 days AFTER enrollment. (Enroll any time before November and we will not invoice you until November.)

You may enroll any time thereafter at a prorated cost depending on the availability of specimens. For every missed event that you are not enrolled, 1/3 of the module price is deducted. The annual administration fee remains. Note: The online ordering form automatically displays prorated prices. See question 4 for more details on prorated pricing.

## **3. Individual International Orders: I live outside the United States and Canada and I am not with a distributor of MLE in my country. Please tell me about the shipping process.**

Individual laboratories outside the U.S. and Canada are subject to a minimum \$50 fee per shipment to cover shipping costs. Some destinations may be subject to additional S/H. Contact MLE Customer Service for specific shipping pricing information. Additionally, MLE cannot replace kits that are delayed or refused entry into your country. We will not issue credit or refunds on such shipments.

When enrolling in any of the MLE modules that involve hazardous material, laboratories outside the U.S., including Canadian laboratories, must send to MLE any copies of the necessary valid permits for attachment to each shipment. The shipments will not be sent without required documentation.

Freight charges are not included in the commercial pricing. You will be invoiced for freight charges AFTER each shipment. These charges are due BEFORE your evaluation is mailed.

## **4. Order Changes: Can I change my order at any time?**

Sure! We make every effort to accommodate new orders or order changes throughout the year, subject to product availability. See "New Orders or Additions" and "Cancelling a Module" for more information.

## **5. Irregular Order Frequency: Can I order modules outside my regular order? If so, do I have to be an MLE participant to order modules from you?**

Proficiency Testing is available upon request at any time during the program year (subject to product availability). Those enrolled with other PT providers are welcome to call upon MLE for help with reinstatement and compliance emergencies. See page 16 for details on off-schedule testing.

## **6. Needing Assistance: What if I need help with my order, testing, or regulations? Who can I turn to for immediate service?**

Our friendly and knowledgeable MLE Customer Service Representatives are available to assist with order selection, billing, address/name changes, order changes, and regulatory information. Additionally, experienced laboratory professionals will guide you through technical issues, interpretation of your results, and steps necessary for corrective action.

# Changes/Cancellations

## New Orders or Additions

All new orders must be submitted in writing to MLE. All changes to an existing order must be submitted in writing to MLE before they can be entered into the order processing system. Please send your order or order changes in writing at least four weeks prior to the next shipping date to avoid additional shipping fees. MLE ships three times per year. You may enroll throughout the year.

**Note:** The MLE catalog lists prices for the full year. After the first event, module pricing is prorated. If you add a module less than four weeks prior to the next shipping date, you MAY be subject to a "rush order" fee. Call MLE Customer Service at 1-800-338-2746, option 5, for more information.

## Cancelling a Module

If we receive your written request for cancellation of a module(s) at least four weeks prior to the next shipping date, you will not be held accountable for payment of the module for the remaining shipments. Unless otherwise requested, we will credit your account for that amount and the credit will be applied to additions to your order or toward enrollment for the next year.

**If you cancel a module less than four weeks prior to the next shipping date, you are financially responsible for the cost of the module for the next shipment.** You will NOT be financially responsible for subsequent shipments. For example, you cancel (in writing) a module on January 4, 2010. The first shipment (M1) is scheduled to be shipped on February 1, 2010. You are responsible for the cost of the module for M1 but not for M2 or M3.

## Cancelling an Analyte

Please submit a "Test Menu Deletion" form if your laboratory reported tests during the previous event that have since been discontinued, but you are not cancelling the module. Download the form at [www.acponline.org/mle/enroll.htm](http://www.acponline.org/mle/enroll.htm), scroll to "Forms", or copy the form in your MLE Program Guide, p. 32.

## Cancelling the Entire Order

We will refund any charges for unshipped specimens if we receive notification in writing four weeks prior to the next shipping date. Once we have shipped orders for pipettes, we cannot cancel the order or refund the cost. The annual administration fee is non-refundable.

## Cancelling an Automatic Renewal Order

If you are enrolled in Module 116 (automatic renewal) and wish to cancel your entire order, you are required to contact MLE in writing **NO LATER THAN December 18, 2009**, to avoid any charges for the upcoming year.

## MLE Proficiency Testing Price List

Code/Description	*Full Year	Code/Description	*Full Year	Code/Description	*Full Year
<b>HEMATOLOGY</b>					
210/Hematology	\$171	644/Urine Culture/Strep Antigen	\$240	<b>NEW!</b> 790/Anti-HIV <b>W</b>	\$132
211/Basic Hematology	\$159	645/Urine/Throat Culture	\$240	<b>NEW!</b> 791/Anti-HIV	\$300
212/Hemoglobin/Hematocrit	\$138	646/GC Culture	\$240	<b>CHEMISTRY</b>	
213/Hemoglobin/Hematocrit <b>W</b>	\$111	647/Urine Culture/Presump.ID/CC	\$279	810/Chemistry	\$294
215/Hemoglobin/Glucose—HemoCue	\$126	648/Colony Count	\$180	811/Cholestech <b>W</b> Chemistry	\$144
223/Abbott 5-Part Diff	\$279	649/Presump.ID/CC/Strep A Antigen	\$267	812/Piccolo Waived Chemistry	\$180
224/Sysmex 3-Part Diff	\$207	650/Gram Stain	\$150	813/Comp. Metabolic Panel	\$222
225/Hematology 3-Part Diff	\$207	652/Throat Culture/Urine Presump ID	\$279	814/Basic Metabolic Panel	\$171
226/Hematology 5-Part Diff	\$279	654/GC Culture <b>A</b>	\$96	815/Hepatic Profile	\$192
227/QBC Hematology	\$279	660/Strep A Antigen Detection	\$141	816/Hepatic Profile <b>A</b>	\$36
228/Hematology 5-Part diff- ACT 5 & Pentra 60C+	\$279	662/Strep A Antigen <b>W</b>	\$84	817/i-STAT Chemistry 1	\$342
229/Hematology 5-Part diff-Sysmex XE/XT	\$279	668/Affirm VP Antigen Testing	\$357	818/i-STAT Chemistry 2	\$201
230/Blood Cell Id <b>A</b>	\$27	670/Chlamydia (EIA, DNA)	\$270	819/Chemistry 1	\$168
231/Blood Cell Id	\$90	673/Chlamydia <b>A</b>	\$114	820/Chemistry 2	\$198
240/Reticulocyte Count	\$180	675/Chlamydia/GC (EIA, DNA)	\$297	821/Chemistry 3	\$228
247/Sed Rate	\$141	678/Dermatophyte Screen	\$153	822/Add'l Chemistry	\$36
248/Sed Rate-Sedimat15	\$141	680/Resp. Antigen Det. <b>W</b>	\$156	823/Enzyme Chemistry	\$36
250/Body Fluid/Cell ct/Cryst	\$138	681/Resp. Antigen Detection	\$249	824/Thyroid Profile	\$204
<b>COAGULATION</b>					
320/Coagulation	\$150	682/C. diff/Rotavirus Ag Det.	\$219	825/Thyroid Profile <b>A</b>	\$45
321/Prothrombin Time	\$141	683/Giardia lamblia/ Cryptosporidium Ag Det	\$201	826/Lipid Profile	\$198
325/CoaguChek S Pro Time	\$189	686/Legionella Antigen Detection	\$156	827/Lipid Profile <b>A</b>	\$36
327/CoaguChek S Pro Time <b>W</b>	\$126	687/Strep Pneumoniae Antigen Det.	\$156	829/Apolipoproteins	\$108
328/i-STAT Pro Time	\$216	690/Parasitology	\$201	830/TDM	\$198
329/ITC Pro Time <b>W</b>	\$126	695/MRSA Screen	\$237	831/TDM <b>A</b>	\$45
330/CoaguChek XS PLUS	\$189	<b>IMMUNOLOGY</b>			
<b>BLOOD BANK</b>					
451/ABO & Rh Factor (D Type)	\$267	750/Immunology	\$228	<b>NEW!</b> 832/i-STAT Chemistry <b>W</b>	\$138
452/Blood Bank I	\$531	751/Rheumatology	\$156	835/Serum Alcohol/Acetone	\$201
453/Blood Bank II	\$549	755/Infectious Mono <b>W</b>	\$87	836/Ammonia	\$135
<b>URINALYSIS</b>					
530/Urinalysis	\$78	761/Infect Mono/Rheumatoid Factor	\$213	841/Neonatal Bilirubin	\$195
531/Urinalysis Dipstick	\$60	762/Infectious Mono	\$150	842/Direct Bilirubin <b>A</b>	\$30
532/Urine Sed Id	\$87	763/Rheumatoid Factor	\$150	<b>NEW!</b> 843/Direct Bilirubin	\$84
533/Urine Sed Id <b>A</b>	\$18	764/CRP	\$87	845/Cardiac Markers	\$159
534/PPM	\$90	765/HS-CRP	\$87	846/BNP	\$180
535/PPM <b>A</b>	\$21	766/ANA LATEX	\$144	847/Blood Gases	\$264
536/Microalbumin—Quant <b>A</b>	\$72	767/ANA (ELISA/IMMUNO ONLY)	\$144	848/Biosite Triage Cardiac Panel	\$351
537/Fecal Occult Blood <b>A</b>	\$66	768/Complement C3, C4	\$171	850/Glycohemoglobin	\$138
538/KOH Slides	\$114	769/Immunoglobulins, IgG, IgA, IgM	\$162	851/Afinion Glycohemoglobin	\$138
539/Microalbumin	\$84	770/Specific Allergen Testing	\$315	855/Fructosamine	\$135
540/Urine hCG <b>A</b>	\$18	771/Rubella	\$147	<b>NEW!</b> 856/Blood Oximetry	\$225
541/Urine hCG	\$42	772/Syphilis Serology	\$162	<b>NEW!</b> 857/Blood Oximetry <b>A</b>	\$90
542/Fecal Occult Blood	\$75	773/Diagnostic Allergy	\$315	859/PSA <b>A</b>	\$36
<b>NEW!</b> 550/AmniSure Fetal Memb. Rupture	\$243	774/Lyme Disease Serology	\$198	860/Endocrinology/Hematology/ Oncol	\$174
<b>MICROBIOLOGY</b>					
630/Bacteriology 1	\$252	775/Viral Markers	\$345	861/PSA	\$93
640/Bacteriology 2	\$243	776/CRP <b>A</b>	\$45	862/Tumor Markers	\$354
641/Throat Culture	\$240	NOT HIGH-SENSITIVITY	\$45	863/Endocrinology 2	\$156
642/Throat Culture/Strep A Antigen	\$240	777/HS-CRP <b>A</b>	\$48	<b>NEW!</b> 864/Thyroid Antibodies	\$195
643/Urine Culture	\$240	778/ANA <b>A</b> (LATEX ONLY)	\$87	865/Serum hCG	\$150
		779/ANA <b>A</b> (ELISA/IMMUNO ONLY)	\$87	866/Serum hCG <b>A</b>	\$75
		780/H. pylori Antibody Det	\$132	868/Urine Drug Screening—Qual	\$168
		781/Mycoplasma Antibody	\$114	870/Whole Blood Glucose	\$231
		782/ANA Expanded	\$204	871/Whole Blood Glucose <b>W</b>	\$132
		783/ANA Expanded <b>A</b>	\$147	880/Add'l Chem Testing Material	\$93
				901/Waived and PPM Package	\$186
				100/Annual Fee (Includes Binder)	\$75
				<b>LAB SUPPLIES</b>	
				121/1mL Pipette	\$20
				126/Pipette Pump	\$24

**W**=Waived • **A**=Add-On • \*Enroll after the 1st event and prices are prorated by 1/3 per event.

