2018 Proficiency Testing Catalog
www.acponline.org/mle

International Catalog

Approved by: CMS, COLA, TJC, U.S. State Agencies and International regulatory bodies. CAP accepted analytes offered.
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To place an order or to change or cancel an existing order, submit your written requests to your MLE distributor. If there is no distributor in your country, contact MLE at mle@acponline.org
How To Order

- Review your MLE 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.**

- Enroll early to ensure you receive shipments for the entire year. You may enroll anytime after the first event at a prorated cost depending on the availability of specimens.

- Complete the PT order form (page 19 of catalog). Photocopy the completed order form for your records. Send the original form to your MLE distributor. Within a few weeks you should receive an Order Verification.

**Note:** MLE cannot process your order directly. You must place your order through your MLE distributor.

Order Changes and Cancellations

**Written requests are to be sent directly to your MLE distributor.**

- **Additions or Cancellations:** All changes to an existing order must be submitted in writing to your MLE distributor before they can be entered into the order processing system. Please send your 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:** After the first event, module pricing is pro-rated. If you add a module less than four weeks prior to the next shipping date, you may be subject to a "rush order" fee.

  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.

- **Cancelling the Entire Order:** We will cancel any unshipped specimens if we receive notification in writing four weeks prior to the next shipping date. Once we have shipped orders, we cannot cancel the order. The annual administration fee is non-refundable.

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.
**Hematology**

Please pay close attention to instrument compatibility notes when selecting hematology modules. Questions? Contact your MLE distributor. See the “Hematology Instrument List” online at www.acponline.org/mle in the Enrollment Information & Forms section.

210 Hematology Module

**Five challenges each.**
- Blood Cell Identification
- Hematocrit
- Hemoglobin
- Platelet Count
- Red Blood Cell Count
- White Blood Cell Count

211 Basic Hematology

**Five challenges each.**
- Hematocrit
- Hemoglobin
- Platelet Count
- Red Blood Cell Count
- White Blood Cell Count

212 Hemoglobin/Hematocrit

**Five challenges each.**

213 Hemoglobin/Hematocrit—Waived

For waived methods only.

**Two challenges each.**

215 Hemoglobin/Glucose

For HemoCue only.

**Two challenges each.**

223 Hematology with 5-part Differential

Compatible with most Abbott CELL-DYN 5-part differential instruments only.

**Five challenges each.**
- Automated Differential
- Hematocrit
- Hemoglobin
- Platelet Count
- Red Blood Cell Count
- White Blood Cell Count

224 Sysmex with 3-part Differential

Compatible with Sysmex 3-part automated differential instruments only.

**Five challenges each.**
- Automated Differential
- Hematocrit
- Hemoglobin
- Platelet Count
- Red Blood Cell Count
- White Blood Cell Count

225 Hematology with 3-part Differential

Compatible with most 3-part differential instruments EXCEPT Sysmex (see 224).

**Five challenges each.**
- Automated Differential
- Hematocrit
- Hemoglobin
- Platelet Count
- Red Blood Cell Count
- White Blood Cell Count

226 Hematology with 5-part Differential

Compatible with most Beckman-Coulter 5-part differential instruments EXCEPT for the AcT 5diff (see 228).

**Five challenges each.**
- Automated Differential
- Hematocrit
- Hemoglobin
- Platelet Count
- Red Blood Cell Count
- White Blood Cell Count

227 Hematology with 5-part Differential

Compatible with Beckman Coulter AcT 5diff and ABX Pentra 5-part differential instruments.

**Five challenges each.**
- Automated Differential
- Hematocrit
- Hemoglobin
- Platelet Count
- Red Blood Cell Count
- White Blood Cell Count

229 Sysmex Hematology with 5 or 6-part Differential

Compatible with most Sysmex 5 or 6 part differential instruments only.

**Five challenges each.**
- Automated Differential
- Hematocrit
- Hemoglobin
- Platelet Count
- Red Blood Cell Count
- White Blood Cell Count
230  Blood Cell Identification (Add-On)
     Same as 231.
     Only available with 223 through 229.

231  Blood Cell Identification
     Stand-alone module.

     **Five challenges consisting of color photographs.**

240  Reticulocyte Count
     Compatible with automated and manual reticulocyte counting methods. Not for use with brilliant cresyl blue staining methods.

     **Two challenges.**

247  Sedimentation Rate
     Not for use with Sedimat 15 / 15 Plus

     **Two challenges.**

     *Sedimentation Rate is not required by CAP.

248  Sedimat 15 ESR
     Compatible with the Polymedco Sedimat 15 / 15 Plus instruments only.

     **Two challenges.**

     *Sedimentation Rate is not required by CAP.

250  **Fluid Cell Count/Crystals**
     Fluid for Hemocytometer cell count and color photographs for identification of crystals.

     **Two challenges each.**
     Crystal Screening     WBC Count
     RBC Count

---

**Coagulation**

320  ✤ Coagulation Module
     **Five challenges each.**
     Fibrinogen
     INR
     Partial Thromboplastin Time
     Prothrombin Time

321  ✤ Prothrombin Time
     **Five challenges each.**
     INR     Prothrombin Time

324  Roche CoaguChek XS INR
     Not for use with CoaguChek XS Plus.

     **Two challenges.**

     INR
     *Waived INR is not required by CAP.

328  i-STAT Prothrombin Time
     Compatible with the i-STAT instruments only.

     **Five challenges each.**
     INR     Prothrombin Time

330  CoaguChek XS Plus Prothrombin Time
     For CoaguChek XS Plus only.

     **Five challenges each.**
     INR     Prothrombin Time

331  CoaguChek XS Plus Prothrombin Time—Waived
     For CoaguChek XS Plus only.

     **Two challenges each.**

     INR     Prothrombin Time
     *Waived PT and INR are not required by CAP.
Blood Bank

450 Rh Factor (D Type)
For Slide Methods ONLY.

Five challenges.

451 ABO & Rh Factor (D Type)
Not for use with slide methods.

Five challenges each.

452 Blood Bank 1
Not for use with slide methods.

Five challenges each.
ABO Group
Rh Factor (D Type)
Unexpected Antibody Detection

453 Blood Bank 2
Not for use with slide methods.

Five challenges each.
ABO Group
Antibody Identification
Compatibility Testing (Crossmatch)
Rh Factor (D Type)
Unexpected Antibody Detection

Provider-Performed Microscopy

534 Provider-Performed Microscopy (PPM)
Color photographs depicting microscopic fields for the examination of:

- Fecal Leukocytes (M2,M3)
- Fern testing (M1,M3)
- Nasal Eosinophils (M1,M2,M3)
- Pinworms (M1,M2)
- Scabies (M1,M2)*
- Sperm (M2,M3)
- Vaginal KOH Preparations (M1,M3)
- Vaginal Wet Mount Preparations (M1,M2,M3)

Six challenges total per shipment as indicated in parentheses above.
*Scabies examination is not required by CAP.

535 Provider-Performed Microscopy (PPM) Add-On
Same as 534. Only available with 530, 531, 532, 541.

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

Two challenges.
Urinalysis & Occult Blood

530 Urinalysis Module

One challenge each unless otherwise noted in parentheses.

- Bilirubin
- Blood/Hemoglobin
- Glucose
- Ketones
- Leukocyte Esterase
- Microalbumin (dipstick only)
- Nitrite
- pH
- Protein
- Specific Gravity
- Urobilinogen
- Urine Sediment Identification (2)

531 Urinalysis Dipstick

hCG not included.

One challenge each.

- Bilirubin
- Blood/Hemoglobin
- Glucose
- Ketones
- Leukocyte Esterase
- Microalbumin (dipstick only)
- Nitrite
- pH
- Protein
- Specific Gravity
- Urobilinogen

532 Urine Sediment Identification

Two challenges consisting of photographs.

533 Urine Sediment Identification (Add-On)

Same as 532. Only available with 531, 534, 541.

536 Urine Microalbumin/Creatinine (Add-On)

Same as 539. Only available with 530, 531, 534, 541, 868, 872.

539 Urine Microalbumin/Creatinine

Stand-alone module.
Compatible with quantitative and semi-quantitative (dipstick) methods.

One challenge each.

540 Urine hCG (Add-On)

Same as 541.
Only available with 530, 531.

541 Urine hCG

Stand-alone module.

One challenge.

537 Fecal Occult Blood (Add-On)

Same as 542.
Only available with 530, 531, 532, 534, 541.

*Fecal occult blood testing is not required by CAP.

542 Fecal Occult Blood

Stand-alone module.

Two challenges.

*Fecal occult blood testing is not required by CAP.

543 ♦ Gastric Occult Blood

Two challenges.

Gastric Occult Blood
pH

* Not CAP accepted

NEW!
Waived Testing Packages

Waived Testing—The Importance of Performing Proficiency Testing

Certificate of Waiver (CW) laboratories must only perform waived laboratory tests. When the Centers for Medicare & Medicaid Services (CMS) began random inspections of some CW laboratories in 2002, many laboratories chose to participate in proficiency testing as a quality assurance check. MLE responded by preparing special two-challenge proficiency modules, designed for the needs of the waived testing laboratory. Our custom selection of cost effective waived modules appears below.

901 Waived and PPM Package

Number of challenges noted in parentheses.

- Fecal Occult Blood* (2)
- Hemoglobin (2)
- Hematocrit (2)
- PPM (6)**
- Urinalysis (1)
- Urine hCG (1)
- Urine Sediment (2)
- Strep A Antigen (2)
- Whole Blood Glucose (2)***

*Fecal occult blood testing is not required by CAP.
**Scabies examination is not required by CAP.
***Strip waived Whole Blood Glucose is not required by CAP.

902 Basic Waived and PPM Package

Number of challenges noted in parentheses.

- Fecal Occult Blood* (2)
- PPM (6)**
- Strep A Antigen Detection (2)
- Urinalysis (1)
- Urine hCG (1)
- Urine Sediment (2)
- Whole Blood Glucose (2)***

*Fecal occult blood testing is not required by CAP.
**Scabies examination is not required by CAP.
***Strip waived Whole Blood Glucose is not required by CAP.

Microbiology

- U.S. Federal law requires a minimum of five CMS regulated (non-waived methods) bacteriology challenges per shipment. Individual state laws may differ. When enrolling, ensure your order meets the requirement that is the more stringent of the two. The number of challenges is noted in parentheses.

- All urine culture specimens are suitable for presumptive identification and/or definitive identification.

Note: The specimens included may contain dangerous pathogens and must be treated with extreme care. These specimens must be handled and disposed of only by personnel trained to work with pathogenic microorganisms.

Bacteriology

630 Bacteriology 1

Six cultures per shipment consisting of the following:
- Antimicrobial Susceptibility Testing (1)
- Genital Culture (1)
- Gram Stain (2)
- Gram Stain Morphology (2)
- Miscellaneous Culture (3)*
- Throat Culture (1)
- Urine Culture (1)

*Possible sources include: Blood, CSF, Ear, Eye, Sputum, Stool, Wound.

640 Bacteriology 2

Antimicrobial Susceptibility Testing (1)
- Genital Culture (1)
- Gram Stain (2)
- Gram Stain Morphology (2)
- Strep A Antigen Detection (1)
- Throat Culture (2)
- Urine Culture (2)
643 Urine Culture
  Antimicrobial Susceptibility Testing (1)
  Gram Stain (1)
  Gram Stain Morphology (1)
  Urine Culture (5)

644 Urine Culture/Strep A Antigen Detection
  Antimicrobial Susceptibility Testing (1)
  Gram Stain (1)
  Gram Stain Morphology (1)
  Urine Culture (5)

645 Urine/Throat Culture
  Antimicrobial Susceptibility Testing (1)
  Gram Stain (1)
  Gram Stain Morphology (1)
  Throat Culture (2)
  Urine Culture (3)

647 Urine Presumptive ID/Colony Count
  Best suited for paddle-dipping methods.
  Antimicrobial Susceptibility Testing (1)
  Colony Count (2)
  Gram Stain (1)
  Gram Stain Morphology (1)
  Urine Presumptive Identification (5)

648 Colony Count
  Colony Count does not contribute to the minimum of five bacteriology challenges.
  No presumptive identification may be submitted for this module.
  Two challenges.

649 Urine Presumptive ID/Strep A Antigen Detection
  Best suited for urine paddle-dipping methods.
  Antimicrobial Susceptibility Testing (1)
  Colony Count (2)
  Gram Stain (1) (directly from sample provided)
  Gram Stain Morphology (1)
  Strep A Antigen Detection (3)
  Urine Culture (2)

652 Urine Presumptive ID/Throat Culture
  Best suited for urine paddle-dipping methods.
  Antimicrobial Susceptibility Testing (1)
  Colony Count (2)
  Gram Stain (1) (directly from sample provided)
  Gram Stain Morphology (1)
  Throat Culture (3)
  Urine Presumptive Identification (2)

650 Gram Stain
  Five fixed glass slides.
  Five challenges each.
  Gram Stain
  Gram Stain Morphology

641 Throat Culture
  Not suitable for Strep A kits.
  Five challenges.

642 Throat Culture/Strep A Antigen Detection
  Strep A Antigen Detection (3)
  Throat Culture (2)

660 Strep A Antigen Detection
  Not suitable for culture.
  Five challenges.

662 Strep A Antigen Detection—Waived
  For waived Strep A Antigen Detection kits only.
  Two challenges.

646 Genital Culture
  Gram Stain (1)
  Gram Stain Morphology (1)
  Genital Culture (5)

653 Genital/Urine Culture
  Antimicrobial Susceptibility Testing (1)
  Genital Culture (3)
  Gram Stain (2)
  Gram Stain Morphology (2)
  Urine Culture (2)
<table>
<thead>
<tr>
<th>Test Code</th>
<th>Name</th>
<th>Challenges</th>
<th>Notes</th>
</tr>
</thead>
<tbody>
<tr>
<td>668</td>
<td>Affirm VP III (DNA)</td>
<td>5</td>
<td>Five challenges each.</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>Candida sp.  Trichomonas vaginalis</td>
</tr>
<tr>
<td>692</td>
<td>Bacterial Vaginosis—Waived</td>
<td>2</td>
<td>Waived</td>
</tr>
<tr>
<td></td>
<td>For Sekisui OSOM BVBlue Test</td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>Two challenges.</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>Bacterial Vaginosis Screen</td>
</tr>
<tr>
<td>670</td>
<td>Chlamydia (EIA, DNA)</td>
<td>5</td>
<td>Five challenges.</td>
</tr>
<tr>
<td>675</td>
<td>Chlamydia/GC (EIA, DNA)</td>
<td>5</td>
<td>Five challenges each.</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>Chlamydia trachomatis</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>Neisseria gonorrhoeae</td>
</tr>
<tr>
<td>673</td>
<td>Chlamydia (EIA, DNA)–Add-On</td>
<td>2</td>
<td>Same as 670. Only available with 630 through 647, 650, 652, 660.</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>Two challenges.</td>
</tr>
<tr>
<td>693</td>
<td>Trichomonas vaginalis—Waived</td>
<td>2</td>
<td>Waived</td>
</tr>
<tr>
<td></td>
<td>For Sekisui OSOM Trichomonas Rapid Test</td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>Two challenges.</td>
</tr>
<tr>
<td>682</td>
<td>C. difficile/Rotavirus Antigen Detection</td>
<td>5</td>
<td>Five challenges each.</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>C. difficile  Rotavirus</td>
</tr>
<tr>
<td>683</td>
<td>Giardia lamblia/Cryptosporidium Antigen Detection</td>
<td>5</td>
<td>Five challenges each.</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>Cryptosporidium  Giardia lamblia</td>
</tr>
<tr>
<td>690</td>
<td>Parasitology</td>
<td></td>
<td>Provides five challenges from among the following: PVA Slide (for permanent stain), Fecal Suspension (direct wet mount examination for ova and parasites), Blood Smear for Parasites.</td>
</tr>
<tr>
<td>691</td>
<td>Parasitology 2</td>
<td></td>
<td>Fecal Suspension (4)  Blood Smear (1)</td>
</tr>
<tr>
<td>680</td>
<td>Respiratory Antigen Detection—Waived</td>
<td>2</td>
<td>Waived</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>Two challenges each.</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>Influenza A  Influenza B</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>Influenza A/B Combo  RSV</td>
</tr>
<tr>
<td>681</td>
<td>Respiratory Antigen Detection</td>
<td>5</td>
<td>Five challenges each.</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>Influenza A  Influenza B</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>Influenza A/B Combo  RSV</td>
</tr>
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**Mycology**

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</tr>
</thead>
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<tr>
<td>678</td>
<td>Dermatophyte Culture</td>
<td>5</td>
<td>Five challenges.</td>
</tr>
<tr>
<td>538</td>
<td>KOH Slides</td>
<td>2</td>
<td>Waived</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>Two challenges.</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>Bacterial Vaginosis Screen</td>
</tr>
</tbody>
</table>

**Parasitology**

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<th>Notes</th>
</tr>
</thead>
<tbody>
<tr>
<td>686</td>
<td>Legionella Antigen Detection</td>
<td>5</td>
<td>Five challenges.</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>For use with Binax NOW Legionella Urinary Antigen Detection kits only.</td>
</tr>
<tr>
<td>687</td>
<td>Streptococcus pneumoniae Antigen Detection</td>
<td>5</td>
<td>Five challenges.</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>For use with Binax NOW Streptococcus pneumoniae Urinary Antigen Detection kit only.</td>
</tr>
<tr>
<td>695</td>
<td>MRSA Screening</td>
<td>5</td>
<td>Five challenges.</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>Screening for the presence or absence of methicillin- resistant Staphylococcus aureus only.</td>
</tr>
</tbody>
</table>
### Immunology

**750 Immunology Module**

- Five challenges each.
  - Anti-Streptolysin O (ASO)
  - Infectious Mononucleosis
  - Rheumatoid Factor

**751 Rheumatology Module**

Number of challenges noted in parentheses.

- C-Reactive Protein (2) (Not for high-sensitivity methods)
- Rheumatoid Factor (5)

**755 Infectious Mononucleosis–Waived**

For waived Infectious Mononucleosis kits only.

- Two challenges.

**752 Infectious Mononucleosis**

- Five challenges.

**761 Infectious Mononucleosis/Rheumatoid Factor**

- Five challenges each.

**763 Rheumatoid Factor**

For IgG methods only.

- Five challenges.

**764 C-Reactive Protein (CRP)**

Not for high-sensitivity methods.

- Two challenges.

**765 High-Sensitivity C-Reactive Protein (HS-CRP)**

- Two challenges.

**777 High-Sensitivity C-Reactive Protein (HS-CRP)—Add-On**

Only available with 750 and 751.

- Two challenges.

**767 Antinuclear Antibody (ANA)**

- Five challenges.

**779 Antinuclear Antibody (ANA)-Add-On**

Same as 767. Only available with 751.

**762 Infectious Mononucleosis**

- Five challenges.

**761 Infectious Mononucleosis/Rheumatoid Factor**

- Five challenges each.

**763 Rheumatoid Factor**

For IgG methods only.

- Five challenges.

**764 C-Reactive Protein (CRP)**

Not for high-sensitivity methods.

- Two challenges.

**765 High-Sensitivity C-Reactive Protein (HS-CRP)**

- Two challenges.

**777 High-Sensitivity C-Reactive Protein (HS-CRP)—Add-On**

Only available with 750 and 751.

- Two challenges.

**767 Antinuclear Antibody (ANA)**

- Five challenges.

**779 Antinuclear Antibody (ANA)-Add-On**

Same as 767. Only available with 751.

**782 ANA Expanded**

- Five challenges each.
  - ANA
  - Anti-dsDNA
  - Anti-RNP
  - Anti-RNP/Sm
  - Anti-SSA
  - Anti-SSA/SSB
  - Anti-SB
  - Anti-Sm

**783 ANA Expanded (Add-On)**

Same as 782. Only available with 750 and 751.

**784 Complement/Immunoglobulins**

- Five challenges each.
  - Complement C3 IgG, Total
  - Complement C4 IgM, Total
  - IgA, Total

**771 Rubella**

For IgG methods only.

- Five challenges.

**772 Syphilis Serology**

- Five challenges each.
  - MHA-TP RPR
  - TPA VDRL
770  ♦ Specific Allergen Testing
   Number of challenges noted in parentheses. Includes 2 sets of samples for large volume requirements. Does not include Total IgE.
   Allergen Specific IgE (14)

740  ♦ Additional Specific Allergen Material
   Includes 1 additional set of samples for large volume requirements. Only available with 773.
   Allergen Specific IgE (14)

773  ♦ Diagnostic Allergy
   Number of challenges noted in parentheses.
   Allergen Specific IgE (14)
   Total IgE (5)

775  Viral Markers
   Five challenges each.
   ♦ Anti-HAV (IgM)  Anti-HCV
   ♦ Anti-HAV (Total/IgG)  Anti-HIV
   ♦ Anti-HBc (IgM)  HBeAg
   ♦ Anti-HBc (Total/IgG)  HBsAg
   Anti-HBs

780  H. pylori Antibody Detection
   Two challenges.

781  ♦ Mycoplasma Antibody
   For IgG methods only.
   Two challenges.

786  Toxoplasma IgG/IgM
   Two challenges.

788  Cytomegalovirus IgG/IgM
   Two challenges.

790  Anti-HIV—Waived
   For waived HIV kits only.
   Two challenges.

791  Anti-HIV
   Five challenges.

905  Syphilis/Viral Marker Combo
   Includes 772 and 775
   Five challenges.

909  Immunology Combination
   Includes 750, 764, and 773
   Five challenges unless noted in parentheses.
   Allergen specific IgE (14)
   Anti-streptolysin O (ASO)
   C-Reactive Protein (CRP) (2)
   IgE, Total
   Infectious mononucleosis
   Rheumatoid factor

910  Inflammatory Module
   Five challenges unless noted in parentheses.
   Anti-Streptolysin O (ASO)
   C-Reactive Protein (2) – Not for high-sensitivity methods
   Rheumatoid Factor

912  Rubella/Toxoplasma/CMV Combo
   Five challenges.
   Rubella
   Two challenges.
   Toxoplasma
   Cytomegalovirus
Chemistry

Please pay close attention to instrument compatibility notes when selecting any of the chemistry modules.

If you need any assistance, contact your MLE distributor.

811 Lipid Panel/Glucose - Waived
For waived testing ONLY.

Two challenges each.
- Cholesterol, LDL - Calculated*
- Cholesterol, HDL
- Cholesterol, Total
- Glucose
- Triglyceride
*Not required by CAP.

812 Piccolo Waived Chemistry
For the Abaxis Piccolo Instrument (waived cartridges ONLY).

Two challenges each.
- Albumin
- Alkaline Phosphatase
- ALT (SGPT)
- Amylase
- AST (SGOT)
- Bilirubin, Total
- Calcium
- Chloride
- Cholesterol, HDL
- Cholesterol, LDL-Calc*
- Cholesterol, Total
- CO2
*Not required by CAP.

817 i-STAT Chemistry 1
Five challenges each.
- Calcium, Ionized
- Chloride
- Creatinine
- Glucose
- Hematocrit
- Hemoglobin
- Lactate
- Sodium
- tCO2*
- Urea Nitrogen
*Not required by CAP.

818 i-STAT Chemistry 2
Five challenges each.
- Calcium, Ionized
- Chloride
- Creatinine
- Glucose
- Hematocrit
- Hemoglobin
- Lactate
- Sodium
- tCO2*
- Urea Nitrogen
*Not required by CAP.

832 i-STAT Chemistry—Waived
Two challenges each.
- Calcium, Ionized
- Chloride
- Creatinine
- Glucose
- Hematocrit
- Hemoglobin
- Lactate
- Sodium
- tCO2*
- Urea Nitrogen
*Not required by CAP.

847 Blood Gases
Compatible with the i-STAT analyzer as well as other blood gas instruments.

Five challenges each.
- Chloride
- Calcium, Ionized
- Lactate
- pH
- pO2
- Potassium
- Sodium
- pCO2

833 Piccolo Waived Chemistry (Add-On)
Same as 812. Only available with 824.
810 Chemistry Module

**Five challenges each.**
- Albumin
- Alkaline Phosphatase
- Alpha-fetoprotein
- ALT (SGPT)
- Amylase
- AST (SGOT)
- Bilirubin, Direct
- Bilirubin, Total
- Calcium
- Chloride
- Cholesterol, HDL
- Cholesterol, LDL - Calc*
- Cholesterol, LDL - Direct
- Cholesterol, Total
- CO2
- Cortisol
- Creatine Kinase (CK)
- Creatinine
- Free T3
- Free Thyroxine (T4)
- GGT

**Glucose**
- Iron
- Lactate (Lactic Acid)
- LDH
- Lipase
- Magnesium
- Phosphorus
- Protein, Total
- Sodium
- T3 Uptake
- Thyroxine (T4)
- TIBC - Direct
- TIBC - Calc*
- TIBC - Direct
- TIBC - Direct
- Urea Nitrogen
- Uric Acid

*Not required by CAP.

814 Basic Metabolic Panel

**Five challenges each.**
- Calcium
- Chloride
- CO2
- Creatinine

**Glucose**
- Potassium
- Sodium
- Urea Nitrogen

813 Comprehensive Metabolic Panel

**Five challenges each.**
- Albumin
- Alkaline Phosphatase
- ALT (SGPT)
- AST (SGOT)
- Bilirubin, Direct
- Bilirubin, Total
- Calcium
- Chloride
- CO2
- Creatinine
- Glucose
- Iron

**Lactate (Lactic Acid)**
- Magnesium
- Phosphorus
- Protein, Total
- Sodium
- TIBC - Calc*
- TIBC - Direct
- Urea Nitrogen
- Uric Acid

*Not required by CAP.

815 Hepatic Profile

**Five challenges each.**
- Albumin
- Alkaline Phosphatase
- ALT (SGPT)
- AST (SGOT)

**Bilirubin, Direct**
- Bilirubin, Total
- Protein, Total

816 Hepatic Profile (Add-On)

Same as 815. Only available with 814, 819-821, 824, 826, 828, 830, 834.

819 Chemistry 1

**Five challenges each.**
- Cholesterol, Total
- Potassium
- Glucose
- Urea Nitrogen

820 Chemistry 2

**Five challenges each.**
- Bilirubin, Total
- Glucose
- Chloride
- Potassium
- Sodium
- Urea Nitrogen
- Creatinine
- Uric Acid

821 Chemistry 3

**Five challenges each.**
- Bilirubin, Total
- Creatinine
- Chloride
- Glucose
- Cholesterol, HDL
- Potassium
- Cholesterol, LDL - Calc*
- Sodium
- Cholesterol, LDL - Direct
- Triglyceride
- Cholesterol, Total
- Urea Nitrogen
- CO2
- Uric Acid

*Not required by CAP.

834 Additional Chemistries

Stand alone module.

**Five challenges each.**
- Albumin
- Calcium
- Iron
- Lactate (Lactic Acid)
- Magnesium
- Phosphorus

**Protein, Total**
- TIBC - Calc*
- TIBC - Direct
- TIBC - Direct
- Urea Nitrogen
- Uric Acid

*Not required by CAP.
822  Additional Chemistries (Add-On)
Same as 834. Only available with 814, 815, 819-821, 824, 826, 828, 830.

828  Enzyme Chemistry - Ship Alone
Five challenges each.
Alkaline Phosphatase Creatine Kinase (CK)
ALT (SGPT) GGT
Amylase LDH
AST (SGOT) Lipase

823  Enzyme Chemistry (Add-On)
Same as 828. Only available with 813-815, 819-821, 824, 826, 830, 834.

824  Thyroid Profile
Five challenges each.
α-fetoprotein Thyroxine (T4)
Cortisol Thyroxine (T4), Free
T3, Free Triiodothyronine (T3)
T3 Uptake TSH

825  Thyroid Profile (Add-On)
Same as 824. Only available with 813-815, 819-821, 824, 826, 830, 834.

826  Lipid Profile
Five challenges each.
Cholesterol, HDL
Cholesterol, LDL - Calc*
Cholesterol, LDL - Direct
Cholesterol, Total
Triglyceride
*Not required by CAP.

827  Lipid Profile (Add-On)
Same as 826. Only available with 813-815, 819, 824, 828, 830, 834.

829  Apolipoproteins
Two challenges each.
Apolipoprotein A1 Apolipoprotein B

830  Therapeutic Drug Monitoring
Five challenges each.
• Acetaminophen Phenytoin
• Carbamazepine Salicylate
• Digoxin Theophylline
• Gentamicin Valproic Acid
• Lithium Vancomycin
• Phenobarbital

831  Therapeutic Drug Monitoring
(Add-On)
Same as 830. Only available with 810, 813-815, 819-821, 824, 826, 828, 834.

835  • Serum Alcohol/Acetone
Five challenges each.

836  • Ammonia
Two challenges.

837  • Blood Lead
Five challenges each.

838  • Blood Lead—Waived
Two challenges.

841  Neonatal Bilirubin
Five challenges each.
Bilirubin, Direct Bilirubin, Total

842  Direct Bilirubin (Add-On)
Same as 843.
Only available with 814, 819-821, 824, 826, 828.

843  Direct Bilirubin
Five challenges each.

845  Cardiac Markers
Five challenges each. Quantitative only.
BNP NT-proBNP
CK-MB Troponin I
D-Dimer Troponin T
Myoglobin
846 BNP/D-Dimer

Two challenges each.
- BNP *
- NT-proBNP
- D-Dimer
*CAP accepted for waived methods only.

850 Glycohemoglobin

Not compatible with Afinion analyzer. CAP accepted for waived methods only.

Two challenges.

851 Afinion Glycohemoglobin

Two challenges.

854 ◆ SHBG/Testosterone

Lyophilized samples.

Two challenges each.
- Sex Hormone Binding Globulin
- Testosterone
- Testosterone, Bioavailable
- Testosterone, Free

859 PSA (Add-On)

Same as 861. Only available with 860.

860 Endocrinology/Hematology/Oncology

Two challenges each.
- CEA
- DHEA-S
- Estradiol
- Ferritin
- Folate
- FSH
- Homocysteine
- LH
- Progesterone
- Prolactin
- Testosterone
- Transferrin
- Vitamin B12

861 PSA

Two challenges.

865 Serum hCG

Five challenges each.

866 Serum hCG (Add-On)

Same as 865. Only available with 810, 813, 814, 815, 817-821, 824, 826, 828, 834.

862 Tumor Markers

Two challenges each.
- Beta (β)-2 Microglobulin
- CA 125
- CA 15-3
- CA 19-9
- CA 27/29

863 Endocrinology 2

Lyophilized samples.

Two challenges each.
- C-Peptide
- Insulin
- Parathyroid Hormone, Intact (PTH)
- Vitamin D, 25-Hydroxy

864 ◆ Thyroid Antibodies

Two challenges each.
- Thyroglobulin Antibody
- Thyroid Peroxidase Antibody (TPO)

870 Whole Blood Glucose

Five challenges.
*Strip waived Whole Blood Glucose is not required by CAP.

871 Whole Blood Glucose—Waived

Two challenges.
*Strip waived Whole Blood Glucose is not required by CAP.

880 Additional Chemistry Testing Material

Includes all analytes in Chemistry Module 810 and Therapeutic Drug Monitoring Module 830. It is the same material used in those modules and will be shipped to your laboratory at the same time as your regular Chemistry samples.
You can use it as:
- Extra PT material in case you have a problem and need extra testing material.
- A way to double-check unacceptable PT results after corrective action.
- An educational tool to train personnel.
- A means to meet the CMS quality assurance requirements for a second chemistry instrument.

◆ Not CAP accepted
906 Thyroid/Immunoassay/Tumor Marker Combo

Five challenges.
Thyroid assays

Two challenges.
Immunoassays
Tumor Markers

907 Thyroid/Immunoassay/Tumor Marker/Serum . hCG Combo
Includes 824, 860, 862, and 865

Five challenges.
hCG
Thyroid assays

Two challenges.
Immunoassays
Tumor Markers

908 Immunoassay/Tumor Marker Combo
Includes 860 and 862

Two challenges.

913 Immunoassay/Tumor Marker/hCG Combo
Includes 860, 862, and 865

Five challenges.
hCG assays

Two challenges.
Immunoassays
Tumor Markers

872 ⇨ Urine Chemistry

Two challenges each.
Amylase
Calcium
Chloride
Creatinine
Glucose
Magnesium
Osmolality
Phosphorus
Potassium
Protein, Total
Sodium
Urea Nitrogen
Uric Acid

867 Urine Drug Screen

Two challenges for the qualitative detection of drugs in urine.

Cannabinoids
Opiates

868 Urine Drug Screen

Two challenges - 10 ml each.
For the qualitative detection of drugs in urine.
Each challenge will include one or more of the following:

Acetaminophen
Amphetamines
Amphetamines/
Methamphetamine
Barbiturates
Benzodiazepines
Buprenorphine
Cannabinoids (THC)
Carisoprodol
Cocaine Metabolites
Cotinine
EDDP
Ethanol (Alcohol)
Fentanyl
Hydrocodone
LSD
MDMA
Meperidine
Methadone
Methamphetamine
Methanol
Methaqualone
6-Monoacetylmorphine
Opiates (Morphine Trihydrate)
Oxycodone
Phencyclidine
Propoxyphene
Tramadol
Tricyclic Antidepressants
Zolpidem

873 ⇨ Ethyl Glucuronide (EtG) (Add-On)
Only available with 868.

Two challenges.

874 ⇨ Adulterated Urine (Add-On)
Only available with 868.
Compatible with quantitative and semi-quantitative (dipstick) methods.

Two challenges each.
Creatinine
Oxidants
pH
Nitrite
Specific Gravity
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CMS regulated analytes for CLIA purposes are in bold.

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- 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.

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What’s New for 2018

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