“Knowing that we provide point-of-care diagnostic technology encourages other specialists to refer to us”

- Scott B. Han, OD, FAAO

Outline

- CLIA
- Basic Blood Tests
- Diabetes Testing
- Lipid Panel
- Iritis
- Ordering Lab Tests

CLIA

- Stands for Clinical Laboratory Improvement Amendments (passed in 1988)

- The Centers for Medicare & Medicaid Services (CMS) regulates all laboratory testing (except research) performed on humans in the U.S.

- A laboratory must be CLIA certified to receive Medicare or Medicaid payments

Resources

- Publisher: Saunders; 6 edition (December 4, 2012)
- ISBN-10: 1455706949
- Paperback: 1232 pages (Also available for tablets)
- $45

labtestsonline.org
To receive a certificate of waiver under CLIA, a lab must only perform tests like the glucose meter test which the Food and Drug Administration (FDA) and the Centers for Disease Control and Prevention (CDC) have determined to be so simple that there is little risk of error.

In addition, these tests are exempted from most CLIA requirements and the laboratories that perform them receive no routine inspections.

Waived laboratories must meet only the following requirements under CLIA:

- Enroll in the CLIA program;
- Pay applicable certificate fees biennially (currently $150); and
- Follow manufacturers’ test instructions.

The types of tests waived under CLIA has increased from 8 to approximately 100 tests since the inception of the program in 1992; thereby, the number of laboratories issued a CoW has grown exponentially from 20% to 69% of the approximate total of the 236,000 laboratories enrolled.

### Sample of CLIA Waived Tests For Eyecare

<table>
<thead>
<tr>
<th>Description</th>
<th>Manufacturer</th>
<th>CPT Code</th>
<th>Reimbursement</th>
</tr>
</thead>
<tbody>
<tr>
<td>Urinary Pregnancy Test</td>
<td>various</td>
<td>81025</td>
<td>$8.63</td>
</tr>
<tr>
<td>Glucose Blood Test</td>
<td>various</td>
<td>82962</td>
<td>$3.20</td>
</tr>
<tr>
<td>RBC and WBC count</td>
<td>various</td>
<td>85651</td>
<td>$4.84</td>
</tr>
<tr>
<td>Lipid Panel</td>
<td>Cholestech Corp.*</td>
<td>80061QW</td>
<td>$18.27</td>
</tr>
<tr>
<td>Glycosylated hemoglobin</td>
<td>Bayer Corp.*</td>
<td>83037QW</td>
<td>$11.79</td>
</tr>
<tr>
<td>Tear lab</td>
<td>Text Lab Corporation</td>
<td>83861QW</td>
<td>$22.54</td>
</tr>
<tr>
<td>Prothrombotic Time</td>
<td>CoaguSense, Inc.*</td>
<td>85610QW</td>
<td>$5.37</td>
</tr>
<tr>
<td>Lyme disease antibody</td>
<td>Wampole Laboratories</td>
<td>86618QW</td>
<td>$23.24</td>
</tr>
<tr>
<td>HIV-1 Antibody</td>
<td>Biotechnical Laboratories, Inc.*</td>
<td>86701QW</td>
<td>$12.12</td>
</tr>
<tr>
<td>Adenosin Plus</td>
<td>Rapid Pathogen Screening, Inc.</td>
<td>87809QW</td>
<td>$16.36</td>
</tr>
</tbody>
</table>

*other manufacturers also

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  - Basic Blood Tests
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  - Ordering Lab Tests
Complete Blood Count (CBC) with Differential

- Red Blood Cells
  - Red Blood Cell Count (RBC)
  - Hemoglobin (Hgb)
  - Hematocrit (HCT)
  - Mean Corpuscular Volume (MCV)
  - Mean Corpuscular Hemoglobin (MCH)
  - Mean Corpuscular Hemoglobin Concentration (MCHC)
  - Red cell Distribution Width (RDW)

- White Blood Cells
  - White Blood Cell Count (WBC)
  - Segmented Neutrophils
  - Lymphocytes (Lymphs)
  - Monocytes (Monos)
  - Eosinophils (Eos)
  - Basophils (Baso)

- Platelet Count (Plt)

Differential WBC count

Red Blood Cells

<table>
<thead>
<tr>
<th>Test</th>
<th>Measurement</th>
</tr>
</thead>
<tbody>
<tr>
<td>Red Blood Cell Count (RBC)</td>
<td>Total Red Blood Cells per unit volume of blood</td>
</tr>
<tr>
<td>Hemoglobin (Hgb)</td>
<td>Measures the amount of the oxygen-carrying protein in the blood</td>
</tr>
<tr>
<td>Hematocrit (HCT)</td>
<td>Measures the percentage of a person’s blood that consists of red blood cells</td>
</tr>
<tr>
<td>Mean Corpuscular Volume (MCV)</td>
<td>Measurement of the average size of red blood cells</td>
</tr>
<tr>
<td>Mean Corpuscular Hemoglobin (MCH)</td>
<td>Calculation of the average amount of oxygen-carrying hemoglobin inside a red blood cell</td>
</tr>
<tr>
<td>Mean Corpuscular Hemoglobin Concentration (MCHC)</td>
<td>Measurement of the average percentage of hemoglobin in a red blood cell</td>
</tr>
<tr>
<td>Red cell Distribution Width (RDW)</td>
<td>Calculation of the variation in size of the RBCs</td>
</tr>
</tbody>
</table>

White Blood Cell Count (WBC)

- Measures the total number of white blood cells per unit volume of blood.
- Elevated with infection
- Low with bone marrow damage, autoimmune conditions, HIV
- Important to know before placing a patient on systemic steroids

Platelet Count (Plt)

- Measurement of number of platelets per μL of blood
- Low platelet count is known as thrombocytopenia

Postoperative Ischemic Optic Neuropathy

- 22 F Presents with painless vision loss

Anemic Retinopathy

- “Retinopathy in patients with anemia is well documented. Common findings include hemorrhages that can present at all levels of the retina and choroid, Roth’s spots, exudates, cotton wool spots, retinal edema and venous tortuosity.”

Anemic Retinopathy

- Anemic retinopathy may also be a secondary manifestation of other systemic diseases such as cancer, infection or autoimmune disorders. Therefore, in addition to ordering a complete blood count (CBC w/differential), other appropriate medical testing may be necessary. In regards to the management, anemic retinopathy is reversible with correction of the anemia.

Anemia and Hematocrit Levels

Ordering a CBC

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Diabetes Testing

- Random Blood Glucose
- Fasting Plasma Glucose
- Oral Glucose Tolerance Test
- Glycosylated Hemoglobin
**Random Blood Glucose**

- Note when patient ate last:
  - 220mg/dL pp 3 hours pp (post prandial)
  - 140-200 mg/dL = pre-diabetes
  - >200 mg/dL = diabetes

**Fasting Plasma Glucose**

- Must be fasting for at least 8 hours
  - 100-125 mg/dL = prediabetic
  - > 125 mg/dL = diabetic

**Glycosylated Hemoglobin**

- HbA1c
  - Glycosylated hemoglobin stays with red blood cell for its entire life
  - Life of a red blood cell is approximately 90 days
  - ≥ 6.5% = diabetes
  - American Diabetes Association recommends that HbA1c be below 7.0%

**Cost of Tests**

<table>
<thead>
<tr>
<th>Test</th>
<th>Cost</th>
<th>Medicare Reimbursement</th>
</tr>
</thead>
<tbody>
<tr>
<td>Random Blood Glucose</td>
<td>&lt;$100 meter &lt;$1 test strips</td>
<td>$3.20</td>
</tr>
<tr>
<td>Glycosylated Hemoglobin (A1C)</td>
<td>$113 for 10 $170 for 20</td>
<td>$11.79</td>
</tr>
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A1C Now

A1C Now® is a registered trademark of A1C Now® Ltd.
Lipid Panel

- **Total Cholesterol =** VLDL + LDL + HDL (<200)
- **VLDL < 30**
- **LDL < 130**
- **HDL > 40**

Lipid Metabolism

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**Basic lipid panels miss 60% of those at risk for CVD and should not be used in certain patient types**

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**50% of people who have a cardiovascular event have "normal" cholesterol**

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**Lipoprotein Subclasses**

- Lower risk
- Higher risk
- Large l.Dt. (Pattern A)
- Small l.Dt. (Pattern B)

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**Heartpoint.com**

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**eatingacademy.com**
Cost of Tests

- Lipid Panel: $128
- VAP Panel: $39-$79
Iritis
(Anterior Uveitis/Iridocyclitis)

- Consider ordering blood work if the uveitis is:
  - **Bilateral** or
  - **Granulomatous** or
  - **Recurrent** and
  - The history and exam still leave some uncertainty of diagnosis.

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**Iritis**

- **ACE** – Angiotensin Converting Enzyme
- **RPR** – Rapid Plasma Reagin
- **FTA-ABS** – fluorescent treponemal antibody absorbed
- **PPD** – Purified Protein Derivative (a.k.a Mantoux skin test)
- **Lyme Titer**
- **ESR** – Erythrocyte Sedimentation Rate
- **HLA-B27** – Human Leukocyte Antigen B-27

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**Sarcoidosis**

- granulomatous inflammatory response

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**Sarcoidosis is caused by a(n):**

A. **Virus**
B. **Bacterium**
C. **Fungus**
D. **Autoimmune Condition**

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ACE – Angiotensin Converting Enzyme
- Enzyme found mainly in lung epithelial cells
- Also found in smaller amounts in renal tissue and blood vessels
- Converts angiotensin I to angiotensin II – a vasopressor that stimulates the adrenal cortex to produce aldosterone
- Elevated ACE levels strongly correlated to pulmonary sarcoidosis

RPR – Rapid Plasma Reagin
- Tests for the presence of reagin, the antibody specific to the Treponema pallidum spirochete that causes syphilis
- Most useful during the secondary stage of the disease when antibody presence is greatest
- Sensitivity in primary syphilis is poor
- More sensitive and can be done in place of the Venereal Disease Research Laboratory (VDRL)

Syphilis is caused by a(n):
A. Virus
B. Bacterium
C. Fungus
D. Autoimmune Condition

Syphilis
spirochete bacterium Treponema pallidum

FTA-ABS – fluorescent treponemal antibody absorbed
- Most sensitive detection of syphilis in all stages
- Prior to testing, the serum is treated to remove antibodies that could cause false-positive results. Fluorescence microscopy with special filters to decrease the natural fluorescence from the background of the specimen is used. Fluorescein-conjugated antibodies to IgG are added as a counterstain, and treponemes are identified as they fluoresce in combination with the antibodies
- May remain positive indefinitely - Not useful for monitoring

Tuberculosis is caused by a(n):
A. Virus
B. Bacterium
C. Fungus
D. Autoimmune Condition
**Tuberculosis**
*Mycobacterium tuberculosis*

**PPD – Purified Protein Derivative (a.k.a Mantoux skin test)**
- Used for Tuberculosis detection
- Patients are injected intradermally with a mixture of antigens
- Lack of redness and induration of the skin at the site of injection 24-48 hours after injection indicate a negative test
- Poor sensitivity, good specificity
- As of 2005 the CDC no longer recommends PPD, instead recommends newer interferon tests

**Lyme Disease**
*bacterium spirochete Borrelia burgdorferi*

**Lyme Disease** is caused by a(n):
- A. Virus 0%
- B. Bacterium 0%
- C. Fungus 0%
- D. Autoimmune Condition 0%

**Reported Cases of Lyme Disease – United States, 2011**
Lyme Titer

- Testing attempts to detect antibodies to the causative agent, the spirochete Borrelia burgdorferi, carried primarily by the deer tick
- Perform initial enzyme-linked immunosorbent assay (ELISA)
- If negative, then repeat in 2-4 weeks
- If positive, follow-up with IgG and IgM Western blot if less than 8 weeks from onset or with an IgG Western blot confirmatory test if more than 8 weeks from onset.

ESR – Erythrocyte Sedimentation Rate

- Most widely used lab test to monitor the course of inflammatory disease, as well as infections
- Measures the rate red blood cells fall to the bottom of a tube of well-mixed venous blood – measured in mm/hour
- Cannot detect inflammation as quickly or as early as the C-reactive protein test

HLA-B27 – Human Leukocyte Antigen B-27

- HLA-B27 is a major histocompatibility complex molecule whose primary function is to present endogenous peptides to T-cells and receptors on natural killer cells.
- Presence of B-27 antigen is highly correlated with ankylosing spondylitis and rheumatoid arthritis

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Iritis Lab Order

DR. MICHAEL GOODMAN & ASSOCIATES
346 King St
Cape May, NJ 08204
(609) 884-2400
201-445-7999

Rx

Chest X-ray
(r/o sarcoidosis)

Diagnosis: xxx.xx

Cost of Tests

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<thead>
<tr>
<th>Test</th>
<th>Cost*</th>
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<tbody>
<tr>
<td>ACE – Angiotensin Converting Enzyme</td>
<td>$140</td>
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<tr>
<td>RPR – Rapid Plasma Reagin</td>
<td>$28</td>
</tr>
<tr>
<td>FTA-ABS – fluorescent treponemal antibody absorbed</td>
<td>$76</td>
</tr>
<tr>
<td>PPD – Purified Protein Derivative (a.k.a Mantoux skin test)</td>
<td>$36</td>
</tr>
<tr>
<td>Lyme Titer</td>
<td>$172</td>
</tr>
<tr>
<td>ESR – Erythrocyte Sedimentation Rate</td>
<td>$36</td>
</tr>
<tr>
<td>HLA-B27 – Human Leukocyte Antigen B-27</td>
<td>$181</td>
</tr>
<tr>
<td><strong>Total</strong></td>
<td><strong>$669</strong></td>
</tr>
</tbody>
</table>

*Quest Diagnostics (number rounded to nearest dollar)

1QuantiFERON®-TB, Quest Diagnostics, $323

directlabs.com

Lab Cost Comparison

<table>
<thead>
<tr>
<th>Test</th>
<th>Quest</th>
<th>Local Hospital</th>
<th>DirectLabs</th>
</tr>
</thead>
<tbody>
<tr>
<td>CBC w/diff</td>
<td>$41</td>
<td>$55</td>
<td>$29</td>
</tr>
<tr>
<td>Lipid Panel</td>
<td>$128</td>
<td>$56</td>
<td>$29</td>
</tr>
<tr>
<td>CMP</td>
<td>$58</td>
<td>$89</td>
<td>$29</td>
</tr>
</tbody>
</table>