Laboratory Testing for the Optometrist

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Abstract
Laboratory testing, both in-office and by referral, can be crucial to effective diagnosis and management. Indications and interpretation of pertinent lab tests will be covered through a series of case reports.

Learning Objectives
1) To define the role of laboratory testing in the optometric practice.
2) To educate the primary care optometrist about the regulation and certification requirements for point-of-care laboratory testing.
3) To recognize clinical situations in which performing laboratory testing in-office would be useful.
4) To understand how to obtain a test sample and properly interpret the results of in-office laboratory procedures.
5) To enable the primary care optometrist to effectively communicate with other health professionals.
6) To recognize which laboratory tests are useful in managing various ocular diseases with a systemic etiology.

Outline
I. Introduction
   a. The role of laboratory testing in optometric practice
      i. Point of care testing
      ii. Indications for ordering lab tests
   b. Occupational Safety and Health Administration (OSHA) guidelines
   c. Clinical Laboratory Improvement Amendments (CLIA) regulations
      i. Certification for “waived” tests
   d. Billing for in-office laboratory tests
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i. Document medical necessity
ii. Advanced Beneficiary Notice (ABN)
iii. CPT codes for CLIA-Waived tests all have a –QW modifier at the end
iv. Use modifier -59 for second eye

II. Requesting lab testing outside of the office
   a. Breakdown of CBC – what are we testing and what do the values mean?
   b. Case - Uveitis
      i. Inflammatory indications for laboratory testing
      ii. Serology
         1. Syphilis testing
            a. RPR
            b. VDRL
            c. FTA-ABS
         2. Tests for autoimmune disease
            a. ANA
            b. RF
            c. HLA
         3. Lyme ELISA
         4. ACE

III. Case – Diabetic retinopathy
   a. Glucometry using finger stick method
      i. Indications
      ii. Instrumentation and Procedure
         1. CLIA-waived glucometer for home use
      iii. 2008 American Diabetes Association criteria for diagnosis
      iv. Expected results for diabetic and non-diabetic patients
      v. Effectively handling diabetic emergencies in-office
         1. Recognition
            a. Hypoglycemic events
            b. Ketoacidosis
         2. Preparedness
            a. Rapid-acting carbohydrates
            b. Post-crisis management
   b. Hemoglobin A1c/Glycosylated hemoglobin using finger stick method
      i. Indications
         1. Now one of 4 diagnostic criteria for DM from ADA
      ii. Instrumentation and Procedure
         1. CLIA-waived test for home use
      iii. Expected results (percentage of total Hb)
      iv. Clinical Pearls
         1. Estimated Average Glucose (eAG)
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a. A1c derived average glucose study (ADAG)
2. Sources of error
3. Billing and Coding/Average reimbursement rates

IV. Case – Acute red eye
a. Adenovirus detector
   i. Indications
   ii. Instrumentation and Procedure
   iii. Clinical Pearls
      1. Sources of error
      2. Billing and Coding/Average reimbursement rates
      3. Betadine off-label therapy
      4. Future of conjunctivitis testing

V. Case – Temporal arteritis
a. Inflammatory markers—ESR and C-reactive protein
   i. Indications
   ii. Expected results
b. Diagnostic procedures—temporal artery biopsy

VI. Case – Dry Eye
a. Elements to add to routine examination
   i. TBUT, Schirmer Test, specialty dyes
b. Tear Osmolarity Measurement
   i. Increase in osmolarity ..... Increase in ocular inflammation
      1. Perform before other tests – affected by reflex tearing
      2. Can fluctuate throughout day
c. Tear Film Lipid Layer Interferometry
d. MMP-9 testing
   i. Tests for MMP-9s in tears
   ii. Positive if MMP-9 >/= 40ng/mL
   iii. MMP-9 are often elevated w/o other signs of DES
   iv. Procedure Pearls
      1. Perform before any drops
      2. dabbing vs. dragging
      3. Release lid for blinking after 2-3 dabs
      4. Repeat 6-8 times
      5. Let sample pad rest on conj for 5 sec to saturate
      6. Any pink at all = positive
      7. No blue line = invalid test
e. Sjögren’s antibody test -- earlier detection
   i. Instrumentation and Procedure
      1. Kits are free
      2. Finger stick required
ii. Tests for classic and new inflammatory markers for Sjögren’s
   1. Ro
   2. La
   3. SP-1
   4. CA6
   5. PSP

iii. Review of Sjögren’s
   1. SD
      a. Autoimmune disease which leads to loss of salivary gland and lachrymal gland function
      b. Hypergammaglobulinemia
      c. Autoantibody production
      d. Mild kidney and lung disease
      e. Eventual lymphoma
   2. SS
      a. Dry eyes and dry mouth
      b. With or without systemic features
      c. May be secondary to other autoimmune disorders (e.g. SLE)

f. Demodex?
   i. Microscopic slide observation
   ii. Convince yourself....
   iii. ...and/or the patient
   iv. Counting mites
   v. D. follicularis—located more superficially in hair follicles
   vi. D. brevis—deeper, in meibomian glands
   vii. Course is chronic
       1. Prevalent in human population – 20-80%!!
       2. Increases with age – reaching 100% in elderly populations
       3. D. folliculorum more common in females
   viii. How do you get them?
       1. Direct contact with infected individual’s skin or hair
       2. Contact with contaminate objects – towels, combs, sponges, etc
   ix. Associations
       1. 60-97% of blepharitis patients have Demodex
       2. MGD / evaporative DES
       3. Up to 85% of patients with MGD have Demodex
       4. Ocular Allergies
       5. Can be misdiagnosed due to papillary conjunctivitis and itching
       6. Ocular Rosacea
   x. Indications
1. Inflamed eyelid margins, MGD, dry eyes, ocular allergies
2. Cylindrical dandruff – 100%
3. Enlarged blood vessels on eyelid margins
4. Loss of eyelashes, misdirected lashes
5. Many are asymptomatic
6. Itching, FBS
7. Burning
8. Watering
9. Photophobia
10. Hx of failed attempts to improve symptoms

xi. Sample Collection Pearls
xii. Treatment
  1. Goal of treatment: decrease population
  2. Can treat with or without symptoms
  3. Treatment with wipes/foam once every other day

VII. Case – Chronic Follicular Conjunctivitis
  a. Etiologies
    i. Chlamydia
    ii. Molluscum
    iii. Toxic/reactive inflammatory
    iv. Rosacea
  b. Testing
    i. Chlamydiazyme
    ii. PACE 2
    iii. AMP-CT
    iv. QuickVue Chlamydia test
    v. Sterile swab kit -- Amies media without charcoal

VIII. Case – ARMD
  a. Review of Literature
    i. AREDS Review
      1. AREDS – Archives of Ophth 2001
         Looked at the ability of different supplementations to decrease
         progression of moderate/advanced AMD
         a. Placebo
         b. Antioxidants
         c. Zinc
         d. Both antioxidants and zinc
         e. AREDS formula reduced progression of intermediate to
            advanced AMD by 25% and 19% reduction in moderate vision
            loss for those at high risk for geographic AMD or CNVM
2. AREDS 2 – JAMA Ophth 2013
    Looked at the effect of the following in regards to progression:
    a. adding zinc/zeaxanthin or Omega 3s or both
    b. Eliminating beta carotene, lowering zinc
    c. Zinc/zeaxanthin/Omega 3s + AREDS did not further reduce progression; Eliminating beta carotene and lowering zinc do not pose a problem

3. Genetic Testing ???
   b. Papers by Chew, et al.

b. Testing Procedure
   i. No CLIA certification required
   ii. Simple cheek swab
   iii. buccal cytology brushes
   iv. sterile tissue collection bag
v. Interpretation
   1. Risk of progression – low, moderate, high
      a. How closely should you follow?
      b. Patient education/counseling
   2. Genetic classification – Recommendation for vitamin therapy
      a. AREDS II formula
      b. Zinc only
      c. Antioxidants only

vi. Pearls
   1. No food or coffee 30 minutes prior to collection
   2. Wear gloves to avoid contaminating with your DNA
   3. Brush cheek with swab firmly x 20
   4. Avoid gum line
   5. Wave swab gently to let air dry.
   6. Place dried swab into original sleeve (brush end down)

c. The meso-zeaxanthin debate
   i. Lutein
   ii. Zeaxanthin
   iii. Meso-Zeaxanthin ??
      1. No natural dietary source
      2. Body converts from lutein