2016 Point of Care In-Office Lab Testing

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Point of Care Testing (POCT)

- Bedside / chairside / EMS
- Rapid, immediate results
- If CLIA waived (still need CLIA Certificate)
  - Easy, almost fool proof
  - Some are devices / kits FDA approved for home use by consumers as well as for professional use
POCT Examples
Requirements

• Must meet all OSHA, CDC, & CLIA requirements as previously described
• Also lab coat recommended when dealing with blood or other body fluids, tissues
  – Do not wash in home laundry
  – Do not wear outside the workplace
CLIA categorizes laboratory tests according to complexity & states staff qualifications needed for each

- Waived
- Moderate / PPM
- Complex
Who needs a CLIA Certificate?

• **All entities** who perform even 1 lab test, including waived tests, on materials from the human body for purpose of dx, prevention, or treatment of any condition must register with CLIA
  – Required even if not charging for it
Waived & PPM

- Must follow good clinical laboratory practices
  - Follow manufacturer’s recommendations
  - Run and record control values in log and in patient’s chart
  - Maintain a log of patient and control values
  - Maintain record of action taken: referral, etc
Home **collection** kits

- Not technically POCT
- Do **not** require CLIA certificate because you are just collecting not performing the test
- Specimen collected at home or in-office and mailed or transported to medical lab
- Macula Risk PGx, RetnaGene, fluorescent antibody slides preps, etc.
OD most likely to use

- Blood glucose screening
- Hb A1C (glycosylated hemoglobin)
- RPS for Adenovirus & Inflammaddry for dry eye associated with increased MMP-9
- Cholesterol & HDL
- Tear Lab & newer dry eye tests
  - Some use tears, some use blood
- Conjunctival smears (must have PPM level of certificate)
CPT CODES

• A1C Now if performed in provider’s office CPT 83037
• For Medicare or Medicaid 83037QW
• Finger puncture or other capillary blood CPT 364.16
• Venipuncture blood collection CPT 364.15
• You do not have to memorize these
Hgb A1C (glycosylated/glycated hgb)

- Glucose attaches to a hgb molecule/glycates
- Irreversible for life of the RBC (2-3 months)
- A1C has greater affinity for O2
  - Less O2 released to tissues so tissue damage
- Normal non-diabetics: 4-6%
- In known diabetics values of 7% or less often considered good control
A1C

- Used to monitor long term control and tx compliance & for dx
  - Reflects blood glucose over past few months
- Perform no more than every 3-4 months
- Not valid if hgb abnormalities such as sickle cell, hemolytic anemias, etc
- Home self-test which can be used in-office & laboratory procedure also available
A1C

• Fasting not required
• Shows what average of blood glucose was over past 2-3 months
• *Per ADA now recommended for diagnosis as well as monitoring DM patients*
• DX value: \( \geq 6.5\% \)
Relationship of A1C to Average Whole Blood and Plasma Glucose Levels

<table>
<thead>
<tr>
<th>HbA1c %</th>
<th>Mean Blood Glucose (mg/dL)</th>
<th>Average Plasma Glucose (mg/dL)</th>
<th>Interpretation</th>
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</thead>
<tbody>
<tr>
<td>4</td>
<td>61</td>
<td>65</td>
<td>Non-Diabetic Range</td>
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<td>170</td>
<td>Target for Diabetes in Control</td>
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<td>8</td>
<td>188</td>
<td>205</td>
<td>Action Suggested according ADA guidelines</td>
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</table>
A1C studies

- In general lowering A1C by 1% decreases risk of DM complications by 21%
- For eye, kidney, lowers risk of complications by 40%
DCCT A1C levels and the risk of complications in type 1 diabetes
A1CNOW +

- For professional use
- Manufacturer Metrika / Bayer
  - Available from various distributors
  - 10 & 20 cartridge packs/tests
  - Same thing OTC in stores for patients in packs of 2
Bayer A1CNow+

- www.A1cnow.com
- 5 ul blood, 5 minutes
• **CPT**: 83037QW
• $21.06 average reimbursement
Supplies needed
Getting ready

• All parts of kit must be same lot # & at room temp for at least 1 hour
• Avoid performing in direct sun, on cold or warm surfaces
• Control should be run
• If you make mistakes at any point, test will not measure but you won’t know it until after specimen is applied to pad so reagents will be wasted
Wash & dry hands, clean selected finger with alcohol
Dry with clean cotton or gauze
Cap indicates new unused lancet

Only use devices which self-retract
Choose fleshy non-callused finger
Milk if needed
• **Good sample**

• **Not enough blood & too spread out**
Aspirate blood
Fill completely & no bubbles

- Over or under filling will alter results
Fully insert blood collector into sampler body / diluent
Shake/mix vigorously 6-8 times
Stand sampler on table while preparing cartridge
Insert cartridge into monitor
Don’t do this until after collecting blood

Blood must be applied within 2 minutes of inserting cartridge
Remove base of sampler & apply diluted blood to pad

• 5 minutes later reading will appear in window
Error reading

Will not read if not performed properly
Lipid profile

Assay of LDL, HDL, total cholesterol, Chol/HDL, triglycerides along with CHD risk factor

• Total cholesterol does not require fast, but the other lipid profile tests require 12 hr fast

• ADA goals for diabetics: triglycerides <150mg/dl, HDL >40mg/dl, LDL decrease by 40% from baseline
Why order lipid panel?

- Chronic heart disease is the most common cause of death in diabetics
- Low HDL &/or high LDL associated with atherosclerosis & > incidence of retinopathy
- Improving lipid profile may decrease macular exudates and improve acuity in diabetes, HBP, ARMD
CardioChek PA Analyzer Test

- CLIA waived, FDA cleared for professional use, finger stick, results in 1-2 minutes
Thyroid (TSH) Hormone Testing Kits

FDA Cleared and CLIA waived
Results in 10 minutes

CPT code: 84443, Reimbursement $23.40.
Kit cost approx $140- $160 for 20 tests
Adeno Detector

• Currently only available for adenovirus
• Plan for more organisms in future
• Why not used more often? AV typically easy to dx from clinical px, sxs
Rapid Pathogen Screening (RPS) AdenoPlus

- Detects all adenovirus subtypes
- In-office immunodiagnostic 10 minute test
  - Uses antigen detection
- Highly specific (96%) & sensitive (90%)
- Assists in patient management re contagion, need for antibiotics, etc
Procedure

• 1. Assemble the detector
• 2. Dab sampling pad inside lower palp conj 4-6 X. Let pad rest against conj for an additional 3 sec to ensure saturation
• 3. Immerse the assembled detector tip into the buffer vial for 15 sec
Results

• If Results line (red or pink) & Control line (blue) are both present, indicates adenovirus antigen **is** present
  Positive even if pink/red line is faint or uneven

Negative: only 1 line
Tear Lab for osmolarity

- www.TearLab.com
- Use to:
  - Dx presence of dry eye disease (DED)
  - Grade severity of DED
  - Monitor response to treatment
Tear Lab & CLIA

- **CPT code 83861 QW**
- **Reimbursement approx $46.80 per patient**
- **Controls must be run which increases your cost**
Tear hyperosmolarity

- Global biomarker for both aqueous deficiency & evaporative dry eye
- The primary mechanism causing ocular surface inflammation, damage, sx's
- Leads to cell death, loss of goblets, & disturbance of mucin
Rapid, noninvasive
Results

- > 308 mOsms/L are indicative of DED
  Amer Acad Ophthalmology Nov 2009. Clinical trial conducted by Tear Lab
- Others use 316 mOsms/L as cutoff
- > 350 considered severe
- Dx values evolving as test is used more
What is significant?

• High values
• Variability between the eyes
• Difference between OD and OS of greater than 8-10 mOsm/L is a classic indication of loss of homeostatic control and is a confirming indicator of dry eye disease.
• Variability from day to day & during day
Point of Care Tests

• Many more on the horizon
• Becoming more commonplace in Optometric offices
  – Particularly in DM testing, dry eye
• Most CLIA waived
• Immediate results
• Most reimbursable
• It’s not that hard!