

# Point of Care Testing

BOPCC

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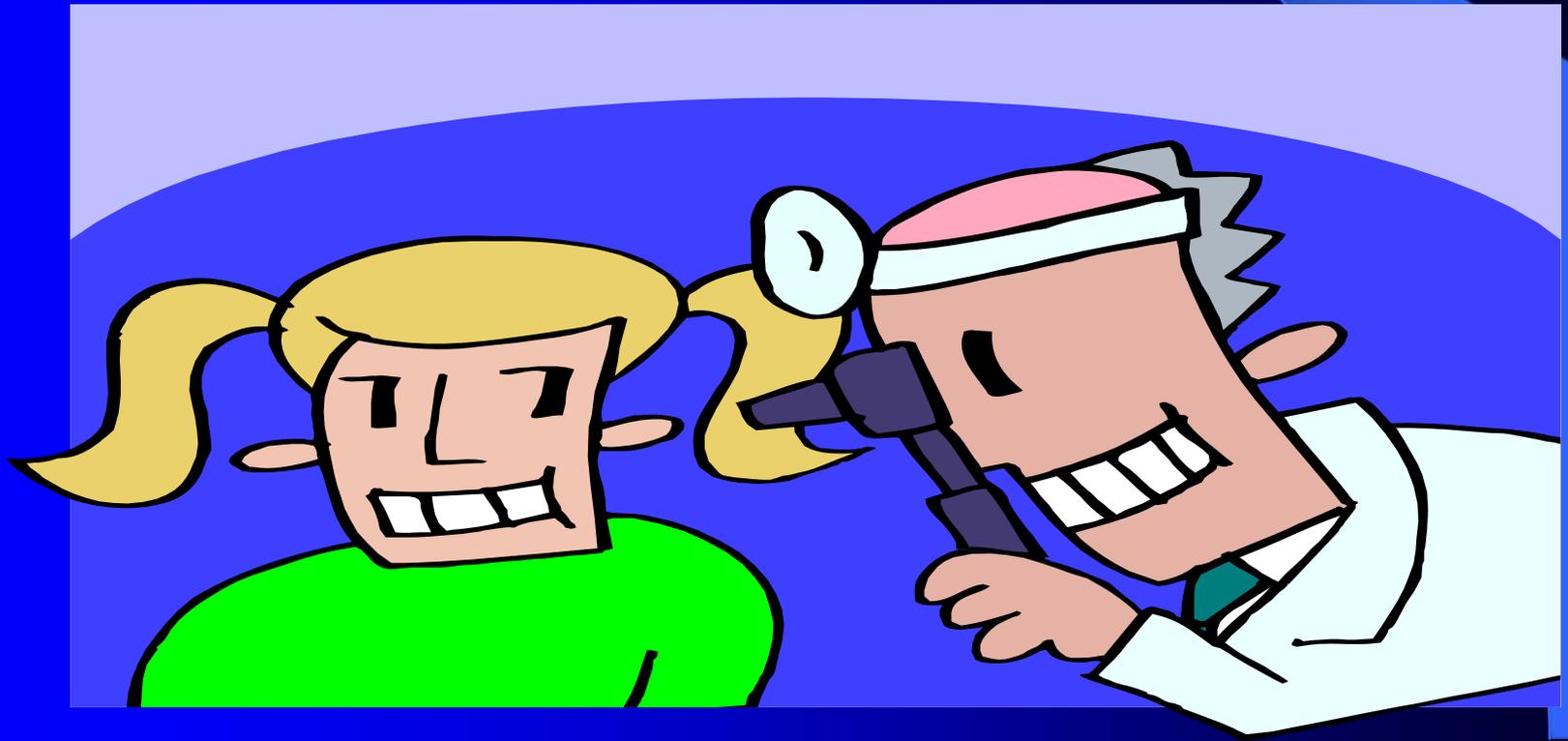
# Objectives

- Describe “Direct patient Care” in California law
- Describe Point of Care testing device
- Identify the personnel authorized to perform waived or point of care testing
- Enumerate requirements for the preceptor training program

# Direct Patient Care

“Direct Patient Care” means medical, psychiatric, nursing or other health care which is legally provided by a care giver or healthcare provider directly to a patient, and which includes observation of the patient’s physical or mental condition to enable the care giver or healthcare provider to report changes in the patient’s condition, CCR 1029.7.

- Legally provided by a care giver or healthcare provider



# Direct patient Care cont.

- Directly to a Patient



# Direct Patient Care cont.

- Includes observation of the patient's physical or mental condition



# Direct Patient Care

- To enable the care giver or healthcare provider to report changes in the patient's condition,



# Point of Care Laboratory testing device (CBPC 1206)

- Portable Instrument
- Used within the proximity of the patient
- Used in accordance with the laboratory patient test management system, the quality control program, and the comprehensive quality assurance program

# Point of Care Testing Device

- Portable Instrument
- Used within the proximity of the patient

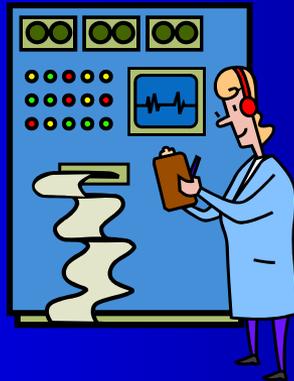


# Point of Care Laboratory testing device Cont.

- It meets the following criteria:
  - Waived or moderate complex tests
  - No preparation after collection
  - Results without calculation or discretionary intervention
  - No calibration or maintenance required

# Point of Care Testing Device cont.

- Used in accordance with the laboratory patient test management system, the quality control program, and the comprehensive quality assurance program



# Laboratory Requirements

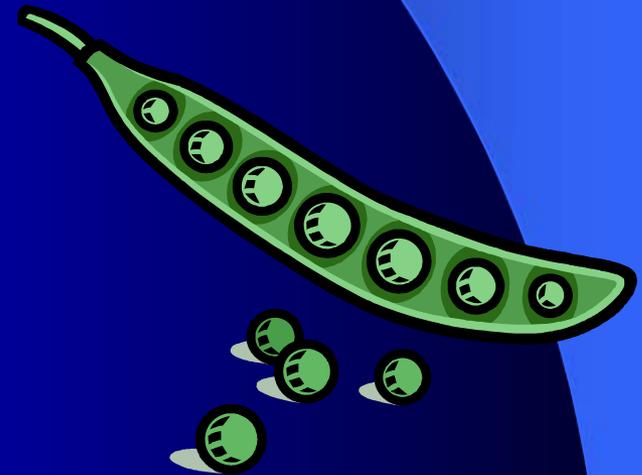
- State Certificate of Registration or license

Plus

- Federal CLIA Certificate of Waiver or Certificate of Compliance or Accreditation

# Hospital Licensing of Lab

- One license
  - Contiguous buildings on hospital campus
  - Common direction
  - Common ownership



# Waived Test Requirement

- Simple system
  - Cleared by FDA for home use
  - Simple-so erroneous results negligible
  - Pose no risk of harm if performed incorrectly

# Example of Waived Tests

- Drugs
- Hormones
- Chemistries
- Blood Chemistry
- Bacteria
- Viruses



# Director Requirements- Waived Tests

- Waived Testing

State-MD, CA Licensed Bioanalyst,

CA licensed PhD-Board Certified

Federal-No specification

# Testing Personnel Comparison – Waived Tests

- California
  - Limited to personnel in BPC 1206.5 (a)
- CLIA
  - No specific educational requirement

# Waived Laboratory Supervisor

- CCR 1036.3 Requirements
  - Listed in B&P 1206.5
  - Minimum BS degree
  - One year training or experience in tests
  - Documented competency semiannual 1<sup>st</sup> year

# Waived Supervisor Responsibilities

- Select Test methods
- Establish QC program from initial receipt
- Resolve technical problems
- Ensure corrective actions taken
- Identify training needs

# Waived Supervisor Responsibilities cont.

- Evaluate and Document Competency
  - Direct observation
  - Monitor recording and reporting of test results
  - Review QC records and preventive maintenance
  - Observe performance of instrument
  - Assess problem solving skills
  - Document competency semiannual 1<sup>st</sup> yr.

# Testing Personnel Authorized to Perform Waived Tests CBPC 1206.5

- Licensed Physician and Surgeon
- Licensed Osteopath
- Licensed Podiatrist
- Licensed Dentist
- Licensed B&P Chapter 3
- Certified Public Health Microbiologists

# Testing Personnel Authorized to Perform Waived Tests

- Licensed Physician Assistant
- Registered Nurse
- Licensed Vocational Nurse
- Certified Perfusionist
- Licensed Respiratory Care Practitioner
- Certified Medical Assistant
- Others, Providers of Direct Patient Care

# Quality Control Waived Tests

FOLLOW THE MANUFACTURER'S INSTRUCTIONS

# Waived Tests-Most Frequent Deficiencies

- Follow the Manufacturer's instructions
- Instruction sheet not available to testing personnel

# Director Requirements- Moderate Complexity

- Moderate Complexity Testing

State-same as for waived testing

Federal-

Must be licensed by state, if required

MD, must have lab training or

1 yr. directing or supervising non-waived

or

20 CE units

# Testing Personnel Comparison- Moderate Complexity Tests

- California

- Limited to personnel in BPC 1206.5 (b)

- CLIA

- Licensed according to state law
- Doctor of medicine or osteopathy
- Earned doctorate, master's or baccalaureate in science
- High school graduate and military specialty
- High school graduate and training.

# Testing Personnel Authorized to Perform Moderate Complexity Tests CBPC 1206.5

- Licensed Physician and Surgeon
- Licensed Osteopath
- Licensed Podiatrist
- Licensed Dentist
- Licensed under Chapter 3
- Certified Public Health  
Microbiologists

# Testing Personnel Authorized to Perform Moderate Complexity Tests (Cont.)

- Licensed Physician Assistant
- Registered Nurse
- Certified Perfusionist
- Licensed Respiratory Care  
Practitioner

# Testing Personnel Authorized to Perform Moderate Complexity Tests (Cont.)

- Licensed Nuclear Medicine Technologist
- Blood Gas Analyst
- Any person within a Physician Office Laboratory
- Pharmacist when performing drug therapy related laboratory tests.

# Testing Personnel Authorized to Perform Moderate Complexity Tests (Cont.)

- Specified providers of direct patient care using a point of care testing device (CCR1054.7)
  - Certified EMT II
  - Paramedic
  - Psychiatric Technician
  - Licensed Vocational Nurse
  - Licensed Midwife
  - Certified Nurse Assistant
  - Certified Home Health Aide

# Preceptor Program Training Point of Care Testing

- Operation of each instrument
- Maintenance and calibration
- Manufacturer's instructions
- Reference ranges, critical values, actions for values outside analytical range

# Preceptor Program cont.

- Reference ranges, critical values, actions for values outside analytical range
- Quality control and assurance protocols, including remedial action and reagent and specimen handling
- Clinical significance of test results

# Preceptor Program cont.

- Physiological conditions that may affect specimen integrity
- Safety and Universal precautions
- Competency determined by director or technical consultant

# Preceptor Program cont.

- Participate in a preceptor program over 20 separate testing events covering the entire range of expected values with 90% correct
- Proficiency requirement is for each separate instrument

# Preceptor Qualifications

- Laboratory director or technical consultant as defined in CLIA or,
- Meets qualifications as technical consultant under CLIA and state to perform tests as moderate complex or,
- Any person listed in subsection (b) of 1206.5 except for (10) (11) and (12) with 2 yrs. experience with the specific instrument

# Information

CMS Web site: [www.cms.hhs.gov/clia](http://www.cms.hhs.gov/clia)

State regs: [www.leginfo.ca.gov/calaw.html](http://www.leginfo.ca.gov/calaw.html)

[www.calregs.com](http://www.calregs.com)

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Questions?