

GOOD LABORATORY PRACTICE

- CLIA NON-WAIVED TESTS

REQUIRED

- ◆ Obtain Federal CLIA (Clinical Laboratory Improvement Amendments-1988) Certificate of Compliance or Certificate of Accreditation

Application at: <http://www.cms.hhs.gov/clia>

- ◆ Perform any test categorized by the FDA (Federal Drug Administration) as waived plus moderate and high complexity tests listed on your CLIA certificate

List at: <http://www.fda.gov/cdrh/clia/#online>, select CLIA Database

- ◆ Follow manufacturer's instructions and agency's requirements
- ◆ For CLIA compliance regulations: <http://www.cms.hhs.gov/clia>
- ◆ For other standards - Follow agency requirements

PERSONAL QUALIFICATIONS

See Code of Federal Regulations Title 42, Section 493

- ◆ **Director** - Sect. 493.1443 (duties Sect. 493.1445)
- ◆ **Clinical Consultant** - Sect. 493.1455 (duties Sect. 493.1457)
- ◆ **Technical Supervisor** - Sect. 493.1449 (duties Sect. 493.1451)
- ◆ **General Supervisor** - Sect. 493.1461 & 493.1462 (duties 493.1463)
- ◆ **Cytology General Supervisor** - Sect. 493.1469 (duties Sect. 493.1471)
- ◆ **Cytology Testing Personnel** - Sect. 493.1483 (duties Sect. 493.1485)
- ◆ **Testing Personnel** - Sect. 493.1489 & 493.1491 (duties Sect. 493.1495)

OVERSIGHT

- ◆ **Cost** - varies by agency and test volume for a two-year cycle
- ◆ **Surveys** - every two years
State agencies schedule visits
Accrediting agency surveys scheduled or unannounced

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GOOD LABORATORY PRACTICE

- CLIA NON-WAIVED TESTS MODERATELY COMPLEX PROVIDER PERFORMED MICROSCOPY PROCEDURES (PPM)

REQUIRED

- ◆ Obtain Federal CLIA (Clinical Laboratory Improvement Amendments–1988)
- ◆ Certificate of Compliance or Certificate of Accreditation
 - Application at: <http://www.cms.hhs.gov/clia>
- ◆ Perform any test categorized by the FDA (Federal Drug Administration) as waived and any of nine microscopic tests
 - **Fecal leukocyte (WBCs)**
 - **Post-coital (vaginal or cervical)**
 - **Semen analysis (presence / absence)**
 - **Fern test**
 - **Urinalysis (microscopic)**
 - **Potassium hydroxide (KOH) Urinalysis – two or three glass test**
 - **Nasal smear for granulocytes**
 - **Pinworm**
 - **Wet mounts**
- ◆ Follow applicable CLIA microscopic test regulations found in the Code of Federal Regulations, Title 42, Section 493, (subparts A, C, J, K)

PERSONAL QUALIFICATIONS

See Code of Federal Regulations Title 42, Section 493

- ◆ **Director** – Sect. 493.1357 (duties Sect. 493.1407)
- ◆ **Testing Personnel** – Sect. 493.1423 (duties Sect. 493.1425)

OVERSIGHT

- ◆ **Cost** – \$200 every two years
- ◆ **Surveys** – no routine visits, complaints only

Note: Approved tests only performed by state licensed MD, DO, dentist or mid-level practitioners

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GOOD LABORATORY PRACTICE

- CLIA NON-WAIVED TESTS MODERATELY COMPLEX

REQUIRED

- ◆ Obtain Federal CLIA (Clinical Laboratory Improvement Amendments–1988)
- ◆ Certificate of Compliance or Certificate of Accreditation
Application at: <http://www.cms.hhs.gov/clia>
- ◆ Perform any test categorized by the FDA (Federal Drug Administration) as waived plus moderate and high complexity tests listed on your CLIA certificate
List at: <http://www.fda.gov/cdrh/clia/#online>, select CLIA Database
- ◆ Follow manufacturer's instructions and agency's requirements
- ◆ For CLIA compliance regulations: <http://www.cms.hhs.gov/clia>
- ◆ For other accredited standards, follow agency requirements

PERSONAL QUALIFICATIONS

See Code of Federal Regulations Title 42, Section 493

- ◆ **Director** – Sect. 493.1405 & 493. (duties Sect. 493.1407)
- ◆ **Clinical Consultant** – Sect. 493.1417 (duties Sect. 493.1419)
- ◆ **Technical Supervisor** – Sect. 493.1411 (duties Sect. 493.1413)
- ◆ **Testing Personnel** – Sect. 493.1423 (duties Sect. 493.1425)

OVERSIGHT

- ◆ **Cost** – varies by agency and test volume for a two-year cycle
- ◆ **Surveys** – every two years
State agencies schedule visits
Accrediting agency surveys scheduled or unannounced

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GOOD LABORATORY PRACTICE

- CLIA WAIVED TESTS

REQUIRED

- ◆ Obtain Federal CLIA (Clinical Laboratory Improvement Amendments–1988) Certificate of Waiver (or higher level certificate)

Application at: <http://www.cms.hhs.gov/clia>

- ◆ Perform any test categorized by the FDA (Federal Drug Administration) as waived

List at: <http://www.fda.gov/cdrh/clia/cliawaived.html>

- ◆ Follow manufacturer's instructions for testing

See package insert or device manual

PERSONAL QUALIFICATIONS

See Code of Federal Regulations Title 42, Section 493

- ◆ **Director** – no requirements
- ◆ **Testing Personnel** – no requirements

OVERSIGHT

- ◆ **Cost** – \$150 every two years
- ◆ **Surveys** – no routine visits, complaints only

State agencies visit 2% of waived laboratories each year

Visit is scheduled with facility

Surveyor uses educational approach

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GOOD LABORATORY PRACTICE

SAMPLE COLLECTION - STERILE BLOOD - BLOOD CULTURE

BEFORE COLLECTION

- ◆ Train on procedure and safety
- ◆ Check requisition and patient ID
- ◆ Get supplies
 - Tourniquet - puncture device - tubes or bottles -
 - disinfectant wipes - gauze - bandage - biohazard container
- ◆ Wash hands - put on gloves

COLLECTION

- ◆ Apply tourniquet and select site
- ◆ Use peripheral veins (catheters may be contaminated)
- ◆ Clean site with disinfectant
- ◆ Swab in a circular motion from the center out
- ◆ Air dry before venipuncture
- ◆ Clean top of the tubes or bottles the same way
- ◆ After venipuncture, release tourniquet
- ◆ Collect blood culture first, then additional tubes if needed
- ◆ Remove needle - apply pressure with dry gauze pad
- ◆ Place entire puncture device in biohazard box
- ◆ Bandage puncture site
- ◆ Label samples with name, unique ID and DOB before leaving the patient

AFTER COLLECTION

- ◆ Process, store or transport sample(s) as required by testing laboratory
- ◆ Remove gloves, dispose in biohazard waste and wash hands

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GOOD LABORATORY PRACTICE

SAMPLE COLLECTION - NP (NASO-PHARYNGEAL) SWAB

BEFORE COLLECTION

- ◆ Train on procedure and safety
- ◆ Check requisition and patient ID
- ◆ Get supplies
 - Sterile flexible swab (see collection requirements) - holding media, culture plate or test kit transport tube
- ◆ Label media or test tube including patient name, unique identifier, date and time collected
- ◆ Wash your hands - put on gloves

COLLECTION

- ◆ Tell the patient they may experience an uncomfortable feeling or tickling
- ◆ Clear the nose of mucous and/or have patient cough
- ◆ Tilt the head back
- ◆ Gently insert swab until it meets resistance
- ◆ Quickly rotate and remove swab

AFTER COLLECTION

- ◆ Use swab for sampling procedure
- ◆ Place swab in holding media or roll over top 1/3 of culture plate or follow test kit procedure
- ◆ Discard collection materials in biohazard container
- ◆ Remove gloves, dispose in biohazard container and wash hands

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GOOD LABORATORY PRACTICE

SAMPLE COLLECTION - SPUTUM

PREPARE PATIENT

- ◆ Tell patient to drink plenty of fluids the night before. First morning specimen is preferred.

BEFORE COLLECTION

- ◆ Train on procedure
- ◆ Check requisition and patient ID
- ◆ Get supplies
 - Sterile screw-capped container and tissues
- ◆ Label container
 - Patient name, unique identifier, date and time collected
- ◆ Wash hands - put on gloves



COLLECTION

- ◆ Tell patient to do the following:
 - Sit upright
 - Take three deep breaths,
 - Cough deeply to bring sputum from lungs
 - Spit sputum into the container
 - Do not to place mouth on container lip or collect saliva or nasal drainage



AFTER COLLECTION

- ◆ Screw lid on tightly
- ◆ Place specimen in a biohazard container - transport to the testing laboratory
- ◆ Remove gloves - dispose in biohazard container - wash hands



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GOOD LABORATORY PRACTICE

SAMPLE COLLECTION

- SWAB - THROAT CULTURE / RAPID STREP TEST

BEFORE COLLECTION

- ◆ Train on procedure and safety
- ◆ Check requisition and patient ID
- ◆ Get supplies
 - Sterile Dacron swab - sterile tongue depressor - holding media
 - culture plate or rapid strep test kit
- ◆ Label media or test cartridge
 - Patient name - unique identifier - date and time collected
- ◆ Wash your hands - put on gloves

COLLECTION

- ◆ Tell patient they may feel tickling or a gag reflex
- ◆ Have patient open mouth wide
- ◆ Hold the back third of the tongue down
- ◆ Look for swelling, pus, red or white spots
- ◆ Roll swab over the tonsil area

AFTER COLLECTION

- ◆ Place swab in holding media or, Roll over top 1/3 of culture plate or
- ◆ Follow rapid strep test kit procedure
- ◆ Discard collection materials in biohazard container
- ◆ Remove gloves - dispose in biohazard container - wash hands

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GOOD LABORATORY PRACTICE

SAMPLE COLLECTION - URINE - CLEAN VOIDED

BEFORE COLLECTION

- ◆ Train on procedure
- ◆ Check requisition and patient ID
- ◆ Get supplies
 - Sterile container - patient cleansing kit and patient instructions
- ◆ Specimen required
- ◆ Freshly voided urine (first morning specimen preferred) - Fresh bladder catheter specimen or suprapubic aspiration are acceptable
- ◆ Label container
 - Patient name, unique identifier, date and time collected
- ◆ Wash your hands - put on gloves

INSTRUCT PATIENT

- ◆ Instruct patient in cleansing and obtaining midstream sample
- ◆ Provide written instructions to the patient
- ◆ Verify the instructions with patient

AFTER COLLECTION

- ◆ Put on gloves to handle sample
- ◆ Screw lid on tightly
- ◆ Put specimen in a biohazard bag for transport
- ◆ Deliver fresh samples to testing laboratory immediately or refrigerate samples at 2 - 8°C or transfer to a preservative tube if not cultured immediately



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GOOD LABORATORY PRACTICE

SAMPLE COLLECTION - VENOUS BLOOD

BEFORE COLLECTION

- ◆ Train on procedure and safety
- ◆ Check requisition and patient ID
- ◆ Get supplies
 - Tourniquet - puncture device - tubes or bottles - disinfectant wipes - gauze - bandage - biohazard container
- ◆ Wash hands - put on gloves

COLLECTION

- ◆ Apply tourniquet and select site
- ◆ Use peripheral veins (catheters may be contaminated)
- ◆ Clean site with disinfectant
- ◆ For multiple tubes, follow “draw order”
- ◆ Follow collection tube instructions (i.e. proper volume, mixing etc.)
- ◆ Remove needle - apply pressure with dry gauze pad
- ◆ Place entire puncture device in biohazard box
- ◆ Bandage puncture site
- ◆ Label samples with name, unique ID and DOB before leaving the patient

AFTER COLLECTION

- ◆ Process, store or transport sample(s) as required by testing laboratory
- ◆ Remove gloves, dispose in biohazard waste and wash hands

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GOOD LABORATORY PRACTICE

SAMPLE COLLECTION - SWAB - WOUND

BEFORE COLLECTION

- ◆ Train on procedure
- ◆ Check requisition and patient ID
- ◆ Get supplies
 - Sterile Dacron swab - alcohol wipes - holding media or culture plates
- ◆ Label media or culture plates
 - Patient name, unique identifier, date and time collected
- ◆ Wash hands and put on gloves

COLLECTION

- ◆ Cleanse the wound site and surrounding skin with alcohol wipe - Air dry
- ◆ Remove crusty scabs or surface debris
- ◆ Roll swab in the interior of the wound.
 - Avoid contaminating swab with normal skin bacteria

AFTER COLLECTION

- ◆ Place swab in holding media or roll over top 1/3 of culture plates
- ◆ Discard collection materials in biohazard container
- ◆ Process, store or transport sample(s) as required by testing laboratory
- ◆ Remove gloves dispose in biohazard container - wash hands

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SPECIMEN COLLECTION REFERENCES

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Specimen Collection Instruction Manual, Clinical Reference Laboratory
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<http://www.enotes.com/nursing-encyclopedia/blood-specimen-collection>

BD LabNotes - Volume 14, No.2, 2004
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<http://www.bd.com/vacutainer/labnotes/Volume14Number2/>

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<http://www.nlm.nih.gov/medlineplus/ency/article/007487.htm>

Clean Catch Urine Overview
University of Maryland Medical Center
<http://www.umm.edu/ency/article/003751.htm>

Good Laboratory Practices for Waived Testing Sites, MMWR
<http://www.cdc.gov/mmwr/PDF/rr/rr5413.pdf>

CLIA - Clinical Laboratory Improvement Amendments - Currently Waived Analytes
<http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfClia/analyteswaived.cfm>

Ready? Set? Test!
<http://wwwn.cdc.gov/dls/waivedtests/>

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