



## **Before we start**

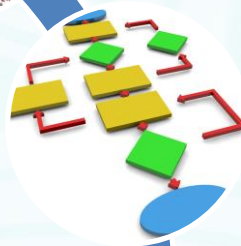
**Najwa Adlan, CPHQ**  
**Medical Laboratory supervisor, POCT**  
**Department Of Pathology & Laboratory Medicine**  
**King Faisal specialist Hospital & Research Center**



# Agenda



Important Terminology



Road map for this workshop



IQCP Eligibility

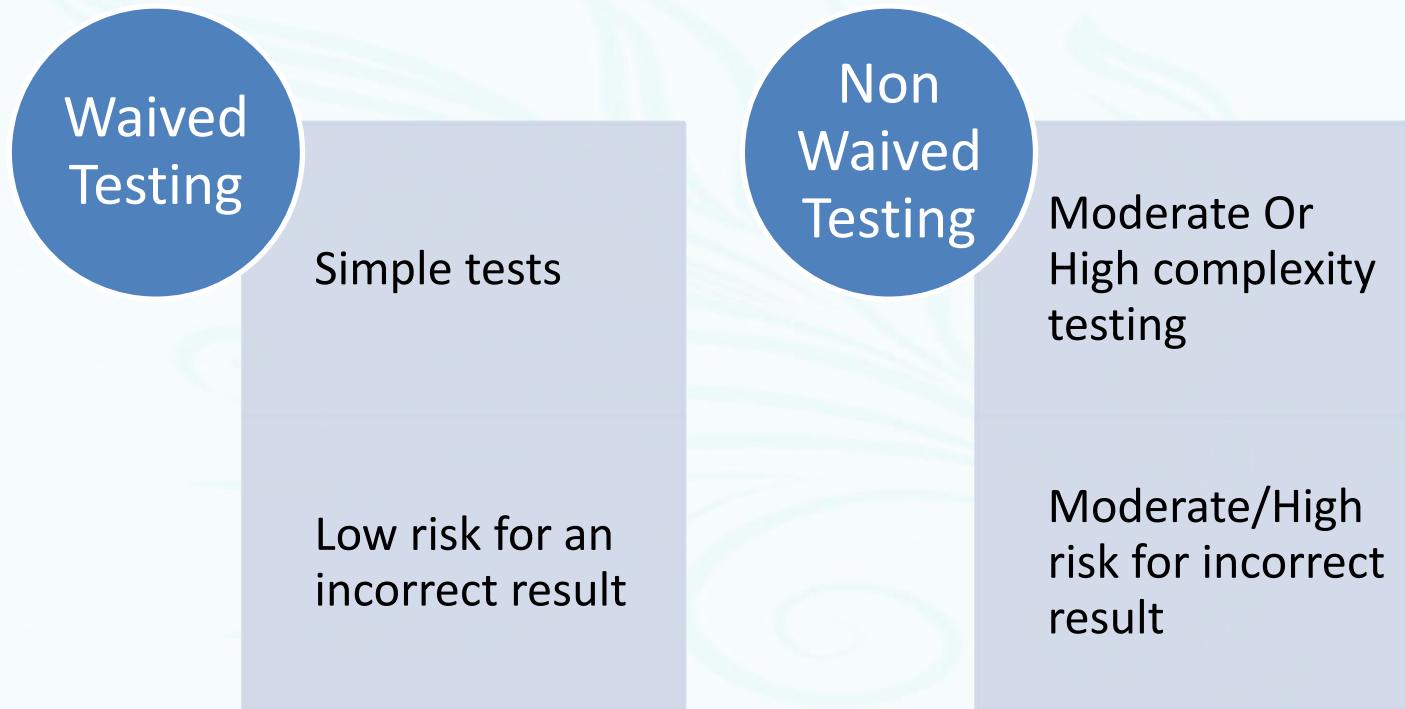


Examples

# EDIC



## Testing complexity



<http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfClia/analyteswaived.cfm>

# Important Terminology to know



## CMS

- **Do you know what is CMS?**

## CLIA

- **Do you know what is CLIA?**

## CAP/JCI

- **Do you know what is CAP/JCIA?**

## CLIA-exempt"

- **Do you know what CLIA-Exempt means?**

## Testing Complexity

- **Do you know what is the difference between waived and non waived?**



# Terminologies

## CMS

### Centers for Medicare & Medicaid Services

- is part of the Department of Health and Human Services (HHS) in USA.

## CLIA

### Clinical Laboratory Improvement Amendment

- CLIA is a US Federal legislation and the personnel and procedures established by it under the Centers for Medicare & Medicaid Services (CMS) for the surveillance and regulation of all clinical laboratory procedures in the United States.

## CAP/JCI

- Accreditation firms

## CLIA-exempt”

- A laboratory that has been licensed or approved by a state where CMS has determined that the state has enacted laws relating to laboratory requirements that are equal to or more stringent than CLIA requirements

## Testing Complexity

- Clinical laboratory test systems are assigned waived non waived (moderate or high complexity) category on the basis of seven criteria given in the CLIA regulations.
- test complexity is determined by the FDA during the pre-market approval process as waived and non-waived

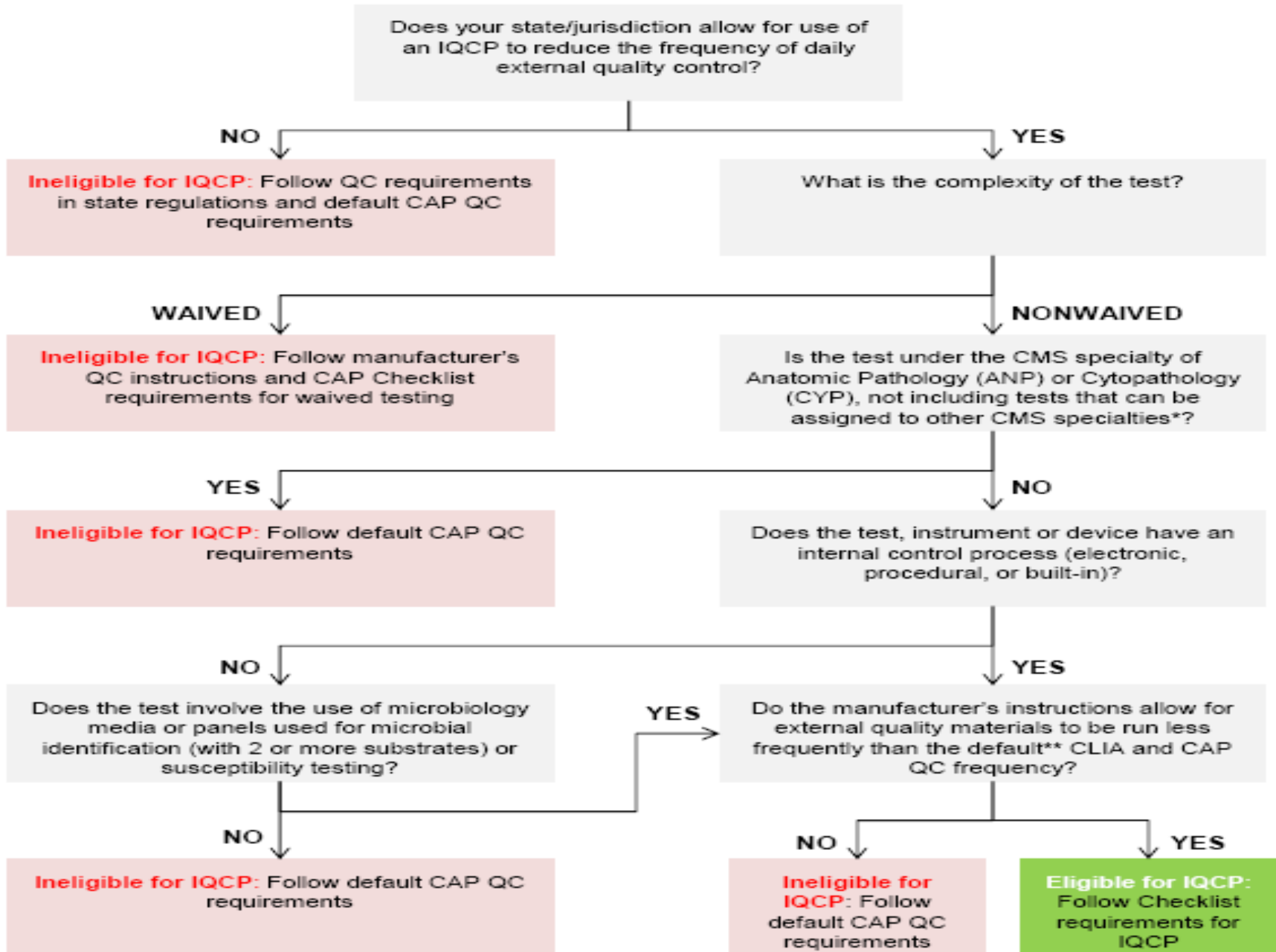


## **Information you need to determine IQCP Eligibility for a given test/method**

- **The Accreditation guidelines regarding lowering the QC Frequency**
- **The Testing Complexity**
- **Is it under Anatomical Pathology Or Cytology**
- **Manufacture QC Recommendation**
- **CLIA QC Recommendation**



## Eligibility Determination for Individualized Quality Control Plan (IQCP) Option







## Eligibility for IQCP

**Nonwaived tests in all CLIA specialties/subspecialties are eligible for IQCP except those in.....**

- 1. Pathology**
- 2. Histopathology**
- 3. Oral Pathology**
- 4. Cytology**

**Although general QC requirements are eligible, certain specific QC requirements are not eligible for IQCP in.....**

- 1. Routine Chemistry**
- 2. Immunohematology**
- 3. Clinical Cytogenetics**
- 4. Histocompatibility Testing**

# Examples



Illegible or not? [Slide 8](#)

---

Pregnancy testing

Waived test

---

Manufacture QC requirement is less or equal to CLIA

---

---

ESR Testing

Non- Waived test

---

Manufacture QC requirement is less or equal to CLIA

---

No internal QC , EQC or built in QC

---

---

Pap Smear

Non- Waived test

---

Manufacture QC requirement is less or equal to CLIA

---

No internal QC , EQC or built in QC

---

---

Gram stain

Non- Waived test

---

Manufacture QC requirement equal to CLIA

---

No internal QC , EQC or built in QC

---



Test	QC Frequency CMS/CLIA 493.1261 (a)	QC Frequency CAP MIC.14583
Direct Antigen Test with an internal control	<u>Each day of patient testing (for external controls (pos. and neg.)</u>	
	Manufacture recommendation fro QC is less than CLIA	

Test	QC Frequency CMS/CLIA Subpart K: 493.1256 (e) (1)	QC Frequency CAP MIC.21624
Germ Tube	Each new batch, lot # and shipment	
ONPG	Each new batch, lot # and shipment	
Optochin	Each new batch, lot # and shipment	
Oxidase	Each new batch, lot # and shipment	
Spot indole	Each new batch, lot # and shipment	
X & V factor strips/disk	Each new batch, lot # and shipment	
Other reagents, disks / strips/stains (e.g. PYR, Mcat disk and others)	Each new batch, lot # and shipment	

[Linda.Bruno@advocatehealth.com](mailto:Linda.Bruno@advocatehealth.com)

More to think of



- Additional consideration after determining the illegibility:
  1. Cost of Reagents and the frequent QC
  2. Cost of Manpower
  3. Work load & Ease of use for end users

## Summary

