POC Diagnostics: Role, Regulation, and Issues for Innovators

Leanne Kiviharju, AdvaMed POC Diagnostics Subteam

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Point of Care (POC) Diagnostics

- **Value and Role of POC Diagnostics**
  - Support timely healthcare and useful clinical Information to support treatment decisions
  - Facilitate early detection, accurate diagnosis
  - Usually portable, support access at site of service
  - Increased healthcare efficiency
  - Help address healthcare disparities
  - Improve patient satisfaction
  - Overall benefits to public health (e.g., infectious disease, battlefield, patient-centered care)

- **Appreciate FDA Holding of POC Diagnostic Devices Vendor Day (1/26)**

Points to Consider

- *FDA has no definition for Point of Care (POC) or "*decentralized" care
- Assumption that all POC devices are waived (e.g., ADA)—not correct
- Reference to assays for use in point of care environments – not defined
- Reference to temperature requirements for POC devices
- Reference to less familiar operators at point-of-care sites
- Reference to new standard of clearance review, different than that of SE (risk as compared to other assays)
- FDA initiates guidance with point of care defined – "prescription point of care" and "over the counter" BGMS
  - BGM-specific, but not a model for future; major Qs remain
- Is there a different emphasis on study design – performance or workflow?
- Public health benefits of POC

POC Definitions

Various definitions, none specific to a type of test but reflect the diversity of settings. For example…

CDC—defines "point-of-care testing" as "a phrase used to describe the location where testing is performed, such as at the bedside or near the site of patient care
http://www.cdc.gov/clia/resources/testcomplexities.aspx

Per CLSI POCT4-A2—Point of Care Testing (bedside, near patient testing, POCT):

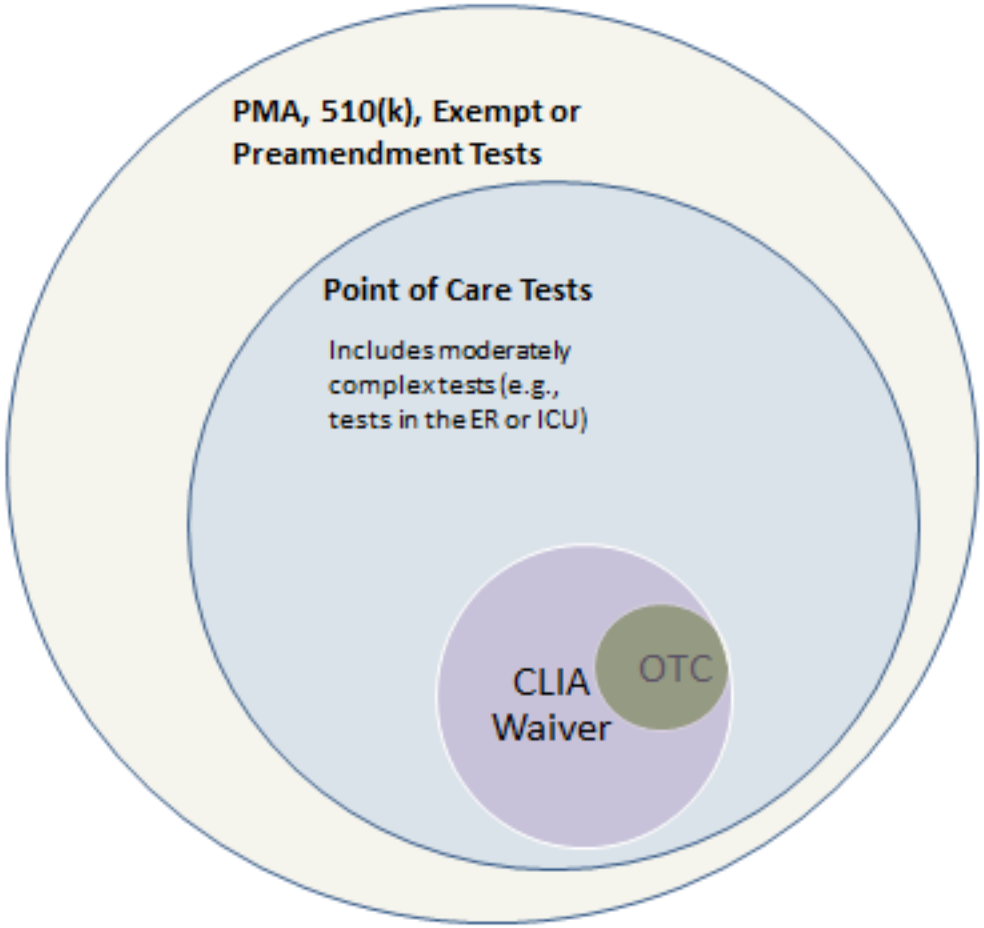
- Testing that is performed near or at the site of the patient
- Testing performed outside a central laboratory environment, generally nearer to, or at the site of the patient/client

Per CLSI POCT2—the healthcare environment immediately surrounding a patient. Examples include bedside on a medical unit, the operating room, ambulance, or mobile transport vehicle and physician's office.

Per ISO/22870—near patient testing; alternative site testing; diagnostic testing that is performed near to or at the site of the patient care

Definition is important—Medical diagnostic test performed at or near the patient. Refers to setting, not the test itself. Does not equal CLIA waiver.

Point of Care Tests as Part of Dx



Recent POC Examples

Recent advisory panel related to clearance for a diagnostic claim "for use in point of care environments"

- Apparent new standard of premarket review, different than that of substantial equivalence
- Equating POC with CLIA waiver (bringing CLIA waiver into moderate complexity submission)
- Blurs lines between two regulatory processes – 510(k) and CLIA waiver application
- Leaves innovators with unclear path forward

Narrowing of issues, for ex, operating temperature range of device POC system

- Reference to current operating temp range of device POC system (e.g., 18-28C)
- View that presenting risks to patients at very low or very high temperature. Range too narrow for a POC device (e.g., 16-30C)

Overall Question: Are we striking the right balance in the best interests of the public health and innovation?

Some Questions for FDA Consideration

- How does FDA educate reviewers and other groups that POC and CLIA waived tests are not the same?
- Why does FDA identify differences in POC tests compared to mainframe tests that are also moderate complexity?
- When a POC predicate is traceable to a standard, such as NIST, what is the scientific reason for requesting a method comparison of the new POC device with a clinical laboratory device in addition to the traceable POC device?
- Other?

Next Steps

- Dialogue
  - Upcoming vendor day is a good first step
- Continue discussion on POC definition
- Discuss key questions with industry
- Identify clear and workable approach moving forward
- Welcome collaboration with FDA