

POC TESTING and/in WOMEN'S HEALTH

October 11, 2018

Erika Ammirati, RAC, MT(ASCP)

Ammirati Regulatory Consulting



POC- WHY the NEED?

- Usually time related
- Brings result and action together
- More efficient for the patient
- In theory, may be more cost effective

Regulatory POC Points to Consider #1

- Different types of POC “flavors” and definitions have not always been consistent.
- Examples (in the order of maximum regulatory oversight):
 - Home testing
 - Doctor’s office
 - Clinics (free-standing and hospital associated)
 - Departments in hospitals (EDs, ORs, patient bedside, ambulances)

Regulatory POC Points to Consider #2

- CLIA Waiver and the Impact of POC Location
 - Home testing- all IVDs cleared for home use are CLIA waived for professional use with appropriate data.
 - Doctor's office- this location enjoys the largest benefit of CLIA waiver.
 - Clinics (free-standing and hospital associated)
 - Departments in hospitals (EDs, ORs, patient bedside, ambulances)

Regulatory POC Points to Consider #3

- CLIA Waiver- continued
 - Clinics (free-standing and hospital associated)- if free-standing, same situation as doctor's office; if hospital associated, then no benefit of CLIA waiver "torture" and better to stick with "moderate." The hospital laboratory will hold the CLIA license and will provide oversight to the satellite labs.
 - Departments in hospitals (EDs, ORs, patient bedside, ambulances*)- same as hospital clinic.

Data-Related POC Points to Consider #1

- POC IVDs have additional data requirements as compared to traditional lab IVDs (whether waived or moderate).
 - Greater focus on operator proficiency
 - Require 3-site data from typical sites
 - Preference for multiple operators per site (but not mandatory except for waiver, then 9 across 3 sites).

Data-Related POC Points to Consider #2

- The balance of the data requirements are largely the same, i.e.,
 - LoB, LoD, LoQ
 - Precision
 - Sensitivity/Specificity
 - Accuracy, etc.
- Depending on the technology and intended use, user questionnaires may be appropriate.

Examples of POC in Women's Health

- Two major categories:
 - General Urinalysis/Microbiology/STDs (both genders)
 - Infertility (both genders)

General Urine Testing- POC

- Males and females
- Urine dipsticks-
 - Mainly glucose and UTI related
 - White cells and Nitrite
 - Protein
 - Blood
 - Drugs of abuse
 - Multi-parameter

Microbiology/STD POC

- Males and females
- Test for Chlamydia and Gonorrhoeae
 - Cepheid Xpert CT/NG
 - Other tests in this space are in development
 - CT/NG plus other organisms

Infertility (Fertility Status) POC- female

- Hormonal Tests- require frequent samplings
 - Urinary hCG for pregnancy
 - Urinary FSH and LH for ovulation prediction
 - Urinary E3G (urinary metabolite of estrogen
 - Pregnanediol glucuronide (PDG) for ovulation confirmation (urinary metabolite of progesterone)

Infertility (Fertility Status) POC- male

- Semen tests for:
 - Sperm count
 - Motility
 - Other semen parameters
- Extra factor for labile specimen

Thank You

- Questions