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FDA Regulation of Point of Care Testing Coagulation Devices

Focused on PT INR POC Testing

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Overview

- Point of Care testing (POCT) spectrum
- Benefits and challenges of POCT
- Considerations for device validation



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Not all POC devices are alike...



POCT Spectrum

- **Wide spectrum of sites:**
 - Coagulation clinics, emergency department, physician's offices, ambulance, nursing facilities, home
- **Wide spectrum of operators:**
 - Laboratory professionals to lay people or patients
- **Wide spectrum of regulatory claims:**
 - Matrixes, analytical measurement ranges, analyte, etc.



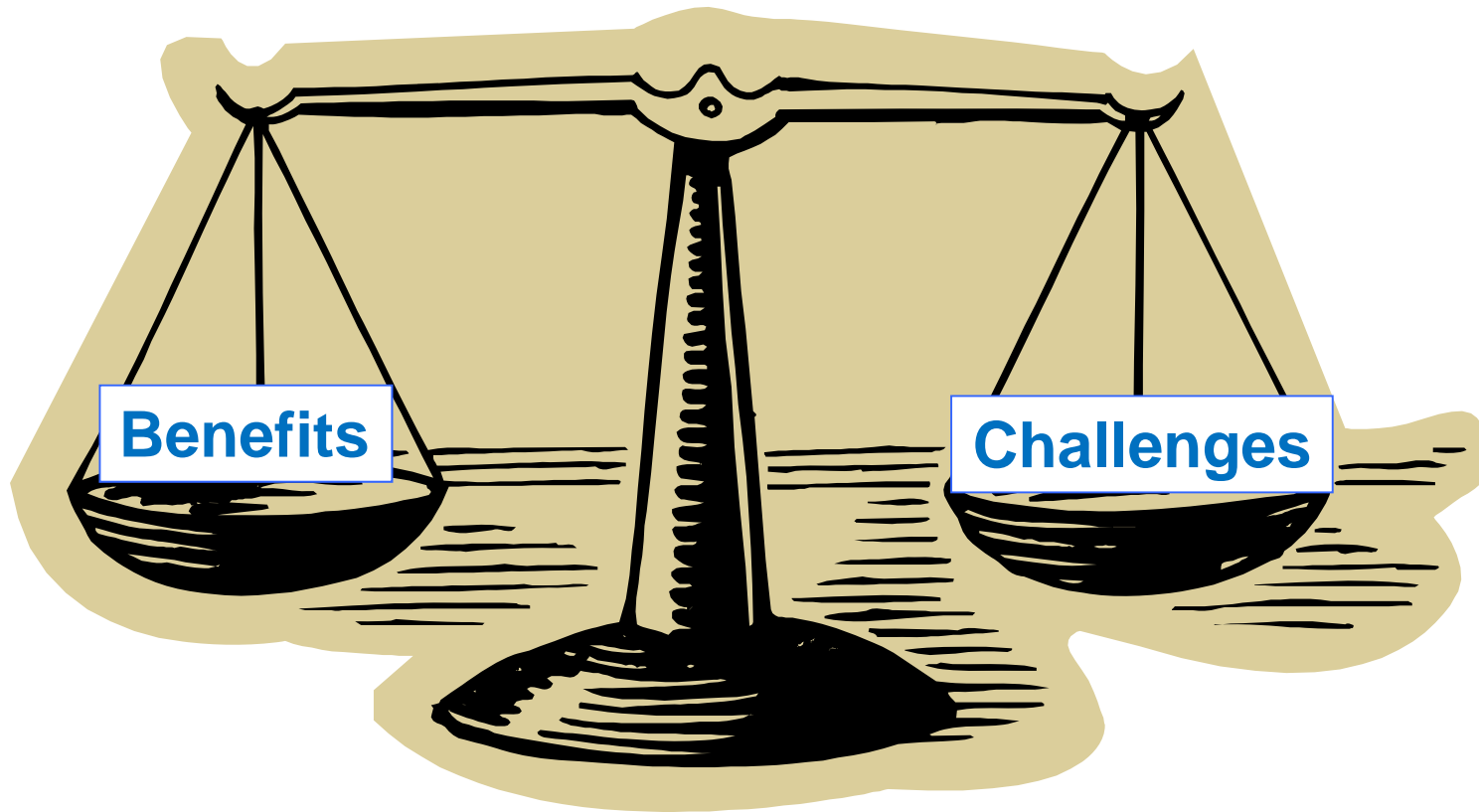
Examples of POC Scenarios

- **Emergency Room:**
 - Performed by nurses and professional laboratory staff
- **Physicians Office:**
 - Performed by nurses, PAs, office staff
- **Home Use:**
 - Performed by patients, lay or other caregivers



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Benefits of POC Testing

- Rapid Therapeutic Turnaround Time (TTAT)
 - Reduced time until treatment onset
- Reduce number of physician office visits
 - Cost reduction
 - Increased time in therapeutic range
- Increased access
- Ease of use
- Smaller specimen



Challenges of POC Testing

- Less controlled testing environment
- Pre-analytic variables
- Specimen/reagent/control degradation
- Effect of sample matrixes
- Limited/current operator training
- Patient condition (HCT and PLT count)
- Risk of infection in multiple use settings

PT INR Devices:

- Narrow therapeutic range for warfarin therapy
- Severity of adverse events



Challenge

Performance Validation

Increased testing variability:

- Less controlled testing environment
- Pre-analytic variables

Repeatability: Duplicate testing in method comparison study

Reproducibility: Both patient samples and control material for instrument and operator variability

Specimen/reagent/control degradation

Stability testing: Specimen, reagent and controls

Patient condition (HCT and PLT count)

Interference testing



Challenge

Effect of sample matrices

- Venous whole blood
- Capillary whole blood etc.

Limited/current operator training

Risk of infection in multiple use settings

Performance Validation

Matrix comparison studies

Evaluation of performance in each matrix

Review of training protocols

Prescription Home Use/ Single Patient Use:

Ease of use, need to demonstrate that lay user can successfully and reliably operate device and interpret output, training material

Performance testing by intended users

Cleaning and disinfection testing to mitigate risk of transmission of blood-borne pathogens



Challenge

PT/INR Devices

- Narrow therapeutic range for warfarin therapy
- Severity of adverse events

Performance Validation

Narrow acceptance criteria to ensure clinically acceptable performance

Accuracy: Closeness of agreement between a measurement and plasma-based laboratory reference

Method comparison: Comparison to a cleared POC device (in addition to laboratory reference)



Additional Considerations for Performance Validation

- **Intended Use population** (Patients on stable warfarin therapy, not transitioning)
- **Intended User population** (Health care professionals, lay users, etc.)
- **Intended Use setting** (Hospital, home, etc.)
- **Intended Use matrix** (Venous, capillary, etc.)
- **AMR**



Conclusions

- Point of Care testing (POCT) spectrum
- Benefits and challenges of POCT
- Considerations for device validation



Resources

- Presubmission Guidance:

<http://www.fda.gov/downloads/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/UCM311176.pdf>



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Thank you for your attention.....

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