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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.



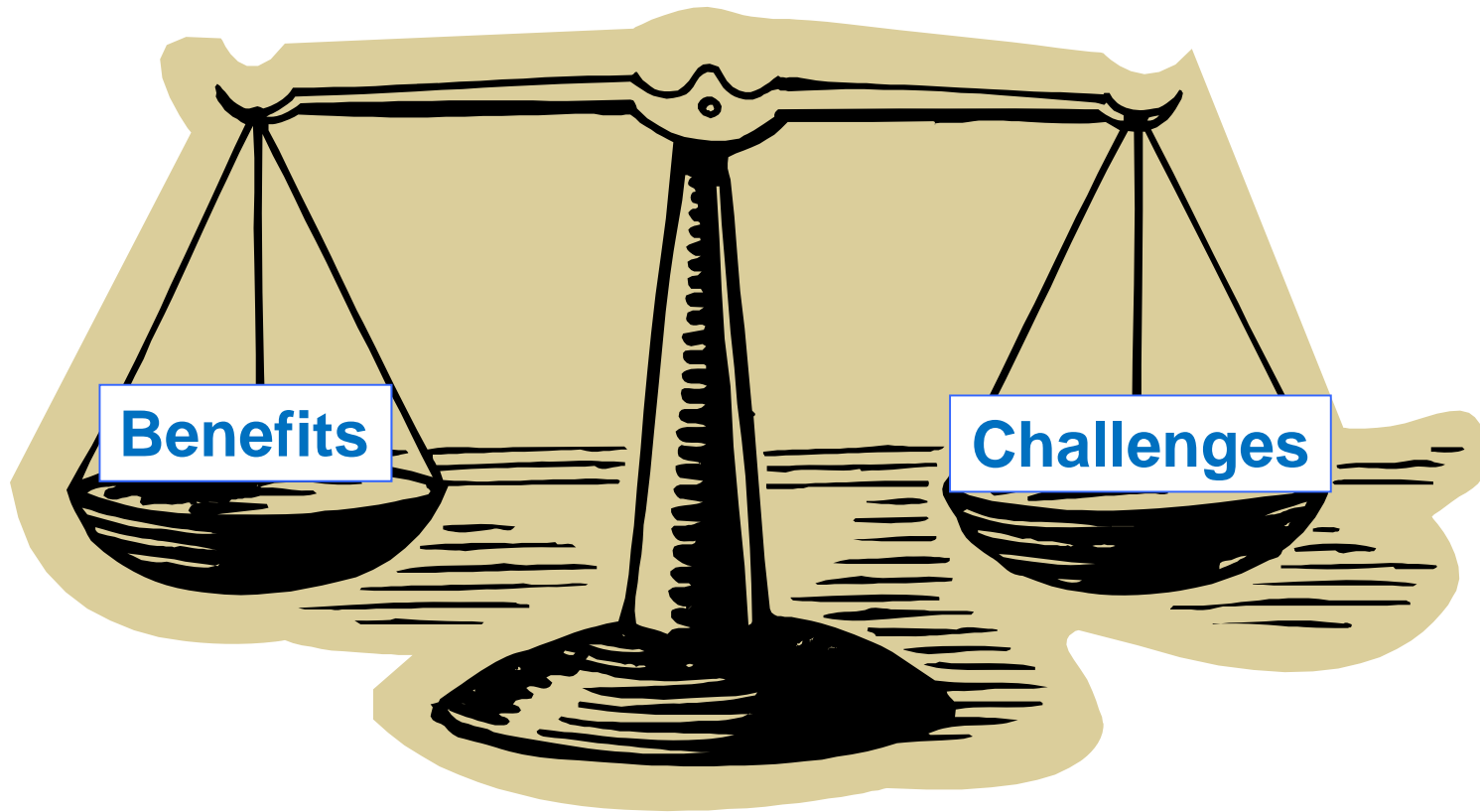
# Examples of POC Scenarios

- **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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