

ASCLS Mission:

The mission of ASCLS is to make a positive impact in health care through leadership that will assure excellence in the practice of laboratory medicine.



ADDITIONAL RESOURCES:

Abbott iStat (clinic usage only)

<https://www.pointofcare.abbott/>

Roche CoaguCheck (patient or clinic usage)

<https://diagnostics. Roche.com/us/en/coagucheck-hcp-home.html>

Home monitoring brochure:

<https://www.alerecoag.com/>

REFERENCES:

FDA Caregiver Tips for INR Testing:

<https://www.fda.gov/MedicalDevices/ProductsandMedicalProcedures/InVitroDiagnostics/WarfarinINRTestMeters/ucm595953.htm>

FDA Provider Tips for INR Testing:

<https://www.fda.gov/MedicalDevices/ProductsandMedicalProcedures/InVitroDiagnostics/WarfarinINRTestMeters/ucm595962.htm>

FDA Warfarin Test Meters:

<https://www.fda.gov/MedicalDevices/ProductsandMedicalProcedures/InVitroDiagnostics/WarfarinINRTestMeters/default.htm>

Recommended Test Frequency:

<https://www.ncbi.nlm.nih.gov/pubmed/24884750>

The content in this brochure is not intended to be a substitute for professional medical advice, diagnosis, or treatment. Always seek the advice of a physician or other qualified health provider with any questions you may have regarding a medical condition. Never disregard professional medical advice or delay in seeking it because of something you have read or accessed on the internet.

**Your Safety and Service Experience
Are Important To Us!**

Laboratory Patient Safety Tips:

INR Point of Care Testing (POCT) Performed by Provider or Caregiver



What is INR POCT testing?

Point of Care Testing (POCT) for Prothrombin Time (PT) and International Normalized Ratio (INR) is coagulation testing performed on a near patient device or meter, as opposed to testing performed by a clinical laboratory on a coagulation analyzer. INR is a calculated value utilized to standardize results between testing systems and laboratories. INR is used to monitor patient anticoagulation therapy dosing of warfarin, available in generic form or under brand names Coumadin®/Jantoven.

How do INR POCT test meters compare to clinical laboratory analyzers?

Point of Care Testing INR levels usually correlate well with traditional laboratory testing except for **values above 4.5, at which the FDA recommends that “a laboratory test for result confirmation be completed” prior to clinical interventions being taken.** It is also recommended that INR meter results are initially and routinely compared to laboratory INR testing, especially if values do not clinically correlate.

Which patients are not good candidates for INR POCT testing?

Patients are not good candidates if they have:

- Chronic kidney disease (CKD)
- Moderate to severe anemia
- Conditions with high creatinine levels
- INR results above 4.5
- Specific malignancies such as leukemia or polycythemia vera
- Certain medications such as antibiotics
- Wide fluctuations in test results. INR POCT should not be utilized until patient is at steady state warfarin dose.

Under these conditions, it is recommended to perform coagulation testing on a clinical laboratory analyzer. Testing prior to steady state warfarin dosing should follow PT in seconds to assure trending in right direction.

Important INR meter and test strip care tips

- Make sure to follow manufacturer's instructions and instructions of the provider
- Do not use bleach or other cleaners on meters
- Always follow each manufacturer's instructions for meter cleaning to ensure a clean meter for accurate testing.
- Do not place in dishwasher, submerge, or place near water
- Do not drop meter
- Do not refrigerate or freeze test strips
- Do not leave test strips in hot cars or outside
- Make sure containers are capped at all times

What can cause erroneous results?

- Contamination with excess interstitial or intracellular fluid or hemolysis of patient specimen (blood)—may be caused by milking of finger
- Insufficient blood drop
- High patient creatinine level
- Cognitive aspects
- Incorrect testing practice
- Waiting too long to place blood drop on test strip
- Not replacing a code chip with use of a new bottle of test strips (if required by the manufacturer)
- Not entering a correct date into the meter as instructed (if required by the manufacturer)
- Using recalled meters or test strips

Other guidelines & helpful tips

- When replacing batteries, remember to re-enter the correct date (if date setting is available)
- Not enough blood on test strip may cause an error code
- Refer to the meter's User Manual for troubleshooting tips or for resolving meter error codes
- Incorrect warfarin dosing may result in higher or lower than expected INR result values



What is the recommended test frequency?

Studies indicate PT/INR testing should be done every week for optimal clinical outcomes

Informatics Considerations

- PT and INR values are entered into Information System correctly
- Be aware of differing reference intervals and/or flags between POCT PT/INR results and clinical laboratory PT/INR results performed on a coagulation analyzer

What do providers need to know about performing POCT INR testing in their clinic?

- A valid CLIA certificate (new or under an existing laboratory) is needed prior to initiating patient testing to be regulatory compliant
- May wish to consult with pharmacists who operate warfarin clinics in the area, especially for dosing
- May wish to consult laboratory professionals at their affiliated laboratory for guidance on meter use and quality requirements
- Keep up-to-date on and follow all manufacturer instructions, regulatory documentation, quality control, and calibration requirements

When is quality control and calibration needed ?

- Quality control is needed a minimum of once per shipment of reagent strips, strip lot number changes, for every new user, and when troubleshooting instrument errors.
- Calibration should be done according to manufacturer's instructions at their designated frequency. It may involve a "Code Chip" change or update of vendor software.

What do I need to know about CLIA documentation?

The Clinical Laboratory Improvement Amendments (CLIA) website has information needed for certificates, testing regulations, etc. www.cms.gov/CLIA