

The Manufacturer's Package Insert and Patient Safety– “WIIFM” (What's In It For Me?)



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The Manufacturer's Package Insert and Patient Safety–WIIFM?



- ❑ Clinical Laboratory Improvement Amendments (CLIA) states that you must follow manufacturer's instructions
- ❑ One of the most common deficiencies cited during inspections is not following manufacturer's instructions
- ❑ Not following manufacturer's instructions can affect patient safety



College of American Pathologists



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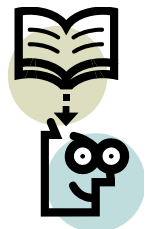
Morbidity and Mortality Weekly Report Nov. 2005

Good Laboratory Practices for Waived Testing Sites Survey Findings from Testing Sites Holding a Certificate of Waiver Under the Clinical Laboratory Improvement Amendments of 1988 and Recommendations for Promoting Quality Testing

“The OIG report indicated that approximately half of the state respondents reported problems related to quality issues with the waived laboratories in their states (e.g., failure to follow manufacturers' instructions or failure to identify incorrect results and performing unauthorized testing)”

The Manufacturer's Package Insert and Patient Safety–WIIFM?

- Manufacturer's instructions, interferences, limitations, precautions, and procedural notes, are listed in the package insert for the POCT along with directions for storage and handling of reagents
- As a POCC, it is our responsibility to become familiar with these details to help determine which manufacturer's instrument or testing kit will work best for the intended testing environment
- Sometimes we need to “translate” for non-laboratorians





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□ **Manufacturer's Intended Use**

- 👁️ Look for statements related to the patient population the test (or instrument) is intended to be used for
- 👁️ Look for any inclusion or exclusion criteria mentioned
- 👁️ Failure to adhere to the instructions for use constitutes off-label use and can result in the test being categorized as High Complexity!

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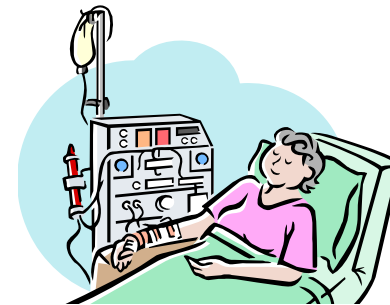
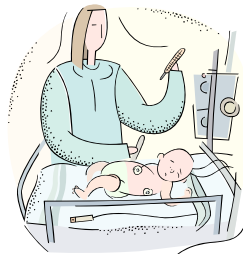
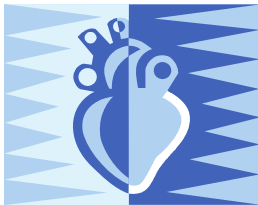
□ Specimen Collection and Handling

- 👁️ Look at what specimen types can be used (i.e. venous, capillary, arterial, anticoagulated)
- 👁️ Look at how quickly a specimen must be tested
- 👁️ Look at any special considerations for specimen handling (ex. Wipe away first drop or not?)



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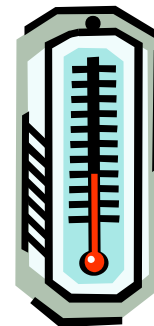
- Limitations, Interfering Substances, Precautions, Procedural Notes
- 👁️ Look for limitations
- 👁️ Look for interfering substances and at what concentrations–do you have a patient population that may be affected? If so, educate and build alternative testing into policy



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□ Reagent Handling and Storage

- 👁️ Look at storage requirements—Refrigerated reagent expiration versus room temperature storage expiration—pay close attention!
- 👁️ Look at timing considerations—ex. Do not remove cartridge from packaging, test strip from bottle or cassette from foil package until just before use etc. (Sometimes nursing is used to laying everything out well in advance—explain how this can affect test results)
- 👁️ Keep droppers in tightly sealed pouch



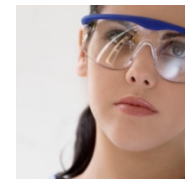
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- **Manufacturer's Recommendations**
- ☞ Manufacturer's recommendations for QC
- ☞ Confirmation testing recommended/required?



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- **Incorporate Patient Safety considerations**
 - ☞ Into policies
 - ☞ Into training/competency tools
 - ☞ Into train-the-trainer sessions
 - ☞ Into exams/quizzes for problem solving
 - ☞ Into job aides
 - ☞ Don't forget Operator safety too!



The Manufacturer's Package Insert and Patient Safety—WIIFM?

- Read package insert—early and often!
- 👓 Package inserts can change
- 👓 Some change often!
- 👓 Check manufacturer's website
- 👓 Review at least at time of policy review
- 👓 Include package insert revision date in your policy reference



The Manufacturer's Package Insert and Patient Safety–

- **When safety issues arise–
Investigate and Educate**



- 👓 Emphasize repeat patient testing

- 👓 Emphasize repeat QC testing

- 👓 Utilize manufacturer's technical support



- 👓 A “Questionable Result” investigation tool can help



POCC's are in a unique position to affect a change and improve patient safety—beginning with the manufacturer's package insert!

Thank you
and be careful out there.....

