

## NEWEST MESSAGES FIRST

Peggy Mann: Ann, it was our pleasure! Have a great summer all!

Lou Ann Wyer: See everyone in Philly at AACC!

Ann Snyder: Thank you for the opportunity to chat!

Nadia Cristo: Thank you, Ann.

Lou Ann Wyer: Thanks again to Ann Snyder for her wonderful presentation and time for questions from us! Thanks to everyone for joining us today. I hope everyone has enjoyed the conference.

Ann Snyder: Nadia, CMS has not finalized the S&C memo you reference.

Peggy Mann: Nada

Nadia Cristo: Has a final decision been made regarding off-label use and critically ill patients? Is it still in the draft phase?

Ann Snyder: I am back. If someone has not had their question ask, please ask it again.

Lou Ann Wyer: We can get a response from Ann and include that in the Q&A transcript.

Peggy Mann: OK! Now, back to making 'citizen arrests' at nursing stations...are we all 'in'?

Peggy Mann: By the way, I have to applaud our Pacific time zone friends for logging on so early (for them) thank you Shana and Jane! (and anyone else who did so!)

Nadia Cristo: Has a final decision been made regarding off-label use and critically ill patients? Is it still in the draft phase?

Mary Snyder: Thank you Ann

Jane Tansiongco: That's why the manufacturer stated what the physician deemed best for patient care - and they are using ACT to see if the patient is anti-coagulated with Angiomax

Ann Snyder: Mary, good question.....how to monitor compliance. I suggest you build quality assessment monitors around the parameters of your definition for critically ill. Use the data management system to mine information, you could compare fingerstick glucose results to confirmations sent to the lab. Again, a discussion to have with your laboratory director.

Marcia Zucker: different parts of the FDA- this was pre-combination clearances

Lou Ann Wyer: How was the labeling approved for an ACT but no device is approved to do the ACT?

Marcia Zucker: Nadia- you can ask the manufacturer if the population was ever evaluated. Newer tests are required to be very specific about populations, but that has only started within the last 5 years or so.

Jane Tansiongco: Thanks Marcia and Ann for the response.

Marcia Zucker: Angiomax is bivalirudin - an analog of leech spit. The Angiomax labeling requires an ACT be performed to determine that the drug was given correctly. FDA has not cleared ANY ACT for use with Angiomax.

Nadia Cristo: So, if any waived test does not state that it can be used on critically ill patients, we are to assume that it can't be? This seems to be a very loose translation. Hemocult cards don't state that they can be used on a patient who has moles - does that mean they can't?

Ann Snyder: Jane, I am not certain what the chemical make-up is for Angiomax, but I believe it is not heparin.

Lou Ann Wyer: Are there any further questions for Ann?

Lou Ann Wyer: Thanks, Ann

Ann Snyder: Lou Ann - Following the manufacturer's instructions using the correct specimen type would not be considered a modification of a test. However, if the laboratory uses the test as nonwaived and has a Certificate of Waiver, that would be a compliance issue. The laboratory is performing testing beyond the appropriate certificate type and would be required to upgrade to a Certificate of Compliance.

Mary Snyder: Love it Peggy

Kimberly Skala: Love the citizen's arrest comment Peggy!

Ann Snyder: Devorah, How many samples.....that would be a discussion to have with your laboratory director. He would have to decide how many specimens are appropriate to establish precision, accuracy and the rest of the CLIA requirements I discuss in my ppt.

Kimberly Skala: Good presentation Ann. Thank you.

Shana Nowelani Gaug: Thanks Ann.

Peggy Mann: Ann, if we propose to CMS that POCCs should be legally allowed to 'make a citizen's arrest' at a nursing station when observation clearly identifies a POC Operator is not abiding their training, will you present it to 'the board of directors' for us? So frustrating to keep going over ...and over...with 2,000 POC Operators...you know that drill!

Lou Ann Wyer: thanks Ann!

Lou Ann Wyer: Ann/Marissa, that is good advice. Sometimes only a MD can get another MD to listen/understand the situation.

Marissa Chupp: Unfortunately, the VP is also a MD and tends to side with them. I feel like things aren't going to change unless we are penalized by an inspector. Thanks!

Nadia Cristo: Has a final decision been made regarding off-label use and critically ill patients? Is it still in the draft phase?

Ann Snyder: Lou Ann, a RN with a bachelor's degree in nursing meets the requirement of having earned a bachelor's degree in a biological science for high complexity testing personnel. The laboratory may show a Primary Source Verification report verifying that a bachelor's degree in nursing was earned, a diploma with the type of degree earned, or transcripts as evidence of meeting the education personnel requirements.

Ann Snyder: Marissa, I suggest that your laboratory director have a frank discussion with those providers. Sometimes they only listen to their peers. Alternatively, ask someone close to these providers for advice on how to best speak with them.

Ann Snyder: Shana, always read the manufacturer's instructions. For the most part there should be an intended use statement. If there is ever a question, go directly to the manufacturer. Absence of the information does not mean you can test.

Peggy Mann: Wahoo, thanks Ann

Ann Snyder: I have finally arrived....so sorry for the difficulties...let me catch up.

Lou Ann Wyer: Thanks Ann!

Ann Snyder: Let's try this again...

Mary Snyder: What is the best method to monitor compliance of a critically ill policy?

Shana Nowelani Gaug: Maika'i (Job well done) to the organizers and speakers. What a wonderful event!

Jane Tansiongco: Hi Ann. Great presentation. Why is use of ACT for Angiomax considered off-label? What can be used to measure ACT for Angiomax?

Lou Ann Wyer: Yes, the speakers have been terrific and I loved this forum! Can't wait to do it again!

Lori Williams: Great conference.

Peggy Mann: Ann will be with us momentarily, keep the questions coming!

Lou Ann Wyer: We will be ready to go in just a minute folks! Thanks for hanging in there with us to the end! I have thoroughly enjoyed the conference today. I hope you have too!

Lou Ann Wyer: If a CLIA COW laboratory performs a test where the pkg insert indicates the test is waived/nonwaived depending on the specimen type used, is the nonwaived test then considered a modification if performed?

Devorah Alexander: Some arthro physicians want to be able to perform dipstick on joint fluid to screen for leukocytes using the urine dipstick. Of course I know this is off-label. I don't know if there's anything on the market to test for leukocytes in joint fluid? How to even begin to validate this? One reason is that the samples would be hard to retrieve. How many samples would be needed?

Lou Ann Wyer: Would a RN meet the CLIA requirements to perform high complexity testing?

Marissa Chupp: I struggle with providers using occult blood and streps off label. Any suggestions?

Peggy Mann: Welcome participants - please submit your questions to Ms Snyder!

Peggy Mann: Welcome all to Ann Snyder's Q&A. Thank you so much Ann for this informative talk!

Shana Nowelani Gaug: Aloha Ann. Thank you for the great talk. How can we tell if our nonwaived devices have been approved for all patients? E.g., with iSTATs or other blood gas analyzers, most specify only sample type with no reference that they've been cleared for critically ill patients.