Answers to Your Questions About Blood Bank Proficiency, Competency and QC

Follow Up to April 28, 2016 Webinar

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Dear Dickie,

This is a reminder that you are registered to attend: "Answers to Your Questions About Blood Bank Proficiency, Competency and QC" which will begin in 1 Hour on:

Thursday, June 23, 2016

Add to Calendar: Outlook® Calendar | Google Calendar™ | iCal®

Please send your questions, comments and feedback to: dnichols@immucor.com

Handouts for this webinar may be downloaded from the following site. Please copy and paste the following link into your web browser to access your handouts:

http://www.immucor.com/en-us/Pages/Educational-Program-Handouts.aspx

To receive CE for this webinar each participant must register after completing the session. Please be sure to distribute this information to each participant.
To register, please copy and paste the following link into your web browser to access the registration site:

https://www.surveymonkey.com/r/QCWebinarII

DEADLINE TO REGISTER FOR CE IS July 8, 2016. Certificates of attendance will be sent out by July 22, 2016.
NO REGISTRATION WILL BE ACCEPTED AFTER July 8, 2016.

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Handouts

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- PACE, California DHS
  - 437-305-16
- Florida BPR
  - 20-535259
- 1.5 Contact Hours
- Each attendee registers at:
  https://www.surveymonkey.com/r/QCWebinarII

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- *No other form of CE registration will be accepted*
- *Certificates will be sent via email by July 22, 2016*

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Other

- Session is being recorded and will be posted on LEARN in about 2 weeks
  - *All registrants will be notified when recording is available*
  - *No CE will be issued for participating in recorded session*
- You are all muted
- Q&A following session – if time allows

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Objectives

- Answer questions posed at previous webinar: "Blood Bank Proficiency, Competency and QC: A practical approach to CLIA requirements and AABB, CAP and Joint Commission expectations"
- Clarify intent of recommendations, interpretations, requirements for appropriate accrediting organization

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Define "Recommend"

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Proficiency

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Proficiency

1. Does testing such as adsorptions, ficin treatment, DTT treatment, thermal amplitude or D-L testing require proficiency testing or blind samples?
2. What is the difference between regulated and unregulated analytes with regards to proficiency testing
3. Would antibody identification and antibody screening be considered one analyte?
4. Explain the difference between blind samples and previously analyzed samples that may be used for PT samples.
5. Is it required to have both positive and negative unknowns?

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Proficiency

1. Is proficiency testing required for Electronic Crossmatch?
2. Please give an example of how proficiency samples would be integrated within routine lab work?
3. If a tech performs PRN work at two different labs, can they participate in proficiency testing at each lab?

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Proficiency

- What are the minimum proficiency samples a laboratory has to participate in for CLIA?
  - https://www.cms.gov/Regulations-and-Guidance/Legislation/CLIA/Downloads/CLIAbrochure8.pdf

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Attestation

- 42 CFR 493.801(b)(1) states the laboratory director needs to sign for PT attestation. Please clarify the requirements for:
  - High complexity testing
  - Moderate complexity testing
  - Which category does blood bank testing fall under?
  - Watch for the "*"

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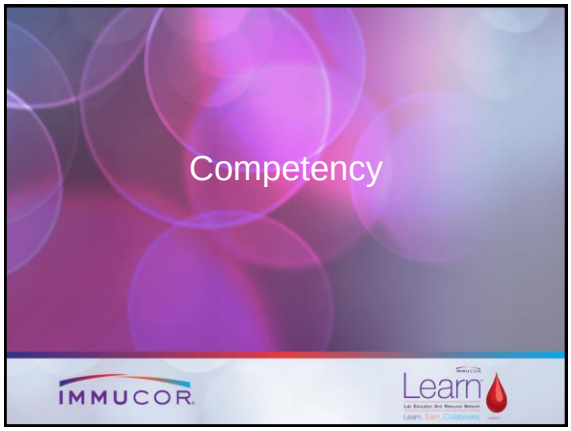

Competency

- How is "test system" defined. Is it defined by the facility or is there any guideline on defining "test system"
- *"Test system" means the instructions and all of the instrumentation, equipment, reagents, and supplies needed to perform an assay or examination and generate test results."*

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Competency

1. Is competency testing required for tests only or also for tasks such as issuing units or operation of the irradiator?
   – How are these tasks defined?
2. When implementing a new testing platform (e.g. automation) or replacing old equipment, does the semi-annual competency rule apply to all employees during the first year the new instrumentation is in use?
   – Training versus competency

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Competency

1. When performing 2 tests using the same methodology (e.g. antibody screen and antibody identification), is competency required for both?
2. What about two different methodologies for the same test (e.g. antibody ID by tube versus Capture)
3. What about same technology on different platforms (manual versus automated Capture)
4. Same Methodology for different tests (molecular testing for red cells versus platelets)

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Competency

1. Who can perform direct observation for competency?
   – Non-supervisory staff?
   – MLTs?
   – Peers?
2. Who can sign off on competency?

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Competency

- How do you perform competency testing on a test that is performed once a year or less?

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Competency Intervals

1. Please re-define the first year intervals required for competency by each organization:
   – Timeline for each accreditor
2. All 6 elements each time?

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Reagent QC

Positive and Negative Controls

1. How do you determine whether both a positive and negative control are required for a test?
2. If the package insert does not indicate a negative control is required, do I still have to perform a negative control?

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QC Testing Requirements

- What is required to QC the following:
  - Panel cells
  - Outdated cells used for selected cells

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QC testing requirements

1. Multiple reagent racks:
   - Each open vial on different racks even if same lot number?
   - When a vial from a new lot number is opened?
2. Can different methods (e.g. tube, SPRCA or gel) be QC'd by different shifts…e.g. 1st shift tube, 2nd shift SPRCA and 3rd shift gel?
3. Must QC be rotated amongst personnel and shifts?

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IQCP

- Does Verax bacterial testing for platelets require IQCP?

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Lot to Lot

- Is it sufficient to run a kit's controls from the current lot (e.g. for Fetal bleed kit) with the new lot and the new lot's controls with the current lot to do a lot to lot comparison?
- Must the comparison be performed prior to the previous lot expiring?
- Do you need to run a lot to lot comparison when the package insert states the reagents are interchangeable between lots?
- We make sure that a new lot of Reagent cells are opened on a different day than a new QC kit lot with the intent that this will fulfill the lot to lot comparison. Is that sufficient?

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Lot to Lot

1. Is this comparison required for the following:
   - EluKit II
   - EGA
   - Sickle cell screening
   - Solid Phase test strips used only on automation
2. Is parallel testing required or only a lot to lot comparison?

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Method to Method

1. How many samples are required for method comparison done every 6 months?
2. Is method correlation between tube/LISS and tube/PeG for antibody screen and ID required?
   - How does one address the difference in strength of reaction between methods?

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Miscellaneous

1. Is it required to have a binder with all reagent package inserts in one place?
2. What will be the recommended resolution to correct a deficiency due to limitations of the IS and/or EHR?

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The Joint Commission Contact Information

Joint Commission Standards Interpretations
qualitylabs@jointcommission.org

630-792-5900
8:30 am - 5:00 pm CT

Online question form for Standards Interpretation
https://web.jointcommission.org/sigsubmission/sigquestionform.aspx

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