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**From:** Daniel Young  
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Here are my notes from the audit yesterday.

I have not yet sent this to the CLIA team.

Please let me know if you have any questions.

Thanks,

Daniel

## CLIA Laboratory Audit

12/03/2013

### Meeting Minutes

- 1) Forms review
- 2) Urine Microscopy
  - a. Auditor asked if we do urine microscopy and who does it
    - i. Adam said CLS do it, but we have not done it in a long time; also no microscope, just use IRIS platform
    - ii. Adam said we have not done casts
- 3) EIA:
  - a. Auditor asked if we offer EIA
    - i. Adam: no
  - b. Auditor asked if we have any auto-antibody LDTs?
    - i. Adam: no
    - ii. **Action needed: DLY to confirm**
- 4) Personnel:
  - a. Reviewed roster
  - b. We were missing check marks for "clinical consultant"; should be Adam
  - c. We were ok with years of experience for GS and TS roles
- 5) Tests:
  - a. Auditor asked if we have any new tests offered since last audit
    - i. Adam said yes and spoke about all LDTs (GC, cyto, ELISA)
      1. Mentioned Edison 3.5, Flow Cytometer, Advia, and Normandy lab
- 6) Competency review:
  - a. Sarah's and Nereyda's personnel folders were reviewed and approved
    - i. In reviewing competency files, auditor noted that in one set of data, basophil counts were high. Auditor asked if this would trigger a manual review.
    - ii. Our policy was not clearly explained to auditor. Adam showed our manual smear SOP, but this was not what the auditor wanted to see.
    - iii. Our review SOP was not available to show auditor, and we noted that flags on the Ruby analyzer would trigger a manual review. Auditor requested that we show her this process in the lab, but this was not done during lab tour due to lack of time.
    - iv. **Action needed: review policy and document in an SOP if it does not exist already**
  - b. Nick Haase's role was discussed
    - i. Kerry noted that Nick acted as a trainer;
    - ii. Auditor said that this was not appropriate; auditor noted that training signoff needs to be done by a CLS
- 7) Test volume: auditor noted that the increasing test volume will likely cause our fees to increase

- 8) PT review:
- a. Auditor reviewed that we are enrolled in PT for all our offered tests
  - b. During the review, it was apparent that the test list we provided included tests that are not offered, but rather are used only for internal research right now
  - c. It took us a long time to track down all the PT supporting data (not well organized)
  - d. It was suggested that we enroll in a program to track our offered assays and PT enrollment
  - e. It was concluded that we are not enrolled in PT for ammonia
    - i. Action needed to enroll in PT for ammonia
- 9) Accessioning:
- a. Auditor asked if we receive paper and electronic orders
  - b. Adam responded yes, that we receive both (and mentioned SuperMario)
- 10) Blood banking specialty:
- a. Auditor asked if we are doing any tests under the blood banking specialty
  - b. Adam responded "no"
  - c. Auditor asked for example, blood typing. Adam responded "no"
  - d. Action: DLY to check why Adam said no, as we do blood typing.
- 11) LDT Validation:
- a. Auditor asked to see a representative LDT validation report
  - b. She picked creatinine as an example
  - c. This report did not appear to be the latest with the linearity data
  - d. Action: DLY to check why the latest reports were not checking into doc control
- 12) Proficiency testing:
- a. Auditor asked Adam what our SOP is for 4/5 passing events or when the events cannot be scored
  - b. Adam said that they have not been doing any type of internal review of these
  - c. Auditor said that we must
  - d. DLY pulled up SOP, and it did say that our policy is to review and document such investigation of PT situations; auditor asked that DLY print it for her, which was done.
  - e. Auditor said that she plans to document this in her report
  - f. Action item: ensure that we follow our SOP; review all prior PT events and document it per SOP
- 13) Lab Visit:
- a. Ruby:
    - i. Checked that all controls were run and if they passed
    - ii. Auditor said that we need to print out results and keep records
    - iii. Auditor asked who reviews the daily QC data on a periodic basis? What is our SOP?
    - iv. Auditor said that we need to review our daily QC data every month (Adam said we have not been documented this)

- v. Auditor asked about our QC acceptance rules. Adam said that all 3 values had to be within 2 SD, but Hoda showed that we are passing results that show 1/3 outside. Hoda confirmed that this is our SOP.
- b. ESR device: we reviewed briefly the controls used
- c. Coag device:
  - i. we reviewed that the ISI information was correct and controls were being run properly
  - ii. it was noted that this device is not connected to our LIS.
    - 1. Action: DLY to confirm if this is that case and why
- d. Immulite:
  - i. Reviewed QC data extensively
  - ii. Why do some of the assays show "over due" status?
    - 1. Action: Hoda to review
  - iii. Labdaq and Instrument are showing difference QC acceptance ranges in some cases
  - iv. Labdaq was missing some QC acceptance ranges.
  - v. Is it true that Labdaq cannot show old lot QC ranges? Makes review of QC data very difficult.
  - vi. Action: We need to review our SOP for inputting and reviewing QC ranges
- e. Advia:
  - i. Reviewed QC data
  - ii. Auditor made a note about the right lot info needing to be entered
  - iii. Action: Kerry to correct

#### 14) Calibration Verification:

- a. Auditor mentioned that she wanted to review our policy and performance of calibration verification. But we ran out of time.
- b. Action: team to review our SOP and that we are following it

#### 15) QC Policy:

- a. Auditor asked to see our QA Policy.
- b. She reviewed it and said that it should be more specific, ie, need to patient reports, results, patient names, etc.
- c. DLY found such SOPs that exist, but did not bring them up in the meeting since Adam could not confirm to DLY during the meeting that we were following our SOPs
- d. Action: need to make sure we are following all our QC policies