# *HEADS UP…*

## *TOPIC: Surveillance of Patient Results and Records*
## *SETTING:* Laboratory Accreditation Program (LAB)

## Why is this important?

In order to ensure the quality of laboratory services, it is essential that surveillance programs are established and maintained. Monitoring processes related to the review of laboratory records, analytics, and quality control/assessment documentation regulates staff performance and ensures compliance. Health care decisions and diagnoses often rely on laboratory services and findings making them a critical component in patient care and safety.

## Scope of the Problem:

Time period of inquiries: **January 1, 2021 to July 31, 2021**
Number of full surveys performed: **491**
Number of high and moderate risk findings: **43 (8.6%)**
**Relevant Standard/EP**: **QSA.02.11.01 -** The laboratory conducts surveillance of patient results and related records as part of its quality control program. **EP 7 -** The laboratory performs review of other records (for example, work records, equipment records, quality control summaries) at a frequency defined by the laboratory, but at least monthly. The review is documented. (See also QSA.02.02.01, EP 5). Please note: QSA.02.011.01 EP 7 does not define the qualifications of the individual who conducts the review, please refer to standard LD.04.05.07 EP 4 (bullet 2) which requires the laboratory director or technical supervisor (high complexity) or technical consultant (moderate complexity) to review quality control and proficiency testing data. In the cases where the monthly review is performed by someone other than the lab director, technical supervisor or technical consultant and is forwarded for their review, it is highly recommended and common laboratory practice that the summary of the data also be reviewed in a monthly time frame. *See also CLIA §493.1239(c), §493.1289(a), §493.1289(c), §493.1256(c)(1), §493.1281(b)(1), §493.1281(b)(2), §493.1281(b)(3), §493.1281(b)(4), §493.1281(b)(5), §493.1281(c), §493.1299(a), §493.1407(e)(5), §493.1445(e)(5), §493.1445(e)(6), §493.1463(a)(4).*

### Sample survey observations [from surveyor notes] and contributing factors

- There was no documentation of review of daily, weekly, or monthly urinalysis maintenance records or the HCG testing logs in [date redacted].
- The laboratory did not have documentation of monthly review for histology such as temperature and humidity, preventative maintenance for the tissue processor, preventive maintenance for the tissue stainer, and preventive maintenance for the cryostat. This was confirmed by the manager of laboratory services.
- In 2 of 3 blood cultures reviewed, the monthly review for the antibiotic susceptibility testing on the Vitek did not have the date of review.
- The organization could not provide documentation of monthly review of quality control for blood gases (G3+ cartridge) performed on the i-STAT since [date redacted].

### Potential contributing factors:

- Written policies and procedures related to surveillance of laboratory records and quality control documentation were unclear.
- Lack of oversight by leadership and/or of the laboratory manager.
- Job duties and responsibilities involving laboratory surveillance were not clearly defined.

## How to identify potential problems in your organization

### Review policies, procedures, and protocols

☐ Does the laboratory have clearly written policies and procedures related to the surveillance of laboratory records, results, and quality control/assessment documentation?

- How are records and patient-related documentation/results reviewed?
    - Who is designated to review these documents?
    - How is this approach communicated within the laboratory?
- Who is responsible for overseeing quality control and assessment protocols?
- Is there an ongoing mechanism to monitor, assess and, when indicated, correct problems identified?
    - Does the laboratory have a system to identify and assess patient test results that appear inconsistent (e.g., patient age, sex, diagnosis, or pertinent clinical data)?
- How frequently does the laboratory monitor records, analyses, results, and quality control assessments?
- How are staff educated and trained on these processes?
    - Is there an ongoing education process?

### Interview staff

☐ Is staff aware of surveillance protocols and schedules per written policy?

☐ Does staff understand how to effectively monitor, and review records of the laboratory services provided?

- How often are temperature-controlled spaces and equipment monitored?
- How often are reagent storage temperatures and humidity documented?
- For tests requiring interpretation, can they describe how the person who provides interpretation authenticates signs out the results?

☐ Does staff know what steps to take when an error is identified in existing records and documentation?

- What corrective actions/procedures are established?

### Assess your environment

☐ Review all surveillance requirements and policies.

☐ Does staff have access to all required written protocols and/or instructions?

### Evaluate implementation

☐ Directly trace a surveillance process and review quality control records and analytic results.

☐ Review documentation of a corrective procedure to verify that it is completed per organization policy.

☐ Assess staff knowledge and comprehension of surveillance/monitoring protocols.

☐ Review policies and procedures annually to ensure they are updated.

## What are some resources that can assist in mitigating risks in these areas?

- Clinical Laboratory Improvement Amendments of 1988 (CLIA ’88). Complete description of the requirement is located at https://www.ecfr.gov/cgi-bin/text-idx?SID=1248e3189da5e5f936e55315402bc38b&node=pt42.5.493&rgn=div5#sp42.5.493.m