



Delaware Public Health Laboratory Complaint Investigations

CLIA regulations require that a laboratory must have a system in place to ensure that it documents all complaints and problems reported to the laboratory (**§493.1233**). *The laboratory* must conduct investigations of complaints, when appropriate.

A complaint is any concern related to the proper operation of the laboratory. Examples include the following:

- Quality of Testing
- Unethical practices
- Confidentiality of patient information
- Laboratory personnel issues
- Any other concerns related to the proper operation of the laboratory

Complaints can be reported by any individual or agency that utilizes the services of the Division of Public Health Laboratory. This includes (but is not limited to), state agencies, private physician's offices, hospitals and private individuals. A blank form is available to download from the DPHL website, and should be utilized when reporting a complaint to the DPHL.

All complaints received by the DPHL will be investigated as follows:

1. The initial investigation will be conducted by the Quality Systems Manager to assess if the complaint is valid. The Quality Systems Manager will contact the individual who filed the complaint to ensure all relevant information has been documented.
2. The Quality Systems Manager will work with the appropriate lab manager(s) to determine the cause(s) of the complaint and the appropriate corrective action.
3. Upon completion of the investigation the Quality Systems Manager will report their findings to the Director, who will determine the appropriate method for notifying the complainant of the results.