Opinion: Legiolert vs Other *Legionella* Testing Methods, Are the Data Legally Defensible?

Jennifer L. Clancy, Ph.D., M.S. Law, BCES
President, ESPRI

Summary: Results from Legiolert testing are legally defensible data.

What determines whether a test result is legally defensible and will "hold up in court"?

- Microbiological and chemical environmental test results are ***legally*** *defensible* as long as they are ***scientifically*** *defensible*.

- The Legiolert® test is an internationally validated culture method which can be used to generate scientifically defensible data.

  The Legiolert test has been validated by globally recognized third parties, including the Association Française de Normalisation (AFNOR) and state accrediting agencies in the US. Legiolert's performance characteristics have been documented in an ISO 13843 study and it has been validated against multiple standard spread-plate methods in studies published in various peer-reviewed scientific journals.

- Scientifically defensible means:

  a) each step involved in data generation meets the accepted standards for the sampling and analytical process, and

  b) the sampling and analytical process is sufficiently documented to demonstrate it meets the accepted standards.

  US federal agencies (EPA, USGS, etc.) all have guidelines describing the development of scientifically defensible data; many publications also describe this process. Research studies funded by federal agencies are required to meet these criteria.

  Legal defensibility is <u>not</u> influenced by choice of testing method as long as a laboratory has adequately demonstrated its capability to run that method and documents its analytical process.

- The following criteria should be met to ensure that testing data is scientifically defensible.

  - **Contract with an accredited environmental laboratory**
    For environmental testing, the lab should be certified or accredited by a recognized independent body. In the US this may be a state agency or may be an accreditation body

such as A2LA, ANAB and others. The ISO/EC17025 standard for accreditation of environmental testing labs has gained acceptance in the US. Accreditation indicates that the lab and staff have undergone review, including an on-site inspection, and satisfied the basic quality system requirements to conduct testing.

Testing methods and reporting limits are part of a laboratory's demonstrated capabilities. In the case of *Legionella* testing, the lab will list *Legionella* testing as a capability and will have demonstrated that they can perform the testing (e.g., blind proficiency testing [PT] samples, internal PT samples).

The Legiolert method can be added to the scope of any laboratory accredited under the ISO 17025, AIHA EMLAP and other recognized standards. The lab will also be able to demonstrate other aspects of its capacity to undertake the testing (e.g., ability and schedule to receive samples, staff and equipment availability, turn-around-time, etc.).

- **Ensure every aspect of the process that results in data generation is properly documented**

  Documenting the process begins with sampling. If the lab supplies the sample bottles, it should document the bottle lot and processing information, if any. If the lab supplies the sampling information, this will be set out in a sampling standard operating procedure (SOP) provided to the client. Field sheets and Chains of Custody forms are required to document all aspects of the sampling and sample handling.

  Once the samples are received in the lab, the lab's analytical SOPs govern and describe how the samples are handled from receipt through analysis to reporting. The process includes analysis of quality control (QC) samples that include positive (target analyte) and negative (non-target) controls. The lab may include recoveries of known spiked organisms into a sample to assess matrix effects, e.g. recovery. When the analysis is completed according to the SOP, the results will be reviewed by the Quality Assurance (QA) staff and a report generated. Deviations in any of the steps will be documented and described. Documentation occurs at each step in the process.

  This documentation process allows the data to be scientifically, and hence legally, defensible. Any method can result in scientifically defensible data if those data are generated and documented as described above.

Dr. Jen Clancy is an internationally-recognized microbiologist who has worked on drinking water microbiology and water quality and treatment for 40 years. She has provided litigation support in cases involving Legionnaires' disease and diseases caused by other waterborne pathogens including Pseudomonas aeruginosa, E.coli O157:H7, Cryptosporidium parvum, Giardia lamblia, and the brain-eating amoeba - Naegleria fowleri.