

**641—12.9(730) Documentation of the confirmatory testing process.** The following documents shall be retained for at least two years and, if requested, made available for inspection.

**12.9(1)** Chain of custody documentation shall be maintained for each sample tested with the identification of the sample, the person(s) handling and testing the sample, the storage of the sample, and the eventual disposal of the sample.

**12.9(2)** Documents regarding the following: analytical information for each batch assayed, instrument identification, calibration records, identification of reagent lot numbers and expiration dates, quality control results, and any other pertinent information.

**12.9(3)** Copies of proficiency testing results for ongoing monitoring and evaluation of laboratory performance. Approved confirmatory laboratories inspected by the SHL shall submit copies of proficiency testing results to the SHL or shall ensure that proficiency testing programs submit copies of proficiency testing results directly to the SHL on their behalf.

**12.9(4)** Current procedure manuals must be maintained for all procedures.

**12.9(5)** An annual review of manuals shall be performed and documented. Alterations and additions to procedures shall be incorporated into manuals and approved by the laboratory director before implementation.

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