**D3031**
**(Rev. 140, Issued: 05-29-15, Effective: 05-29-15, Implementation: 05-29-15)**

## §493.1105 Standard: Retention requirements

**(a)(3) Analytic systems records. Retain quality control and patient test records (including instrument printouts, if applicable) and records documenting all analytic systems activities specified in §§493.1252 through 493.1289 for at least 2 years. In addition, retain the following:**

**Interpretive Guidelines §493.1105(a)(3)**

The records must include instrument charts, graphs, printouts, transcribed data, and manufacturers' assay information sheets for control and calibration materials. If data are transcribed, ensure that the original and the transcribed copy are retained for 2 years.

Printouts from an instrument that is not directly interfaced with the laboratory information system must be retained for 2 years.

**NOTE**: Thermal paper or pressure sensitive paper may fade over time. Where necessary, the laboratory is expected to make an electronic or hard copy of applicable result printouts to ensure that they are retrievable and legible for at least two years.

The laboratory is responsible for retaining records of interpretive slide results of each

gynecologic and nongynecologic cytology case that each cytotechnologist examined or reviewed for at least five years.