(iv) Direct observation of performance of instrument maintenance and function checks;
(v) Assessment of test performance through testing previously analyzed specimens, internal blind testing samples or external proficiency testing samples; and
(vi) Assessment of problem solving skills; and
(9) Evaluating and documenting the performance of individuals responsible for high complexity testing at least semiannually during the first year the individual tests patient specimens. Thereafter, evaluations must be performed at least annually unless test methodology or instrumentation changes, in which case, prior to reporting patient test results, the individual’s performance must be reevaluated to include the use of the new test methodology or instrumentation.

(c) In cytology, the technical supervisor or the individual qualified under § 493.1449(k)(2)—
(1) May perform the duties of the cytology general supervisor and the cytotechnologist, as specified in §§ 493.1471 and 493.1485, respectively;
(2) Must establish the workload limit for each individual examining slides;
(3) Must reassess the workload limit for each individual examining slides at least every 6 months and adjust as necessary;
(4) Must perform the functions specified in §493.1274(d) and (e);
(5) Must ensure that each individual examining gynecologic preparations participates in an HHS approved cytology proficiency testing program, as specified in §493.945 and achieves a passing score, as specified in §493.855; and
(6) If responsible for screening cytology slide preparations, must document the number of cytology slides screened in 24 hours and the number of hours devoted during each 24-hour period to screening cytology slides.