COLLEGE of AMERICAN PATHOLOGISTS

Checklist Requirement – GEN.43875	
Question -	**Answer -**
We perform LIS upgrades quarterly. Do we have to validate everything each quarter or can we pick a few items to test?	The Laboratory General checklist item GEN.43875 requires laboratories to validate the autoverification process initially and revalidate it when there are changes that could affect the autoverification logic. Ideally, the initial validation should include all analytes. The checklist item does not provide any guidelines on the extent of the testing needed following a LIS upgrade; therefore, it is left to the discretion of the laboratory director to establish appropriate procedures for revalidation following good laboratory practice. Clinical and Laboratory Standards Institute guidelines, AUTO10-A, Autoverification of Clinical Laboratory Test Results; Approved Guideline and AUTO15-ED1:2019 Autoverification of Medical Laboratory Results for Specific Disciplines, 1st Edition address the validation and revalidation of laboratory autoverification algorithms. The CLSI guidelines suggest the following: • Algorithm updates – perform validation testing to confirm that changes were properly implemented. The scope of the validation should be based on the changes made. • Software updates – whenever there are software changes to the analyzer, the LIS or the middleware, the software must be validated prior to use in patient testing. Test cases developed for initial autoverification validation may be used for the re-validation and results compared to the initial testing in order to ensure that the algorithms function as intended. The requirement to revalidate the autoverification process on an annual basis was discontinued in the 2020 Checklist edition.
What are specific examples of things that may affect the autoverification process?	Examples of changes that require revalidation of the autoverification process include: • Changes in the test procedure that impacts autoverification – this could include changes in specimen type, specimen handling, patient population, or significant changes in calibration materials, reagents or equipment • Changes to autoverification algorithms, such as data element changes to patient descriptors, critical values, instrument status (e.g., QC, calibration), result flags, comparisons with previous results (e.g., delta checks). Laboratories are responsible for defining what to include (or exclude) in

	autoverification algorithms and need to ensure that the algorithms work properly. • Software updates in the analyzer, LIS, or middleware which directly impact the operation of the autoverification algorithms Analytical changes, such as changes in reagent lots, calibrator lots, and QC materials do not typically affect the autoverification process. The Clinical and Laboratory Standards Institute guideline, AUTO10-A, Autoverification of Clinical Laboratory Test Results; Approved Guideline and AUTO15-ED1:2019 Autoverification of Medical Laboratory Results for Specific Disciplines, 1st Edition are excellent resources.