

COMPLIANCE SELF-ASSESSMENT CHECKLIST FOR NON-ACCREDITED MINIMAL COMPLEXITY TESTING SITES

USE OF FORM: SUBMITTED WITH REQUEST FOR RENEWAL OF CERTIFICATE FOR MINIMAL COMPLEXITY IN CONJUNCTION WITH A MEMORANDUM OF COMPLIANCE

Name of Lab/CLIP No./Registration or Accreditation Date: _____

POC Name/Phone Number/e-mail: _____

COMPLIANCE ITEM	IN <u>COMPLIANCE?</u>		COMMENTS
	YES	NO	
Is the CLIP certificate of the laboratory current? (Note: A CLIP certificate is valid for a period of two years.)			
Is the laboratory performing only those tests listed on the certificate application form or as amended by notification to the CLIP office?			
Are the name of the laboratory, the location of the laboratory, and Laboratory Director as identified on the CLIP certificate?			
Is a current copy of the manufacturer's package insert for each test performed on-hand?			
For each test performed, does the procedure SOP follow the manufacturer's package insert instructions?			
Are manufacturer's package inserts checked each time a shipment of test kits/reagents is received to determine whether the package insert has been revised? Is the check documented? Are SOPs revised in conjunction with the receipt of revised package inserts?			
Has each individual performing testing read the applicable SOPs and are the initial and annual reviews documented? Are reviews documented after a change is made to a SOP? Is the documentation of reviews retained for a period of at least two years?			
Are the SOP/manufacturer's instructions for performing the test followed during test performance?			
Are test results documented in accordance with SOP instructions?			
Are reference ranges, as appropriate, documented in the patient/applicant record with the test result?			
Are quality control procedures performed in accordance with the manufacturer's instructions with at least the frequency specified within the manufacturer's instructions?			

COMPLIANCE SELF-ASSESSMENT CHECKLIST (cont)

Name of Lab/CLIP No.: _____

COMPLIANCE ITEM	IN <u>COMPLIANCE?</u>		COMMENTS
	YES	NO	
Are quality control results within the acceptable ranges prior to testing of patient/applicant specimens, i.e., are quality control results that are out-of-range resolved/corrected before patient/applicant tests are performed? Actions to resolve out-of-control results, in order of precedence, include: re-run with same control; re-run with new control; re-run with new reagent (e.g., open new bottle of urine dipsticks, open new pregnancy testing kit, open new occult blood testing kit); review testing personnel performance to ensure the test is being performed correctly, try controls/reagents received in a different shipment, seek manufacturer or other assistance).			
When the corrective actions taken to resolve an out-of-control incident require more than retesting with the same or new control are all patient/applicant results since previous within-control results were obtained reassessed to determine if the patient/applicant test results were adversely affected? Is the reassessment documented? Are patient/applicant specimens retested if the reassessment shows the patient/applicant test results were adversely affected? Are health care providers notified of all amended results and is this notification documented?			
Are quality control results documented (i.e., control material identification (lot number, expiration date, etc.); reagent/kit identification (lot number, expiration date, etc.); quality control test result – initial and any re-runs, if necessary; whether the result was in or out of the acceptable range; corrective action, if necessary; and testing personnel identification)? Is the documentation retained for a period of at least 2 years?			
Has each individual performing tests been trained on the tests the individual is performing and is documentation of the initial training and competency assessment available? (For a new employee, documentation should be available for initial training and competency assessment and competency assessment at the 6 month and 12 month points.)			
Has each individual received training on new or changed procedures and is documentation of the training and competency assessment available?			
Has each individual been competency assessed at least once each calendar year and is documentation of the annual competency assessment available?			
Are testing personnel re-trained and is competency reassessed after performance problems have been identified?			
Are training and competency assessment records available for the term of employment plus two years?			

COMPLIANCE SELF-ASSESSMENT CHECKLIST (cont)

Name of Lab/CLIP No.: _____

COMPLIANCE ITEM	IN <u>COMPLIANCE?</u>		COMMENTS
	YES	NO	
Does the laboratory participate in a proficiency testing program appropriate for the tests being performed?			
Are proficiency testing samples examined or tested in the same manner as patient/applicant specimens are tested?			
Are proficiency testing samples examined or tested with the laboratory's regular workload by personnel who routinely perform the testing in the laboratory, using the laboratory's routine methods (e.g., one individual cannot be appointed to perform all proficiency testing; proficiency testing must be rotated among all personnel who routinely perform the testing in the laboratory)?			
Are proficiency testing samples tested the same number of times that patient/applicant samples are tested (e.g., no duplicate/repeat testing of proficiency testing samples is allowed if patient/applicant testing is not conducted in a like manner)?			
Interlaboratory communication pertaining to the results of proficiency testing samples is not allowed until after the date by which the laboratory must report proficiency testing results to the proficiency testing provider for the testing event in which the samples were sent. Does the laboratory comply with this prohibition?			
Sending proficiency testing samples or portions of samples to another laboratory for any analysis which the laboratory is certified to perform in its own laboratory is not allowed. Does the laboratory comply with this prohibition?			
Is the handling, preparation, processing, examination, and each step in the testing and reporting of results documented for all proficiency testing samples?			
Are proficiency testing results reviewed by appropriate supervisory personnel? Is the review documented?			
Are unacceptable and ungraded proficiency testing results assessed to determine the cause of the error (unacceptable results) or correctness of the laboratory's response (ungraded results) and is appropriate corrective action taken when necessary? Are the assessment and corrective action appropriately documented?			
Are all proficiency testing records maintained for a period of at least 2 years, including the signed report form attestation statement?			

NOTES: