Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	01D0923800	05/12/2021
Name of Provider or Supplier	**Street Address, City, State**	
Microphase Clinical Laboratory	1428 Weatherly Road, Suite 109, Huntsville, AL	

For information on the provider's plan to correct this deficiency, please contact the provider or the state survey agency.

(X4) ID Prefix Tag	Summary Statement of Deficiencies
D5211	EVALUATION OF PROFICIENCY TESTING PERFORMANCE CFR(s): 493.1236(a) The laboratory must review and evaluate the results obtained on proficiency testing performed as specified in subpart H of this part. This STANDARD is not met as evidenced by: Based on a review of the 2019-2021 API (American Proficiency Institute) proficiency testing (PT) records, and an interview with the Technical Supervisor, the surveyor determined the laboratory failed to document reviews of returned proficiency testing evaluations for fourteen of fourteen PT surveys. The surveyor further noted the laboratory failed to ensure ungraded analytes were reviewed and a self-evaluation was performed and documented. The findings include: 1. A review of the returned survey results for the API 2019-2021 surveys, including seven Bacteriology surveys, six Mycology surveys, and one SARS COV-2 antibody survey revealed no documentation of review (as indicated by a signature and date). 2. A review of the 2019-2021 Bacteriology surveys revealed ungraded results for Urine Culture "MIC /ZONE Diameter" (antibiotic sensitivities), (2019-Event #3, 2020-Events #1, #2, #3, and 2021 Event #1), however the laboratory had failed to document a comparison of their results with the peer group to ensure their results were acceptable. The surveyor further noted the laboratory failed to perform and document a self-evaluation for ungraded Educational Identification / Susceptibility challenges which instructed the laboratory to "See Data Summary". 3. During an interview on 5/12/2021 at 1:10 PM, the Technical Supervisor confirmed he always looked at the results, but failed to document his review on the surveys. The surveyor also reviewed the CLIA requirement to perform and document a self-evaluation of any ungraded results. .
D5421	ESTABLISHMENT AND VERIFICATION OF PERFORMANCE CFR(s): 493.1253(b)(1)

	Each laboratory that introduces an unmodified, FDA-cleared or approved test system must do the following before reporting patient test results: (1)(i) Demonstrate that it can obtain performance specifications comparable to those established by the manufacturer for the following performance characteristics: (1)(i)(A) Accuracy. (1)(i)(B) Precision. (1)(i)(C) Reportable range of test results for the test system. (1)(ii) Verify that the manufacturer's reference intervals (normal values) are appropriate for the laboratory's patient population. This STANDARD is not met as evidenced by: Based on a review of the installation and validation for the Quidel Solana, and an interview with the Technical Supervisor, the laboratory failed to ensure the manufacturer's performance specifications for accuracy and precision were verified, and the Laboratory Director's review and approval documented before patient testing began. This affected one of one new instruments in use at this facility. The findings include: 1. A review of the validation procedures for the Quidel Solana revealed several pages of qualitative test results run in 2020-2021 for the following assays: A) SARS COV-2 B) RSV (Respiratory Synctial Virus) C) Bordetella (pertussis and parapertussis) D) hMPV (human Meta Pneumo Virus), and E) Streptococcus However, there was no documentation the data was analyzed and evaluated to confirm the accuracy and precision of the instrument as stated in the manufacturer's performance specifications. 2. The validation and installation records also failed to include the Laboratory Director's signature and date indicating review and approval of the new test procedures before patient testing began on 1/19/2021. 3. During an interview on 5/12/2021 at 3:20 PM, the Technical Supervisor explained the laboratory had run validation samples supplied by the manufacturer, Quidel; the laboratory had obtained expected results. The surveyor explained the laboratory must collate the raw data and demonstrate their results were comparable to those established by the manufacturer for accuracy and precision. .
D6120	TECHNICAL SUPERVISOR RESPONSIBILITIES CFR(s): 493.1451(b)(7)(8) (7) The technical supervisor is responsible for identifying training needs and assuring that each individual performing tests receives regular in-service training and education appropriate for the type and complexity of the laboratory services performed; (8) Evaluating the competency of all testing personnel and assuring that the staff maintain their competency to perform test procedures and report test results promptly, accurately and proficiently. This STANDARD is not met as evidenced by: Based on a review of personnel listed on Form CMS-209, a lack of personnel files, and an interview with the Technical Supervisor, the surveyor determined the Technical Supervisor failed to ensure two of three new testing personnel had documentation of training for high-complexity testing completed before performing patient testing. The findings include: 1. A review of Form CMS-209 revealed three new testing personnel (TP) had been hired since the previous survey on 12/6/2018. The Technical Supervisor provided educational documentation, however he had no training or other records for TP #4 and #5. 2. During an interview on 5/12/2021 at 1:45 PM, when asked about the job responsibilities for the new testing personnel, the Technical Supervisor stated TP #4 performed molecular diagnostic testing on the new Quidel Solana, and TP #5 worked PRN (as needed) in Bacteriology. The Technical

	Supervisor confirmed he did not have documentation of training for the new testing personnel. SURVEYOR IS #32558 Licensure and Certification Surveyor