

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 01D0923800	(X3) Date Survey Completed 12/06/2018
Name of Provider or Supplier Microphase Clinical Laboratory	Street Address, City, State 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
D2000	<p>ENROLLMENT AND TESTING OF SAMPLES CFR(s): 493.801</p> <p>Each laboratory must enroll in a proficiency testing (PT) program that meets the criteria in subpart I of this part and is approved by HHS. The laboratory must enroll in an approved program or programs for each of the specialties and subspecialties for which it seeks certification. The laboratory must test the samples in the same manner as patients' specimens. For laboratories subject to 42 CFR part 493 published on March 14, 1990 (55 FR 9538) prior to September 1, 1992, the rules of this subpart are effective on September 1, 1992. For all other laboratories, the rules of this subpart are effective January 1, 1994.</p> <p>This CONDITION is not met as evidenced by: Based on a review of the laboratory test menu, the proficiency testing (PT) records and an interview with the Technical Supervisor, the surveyor determined the laboratory failed to enroll in an approved proficiency testing program for moderate- and high-complexity regulated tests in 2017. The findings include: 1. During the initial tour of the laboratory on 12/7/2018 at approximately 9:35 AM, the Technical Supervisor included on the test menu the following Microbiology specialties: Mycology: Fungal Cultures for growth or no growth, and Bacteriology: Cultures for Identification and Antibiotic Susceptibility testing However, upon the surveyor's request for the laboratory records at approximately 9:45 AM, the Technical Supervisor explained he had not performed any proficiency testing in 2017 because he had forgotten to renew the order with API (American Proficiency Institute). 2. A review of the proficiency testing records revealed the laboratory had used API as the PT provider thru 2016, and then no other PT was performed until Mar 2018. Thus, the above noted findings were confirmed. .</p>
D6015	<p>LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(4)</p>

The laboratory director is responsible for the overall operation and administration of the laboratory, including the employment of personnel who are competent to perform test procedures, and record and report test results promptly, accurate, and proficiently and for assuring compliance with the applicable regulations. (e) The laboratory director must-- (e)(4) Ensure that the laboratory is enrolled in an HHS approved proficiency testing program for the testing performed.

This STANDARD is not met as evidenced by:
Based on a review of the laboratory test menu, the proficiency testing (PT) records and an interview with the Technical Supervisor, the surveyor determined the Laboratory Director failed to ensure the laboratory was enrolled in an approved proficiency testing program for moderate- and high-complexity regulated tests in 2017. (Refer to D2000.) .

D6054

TECHNICAL CONSULTANT RESPONSIBILITIES
CFR(s): 493.1413(b)(9)

The technical consultant is responsible for evaluating and documenting the performance of individuals responsible for moderate complexity testing at least annually, after the first year.

This STANDARD is not met as evidenced by:
Based on a lack of documentation in the personnel file for Testing Personnel #2 and an interview with the Technical Consultant (also the Technical Supervisor), the surveyor determined the Technical Consultant failed to ensure the 2017 annual competency evaluation was performed and documented for one of two testing personnel (TP) who perform moderate- and high-complexity patient testing. The findings include: 1. A review of the Form CMS-209 Laboratory Personnel Report revealed two testing personnel performing moderate and high complexity patient testing employed by the facility since the previous survey. 2. A review of the personnel file for TP #2 revealed no documentation of an annual competency evaluation in 2017. 3. In an interview on 12/6/2018 at 11:00 AM, the Technical Consultant (also the Technical Supervisor) confirmed he had failed to document a 2017 competency evaluation for TP #2. SURVEYOR: Laura T. Williams, BS, MT (ASCP) Licensure and Certification Surveyor