

<b>Statement of Deficiencies</b>	<b>(X1) Provider/Supplier/CLIA Identification Number</b>  01D0981717	<b>(X3) Date Survey Completed</b>  10/30/2018
<b>Name of Provider or Supplier</b>  Medical Park Family Care	<b>Street Address, City, State</b>  1034 South Tallassee Street, Dadeville, AL	
For information on the provider's plan to correct this deficiency, please contact the provider or the state survey agency.		

<b>(X4) ID Prefix Tag</b>	<b>Summary Statement of Deficiencies</b>
<b>D2000</b>	<p><b>ENROLLMENT AND TESTING OF SAMPLES</b> 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 CAP (College of American Pathologists) proficiency testing (PT) records and website information, and interviews with the Technical Consultant and Testing Personnel (TP) #2, the surveyor determined the laboratory failed to enroll in a timely manner with an approved proficiency testing program to ensure receipt of all three 2018 PT events for moderate-complexity regulated tests. The findings include: 1. During the initial tour of the laboratory on 10/30/2018 at approximately 9:15 AM, TP #2 stated a Complete Blood Count (CBC) performed on the Sysmex KX-21N Hematology analyzer was the laboratory's only moderate-complexity test. 2. A review of the proficiency testing records revealed the laboratory had used CAP as the PT provider in 2017 and 2018, however there were no results for the 2018 first event (2018 FH1-A) Hematology survey. The only records in the binder for the first survey were instrument print-outs dated 3/8/2018 from five patient samples; a note on a corrective action sheet documented a comparison study had been performed in lieu of the survey, and the patient "results were within 20 percent". 3. A review of the PT Schedule on the CAP website revealed the 2018 FH1-A Hematology survey was shipped to laboratories on 1/22/2018. 4. During an interview with the Technical Consultant on 10/30/2018 at 10:</p>

35 AM, the surveyor asked why the laboratory had not performed the 2018 FH1-A Hematology survey. The Technical Consultant explained the PT renewal had been e-mailed to an individual no longer employed at the clinic. When it was discovered the clinic laboratory had not received the first PT survey, the Technical Consultant contacted CAP, however PT samples for the first Hematology event were no longer available. Thus the above noted findings were confirmed. .

**D6015**

**LABORATORY DIRECTOR RESPONSIBILITIES**  
CFR(s): 493.1407(e)(4)

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 2018 CAP (College of American Pathologists) proficiency testing (PT) records and website information, and interviews with the Technical Consultant and Testing Personnel #2, the surveyor determined the Laboratory Director failed to ensure the laboratory enrolled in a timely manner with an approved proficiency testing program. The surveyor noted the first of three 2018 PT Hematology surveys was not performed due to late enrollment. (Refer to D2000.)  
SURVEYOR: Laura T. Williams, BS, MT (ASCP) Licensure and Certification Surveyor