

<b>Statement of Deficiencies</b>	<b>(X1) Provider/Supplier/CLIA Identification Number</b> 44D0981845	<b>(X3) Date Survey Completed</b> 06/14/2018
<b>Name of Provider or Supplier</b> Memphis Pathology Laboratory	<b>Street Address, City, State</b> 2100 Exeter Rd, Suite 101, Germantown, TN	
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>D5209</b>	<p><b>PERSONNEL COMPETENCY ASSESSMENT POLICIES</b> CFR(s): 493.1235</p> <p>As specified in the personnel requirements in subpart M, the laboratory must establish and follow written policies and procedures to assess employee and, if applicable, consultant competency.</p> <p>This STANDARD is not met as evidenced by: Based on review of the procedure manual, the personnel records and interview with the technical consultant, the laboratory failed to follow the procedure for first six months of employment competency for testing personnel number one. The findings include: 1) Review of the procedure manual revealed, "POLICY: All testing personnel at GTSC are evaluated for competency after the initial training period, again after the first six months of employment, and on a yearly basis after that". 2) Review of the personnel records revealed testing personnel number one hire date is 09-18-17 with no documentation of six month competency. 3) Interview on June 14, 2018 at 12:10 p.m. with the technical consultant confirmed the six month competency was not performed and documented for testing personnel number one.</p>
<b>D5219</b>	<p><b>EVALUATION OF PROFICIENCY TESTING PERFORMANCE</b> CFR(s): 493.1236(c)(2)</p> <p>At least twice annually, the laboratory must verify the accuracy of any test or procedure listed in subpart I of this part for which compatible proficiency testing samples are not offered by a CMS-approved proficiency testing program.</p> <p>This STANDARD is not met as evidenced by: Based on observation of the laboratory, review of the proficiency testing records, the procedure manual, and interview with the technical consultant, the laboratory failed to</p>

verify the accuracy of the platelet function testing (PFA) in 2016, 2017 and 2018. The findings include: 1) Observation of the laboratory on June 14, 2018 at 10:15 a.m. revealed the PFA 100 analyzer in use for patient testing. 2) Review of the PT records revealed no PTA testing for PT in 2016, 2017 and 2018. 3) Review of the procedure manual revealed, "This laboratory participates in the PT program provided by the American Pathology Institute. This program covers all analytes tested by the laboratory." 4) Interview on June 14, 2018 at 11:45 a.m. with the technical consultant confirmed the laboratory does not verify the accuracy of the PFA at least twice per year, in 2016, 2017 and 2018, with patient testing reported.

**D6032**

**LABORATORY DIRECTOR RESPONSIBILITIES**  
CFR(s): 493.1407(e)(14)

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)(14) Specify, in writing, the responsibilities and duties of each consultant and each person, engaged in the performance of the preanalytic, analytic, and postanalytic phases of testing, that identifies which examinations and procedures each individual is authorized to perform, whether supervision is required for specimen processing, test performance or results reporting, and whether consultant or director review is required prior to reporting patient test results.

This STANDARD is not met as evidenced by:  
Based on review of the laboratory procedure manual, the personnel records and interview with the technical consultant, the laboratory director failed to establish in writing the responsibilities and duties of the laboratory personnel, including the laboratory director, clinical consultant, technical consultant and testing personnel. The findings include: 1) Review of the laboratory procedure manual revealed no responsibilities and duties included for the laboratory personnel. 2) Review of the personnel records revealed no responsibilities, duties and qualifications available. 3) Interview on June 14, 2018 at 11:30 a.m. with the technical consultant confirmed the laboratory personnel responsibilities and duties were not available.