

<b>Statement of Deficiencies</b>	<b>(X1) Provider/Supplier/CLIA Identification Number</b>  44D0910650	<b>(X3) Date Survey Completed</b>  12/05/2018
<b>Name of Provider or Supplier</b>  Jackson Clinic Pa South, The	<b>Street Address, City, State</b>  1893 South Highland Avenue, Jackson, 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>D6007</b>	<p><b>LABORATORY DIRECTOR RESPONSIBILITIES</b> CFR(s): 493.1407(e)(1)</p> <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)(1) Ensure that testing systems developed and used for each of the tests performed in the laboratory provide quality laboratory services for all aspects of test performance, which includes the preanalytic, analytic, and postanalytic phases of testing;</p> <p>This STANDARD is not met as evidenced by: Based on observation of the laboratory, review of the verification of performance specification records, the complete blood count patient testing records and interview with the laboratory director, the laboratory director failed to review and approve the complete blood count instrument verification records prior to patient testing in 2018. The findings include: 1) Observation of the laboratory on December 5, 2018 at 1:30 p. m. revealed the pocH-100i XP-300 serial number B3614 complete blood count instrument in use for patient testing. 2) Review of the verification of performance specification records revealed the pocH-100i XP-300 installation date January 9, 2018. The incorrect serial number B3416 on the verification of performance specification paperwork was signed for approval by the laboratory director on January 25, 2018. 3) Review of the complete blood count patient testing records revealed patient testing began on January 18, 2018, with the new pocH-100 XP-300 serial number B3614 complete blood count instrument. 4) Interview on December 5, 2018 at 2:30 p.m. with the laboratory director confirmed the new pocH-100i XP-300 serial number B3614 complete blood count instrument was installed January 9, 2018, patient testing began January 18, 2018.</p>