

<b>Statement of Deficiencies</b>	<b>(X1) Provider/Supplier/CLIA Identification Number</b>  01D1069264	<b>(X3) Date Survey Completed</b>  10/08/2019
<b>Name of Provider or Supplier</b>  Whitfield Regional Hospital, Cancer Care Center	<b>Street Address, City, State</b>  105 Us Hwy 80 East, Demopolis, 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 API (American Proficiency Institute) proficiency testing records, a lack of documentation, and interviews with the Laboratory Director (also serves as the Technical Consultant) and with the testing personnel, the surveyor determined the laboratory failed to enroll in proficiency testing for Hematology (Complete Blood Counts) for the first half of 2019. Patient testing of Hematology specimens continued, although the laboratory was not enrolled in proficiency testing. This affected year, 2019. The findings include: 1. A review of API proficiency testing records revealed no documentation of participation in the first two testing events of 2019. The laboratory documented the failure to enroll in 2019 was not discovered until July of 2019. The first event was missed. When the laboratory realized in July, no enrollment had been completed for 2019, the laboratory enrolled and requested specimens for the second event. However, the laboratory's request for the second quarter shipment of proficiency testing specimens was too late to be considered for grading by API. The laboratory performed the Complete Blood Count (CBC) testing on the proficiency testing specimens sent by API for the second quarter, and performed a self-evaluation of the results. 2. In an interview on 10/08/2019 at 11:15 AM, with Testing Personnel (TP) #1 (the Clinic Manager), TP #2 and the Laboratory</p>

Director, the surveyor inquired about the laboratory's failure to enroll timely for 2019. The Laboratory Director explained the laboratory had a change of staff, a break-down in communication, and the missed enrollment was not realized until July (2019). The Laboratory Director confirmed the first event testing was missed; and the second event results were self-evaluated by the laboratory staff. 3. Again, the surveyor discussed the above noted findings with the Laboratory Director and the Clinic Manager, during the exit interview on October 8 at 1:47 PM, as well as the possibility of including proficiency testing enrollment in the quality assurance monitoring. .

**D6029**

**LABORATORY DIRECTOR RESPONSIBILITIES**

CFR(s): 493.1407(e)(11)

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)(11) Ensure that prior to testing patients' specimens, all personnel have the appropriate education and experience, receive the appropriate training for the type and complexity of the services offered, and have demonstrated that they can perform all testing operations reliably to provide and report accurate results.

This STANDARD is not met as evidenced by:

Based on a review of the personnel records, including the training documents and competency assessments, a review of the Quality Assurance Policy and Procedure, and an interview with the Laboratory Director (also the Technical Consultant) and Clinic Manager [also Testing Personnel (TP) #1], the surveyor determined the Laboratory Director (LD) failed to ensure: (1) a semiannual competency assessment was done for TP #1, who was hired in December of 2017. (2) testing personnel were trained, prior to performing moderate-complexity testing of patient specimens. This was evident due to the lack of the LD's signature on the training records. This affected TP #1 and TP #3, two of three testing personnel. (3) the competency assessments were performed by the appropriate personnel, as evident due to the lack of the LD's signature on the competency assessments for TP #1 (annual dated 12/06/18) and TP #2 (annuals dated 6/25/18 and 6/25/19). The findings include: 1. A review of the personnel records revealed TP #1 was hired in December of 2017 (which was also stated by the personnel upon entrance interview of the survey on October 8, 2019 at 10:30 AM). TP #1's initial training records were dated, 12/05/2017. An annual competency evaluation was dated 12/06/2018; however there was no semiannual competency assessment performed for TP #1. These training records and competency assessment were not signed by the Laboratory Director, who also serves as the Technical Consultant. 2. According to the documentation in the personnel records, TP #1 was trained in December of 2017, and TP #3 was trained in May of 2019. None of these training records were signed by the Laboratory Director. 3. TP #1's annual competency assessment was dated 12/06/2018; and two annual competency assessments for TP #2 were dated 6/25/2018 and 6/25/2019. None of these assessments were signed by the LD. 4. A review of the Quality Assurance Policy and Procedure revealed the orientation of the laboratory should be signed by the Laboratory Director; a competency assessment would be done within the first six months of hire date and at one year intervals, thereafter, on the employee's anniversary date. This policy and procedure also indicated the competency assessments would be performed by the Laboratory Director. 5. In an interview on October 8, 2019 at 1:47 PM, the surveyor discussed the Laboratory Director's

responsibility for ensuring testing personnel were trained and their competency assessments were performed. The Laboratory Director, who also serves as the Technical Consultant, confirmed the semiannual competency assessment for TP #1 had not been done; as well as confirmed she had not signed any of the training records or competency assessments.