

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 44D0685819	(X3) Date Survey Completed 01/09/2020
Name of Provider or Supplier Bh Services Southeast 1, Pc	Street Address, City, State 18 N Cavalier Dr, Alamo, TN	
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
D0000	493.51 Notification requirements for laboratories issued a certificate of compliance Laboratories issued a certificate of compliance must meet the following conditions: (a) Notify HHS or its designee within 30 days of any change in-- (1) Ownership; (2) Name; (3) Location; (4) Director; or (5) Technical supervisor (laboratories performing high complexity only). (b) Notify HHS no later than 6 months after performing any test or examination within a specialty or subspecialty area that is not included on the laboratory ' s certificate of compliance, so that compliance with requirements can be determined. (c) Notify HHS no later than 6 months after any deletions or changes in test methodologies for any test or examination included in a specialty or subspecialty, or both, for which the laboratory has been issued a certificate of compliance. This requirement is not met as evidenced by: Based on observation of the laboratory, review of laboratory records, and interview with the lead testing personnel, the laboratory failed to notify the state agency of the change in specialties within 6 months of the change in 2019. The findings include: 1. Observation of the laboratory on January 9, 2020 at 12:30 p.m. revealed the Cell-Dyn 1700 on the counter. The instrument was not being used for patient complete blood count testing. 2. Review of the laboratory maintenance log for May 2019 revealed the instrument was removed from use on May 15, 2019. 3. Interview with the lead testing personnel on January 9, 2020 at 2:30 p.m. confirmed the laboratory stopped patient testing for complete blood count on May 15, 2019 and did not notify the state agency within 6 months of the change.
D2007	TESTING OF PROFICIENCY TESTING SAMPLES CFR(s): 493.801(b)(1) The samples must be examined or tested with the laboratory's regular patient workload by personnel who routinely perform the testing in the laboratory, using the laboratory's routine methods This STANDARD is not met as evidenced by:

Based on review of the laboratory's proficiency testing records, the Centers for Medicare and Medicaid Services Laboratory Personnel Report (CLIA) (Form CMS-209), and interview with the lead testing personnel, the laboratory failed to ensure proficiency testing samples were tested by personnel who routinely perform patient testing in 2018 and 2019. The findings include: 1. Review of the laboratory's proficiency testing records revealed attestation statements that were signed by the lead testing personnel for five of five testing events (2018 events two and three, 2019 events one, two and three). 2. Review of the CMS-209 revealed three testing personnel who perform patient testing. 3. Interview with the lead testing personnel on January 9, 2020 at 2:30 p.m. confirmed the laboratory failed to ensure all testing personnel participated in proficiency testing in 2018 and 2019. Only one of three testing personnel performed proficiency testing for the last five testing events.