Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	01D1060808	05/16/2018
Name of Provider or Supplier	**Street Address, City, State**	
Bbh Hoover Primary Care	5295 Preserve Parkway Suite 210, Hoover, AL	

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
D2015	TESTING OF PROFICIENCY TESTING SAMPLES CFR(s): 493.801(b)(5)(6) (5) The laboratory must document the handling, preparation, processing, examination, and each step in the testing and reporting of results for all proficiency testing samples. The laboratory must maintain a copy of all records, including a copy of the proficiency testing program report forms used by the laboratory to record proficiency testing results including the attestation statement provided by the PT program, signed by the analyst and the laboratory director, documenting that proficiency testing samples were tested in the same manner as patient specimens, for a minimum of two years from the date of the proficiency testing event. (6) PT is required for only the test system, assay, or examination used as the primary method for patient testing during the PT event. This STANDARD is not met as evidenced by: Based on a review of the American Proficiency Institute (API) proficiency testing records and an interview with the Laboratory Director (also the Technical Consultant) the laboratory failed to ensure Testing Personnel (TP) signed attestation statements for three of six 2016-2017 surveys. The findings include: 1. A review of the 2016-2017 API proficiency testing records revealed TP had not signed attestation statements for the following surveys: a. third Chemistry event in 2016 b. first Chemistry event in 2017 c. third Hematology event in 2017 2. During an interview on 5/16/2018 at 11:25 AM, the Laboratory Director reviewed the proficiency testing records with the surveyor and confirmed the above noted findings.
D3037	RETENTION REQUIREMENTS CFR(s): 493.1105(a)(4) Proficiency testing records. Retain all proficiency testing records for at least 2 years.

	This STANDARD is not met as evidenced by: Based on a review of 2017-2018 American Proficiency Institute (API) proficiency testing records and an interview the Laboratory Director (also the Technical Consultant), the laboratory failed to retain all proficiency testing records for three of four surveys in 2017- 2018. The findings include: 1. A review of the 2017-2018 API proficiency testing records revealed the laboratory failed to retain the following: a. attestation statement and instrument printouts for the second Chemistry survey event in 2017. b. attestation statement, report form, and instrument printouts for the third Chemistry survey event in 2017. c. attestation statement, report form, and instrument printouts for the first Hematology survey event in 2018. 2. The Laboratory Director (also the Technical Consultant) confirmed during an interview on 5/16/2018 at 11:25 AM, the laboratory had not retained all required proficiency testing records for the above surveys.
D5221	EVALUATION OF PROFICIENCY TESTING PERFORMANCE CFR(s): 493.1236(d) All proficiency testing evaluation and verification activities must be documented. This STANDARD is not met as evidenced by: Based on a review of the 2017 American Proficiency Institute (API) proficiency testing records, policy and procedure manual, and an interview with the Laboratory Director (also the Technical Consultant), the laboratory failed to document corrective action for one of three 2017 Hematology surveys. The findings include: 1. A review of the API proficiency testing records revealed the laboratory failed to document corrective action for Granulocytes that scored 60% (percent) on the first Hematology survey event 2017 resulting in a total score of 80% for the WBC differential. 2. A review of the policy entitled Protocol for Proficiency Testing states "DOCUMENT ALL CORRECTIVE ACTION." 3. During an interview on 5/16/2018 at 11:25 AM, the Laboratory Director stated the laboratory had not performed and documented corrective action for the above survey.
D5437	CALIBRATION AND CALIBRATION VERIFICATION CFR(s): 493.1255(a) Unless otherwise specified in this subpart, for each applicable test system the laboratory must perform and document calibration procedures-- (1) Following the manufacturer's test system instructions, using calibration materials provided or specified, and with at least the frequency recommended by the manufacturer; (2) Using the criteria verified or established by the laboratory as specified in 493.1253(b)(3)-- (2)(i) Using calibration materials appropriate for the test system and, if possible, traceable to a reference method or reference material of known value; and (2)(ii) Including the number, type, and concentration of calibration materials, as well as acceptable limits for and the frequency of calibration; and (3) Whenever calibration verification fails to meet the laboratory's acceptable limits for calibration verification. This STANDARD is not met as evidenced by: Based on a review of the Cell Dyn Emerald Hematology analyzer calibration records, the procedure manual, and an interview with the Laboratory Director (also Technical Consultant), the laboratory failed to perform and document two 2017 calibrations as

	per the laboratory policy which states calibrations should be performed every six months. The findings include: 1. A review of the Hematology calibration records revealed calibrations were performed 3/9/2016, 11/23/2016, and 4/11/2018 (seventeen months later). There was no documentation of calibrations performed in 2017. 2. During an interview on 5/16/2018 at 3:00 PM, the Laboratory Director stated the Testing Personnel had told her, the field service engineer performed the calibrations in 2017, but did not leave any calibration records on site. The Laboratory Director also stated she would contact the company to obtain the calibration records for CLIA. The surveyor then explained the laboratory would be allowed additional time until 9:00 a. m. on Friday 5/18/2018 to submit calibration records to the CLIA office. However, as of 1:00 p.m. 5/18/2018, no calibration records were received in the CLIA office. Thus the above noted findings were confirmed. Jeremy Westry, BS, MT (ASCP) Licensure and Certification Surveyor