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| Statement of Deficiencies | (X1) Provider/Supplier/CLIA Identification Number 01D0300416 | (X3) Date Survey Completed 08/10/2022 |
| Name of Provider or Supplier Bbh Primary Care Network | Street Address, City, State 803 North Street, Talladega, 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 |
|---------------------------|---|
| D2123 | <p>HEMATOLOGY CFR(s): 493.851(c)</p> <p>Failure to participate in a testing event is unsatisfactory performance and results in a score of 0 for the testing event. Consideration may be given to those laboratories failing to participate in a testing event only if-- (1) Patient testing was suspended during the time frame allotted for testing and reporting proficiency testing results; (2) The laboratory notifies the inspecting agency and the proficiency testing program within the time frame for submitting proficiency testing results of the suspension of patient testing and the circumstances associated with failure to perform tests on proficiency testing samples; and (3) The laboratory participated in the previous two proficiency testing events.</p> <p>This STANDARD is not met as evidenced by: Based on a review of the American Proficiency Institute (API) proficiency testing (PT) records and an interview with Testing Personnel #1, the laboratory failed to submit results by the cutoff date specified by the PT provider on one of seven 2020 - 2022 survey events reviewed. The findings include: 1. A review of the API records revealed the laboratory received a score of zero percent on API 2020 Hematology Event #1 due to failure to participate. A review of instructions for this survey revealed the results were due on March 27, 2020, at 11:59 PM, however the laboratory did not perform the survey until March 30, 2020. 2. During an interview on August 10, 2022 at 1:03 PM, Testing Personnel #1 confirmed the above findings.</p> |
| D3037 | <p>RETENTION REQUIREMENTS CFR(s): 493.1105(a)(4)</p> <p>Proficiency testing records. Retain all proficiency testing records for at least 2 years.</p> |

This STANDARD is not met as evidenced by:
 Based on a review of the American Proficiency Institute (API) Hematology proficiency testing (PT) records and an interview with Testing Personnel #1, the laboratory failed to retain API proficiency test records for at least two years. This was noted for five of seven API events reviewed from 2020 to 2022. The findings include:
 1. A review of the API Hematology records revealed the following API documentation was not retained by the laboratory for at least two years: a. 2020 Hematology Event #2- no attestation statement b. 2020 Hematology Event #3- no attestation statement c. 2021 Hematology Event #1- no program (results) forms d. 2021 Hematology Event #3- no attestation statement e. 2022 Hematology Event #1- no program forms or attestation statement. 2. A further review of the API attestation page revealed the following instructions, "...retain the signed statement (or a copy) for a minimum of 2 years. ...". 3. During an interview on August 10, 2022, at 12:30 PM, the surveyor reviewed the attestation statement instruction with Testing Personnel #1 who confirmed the laboratory had failed to make copies of results forms and attestation statements mailed to API, and retain the records for at least two years. .

D5291

GENERAL LABORATORY SYSTEMS QUALITY ASSESSMENT
 CFR(s): 493.1239(a)

The laboratory must establish and follow written policies and procedures for an ongoing mechanism to monitor, assess, and, when indicated, correct problems identified in the general laboratory systems requirements specified at 493.1231 through 493.1236.

This STANDARD is not met as evidenced by:
 Based on a review of the American Proficiency Institute (API) Hematology proficiency testing (PT) records, a review of the Quality Assurance (QA) procedure, and an interview with Testing Personnel #1, the laboratory failed to implement a mechanism to ensure PT results were submitted within the timeframes specified by the PT provider, and failed to ensure QA reviews were performed to ensure PT records were complete and retained for at least two years. This affected six out of seven 2020 - 2022 API PT events reviewed. The findings include: 1. A review of the API PT records revealed the following: A) The laboratory failed to implement a mechanism to ensure PT results were submitted by the cutoff date specified by API (Refer to D2123.) B) The laboratory failed to perform QA reviews of PT records to ensure all required documentation was present and retained for at least two years. (Refer to D3037.) 2. A review of the Proficiency Testing QA records, signed by the Laboratory Director on January 28, 2014, revealed, "PT results are reviewed and retained for a period of at least two years. ...". 3. During an interview on August 10, 2022, at 12:30 PM, Testing Personnel confirmed the above findings. SURVEYOR ID's #32558 and #46291 Licensure and Certification Surveyors