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| Statement of Deficiencies | (X1) Provider/Supplier/CLIA Identification Number 01D2104846 | (X3) Date Survey Completed 02/04/2022 |
| Name of Provider or Supplier Baptist Convenient Care - Millbrook | Street Address, City, State 101 Kelley Blvd Suite D, Millbrook, 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 |
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| D2016 | <p>SUCCESSFUL PARTICIPATION CFR(s): 493.803(a)(b)(c)</p> <p>(a) Each laboratory performing nonwaived testing must successfully participate in a proficiency testing program approved by CMS, if applicable, as described in subpart I of this part for each specialty, subspecialty, and analyte or test in which the laboratory is certified under CLIA. (b) Except as specified in paragraph (c) of this section, if a laboratory fails to participate successfully in proficiency testing for a given specialty, subspecialty, analyte or test, as defined in this section, or fails to take remedial action when an individual fails gynecologic cytology, CMS imposes sanctions, as specified in subpart R of this part. (c) If a laboratory fails to perform successfully in a CMS-approved proficiency testing program, for the initial unsuccessful performance, CMS may direct the laboratory to undertake training of its personnel or to obtain technical assistance, or both, rather than imposing alternative or principle sanctions except when one or more of the following conditions exists: (1) There is immediate jeopardy to patient health and safety. (2) The laboratory fails to provide CMS or a CMS agent with satisfactory evidence that it has taken steps to correct the problem identified by the unsuccessful proficiency testing performance. (3) The laboratory has a poor compliance history.</p> <p>This CONDITION is not met as evidenced by: Based on a review of the CMS (Centers for Medicare and Medicaid) CASPER reports, a review of API (American Proficiency Institute) proficiency testing evaluations, and a telephone interview with the Office Manager, the surveyor determined the laboratory failed to successfully participate in proficiency testing for White Blood Cell Differential for two consecutive testing events. These failures resulted in an initial unsuccessful participation. This affected Event #1 2021 and Event #3 2021. The findings include: 1. A review of the CASPER reports revealed the laboratory scored seventy-three percent (73 %) for White Blood Cell Differential for Event #1 2021 and zero percent (0 %) for Event #3 2021. These two consecutive</p> |

failures of the same analyte resulted in an initial unsuccessful participation in proficiency testing. 2. A review of the API testing evaluations confirmed for Event #1 2021, the lab scored seventy-three percent (73%) for White Blood Cell Differential [twenty percent (20%) for Monocytes/mixed] and failed to participate in Event #3 2021 for Hematology (which includes the White Blood Cell Differential). 3. During a telephone interview on 02/04/2022 at 10:30 AM, the Office Manager stated the Lab Manager left at the end of December 2021 and she was under the impression that the Proficiency Testing was taken care of. She further confirmed the laboratory was still performing Complete Blood Cell (CBC) (which include White Blood Cell Differential) during the time period the laboratory failed to participate in proficiency testing.

D2123

HEMATOLOGY
CFR(s): 493.851(c)

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.

This STANDARD is not met as evidenced by:
Based on a review of the CMS (Centers for Medicare and Medicaid Services) Casper reports, a review of the API (American Proficiency Institute) proficiency testing records, and a telephone interview with the Office Manager, the surveyor determined the laboratory failed to participate in Hematology [Complete Blood Count (CBC)] which includes White Blood Cell Differential testing for Events #3 2021. This failure along with D2130 resulted in an initial unsuccessful participation for the laboratory. The finding include: 1. A review of the CASPER reports revealed the laboratory scored seventy-three percent (73%) for White Blood Cell Differential for Event #1 2021 and for Event #3 2021 the laboratory failed to participate resulting a score of zero for White Blood Cell Differential. 2. A review of the API proficiency testing confirmed the above noted findings. 3. During a telephone interview on 02/04/2022 at 10:30 AM, the Office Manager stated the Lab Manager left at the end of December 2021 and she was under the impression that the Proficiency Testing was taken care of. She further confirmed the laboratory was still performing Complete Blood Cell (CBC) (which include White Blood Cell Differential) during the time period the laboratory failed to participate in Proficiency Testing.

D2130

HEMATOLOGY
CFR(s): 493.851(f)

Failure to achieve satisfactory performance for the same analyte in two consecutive events or two out of three consecutive testing events is unsuccessful performance.

This STANDARD is not met as evidenced by:
Based on a review of the CMS (Centers for Medicare and Medicaid Services) Casper

reports, a review of the API (American Proficiency Institute) proficiency testing records, and a telephone interview with the Office Manager, the surveyor determined the laboratory failed to satisfactorily perform in proficiency testing for White Blood Cell Differential testing for two out of three consecutive testing events. The failures of White Blood Cell Differential resulted in an initial unsuccessful participation for the laboratory. The findings include: 1. A review of the CASPER reports revealed the laboratory scored seventy-three percent (73%) for White Blood Cell Differential for Event #1 2021 and for Event #3 2021 the laboratory failed to participate resulting a score of zero for White Blood Cell Differential. 2. A review of the API proficiency testing confirmed the above noted findings. 3. During a telephone interview on 02/04/2022 at 10:30 AM, the Office Manager stated the Lab Manager left at the end of December 2021 and she was under the impression that the Proficiency Testing was taken care of. She further confirmed the laboratory was still performing Complete Blood Cell (CBC) (which include White Blood Cell Differential) during the time period the laboratory failed to participate in Proficiency Testing.