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| Statement of Deficiencies | (X1) Provider/Supplier/CLIA Identification Number 01D2171687 | (X3) Date Survey Completed 05/24/2021 |
| Name of Provider or Supplier Urgent Care For Children - Vestavia | Street Address, City, State 520 Montgomery Hwy, Vestavia, 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 |
|---------------------------|---|
| 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 scores for the AAFP (American Academy of Family Physicians) proficiency testing (PT) on the CMS (Centers for Medicare and Medicaid) CASPER reports, and an interview with the Office Manager, the surveyor determined the laboratory failed to satisfactorily perform in Hematology proficiency testing on two consecutive testing events, 2020-Event #3 and 2021-Event #1. These failures resulted in an initial unsuccessful performance in proficiency testing. The findings include: 1. A review of the CASPER Report 0155D (Individual Laboratory Profile) revealed the laboratory scored zero percent (0 %) for Hematology (Complete Blood Count [CBC] testing) for 2020-Event #3 and 2021-Event #1. These two consecutive failures</p> |

resulted in an initial unsuccessful performance in proficiency testing. 2. During an interview on 5/24/2021 at 9:32 AM, the Office Manager confirmed the laboratory had failed to perform and submit the results for the 2020-Event #3 and 2021-Event #1 surveys within the timeframe prescribed by the PT provider, and had received scores of 0 % . 3. In an e-mail received by the CLIA surveyor on 5/24/2021, the Office Manager confirmed the 2020-Event #3 survey was due on 10/28/2021, and the 2021-Event #1 survey was due on 3/25/2021. No patient CBC testing was performed in the two-week period prior to the survey due-dates, however the laboratory failed to notify the proficiency testing provider patient testing had temporarily ceased. .

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 scores for the AAFP (American Academy of Family Physicians) proficiency testing (PT) on the CMS (Centers for Medicare and Medicaid) CASPER reports, and an interview with the Office Manager, the surveyor determined the laboratory failed to submit results within the timeframes prescribed by the PT provider on two consecutive testing events, 2020-Event #3 and 2021-Event #1. The findings include: 1. A review of the CASPER Report 0155D (Individual Laboratory Profile) revealed the laboratory scored zero percent (0 %) for Hematology (Complete Blood Count [CBC] testing) for 2020-Event #3 and 2021-Event #1. 2. During an interview on 5/24/2021 at 9:32 AM, the Office Manager confirmed the laboratory had failed to perform and submit the results for the 2020-Event #3 and 2021-Event #1 surveys within the timeframe prescribed by the PT provider, and had received scores of 0 % . 3. In an e-mail received by the CLIA surveyor on 5/24/2021, the Office Manager confirmed the 2020-Event #3 survey was due on 10/28/2021, and the 2021-Event #1 survey was due on 3/25/2021. No patient CBC testing was performed in the two-week period prior to the survey due-dates, however the laboratory failed to notify the proficiency testing program within the specified time frames of the suspension of patient CBC testing and the circumstances associated with failure to perform the PT. .

D2131

HEMATOLOGY
CFR(s): 493.851(g)

Failure to achieve an overall testing event score of satisfactory performance for two consecutive testing 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 scores for the AAFP (American Academy of Family Physicians)

proficiency testing (PT) on the CMS (Centers for Medicare and Medicaid) CASPER reports, and an interview with the Office Manager, the surveyor determined the laboratory failed to satisfactorily perform in Hematology proficiency testing on two consecutive testing events, 2020-Event #3 and 2021-Event #1. These failures resulted in an initial unsuccessful performance in proficiency testing. The findings include: 1. A review of the CASPER Report 0155D (Individual Laboratory Profile) revealed the laboratory scored zero percent (0 %) for Hematology (Complete Blood Count [CBC] testing) for 2020-Event #3 and 2021-Event #1. These two consecutive failures resulted in an initial unsuccessful performance in proficiency testing. 2. During an interview on 5/24/2021 at 9:32 AM, the Office Manager confirmed the laboratory had failed to perform and submit the results for the 2020-Event #3 and 2021-Event #1 surveys within the timeframe prescribed by the PT provider, and had received scores of 0 % . The Office Manager further confirmed the laboratory had not notified AAFP with an acceptable reason for not performing the PT. .

D6017

LABORATORY DIRECTOR RESPONSIBILITIES
CFR(s): 493.1407(e)(4)(ii)

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)(4)(ii) Ensure that results are returned within the timeframes established by the proficiency testing program.

This STANDARD is not met as evidenced by:
Based on a review of scores for the AAFP (American Academy of Family Physicians) proficiency testing (PT) on the CMS (Centers for Medicare and Medicaid) CASPER reports, and an interview with the Office Manager, the Laboratory Director failed to ensure the laboratory submitted PT results within the timeframes prescribed by AAFP on two consecutive testing events, 2020-Event #3 and 2021-Event #1. The findings include: 1. Refer to D2123. SURVEYOR ID#32558 Licensure and Certification Surveyor