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| Statement of Deficiencies | (X1) Provider/Supplier/CLIA Identification Number 15D2267785 | (X3) Date Survey Completed 01/22/2024 |
| Name of Provider or Supplier Calumet Quick Care Ltd | Street Address, City, State 5518 Calumet Ave, Hammond, IN | |
| 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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| D0000 | A proficiency testing desk review survey was completed on 1/22/2024. It was determined that the following condition-level deficiencies existed: 42 Code of Federal Regulation (CFR) 493.803(a)(b)(c) Successful Participation 42 CFR 493.1403 Laboratory performing moderate complexity testing; laboratory director |
| 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 record review and interview, the laboratory failed to successfully participate in a proficiency testing program for two of three proficiency testing events in 2023. The laboratory failed to achieve satisfactory performance of 80% or greater for two consecutive testing events in 2023 (event 2, 2023 and event 3, 2023) for the analyte</p> |

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| | <p>Hematocrit (HCT). Results for event 2 2023 was 60% and for event 3 2023 was 0% for Hematocrit. (Refer to D2130)</p> |
| <p>D2130</p> | <p>HEMATOLOGY CFR(s): 493.851(f)</p> <p>Failure to achieve satisfactory performance for the same analyte in two consecutive events or two out of three consecutive testing events is unsuccessful performance.</p> <p>This STANDARD is not met as evidenced by: Based on record review and interview, the laboratory failed to achieve satisfactory performance of 80% or greater for two consecutive testing events in 2023 (event 2, 2023 and event 3, 2023) for the analyte hematocrit. Results for event 2 2023 was 60% and event 3, 2023 was 0% for hematocrit (HCT) as reported by the American Proficiency Institute (API). Findings include: 1) Review of "Casper Report 0155D," indicated a score of 60% for event 2 2023 and 0% for event 3 2023 for Hematocrit as reported by the American Proficiency Institute (API). 2) In email on 1/29/2024 at 1:26 pm, SP-2 (Testing Person) confirmed the proficiency testing scores for Hematocrit for event 2 and 3 2023. They would email a copy of the API summaries as soon as possible. 3) Review of American Proficiency Institute (API) "Performance Summary 2023 Hematology/ Coagulation- 3rd Event" confirmed the scores for hematocrit, 2023 event 2 was 60% and event 3 was 0%.</p> |
| <p>D6000</p> | <p>MODERATE COMPLEXITY LABORATORY DIRECTOR CFR(s): 493.1403</p> <p>The laboratory must have a director who meets the qualification requirements of 493.1405 of this subpart and provides overall management and direction in accordance with 493.1407 of this subpart.</p> <p>This CONDITION is not met as evidenced by: Based on record review and interview, the laboratory director failed to ensure the laboratory successfully participated in a proficiency testing program for two of three proficiency testing events. The laboratory failed to achieve satisfactory performance of 80% or greater for two consecutive testing events in 2023 (event 2, 2023 and event 3, 2023) for the analyte Hematocrit (HCT). Results for event 2 2023 was 60% and for event 3 2023 was 0% for Hematocrit. (Refer to D6016)</p> |
| <p>D6016</p> | <p>LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(4)(i)</p> <p>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)(i) Ensure that the proficiency testing samples are tested as required under Subpart H of this part;</p> <p>This STANDARD is not met as evidenced by: Based on record review and interview, the laboratory director failed to ensure the</p> |

laboratory successfully participated in a proficiency testing program for two of three proficiency testing events in 2023. The laboratory failed to achieve satisfactory performance of 80% or greater for two consecutive testing events in 2023 (event 2, 2023 and event 3, 2023) for the analyte Hematocrit (HCT). Results for event 2 2023 was 60% and for event 3 2023 was 0% for Hematocrit. (Refer to D2130) Findings include: 1) Review of "Casper Report 0155D," indicated a score of 60% for event 2 2023 and 0% for event 3 2023 for Hematocrit as reported by the American Proficiency Institute (API). 2) In email on 1/29/2024 at 1:26 pm, SP-2 (Testing Person) confirmed the proficiency testing scores for Hematocrit for event 2 and 3 2023. They would email a copy of the API summaries as soon as possible. 3) Review of American Proficiency Institute (API) "Performance Summary 2023 Hematology/ Coagulation- 3rd Event" confirmed the scores for hematocrit, 2023 event 2 was 60% and event 3 was 0%.