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| <b>Statement of Deficiencies</b>   | <b>(X1) Provider/Supplier/CLIA Identification Number</b><br>37D2033686 | <b>(X3) Date Survey Completed</b><br>07/23/2021 |
| <b>Name of Provider or Supplier</b><br>Classen Urgent Care Clinic  | <b>Street Address, City, State</b><br>2818 Classen Blvd, Norman, OK    |   |
| For information on the provider's plan to correct this deficiency, please contact the provider or the state survey agency. |  |   |

| <b>(X4) ID Prefix Tag</b> | <b>Summary Statement of Deficiencies</b>  |
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| <b>D0000</b>              | The recertification survey was performed on 07/23/2021. The laboratory was found in compliance with a standard-level deficiency cited. The findings were reviewed with the technical consultant and clinic manager at the conclusion of the survey.   |
| <b>D5215</b>              | <p><b>EVALUATION OF PROFICIENCY TESTING PERFORMANCE</b><br/>CFR(s): 493.1236(b)(2)</p> <p>The laboratory must verify the accuracy of any analyte, specialty or subspecialty assigned a proficiency testing score that does not reflect laboratory test performance (that is, when the proficiency testing program does not obtain the agreement required for scoring as specified in subpart I of this part, or the laboratory receives a zero score for nonparticipation, or late return or results).</p> <p>This STANDARD is not met as evidenced by:<br/>Based on a review of records and interview with the technical consultant, the laboratory failed to evaluate the accuracy of testing when proficiency results had not been graded by the proficiency program for 4 of 4 Hematology events reviewed. Findings include: (1) On 07/23/2021, the surveyor reviewed proficiency testing records for the first, second, and thirds events in 2020; and the first event in 2021. The following was identified for 4 of 4 Hematology events: (a) First 2020 Hematology Event for Blood Cell ID (Educational) - 5 of 5 results had not been graded by the proficiency testing program: (i) For 1 of 5 results (ECI-01), the following was identified: (aa) ECI-01 - Under "Expected Results" it stated, "See Commentary". There was no evidence the laboratory reviewed the commentary contained in the "Participant Summary Report" to evaluate their result. (ii) For 1 of 5 results (ECI-04), the program's expected result was included on the report which showed the following: (aa) ECI-04 - The laboratory's reported result of Spherocyte did not agree with the "Expected Result" of Microcytic red blood cell. There was no documentation to indicate corrective action had been taken for the unacceptable response. (b) Second 2020 Hematology Event for Blood Cell ID (Educational) - 5 of 5 results had not been</p> |

graded by the proficiency testing program: (i) For 1 of 5 results (ECI-06), the following was identified: (aa) ECI-06 - Under "Expected Results" it stated, "See Commentary". There was no evidence the laboratory reviewed the commentary contained in the "Participant Summary Report" to evaluate their result. (c) Third Hematology Event for Blood Cell Identification - 1 of 5 results had not been graded by the proficiency testing program: (i) For 1 of 5 results (BCI-11), the following was identified: (aa) BCI-11 - Under "Expected Results" it stated, "See Data Summary". There was no evidence the laboratory reviewed the commentary contained in the "Participant Summary Report" to evaluate their result. (d) Third Hematology Event for Blood Cell ID (Educational) - 5 of 5 results had not been graded by the proficiency testing program: (i) For 1 of 5 results (ECI-13), the following was identified: (aa) ECI-13 - Under "Expected Results" it stated, "See Commentary". There was no evidence the laboratory reviewed the commentary contained in the "Participant Summary Report" to evaluate their result. (e) First Hematology Event for Blood Cell ID (Educational) - 5 of 5 results had not been graded by the proficiency testing program: (i) For 1 of 5 results (ECI-13), the following was identified: (aa) ECI-13 - Under "Expected Results" it stated, "See Commentary". There was no evidence the laboratory reviewed the commentary contained in the "Participant Summary Report" to evaluate their result. (2) The surveyor reviewed the records with the technical consultant #1 who stated on 07/23/2021 at 10:30 am, the laboratory had not evaluated the results that were not graded by the proficiency testing program and corrective action had not been taken as indicated.