

| | | |
|--|--|---|
| Statement of Deficiencies | (X1) Provider/Supplier/CLIA Identification Number 52D0959803 | (X3) Date Survey Completed 03/14/2019 |
| Name of Provider or Supplier Aurora Health Center-Caledonia | Street Address, City, State 5333 Douglas Ave, Racine, WI | |
| 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 |
|---------------------------|--|
| D5215 | <p>EVALUATION OF PROFICIENCY TESTING PERFORMANCE 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: Based on surveyor review of proficiency testing (PT) records and interview with the technical consultant, the laboratory did not verify the accuracy of PT results that the PT provider did not score. Findings include: 1. Review of Wisconsin State Laboratory of Hygiene PT reports showed the following ungraded results: 2018 event 2, Hematology Cell Identification Sample XI-10 Expected result: Eosinophil Reported result: Segmented neutrophil 2018 event 2, Urine Sediment Sample PM-3 Expected result: Cellular cast or WBC cast Reported result: RBC/Hemoglobin cast 2018 event 2, Vaginal Wet Preparation Sample PM-3 Expected result: Trichomonas or Yeast and Trichomonas Reported result: Clue Cells, yeast and Trichomonas present 2018 event 3, Hematology Cell Identification Sample XIE-21 Expected result: Normal lymphocyte Reported result: Would Refer - Abnormal Further review of the PT records showed no documented evaluation of these results that the PT provider did not score. 2. Interview with the technical consultant on March 14, 2019 at 11:00 AM confirmed the laboratory did not evaluate the results of the unscored PT samples.</p> |
| D6046 | <p>TECHNICAL CONSULTANT RESPONSIBILITIES CFR(s): 493.1413(b)(8)</p> <p>(b) The technical consultant is responsible for-- (b)(8) Evaluating the competency of all testing personnel and assuring that the staff maintain their competency to perform</p> |

test procedures and report test results promptly, accurately and proficiently.

This STANDARD is not met as evidenced by:

Based on surveyor review of competence assessment records and interview with the technical consultant, the technical consultant did not evaluate the competence of staff B, one of two testing personnel, in 2018. Findings include: 1. Review of the 2018 "Competency Assessment - Testing Personnel Form" for staff B showed the form includes a grid with a space for the technical consultant to indicate for each test system whether the individual is 'Proven Competent Yes/No'. The technical consultant did not enter a determination of competence for any of the sixteen test systems listed. The grid includes a column for the pocH-100i hematology analyzer in this laboratory. The only documented evaluation for this test system was an evaluation of problem solving. The form included an unsigned space for the director or designee's signature and date with the statement "This employee is deemed to be competent to perform unsupervised patient testing in the above test systems". 2. Interview with the technical consultant on March 14, 2019 at 11:00 AM confirmed the competency assessment form for staff B was not complete and did not show the technical consultant had evaluated the competence of staff B to perform testing.

D6054

TECHNICAL CONSULTANT RESPONSIBILITIES
CFR(s): 493.1413(b)(9)

The technical consultant is responsible for evaluating and documenting the performance of individuals responsible for moderate complexity testing at least annually, after the first year.

This STANDARD is not met as evidenced by:

Based on surveyor review of competence evaluations, and interview and email correspondence with the technical consultant, records showing the technical consultant's evaluation of the performance of one of two testing personnel, staff A, in 2017 were not available. Findings include: 1. Review of competence evaluation records for the primary testing personnel, staff A, showed no records of evaluation in 2017. 2. Interview with the technical consultant on March 14, 2019 at 11:00 AM confirmed the records were not available at this laboratory. E-mail correspondence with the technical consultant on March 20, 2019 at 2:11 PM confirmed the laboratory could not find records showing evaluation of staff A in 2017.