

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 52D0390360	(X3) Date Survey Completed 06/21/2021
Name of Provider or Supplier A2c1 Aurora Health Center - Good Hope Rd	Street Address, City, State 3003 W Good Hope Rd, Milwaukee, 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 evaluate the accuracy for fifty-five of fifty-five "Not scored-insufficient peer group" "Hematology-Comprehensive-AF5" PT results for 2020 and 2021 and two of two "Not Graded" "Automated Urine Microscopy" PT results for 2020. Findings include: 1. Review of Wisconsin State Laboratory of Hygiene (WSLH) PT records showed the laboratory did not evaluate the accuracy of the following "Hematology-Comprehensive-AF5" PT results in 2020 and 2021. a. 2021-HemeReg1: Five of five "Not scored-insufficient peer group" "Leukocytes 10⁹/L" results, five of five "Not scored-insufficient peer group" "Lymphocytes%" results, five of five "Not scored-insufficient peer group" "Basophil%" results and five of five "Not scored-insufficient peer group" "Hematocrit%" results. b. 2020-HemeReg1: Five of five "Not scored-insufficient peer group" "Monocytes%" results. c. 2020-HemeReg2: Five of five "Not scored-insufficient peer group" "Lymphocytes%" results, five of five "Not scored-insufficient peer group" "Basophils%" results and five of five "Not scored-insufficient peer group" Erythrocytes 10¹²/L" results. d. 2020-HemeReg3: Five of five "Not scored-insufficient peer group" "Lymphocytes%" results, five of five "Not scored-insufficient peer group" "Basophils%" results and five of five "Not scored-insufficient peer group" Erythrocytes 10¹²/L" results. 2. Review of American Proficiency Institute (API) PT records showed the laboratory did not evaluate the accuracy for two of two</p>

"Not Graded" "Automated Urine Microscopy" results in 2020. 3. Interview with the technical consultant on June 8, 2021 at 10:35 AM confirmed the laboratory did not evaluate the accuracy for fifty-five of fifty-five "Not scored-insufficient peer group" "Hematolgy-Comprehensive-AF5" PT results for 2020 and 2021 and two of two "Not Graded" "Automated Urine Microscopy" PT results for 2020.

D6076

LABORATORY DIRECTOR

CFR(s): 493.1441

The laboratory must have a director who meets the qualification requirements of 493.1443 of this subpart and provides overall management and direction in accordance with 493.1445 of this subpart.

This CONDITION is not met as evidenced by:

Based on surveyor review of the Laboratory Personnel Report (CLIA) form CMS-209 and laboratory records and interview and email with administrative laboratory director, Staff A, the laboratory director has not provided overall management and direction in accordance with 493.1445 of this subpart. Findings include: 1. The laboratory director did not provide overall management and direction for the histopathology testing in the laboratory. See D6079

D6079

LABORATORY DIRECTOR RESPONSIBILITIES

CFR(s): 493.1445(a)(b)

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, record and report test results promptly, accurately and proficiently, and for assuring compliance with the applicable regulations. (a) The laboratory director, if qualified, may perform the duties of the technical supervisor, clinical consultant, general supervisor, and testing personnel, or delegate these responsibilities to personnel meeting the qualifications under 493.1447, 493.1453, 493.1459, and 493.1487 respectively. (b) If the laboratory director reappoints performance of his or her responsibilities, he or she remains responsible for ensuring that all duties are properly performed.

This STANDARD is not met as evidenced by:

Based on surveyor review of previous survey records, Laboratory Personnel Report (CLIA) form CMS-209 and laboratory records and interview and email with administrative laboratory director, Staff A, the laboratory director has not provided overall management and direction for the histopathology testing in the laboratory. Findings include: 1. Review of prior survey records from March 26, 2019 showed a histopathology specialty at this location. 2. Review of Laboratory Personnel Report (CLIA) form CMS-209 signed on June 4, 2021 showed no high complexity testing personnel, no technical supervisor and no general supervisor noted on the form for histopathology. 3. During the interview with Staff A on June 8, 2021 at 1:15 PM revealed the histopathology testing was no longer performed at this location. 4. Email from Staff A on June 11, 2021 at 1:57 PM confirmed that histopathology testing was being performed at this location. 5. Interview with Staff A on June 21, 2021 at 9:10 AM confirmed the laboratory director does have oversight of the histopathology testing at this location and has not provided overall management and direction of the histopathology testing in the laboratory.