Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number** 17D1025577	**(X3) Date Survey Completed** 06/27/2023
Name of Provider or Supplier Adventhealth Medical Group	**Street Address, City, State** 9119 W 74th St, Suite 268, Shawnee Mission, KS	
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**
D6033	TECHNICAL CONSULTANT-MODERATE COMPEXITY CFR(s): 493.1409 The laboratory must have a technical consultant who meets the qualification requirements of 493.1411 of this subpart and provides technical oversight in accordance with 493.1413 of this subpart. This CONDITION is not met as evidenced by: Based on documentation of testing personnel (TP) competencies, review of monthly temperature and humidity records, review of monthly chemistry quality control (QC), and personnel qualifications, the laboratory failed to have a qualified person performing duties as a technical consultant. See D6035. Based on the review documentation for chemistry QC and temperature and humidity records, the technical consultant failed to ensure that analytic performance was maintained throughout the entire testing process. See D6042.
D6035	TECHNICAL CONSULTANT QUALIFICATIONS CFR(s): 493.1411 (a) The technical consultant must be qualified and must possess a current license issued by the State in which the laboratory is located, if such licensing is required. (b) The technical consultant must-- (b)(1)(i) Be a doctor of medicine or doctor of osteopathy licensed to practice medicine or osteopathy in the State in which the laboratory is located; and (b)(1)(ii) Be certified in anatomic or clinical pathology, or both, by the American Board of Pathology or the American Osteopathic Board of Pathology or possess qualifications that are equivalent to those required for such certification; or (b)(2)(i) Be a doctor of medicine, doctor of osteopathy, or doctor of podiatric medicine licensed to practice medicine, osteopathy, or podiatry in the State in which the laboratory is located; and (b)(2)(ii) Have at least one year of laboratory training or experience, or both in non-waived testing, in the designated specialty or

	subspecialty areas of service for which the technical consultant is responsible (for example, physicians certified either in hematology or hematology and medical oncology by the American Board of Internal Medicine are qualified to serve as the technical consultant in hematology); or (b)(3)(i) Hold an earned doctoral or master's degree in a chemical, physical, biological or clinical laboratory science or medical technology from an accredited institution; and (b)(3)(ii) Have at least one year of laboratory training or experience, or both in non-waived testing, in the designated specialty or subspecialty areas of service for which the technical consultant is responsible; or (b)(4)(i) Have earned a bachelor's degree in a chemical, physical or biological science or medical technology from an accredited institution; and (b)(4)(ii) Have at least 2 years of laboratory training or experience, or both in non-waived testing, in the designated specialty or subspecialty areas of service for which the technical consultant is responsible. Note: The technical consultant requirements for "laboratory training or experience, or both" in each specialty or subspecialty may be acquired concurrently in more than one of the specialties or subspecialties of service, excluding waived tests. For example, an individual who has a bachelor's degree in biology and additionally has documentation of 2 years of work experience performing tests of moderate complexity in all specialties and subspecialties of service, would be qualified as a technical consultant in a laboratory performing moderate complexity testing in all specialties and subspecialties of service. This STANDARD is not met as evidenced by: Based on documentation of testing personnel (TP) competencies, review of monthly temperature and humidity records, monthly chemistry quality control (QC), personnel qualifications, and interview, the laboratory failed to have a qualified person(s) performing duties as a technical consultant. Findings: 1. Review of "Access2 2022 Competency" for TP #6 revealed that TP #7 performed the "Direct observation of routine patient test process" and "Direct observation of performance of instrument maintenance." 2. Review of "Access2 2022 Competency" for TP #7 revealed that TP #6 performed the "Direct observation of routine patient test process" and "Direct observation of performance of instrument maintenance." 3. Review of "Temperature /Humidity Chart" for the first five months of 2023 revealed the review was performed by TP #6. 4. Review of "Quality Assurance Checklist" for chemistry QC for the first five months of 2023 revealed the review was performed by TP #6. 5. Review of TP#6 credentials revealed that TP#6 did not qualify as a technical consultant. 6. Review of TP#7 credentials revealed that TP#7 did not qualify as a technical consultant. 7. Interview with the TC 6/27/23 at 10:03 a.m. confirmed, the laboratory failed to have a qualified person(s) performing duties as a technical consultant.
D6042	TECHNICAL CONSULTANT RESPONSIBILITIES CFR(s): 493.1413(b)(4) (b) The technical consultant is responsible for-- (b)(4) Establishing a quality control program appropriate for the testing performed and establishing the parameters for acceptable levels of analytic performance and ensuring that these levels are maintained throughout the entire testing process from the initial receipt of the specimen, through sample analysis and reporting of test results; This STANDARD is not met as evidenced by: Based on the review of monthly temperature and humidity records, monthly chemistry QC, 2023 patient test volumes and interview with the TC, the TC failed to ensure that

	analytic performance was maintained throughout the entire testing process for five of five months in 2023. Findings: 1. Review of "Temperature/Humidity Chart" documents for the first five months of 2023 revealed no review documentation by the TC. 2. Review of "ACCESS QC LOG" documents for the first five months of 2023 revealed no review documentation by the TC. 3. Review of test volumes from 1/1/23 to 6/29/23 revealed 3,113 patient test results were reported. 3. Interview with the TC 6 /27/23 at 10:10 a.m. confirmed, the TC failed to ensure that analytic performance was maintained throughout the entire testing process for five of five months in 2023.
D6117	TECHNICAL SUPERVISOR RESPONSIBILITIES CFR(s): 493.1451(b)(4) The technical supervisor is responsible for establishing a quality control program appropriate for the testing performed and establishing the parameters for acceptable levels of analytic performance and ensuring that these levels are maintained throughout the entire testing process from the initial receipt of the specimen, through sample analysis and reporting of test results. This STANDARD is not met as evidenced by: Based on the review of the CMS 209 personnel form, QC documentation from 1/1/23 to date of survey for semen analysis and interview with the technical supervisor (TS), the TS failed to ensure that acceptable levels of analytic performance were maintained. Finding: 1. Review of the 209 revealed one individual designated as the TS. 2. Review of QC control documents from1/1/23 to date of survey revealed no review documentation by the TS. 3. Semen analysis test results for 350 patients were reported from 1/1/23 to date of survey. 4. Interview with the TS on 6/27/23 at 10:20 a. m. confirmed, the TS failed to ensure that acceptable levels of analytic performance were maintained.