Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	26D0666300	05/25/2021
Name of Provider or Supplier	**Street Address, City, State**	
Ferguson Medical Laboratories Inc	1801 W 32nd St B101, Joplin, MO	

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
D5291	GENERAL LABORATORY SYSTEMS QUALITY ASSESSMENT CFR(s): 493.1239(a) The laboratory must establish and follow written policies and procedures for an ongoing mechanism to monitor, assess, and, when indicated, correct problems identified in the general laboratory systems requirements specified at 493.1231 through 493.1236. This STANDARD is not met as evidenced by: Based on review of procedures and interview with the laboratory director (LD), the laboratory failed to establish written policies and procedures for an ongoing mechanism to monitor, assess, and, when indicated correct problems. Findings: 1. Review of procedures showed a lack of quality assessment (QA) policies or procedures for an ongoing mechanism to monitor, assess, and, when indicated correct problems. 2. Interview with the LD on May 25, 2021 at 11:20 AM confirmed the laboratory failed to establish written QA policies or procedures.
D5401	PROCEDURE MANUAL CFR(s): 493.1251(a) A written procedures manual for all tests, assays, and examinations performed by the laboratory must be available to, and followed by, laboratory personnel. Textbooks may supplement but not replace the laboratory's written procedures for testing or examining specimens. This STANDARD is not met as evidenced by: Review of procedures, review of staining logs and interview with the laboratory director (LD), the laboratory failed to follow "Histology Procedure" and "Filtering and changing of stains and solutions" procedures. Findings: 1. Review of "Histology

	Procedure" stated "H & E Staining Procedure, The entire stain station is changed weekly and dishes washed". Review of staining logs showed no documentation of H & E stain being changed in 2019, 2020 and to date May 25, 2021. 2. Review of "Filtering and Changing of Stains and Solutions" stated "OG and EA stains used for gynecological Pap smears are filtered daily and changed weekly. The hematoxylin is added to each Wednesday and changed totally weekly. The filtering and changing of stains and solutions are documented in a log book. Stains and solutions used in non-gynecological cased are filtered between each case." Review of staining logs showed no documentation of hematoxylin stain, OG-6 stain, EA 50 stain being changed in 2019, 2020 and to date May 25, 2021. 3. Interview with the LD on May 25, 2021 at 11:30 AM confirmed the laboratory failed to follow procedures on when to change stain.
D6128	TECHNICAL SUPERVISOR RESPONSIBILITIES CFR(s): 493.1451(b)(9) The technical supervisor is responsible for evaluating and documenting the performance of individuals responsible for high complexity testing at least annually after the first year, unless test methodology or instrumentation changes, in which case, prior to reporting patient test results, the individual's performance must be reevaluated to include the use of the new test methodology or instrumentation. This STANDARD is not met as evidenced by: Based on review of 2021 personnel performance evaluations and interview with the the laboratory director (LD), the technical supervisor/director failed to evaluate and document one of four testing personnel's performance evaluation for 2021. Findings: 1. Review of 2021 personnel performance evaluations showed the technical supervisor /director failed to evaluate and document annual competency for testing personnel #4. 2. Interview with the LD on May 25, 2021 at 12:00 PM confirmed the technical supervisor/director failed to document annual competency for testing personnel #4 for 2021.
D6168	TESTING PERSONNEL CFR(s): 493.1487 The laboratory has a sufficient number of individuals who meet the qualification requirements of 493.1489 of this subpart to perform the functions specified in 493. 1495 of this subpart for the volume and complexity of testing performed. This CONDITION is not met as evidenced by: Based on review of personnel records and interview with the laboratory director, one of four testing personnel did not meet the academic qualifications required to perform high complexity testing. (Refer to # 6171)
D6171	TESTING PERSONNEL QUALIFICATIONS CFR(s): 493.1489(b) (b) Meet one of the following requirements: (b)(1) 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 or have earned a doctoral, master's or bachelor's degree in a chemical, physical, biological or clinical laboratory

science, or medical technology from an accredited institution; (b)(2)(i) Have earned an associate degree in a laboratory science, or medical laboratory technology from an accredited institution or-- (b)(2)(ii) Have education and training equivalent to that specified in paragraph (b)(2)(i) of this section that includes-- (b)(2)(ii)(A) At least 60 semester hours, or equivalent, from an accredited institution that, at a minimum, include either-- (b)(2)(ii)(A)(1) 24 semester hours of medical laboratory technology courses; or (b)(2)(ii)(A)(2) 24 semester hours of science courses that include-- (b)(2)(ii)(A)(2)(i) Six semester hours of chemistry; (b)(2)(ii)(A)(2)(ii) Six semester hours of biology; and (b)(2)(ii)(A)(2)(iii) Twelve semester hours of chemistry, biology, or medical laboratory technology in any combination; and (b)(2)(ii)(B) Have laboratory training that includes either of the following: (b)(2)(ii)(B)(1) Completion of a clinical laboratory training program approved or accredited by the ABHES, the CAHEA, or other organization approved by HHS. (This training may be included in the 60 semester hours listed in paragraph (b)(2)(ii)(A) of this section.) (b)(2)(ii)(B)(2) At least 3 months documented laboratory training in each specialty in which the individual performs high complexity testing. (b)(3) Have previously qualified or could have qualified as a technologist under 493.1491 on or before February 28, 1992; (b)(4) On or before April 24, 1995 be a high school graduate or equivalent and have either-- (b)(4)(i) Graduated from a medical laboratory or clinical laboratory training program approved or accredited by ABHES, CAHEA, or other organization approved by HHS; or (b)(4)(ii) Successfully completed an official U.S. military medical laboratory procedures training course of at least 50 weeks duration and have held the military enlisted occupational specialty of Medical Laboratory Specialist (Laboratory Technician); (b)(5)(i) Until September 1, 1997-- (b)(5)(i)(A) Have earned a high school diploma or equivalent; and (b)(5)(i)(B) Have documentation of training appropriate for the testing performed before analyzing patient specimens. Such training must ensure that the individual has-- (b)(5)(i)(B)(1) The skills required for proper specimen collection, including patient preparation, if applicable, labeling, handling, preservation or fixation, processing or preparation, transportation and storage of specimens; (b)(5)(i)(B)(2) The skills required for implementing all standard laboratory procedures; (b)(5)(i)(B)(3) The skills required for performing each test method and for proper instrument use; (b)(5)(i)(B)(4) The skills required for performing preventive maintenance, troubleshooting, and calibration procedures related to each test performed; (b)(5)(i)(B)(5) A working knowledge of reagent stability and storage; (b)(5)(i)(B)(6) The skills required to implement the quality control policies and procedures of the laboratory; (b)(5)(i)(B)(7) An awareness of the factors that influence test results; and (b)(5)(i)(B)(8) The skills required to assess and verify the validity of patient test results through the evaluation of quality control values before reporting patient test results; and (b)(5)(i)(B)(8)(ii) As of September 1, 1997, be qualified under 493.1489(b)(1), (b)(2), or (b)(4), except for those individuals qualified under paragraph (b)(5)(i) of this section who were performing high complexity testing on or before April 24, 1995; (b)(6) For blood gas analysis-- (b)(6)(i) Be qualified under 493.1489(b)(1), (b)(2), (b)(3), (b)(4), or (b)(5); (b)(6)(ii) Have earned a bachelor's degree in respiratory therapy or cardiovascular technology from an accredited institution; or (b)(6)(iii) Have earned an associate degree related to pulmonary function from an accredited institution; or (b)(7) For histopathology, meet the qualifications of 493.1449 (b) or (l) to perform tissue examinations.

This STANDARD is not met as evidenced by:
Based on review of academic credentials and interview with the laboratory director (LD), the laboratory failed to provide academic credentials to qualify one of four testing personnel. Findings: 1. The laboratory could not provide documentation

	(academic credentials) to show testing person #4 was qualified to perform high complexity testing. 2. Interview with the LD on May 25, 2021 at 12:00 PM confirmed the documents needed to qualify the testing person #4 were not available for review.