Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	13D0996152	11/02/2020
Name of Provider or Supplier	**Street Address, City, State**	
Family First Medical Center	3820 Crestwood Ln, Idaho Falls, ID	

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
D5209	PERSONNEL COMPETENCY ASSESSMENT POLICIES CFR(s): 493.1235 As specified in the personnel requirements in subpart M, the laboratory must establish and follow written policies and procedures to assess employee and, if applicable, consultant competency. This STANDARD is not met as evidenced by: Based on review of the laboratory's Policy's and Procedures and interview with the laboratory technical consultant (TC) on 11/02/2020, the laboratory failed to establish policies and procedures to assess employee and consultant competency in accordance with 42 C.F.R. 493.1413(b)(8)(9). The findings include: 1. The laboratory personnel form (CMS-209) lists (26) testing personnel who are medical assistants or higher nursing degreed individuals. 2. The laboratory had no documentation of initial training or competency for the 12 new staff hired after the previous survey performed on 3/14/2018. 3. The laboratory had a check list sheet listed as semi-annual and annual competency. The competency form did not indicate or identify which of the six parameters listed in 42 C.F.R. 493.1413(b)(8) were used to determine competency for initial, semi-annual or annual competency. 4. The technical consultant confirmed by interview on 11/2/2020 that the laboratory does not have a policy or procedure for initial training and competency, semi-annual competency or annual competency which includes the six parameters that must be included in competency assessments in accordance with 42 C.F.R. 493.1413(b)(8). (i) Direct observations of routine patient test performance, including patient preparation, if applicable, specimen handling, processing and testing; (ii) Monitoring the recording and reporting of test results; (iii) Review of intermediate test results or worksheets, quality control records, proficiency testing results, and preventive maintenance records; (iv) Direct observation of performance of instrument maintenance and function checks; (v) Assessment of test performance through testing previously analyzed specimens, internal blind testing samples or external proficiency testing samples; and (vi) Assessment of problem

	solving skills; 5. The laboratory has 26 testing personnel and reports performing 7900 patient specimens annually.
D5403	PROCEDURE MANUAL CFR(s): 493.1251(b) The procedure manual must include the following when applicable to the test procedure: (1) Requirements for patient preparation; specimen collection, labeling, storage, preservation, transportation, processing, and referral; and criteria for specimen acceptability and rejection as described in 493.1242. (2) Microscopic examination, including the detection of inadequately prepared slides. (3) Step-by-step performance of the procedure, including test calculations and interpretation of results. (4) Preparation of slides, solutions, calibrators, controls, reagents, stains, and other materials used in testing. (5) Calibration and calibration verification procedures. (6) The reportable range for test results for the test system as established or verified in 493.1253. (7) Control procedures. (8) Corrective action to take when calibration or control results fail to meet the laboratory's criteria for acceptability. (9) Limitations in the test methodology, including interfering substances. (10) Reference intervals (normal values). (11) Imminently life-threatening test results, or panic or alert values. (12) Pertinent literature references. (13) The laboratory's system for entering results in the patient record and reporting patient results including, when appropriate, the protocol for reporting imminently life threatening results, or panic, or alert values. (14) Description of the course of action to take if a test system becomes inoperable. This STANDARD is not met as evidenced by: Based on Quality Control (QC) record review and interview with the laboratory technical consultant (TC) on 11/02/2020, the laboratory failed to have a procedure for corrective actions to take when control results fail to meet the laboratory's criteria for acceptability. The findings include: 1. During a random review of patient records from April 8, 2018 through October 28, 2020, and the laboraory's quality control logs, the laboratory experienced QC failure on one out of the eleven (11) recorded patient testing days reviewed, with no documentation of QC performed for three out of the (11) testing days reviewed. 08/01/2019 No QC documented No corrective actions documented 08/07/2019 No QC documented No corrective actions documented 08/28 /2019 No QC documented No corrective actions documented 11/20/2019 QC failure, Reran x2 No corrective actions documented 2. The laboratory did not have a policy or procedure for corrective actions to be taken for QC failures, or for evaluation and documetaion of corrective actions taken for lack of QC results for acceptability prior to performing and reporting patient specimen results. 3. The laboratory technical consultant confirmed by interview on 11/02/2020 at 11:15 a.m. that the laboratory did not have a policy or procedure for documenting corrective actions taken for QC failures and no documentation for lack of QC performance on the three dates above. 4. The laboratory reports performing 4000 CBC patient specimens annually.
D5429	MAINTENANCE AND FUNCTION CHECKS CFR(s): 493.1254(a)(1) For unmodified manufacturer's equipment, instruments, or test systems, the laboratory must perform and document maintenance as defined by the manufacturer and with at least the frequency specified by the manufacturer.

	This STANDARD is not met as evidenced by: Based on review of the laboratory's maintanence records and interview with the technical consultant (TC) on 11/02/2020, the laboratory failed to perform and document maintenance as defined by the manufacturer and with at least the frequency specified by the manufacturer. The findings included: 1. The laboratory performs complete blood counts (CBC) on the Sysmex XP-100. Upon random review of the laboratory's maintenance records from 04/08/2018 to 10/28/2020, there were four (4) days out of eleven (11) patient testing days in which the daily mantience was not documented as completed and two (2) out of twelve months in which the monthly maintenance was not documented as performed. Daily shut down maintance 04/08 /2019 not documented 08/06/2019 not documented 11/20/2019 not documented 06/05 /2020 not documented Monthly Maintenance 06/05/2020 10/28/2020 2. The technical consultant confirmed by interview on 11/02/2020 at 11:45 a.m. that the laboratory had not documented the daily and monthly maintenance as performed for the above dates. 3. The labortory reports performing 4000 patient CBC specimens annually.
D5481	CONTROL PROCEDURES CFR(s): 493.1256(f)(g) (f) Results of control materials must meet the laboratory's and, as applicable, the manufacturer's test system criteria for acceptability before reporting patient test results. (g) The laboratory must document all control procedures performed. This STANDARD is not met as evidenced by: Based on review of the laboratory's quality control records from 4/8/2018 to 10/28 /2020 and interview with the technical consultant on 11/02/2020, the laboratory failed to document all control procedures performed prior to testing patient specimens. The findings included: 1. A random selection of eleven (11) patient testing days revealed that the laboratory failed to docment the QC performance on three of the (11) patient testing days reviewed. 8/6/2019 No QC documented 94 patient CBC specimens ran and reported 8/7/2019 No QC documented 104 patient CBC specimens ran and reported 8/28/2019 No QC documented 87 patient CBC speciemens ran and reported 2. The laboratory technical consultant confirmed by interview on 11/02/2020 at 11:45 a.m. that the laboratory did not document QC performance on three out of eleven patient testing dates reviewed. 3. The laboratory reports performing 4000 patient CBC specimens annually.
D6029	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(11) 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, and record and report test results promptly, accurate, and proficiently and for assuring compliance with the applicable regulations. (e) The laboratory director must-- (e)(11) Ensure that prior to testing patients' specimens, all personnel have the appropriate education and experience, receive the appropriate training for the type and complexity of the services offered, and have demonstrated that they can perform all testing operations reliably to provide and report accurate results. This STANDARD is not met as evidenced by: Based on review of testing personnel records from 2018-2020 and interview with the

	technical consultant on 11/02/2020, the laboratory director failed to ensure that prior to testing patients' specimens, all personnel have the appropriate education and experience, receive the appropriate training for the type and complexity of the services offered, and have demonstrated that they can perform all testing operations reliably to provide and report accurate results. The findings include. 1. Based on review of the Centers for Medicare and Medicaid Services (CMS) laboratory personnel form (209), and interview with the technical consultant (TC) on 11/02 /2020, the laboratory director failed to ensure policy and procedures were developed to ensure all testing personnel had appropriate training and could demonstrate competency prior to testing patients' specimens. See D5209 2. The laboratory had no documentation of initial training and competency for 12 out of 12 new testing personnel (TP) that included all the six parameters as listed in 42 C.F.R. 493.1413(b)(8). See D6046 3. The laboratory did not have documentation of performance to determine biannual competency for the above 12 testing personnel during their first year of testing in accordance with 42 C.F.R. 493.1413(b)(8)(9). See D6046 4. The laboratory did not have documentation of competency performance for 14 of 26 testing personnel that included the six (6) requirements for determining competency as listed in 42 C.F.R. 493.1413(b)(8). See D6046 5. The laboratory technical consultant confirmed by interview on 11/2/2020 at 11:15 a.m. that the laboratory's policy and procedures manual did not include the parameters or procedures for assessing testing personnel competencies. 6. The laboratory reports performing 4000 hematology patient specimens annually.
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 training and experience record review and interview with the laboratory personnel identified as the technical consultant (TC) on the CMS-209 laboratory personnel form, the laboratory failed to have a technical consultant who meets the qualification requirements of 493.1411 of this subpart. The findings include: 1. The individual identified on the CMS-209 personnel form did not have documentation as to education and experience that meets the qualifications of TC as identified in 42 C.F.R. 493.1411. See D6035
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 review of the centers for medicare and medicaid services (CMS) laboratory personnel report (209) and review of educational documents submitted for the new technical consultant (TC), the individual identified as the TC does not meet the qualifications for educational degree and experience in the biological, physical or chemical science, for moderate complexity testing as defined at 42 C.F.R.493.1411 . The findings included: 1. The individual identified on the CMS-209 had documentation of a diploma issued for BS in Health Science, but did not have documentation of education in biological, physical or chemical science or documentation of (2) years of laboratory experience in non-waived testing in the specialty of Hematology. 2. The individual identified as the TC has been performing in this capacity from January 2019 to present. 3. The individual identified as TC confirmed by interview on 11/02/2019 that she holds a Bacholor of Science degree in Health Science, but did not have educational transcripts, or laboratory training /experience documents for the specialty of hematology available at the time of survey. 4. The laboratory reports performing 4000 patient Hematology patient specimens annually.
D6046	TECHNICAL CONSULTANT RESPONSIBILITIES CFR(s): 493.1413(b)(8) (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 test procedures and report test results promptly, accurately and proficiently. This STANDARD is not met as evidenced by: Based on review of the laboratory's personnel training and competency records, and interview with the technical consultant on 11/02/2020 the technical consultant failed to establish and follow written policies and procedures for evaluating the competency

	of all testing personnel and assuring that the staff maintain their competency to perform test procedures and report test results promptly, accurately and proficiently. The findings included: 1. The laboratory testing personnel record identifies 26 testing personnel for performing moderate and waived testing. 2. The laboratory had no documentation of initial training and competency for 12 out of 12 new testing personnel (TP). TP Start Date (A) 7/15/2019 (KA) 11/18/2018 (HH) 8/4/2020 (I) 7/29 /2020 (KN) 11/19/2018 (G) 1/6/2020 (B) 1/6/2020 (HY) 8/17/20 (T) 8/4/2019 (S) 10 /28/2019 (P) 9/4/2018 (C) 3/20/2018 3. The laboratory had no documentation of semi-annual competency for five (5) of the (26) testing personnel for 2019 and no annual competency for (14) of the 26 testing personnel for 2019 and 2020 which included the six parameters as required in 42 C.F.R. 493.1413(b)(8). See D5209 4. The laboratory records revealed gaps in compliance with daily and monthly maintenance and quantity control records. See D5429, D5481. 5. The technical consultant confirmed by interview on 11/02/2020 that the laboratory did not perform competency assessments in accordance 42 C.F.R. 493.1413(b)(8)(9). 6. The laboratory reports performing 7.900 moderate and waived patient specimens annually.