Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	39D2187882	12/07/2021
Name of Provider or Supplier	**Street Address, City, State**	
Steelfusion/Rj Lee Group Laboratory	300 Frankfort Road, Monaca, PA	

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: A. Based on review of the laboratory's QSPM/Quality system for SARS-Cov-2 Testing procedure manual, competency assessment record review, and interview with the Quality Assessment Manager (QAM), the Laboratory failed to have a written procedure to assess the competency of 3 of 3 Technical Consultants (TC) and 3 of 3 General Supervisors (GS) for their supervisory responsibilities in 2020 and 2021. Findings include: 1. On the day of survey, 12/07/2021 at 01:35 p.m. the QAM could not provide a policy that assess the competency of 3 of 3 TC and 3 of 3 GS in 2020 and 2021. 2. The QAM could not provide competency assessment documentation for 3 of 3 TC and 3 of 3 GS for their regulatory responsibilities. 3. The QAM confirmed the findings above on 12/07/2021 at 03:15 p.m. B. Based on review of the laboratory's QSPM/Quality system for SARS-Cov-2 Testing procedure manual, competency assessment record review, and interview with the Quality Assessment Manager (QAM), the Laboratory failed to follow the Laboratory's written procedure to assess the competency of 1 of 6 testing personnel (TP) who performed SARS-Cov-2 Testing in 2021. Findings Include: 1. The laboratory's QSPM/Quality system for SARS-Cov-2 Testing procedure manual (page 22 and page 24) under competency requirements states: - " Assessment of test performance through testing previously analyzed specimens, internal blind testing samples or external proficiency testing samples." 2. On the day of survey 12/07/2021 at 01:40 p.m., review of the competency assessment records revealed the laboratory did not follow their Policy to evaluate 1 of 6 TP

	(TP#6) through testing previously analyzed specimens, internal blind testing samples or external proficiency testing samples in 2021 3. The QAM confirmed the findings above on 12/07/2021 at 03:15 p.m..
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 the CLIA's Laboratory Personnel Report (Form CMS-209), review of personnel qualification records, and interview with the Quality Assurance Manager (QAM), the laboratory failed to ensure that each individual performing High Complexity testing (1 of 6 TP) is qualified. Refer to D6171
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 the CLIA's Laboratory Personnel Report (Form CMS-209), review of personnel qualification records, and interview with the Quality Assurance Manager (QAM), the laboratory failed to ensure that each individual performing High Complexity testing (1 of 6 TP) had the minimum qualifications required from 08/11/2020 to the day of survey. Findings Include: 1. On the date of survey 12/07/2021 at 01:00 p.m, the surveyor reviewed the credentials of the testing personnel listed on the CMS 209 (TP6) and discovered that 1 of 6 testing personnel who performed SARS-CoV-2 by Polymerase Chain Reaction (PCR) examinations from 08/11/2020 through the day of survey, did not have the minimum qualifications. 2. The QAM confirmed the finding above on 12/07/2021 at 03:15 p.m. .