Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	26D1094558	10/08/2020
Name of Provider or Supplier	**Street Address, City, State**	
St Louis Medical Professionals	8790 Watson Rd, Suite 100, Saint Louis, 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
D2015	TESTING OF PROFICIENCY TESTING SAMPLES CFR(s): 493.801(b)(5)(6) (5) The laboratory must document the handling, preparation, processing, examination, and each step in the testing and reporting of results for all proficiency testing samples. The laboratory must maintain a copy of all records, including a copy of the proficiency testing program report forms used by the laboratory to record proficiency testing results including the attestation statement provided by the PT program, signed by the analyst and the laboratory director, documenting that proficiency testing samples were tested in the same manner as patient specimens, for a minimum of two years from the date of the proficiency testing event. (6) PT is required for only the test system, assay, or examination used as the primary method for patient testing during the PT event. This STANDARD is not met as evidenced by: Based on review of proficiency testing (PT) records for 2019 and 2020 and interview with the technical supervisor (TS) the laboratory director (LD) failed to sign 5 of 9 attestation statements. Finding: 1. Review of 2019 and 2020 PT records showed the LD did not sign three attestation statements for second and third events 2019 and two attestation statements for first and second events 2020. 2. Interview with the TS on September 30, 2020 at 10:30 A.M. confirmed the LD failed to sign the attestation statements documenting PT samples were tested in the same manner as patient specimens.
D5400	ANALYTIC SYSTEMS CFR(s): 493.1250 Each laboratory that performs nonwaived testing must meet the applicable analytic systems requirements in 493.1251 through 493.1283, unless HHS approves a procedure, specified in Appendix C of the State Operations Manual (CMS Pub.7), that

	provides equivalent quality testing. The laboratory must monitor and evaluate the overall quality of the analytic systems and correct identified problems as specified in 493.1289 for each specialty and subspecialty of testing performed. This CONDITION is not met as evidenced by: 43990 This CONDITION is not met as evidenced by: Based on record review, observation and interview the laboratory failed to monitor and evaluate the overall quality of the analytic systems and correct identified problems.The laboratory failed to monitor temperature and humidity conditions (Refer to D5411); failed to verify performance specifications (Refer to D5421); failed to establish a maintenance protocols (Refer to D5433); and failed to evaluate and define relationship between test systems at least twice a year (Refer to D5795).
D5411	TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(a) Test systems must be selected by the laboratory. The testing must be performed following the manufacturer's instructions and in a manner that provides test results within the laboratory's stated performance specifications for each test system as determined under 493.1253. This STANDARD is not met as evidenced by: Based on review of manufacturer's package inserts and interview with the technical supervisor, the laboratory failed to follow manufacturer's instructions for temperature and humidity conditions in the COVID-19 testing section and hematology testing section. Finding: 1. Review of the manufacturer'sassay procedure stated controlled room temperature of "20 to 25 degrees Celsius" required for COVID-19 testing. 2. Review of COVID-19 testing section showed laboratory did not monitor room temperature. 3. Review of the manufacturer's product insert for performance specifications for hematology analyzer revealed an acceptable range of relative humidity of "10 to 80% percent." 4. Review of the room temperature documentation logs showed the laboratory failed to document humidity for the hematology testing section. 5. Interview with the TS on September 29, 2020 at 10:00 AM confirmed the laboratory failed to follow the manufacturer's instructions for temperature and humidity conditions.
D5421	ESTABLISHMENT AND VERIFICATION OF PERFORMANCE CFR(s): 493.1253(b)(1) Each laboratory that introduces an unmodified, FDA-cleared or approved test system must do the following before reporting patient test results: (1)(i) Demonstrate that it can obtain performance specifications comparable to those established by the manufacturer for the following performance characteristics: (1)(i)(A) Accuracy. (1)(i)(B) Precision. (1)(i)(C) Reportable range of test results for the test system. (1)(ii) Verify that the manufacturer's reference intervals (normal values) are appropriate for the laboratory's patient population. This STANDARD is not met as evidenced by: Based on review of the performance verification procedures for the Healgen Covid-19 IgG/IgM rapid test, patient records and interview with the laboratory director (LD),

	the laboratory failed to verify performance specifications. Findings: 1. Review of the verification procedures for the Healgen Covid-19 IgG/IgM rapid test which the laboratory started patient testing on August 8, 2020 showed no accuracy, precision, reportable range and no verification that the manufacturer's reference intervals (normal values) are appropriate for the laboratory's patient population. 2. Review of patients test results showed 32 patients have been tested since August 8, 2020 3. Interview with the LD on September 29, 2020 at 10:30 AM confirmed the laboratory failed to verify performance specifications prior to performing patient testing.
D5433	MAINTENANCE AND FUNCTION CHECKS CFR(s): 493.1254(b)(1) For equipment, instruments, or test systems developed in-house, commercially available and modified by the laboratory, or maintenance and function check protocols are not provided by the manufacturer, the laboratory must establish a maintenance protocol that ensures equipment, instrument, and test system performance that is necessary for accurate and reliable test results and test result reporting. The laboratory must perform and document the maintenance activities specified in paragraph (b)(1)(i) of this section. This STANDARD is not met as evidenced by: Based on observation of the steriguard 111 advance safety cabinet hood and interview with the laboratory director (LD), the laboratory failed to establish a maintenance protocol that ensures equipment performance. Findings: 1 Observation of the steriguard 111 advance safety cabinet hood showed no maintenance was documented for 2017, 2018, 2019 and to date September 28, 2020. 2. Interview with the LD on September 28, 2020 at 12:15 PM confirmed the laboratory failed to establish a maintenance protocol for the steriguard 111 advance safety cabinet hood.
D5775	COMPARISON OF TEST RESULTS CFR(s): 493.1281(a)(c) (a) If a laboratory performs the same test using different methodologies or instruments, or performs the same test at multiple testing sites, the laboratory must have a system that twice a year evaluates and defines the relationship between test results using the different methodologies, instruments, or testing sites. (c) The laboratory must document all test result comparison activities. This STANDARD is not met as evidenced by: Based on review of chemistry and coagulation instrument comparisons and interview with the laboratory director (LD), the laboratory failed to evaluate and define relationship between test results using different methodologies or instruments twice a year for 2018, 2019 and to date September 29, 2020. Findings: 1. Review of Olympus AU400 chemistry analyzer and Piccolo analyzer for the analytes: alanine aminotransferase, alkaline phosphatase, aspartate aminotransferase, total carbon dioxide, total bilirubin, total protein, creatinine, albumin, calcium, chloride, glucose, potassium, sodium and urea nitrogen showed no documentation and evaluation between test results using different methodologies twice a year for 2018, 2019 and to date September 29, 2020. 2. Review of the Stago sta satellite analyzer and Coag-Sense analyzer for prothrombin time showed no documentation and evaluation between test results using different methodologies twice a year for 2018, 2019 and to date

	September 29, 2020. 3. Interview with the LD on September 29, 2020 at 11:30 AM confirmed the laboratory failed to evaluate and define relationship between test results using different methodologies or instruments twice a year.
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: 43990 This CONDITION is not met as evidenced by: Based on observation, record review and interviews the laboratory director (LD) failed to provide overall management and direction to the laboratory. The LD failed to provide a safe environment in which employees are protected from chemical and biological hazards (Refer to D6084); failed to ensure the verification procedures were adequate to determine the accuracy, precision and other pertinent performance characteristics of the method (Refer to D6086); failed to ensure appropriate staff evaluated the laboratory's performance and identify any problems that required corrective action (Refer to D6091); failed to ensure quality control (QC) was performed and maintained (Refer to D6093); failed to maintain the QA program and identify failures as they occur (Refer to D6094); failed to ensure testing personnel received appropriate training (Refer to D6102); and failed to ensure approved procedures were available to all testing personnel (Refer to D6106).
D6084	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1445(e)(2) The laboratory director must ensure that the physical plant and environmental conditions provide a safe environment in which employees are protected from physical, chemical, and biological hazards. This STANDARD is not met as evidenced by: Based on observation of the employee break room, testing area where the Quidel Lyra Direct SARS-CoV-2 Assay test was performed on the ABI 7500 Fast Dx Real time PCR analyzer and the Healgen Covid-19 IgG/IgM rapid test were prepared and analyzed and interview with laboratory director, the laboratory director failed to provide a safe environment in which employees are protected from chemical and biological hazards. Findings: 1. Observation of the employee break room showed an approximately 30 foot long by 40 foot wide open room with a approximately 8 foot long wall separating the employee lunch table, food refrigerator, microwave and toaster. On the other side of the wall was the laboratory testing area which contained reagents, calibrators, controls, and patient specimens, refrigerators, freezers, ABI 7500 Fast Dx Real time PCR analyzer, Covid-19 IgG/IgM rapid test and hood all contained in the 30 foot long by 40 foot wide room . 2. Interview with the laboratory director on September 29, 2020 at 10:00 AM confirmed the laboratory director failed to provide a safe environment free from biological hazards for employees.
D6086	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1445(e)(3)(ii)

	The laboratory director must ensure that verification procedures used are adequate to determine the accuracy, precision, and other pertinent performance characteristics of the method. This STANDARD is not met as evidenced by: Based on review of verification procedures for Sight diagnostics Olo hematology analyzer, Quidel Lyra Direct SARS-CoV-2 Assay performed on the ABI 7500 Fast Dx Real time PCR analyzer, Stago Sta Satellite, patient testing records and interview with the technical supervisor, the laboratory director failed to ensure the verification procedures used are adequate to determine the accuracy, precision and other pertinent performance characteristics of the method. Findings: 1. Review of the verification procedures for the Sight diagnostics Olo hematology analyzer showed no reportable range and no verification that the manufacturer's reference intervals (normal values) are appropriate for the laboratory's patient population for the analytes: white blood cell, red blood cell, hemoglobin, hematocrit, platelet, mean corpuscular volume, mean corpuscular hemoglobin, mean corpuscular hemoglobin concentration, RDW, Neutraphil, lymphocyte, mono, eosinophil and basophil. 163 patients have been tested and reported. 2. Review of the verification procedures for the Quidel Lyra Direct SARS-CoV-2 Assay performed on the ABI 7500 Fast Dx Real time PCR testing showed no reportable range, no verification that the manufacturer's reference intervals (normal values) are appropriate for the laboratory's patient population, no analytical sensitivity and no analytical specificity to include interfering substances. 833 patients have been tested and reported. 3. Review of the Stago Sta Satellite analyzer showed no reportable range and no verification that the manufacturer's reference intervals (normal values) are appropriate for the laboratory's patient population for prothrombin time and partial thromboplastin time. The laboratory reported 35 prothrombin time tests from July 10, 2020 through October 1, 2020. 4. Interview with the laboratory director on September 29, 2020 at 10:30 AM confirmed the laboratory failed to verify performance specifications.
D6091	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1445(e)(4)(iii) The laboratory director must ensure all proficiency testing reports received are reviewed by the appropriate staff to evaluate the laboratory's performance and to identify any problems that require corrective action. This STANDARD is not met as evidenced by: Based on review of chemistry and hematology proficiency testing (PT) results for 2020 and interview with technical supervisor (TS), the laboratory director (LD) failed to ensure appropriate staff evaluated the laboratory's performance and identify any problems that required corrective action. Findings: 1. Review of the first chemistry PT event for 2020 revealed the laboratory obtained unacceptable results of 20 percent for the analyte GGT, 0 percent for Amylase and 40 percent for Triglycerides. 2. Review of the second chemistry PT event for 2020 revealed the laboratory obtained unacceptable results of 0 percent for the analyte's; Cholesterol, HDL, GGT, Triglycerides and Lipase. 3. Review of the second hematology event for 2020 revealed the laboratory obtained unacceptable results of 60 percent for erythrocyte count, hematocrit, hemoglobin and mean corpuscular hemoglobin concentration (MCHC). 4. The laboratory did not have documentation to show appropriate staff

	reviewed the unacceptable results that required corrective action. 5. Interview with the Technical Supervisor (TS) on September 29, 2020 at 12:30 PM confirmed the LD failed to ensure appropriate staff documented review of unacceptable PT results.
D6093	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1445(e)(5) The laboratory director must ensure that the quality control programs are established and maintained to assure the quality of laboratory services provided and to identify failures in quality as they occur. This STANDARD is not met as evidenced by: Based on review of Healgen Covid-19 IgG/IgM Rapid Test quality control (QC) log, patient results and interview with the laboratory director, the laboratory director failed to ensure QC was performed and maintained. Findings: 1. Review of Healgen Covid-19 IgG/IgM Rapid Test QC showed no Healgen Covid-19 IgG/IgM QC performed on September 12, 2020. 2. Review of Healgen Covid-19 IgG/IgM Rapid Test patients results showed two patients resulted on September 12, 2020. 3. Interview with the laboratory director on September 29, 2020 at 12:15 PM confirmed the laboratory director failed to ensure QC was performed and maintained.
D6094	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1445(e)(5) The laboratory director must ensure that the quality assessment programs are established and maintained to assure the quality of laboratory services provided and to identify failures in quality as they occur. This STANDARD is not met as evidenced by: Based on review of the laboratory's quality assessment (QA) program, patient COVID-19 testing records for September 2020 and interview with the technical supervisor, the laboratory director failed to maintain the QA program and identify failures as they occur. The laboratory failed to document and establish criteria for accepting or rejecting patient test results during September 2020 based on positivity rate for COVID-19 patient testing. Findings: 1. The QA program did not establish criteria for identifying problems or potential problems for positivity rates associated with COVID-19 patient runs to determine acceptability or rejection. 2. Review of patient tests showed on September 18, 2020, 7 patient's were resulted and 5 were positive. 3. Interview with the laboratory director on September 29, 2020 at 10:00 AM confirmed the laboratory failed to document and establish criteria for accepting or rejecting patient test results during September 2020 based on positivity rate for COVID-19 patient testing
D6102	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1445(e)(12) The laboratory director must 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 2018, 2019 and to date September 29, 2020 testing personnel competencies and interview with the technical supervisor the laboratory director failed to ensure two of three testing personnel received appropriate training. Findings: 1. Review of testing personnel #1 (whom is also the laboratory director) competency showed no competency documentation for 2018, 2019 and to date September 29, 2020. 2. Review of testing personnel #2 competency (whom is also the technical supervisor) showed no competency documentation for 2018, 2019 and to date September 29, 2020 with laboratory director approval. 3. Interview with the technical supervisor on September 29, 2020 at 11:00 AM confirmed the laboratory director failed to ensure two testing personnel received appropriate training.
D6106	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1445(e)(14) The laboratory director must ensure that an approved procedure manual is available to all personnel responsible for any aspect of the testing process. This STANDARD is not met as evidenced by: Based on review of procedures and interview with the laboratory director on September 29, 2020 at 12:30 PM confirmed the laboratory director failed to ensure that an approved Healgen Covid-19 IgG/IgM Rapid Test procedure was available to all testing personnel.
D6108	LABORATORY TECHNICAL SUPERVISOR CFR(s): 493.1447 The laboratory must have a technical supervisor who meets the qualification requirements of 493.1449 of this subpart and provides technical supervision in accordance with 493.1451 of this subpart. This CONDITION is not met as evidenced by: 43990 This CONDITION is not met as evidenced by: Based on review quality control records, personnel records and interview, the technical supervisor failed to provide technical supervision to the laboratory. The TS failed to review quality control (QC) in the laboratory (Refer to D6117); and failed to document training for laboratory personnel (Refer to D6120).
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 review of 2019 and 2020 hematology, chemistry, microbiology quality control (QC) and interview with the technical supervisor, the technical supervisor failed to review QC on the Sight Olo hematology analyzer, Stago sta satellite analyzer, Olympus AU400 analyzer and Healgen Covid-19 IgG/IgM Rapid Test. Findings: 1. Review of the Sight Olo hematology analyzer QC for complete blood count showed the technical supervisor failed to review the records to verify instrument accuracy from July 6, 2020 to date September 29, 2020. 2. Review of Stago sta satellite analyzer QC for prothrombin time and partial thromboplastin time showed the technical supervisor failed to review the records to verify instrument accuracy in 2019 to date September 29, 2020. 3. Review of the Olympus AU400 analyzer QC for albumin, alanine transaminase, alkaline phosphatase, aspartate aminotransferase, blood urea nitrogen, cholesterol, creatine kinase, carbon dixode, creatinine, direct bilirubin, GGT, glucose, lipase, magnesium, phosphate, total bilirubin, thyroid globulin, total protein, uric acid, sodium, potassium, chloride and calcium showed showed the technical supervisor failed to review the records to verify instrument accuracy in 2019 to date September 29, 2020. 4. Review of Healgen Covid-19 IgG /IgM Rapid test QC showed the technical supervisor failed to review the records to verify accuracy from August 8, 2020 to date September 29, 2020. 5. Interview with the technical supervisor on September 29, 2020 at 12:15 PM confirmed the technical supervisor failed to review QC on the Sight Olo hematology analyzer, Stago sta satellite analyzer, Olympus AU400 analyzer and Healgen Covid-19 IgG/IgM Rapid Test.
D6120	TECHNICAL SUPERVISOR RESPONSIBILITIES CFR(s): 493.1451(b)(7)(8) (7) The technical supervisor is responsible for identifying training needs and assuring that each individual performing tests receives regular in-service training and education appropriate for the type and complexity of the laboratory services performed; (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 observation of new hematology analyzer, new Covid-19 testing, review of competencies, training documents and interview with the technical supervisor, the technical supervisor failed to identify and document training needs for three of three testing personnel in 2020. Findings: 1. Review of Sight Olo hematology analyzer showed no training documents or competencies for testing personnel #1, #2 and #3. Laboratory started patient testing on July 6, 2020. 2. Review of Healgen Covid-19 IgG /IgM Rapid Test showed no training documents or competencies for testing personnel #1, #2 and #3. Laboratory started patient testing on August 8, 2020. 3. Review of Lyra Direct SARS-COV-2 performed on the ABI 7500 Fast DX Real Time PCR showed no training documents or competencies for testing personnel #1, #2 and #3. Laboratory started patient testing on September 4, 2020. 4. Interview with the technical supervisor on September 29, 2020 at 11:00 AM confirmed the technical supervisor failed to identify and document training needs for three of three testing personnel in 2020.
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 technical supervisor confirmed, one of three testing personnel did not have 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 the lack of academic credentials and interview with the technical supervisor, the laboratory failed to provide academic credentials to qualify one of three testing personnel. Findings: 1. The laboratory could not provide documentation (academic credentials) to show testing person #3 was qualified to perform high complexity testing. 2. Interview with the technical supervisor on September 29, 2020 at 11:00 AM confirmed the documents needed to qualify the testing person #3 were not available for review.