Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	26D1094558	11/17/2020
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
D2000	ENROLLMENT AND TESTING OF SAMPLES CFR(s): 493.801 Each laboratory must enroll in a proficiency testing (PT) program that meets the criteria in subpart I of this part and is approved by HHS. The laboratory must enroll in an approved program or programs for each of the specialties and subspecialties for which it seeks certification. The laboratory must test the samples in the same manner as patients' specimens. For laboratories subject to 42 CFR part 493 published on March 14, 1990 (55 FR 9538) prior to September 1, 1992, the rules of this subpart are effective on September 1, 1992. For all other laboratories, the rules of this subpart are effective January 1, 1994. This CONDITION is not met as evidenced by: Based on review of proficiency testing (PT) records for 2020 and interview with the technical supervisor, the laboratory failed to enroll in an approved PT program for regulated analytes listed in subpart I performed on the Sight Diagnostics Olo hematology analyzer. Findings: 1. Review of PT records for 2020 revealed the laboratory did not enroll in an approved PT program for the following regulated analytes performed on the Sight Diagnostics Olo hematology analyzer: Leukocyte count Erythrocyte count Hemoglobin Hematocrit Platelet count Cell identification /White blood cell differential 2. Interview with the technical supervisor on November 10, 2020 at 11:30 AM confirmed the laboratory failed to enroll in an approved PT program for the regulated analytes listed above in finding #1.
D3000	FACILITY ADMINISTRATION CFR(s): 493.1100 Each laboratory that performs nonwaived testing must meet the applicable requirements under 493.1101 through 493.1105, unless HHS approves a procedure that provides equivalent quality testing as specified in Appendix C of the State

	Operations Manual (CMS Pub. 7). (a) Reporting of SARS-CoV-2 test results During the Public Health Emergency, as defined in 400.200 of this chapter, each laboratory that performs a test that is intended to detect SARS-CoV-2 or to diagnose a possible case of COVID-19 (hereinafter referred to as a "SARS-CoV-2 test") must report SARS-CoV-2 test results to the Secretary in such form and manner, and at such timing and frequency, as the Secretary may prescribe. This CONDITION is not met as evidenced by: Based on observation and interview, the laboratory failed to maintain a uni-directional workflow process to prevent contamination of COVID-19 PCR testing (Refer to D3005).
D3005	FACILITIES CFR(s): 493.1101(a)(3) Molecular amplification procedures that are not contained in closed systems have a uni-directional workflow. This must include separate areas for specimen preparation, amplification and product detection, and, as applicable, reagent preparation. This STANDARD is not met as evidenced by: Based on observation of the COVID-19 testing room, review of the Lyra Direct SARS-CoV-2 assay procedure, observation of the Healgen COVID-19 IgG/IgM rapid test, and interview with the technical supervisor (TS), the laboratory director (LD), and testing personnel (TP) #3, the laboratory failed to have a uni-directional workflow that includes separate areas for specimen preparation, amplification, and product detection for COVID-19 using the Lyra Direct SARS-CoV-2 assay. Uni-directional workflow refers to the manner in which testing personnel and patient specimens move through the molecular testing process to prevent cross-contamination of patient specimens, and consists of separate areas for reagent preparation, pre-amplification, and post-amplification. Findings: 1. Observation of the COVID-19 testing room showed one hood located in the corner for processing and setting up the patient extraction 96 well plate. One desk area is located in the middle of the room for putting buffer into tubes, heating patient tubes in heat block, mixing patient tubes, preparing master mix, pipetting master mix into PCR plate, vortexing specimens in PCR plate, and performing the Healgen COVID-19 IgG/IgM rapid test. One Applied Biosystems 7500 Fast Real Time PCR analyzer is located on the wall by the hood for performing COVID-19 testing. One refrigerator and two freezers on the wall are located on the opposite side to the desk area and down the wall 2 more refrigerators and tables are located for patient specimens. The COVID-19 pre-amplification and molecular amplification area did not include a uni-directional workflow process to prevent contamination during reagent preparation, specimen preparation, amplification, and detection. 2. Interview with TP #3 on November 20, 2020 at 08:45 AM confirmed the laboratory could not provide a diagram, floorplan, mechanism or describe an acceptable workflow pattern to demonstrate uni-directional workflow for molecular amplification procedures to prevent cross-contamination. TP #3 explained the workflow process which included pre-amplification and amplification procedures performed at same desk area as well as testing personnel walking back and forth several times on a single run to obtain specimens, set up, obtain reagents, quality control, and supplies. 3. Review of the Lyra Direct SARS-CoV-2 Assay procedure states "Proper workflow planning is essential to minimize contamination risk. Always plan laboratory workflow in a uni-directional manner, beginning with pre-

	amplification and moving through amplification and detection. Use dedicated supplies and equipment in pre-amplification and amplification areas. Do not allow cross movement of personnel or equipment between areas. Keep amplification supplies separate from pre-amplification supplies at all times." 4. Observation of the Healgen COVID-19 IgG/IgM rapid test showed the Healgen rapid test is performed on same desk as the pre-amplification and amplification procedures are performed for the Lyra Direct SARS-CoV-2 Assay. 5. Interview on November 10, 2020 at 11:30 AM with the TS and LD confirmed the laboratory failed to have a uni-directional workflow to include separate areas to prevent contamination of patient specimens, equipment, instruments, reagents, materials, and supplies.
D5469	CONTROL PROCEDURES CFR(s): 493.1256(d)(10)(g) Unless CMS Approves a procedure, specified in Appendix C of the State Operations Manual (CMS Pub. 7), that provides equivalent quality testing, the laboratory must--Establish or verify the criteria for acceptability of all control materials. (i) When control materials providing quantitative results are used, statistical parameters (for example, mean and standard deviation) for each batch and lot number of control materials must be defined and available. (ii) The laboratory may use the stated value of a commercially assayed control material provided the stated value is for the methodology and instrumentation employed by the laboratory and is verified by the laboratory. (iii) Statistical parameters for unassayed control materials must be established over time by the laboratory through concurrent testing of control materials having previously determined statistical parameters. (g) The laboratory must document all control procedures performed. This STANDARD is not met as evidenced by: Based on review of Sight Diagnostics Olo hematology analyzer quality control (QC), and interview with the technical supervisor (TS), laboratory director (LD), and testing personnel #3, the laboratory failed to establish or verify the criteria for acceptability of hematology QC material from September 4, 2020 to date November 10, 2020. Findings: 1. Review of Olo hematology QC showed no acceptable ranges and no criteria for acceptability of QC. 2. Interview with the TS and LD on November 10, 2020 at 12:20 PM confirmed the laboratory failed to establish or verify the criteria for acceptability of hematology QC material.