Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	23D2096521	04/28/2022
Name of Provider or Supplier	**Street Address, City, State**	
Exclusive Physicians, Pllc	911 E 9 Mile Rd Suite 100, Ferndale, MI	

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
D1001	CERTIFICATE OF WAIVER TESTS CFR(s): 493.15(e) Laboratories eligible for a certificate of waiver must-- (1) Follow manufacturers' instructions for performing the test; and (2) Meet the requirements in subpart B, Certificate of Waiver, of this part. This STANDARD is not met as evidenced by: . Based on record review and interview with Technical Consultant #2 (TC2), the laboratory failed to ensure all authorized fact sheets were included with test results for 1 (Accula SARS-CoV-2 Test) of 3 tests used to detect SARS-CoV-2 infections. Findings include: 1. A review of the laboratory's "Accula SARS-CoV-2 Test" Instructions For Use (IFU) revealed a section stating "Authorized laboratories using the Accula SARS-CoV-2 test must include with test result reports all authorized Fact Sheets. Under exigent circumstances, other appropriate methods for disseminating these Fact Sheets may be used, which may include mass media." 2. An interview on 4 /28/22 at 2:40 pm with TC2 revealed the laboratory did not include with test results all authorized fact sheets for the Accula SARS-CoV-2 assay.
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: . Based on record review and interviews, the laboratory failed to meet applicable analytic system requirements and correct identified problems. Findings include: 1. The laboratory failed to establish policies and procedures for specimen collection, criteria for specimen acceptability and rejection for its laboratory-developed molecular Urinary Tract Infection (UTI) and Respiratory panels. Refer to D5403. 2. The laboratory failed to perform calibration verification at least every 6 months for Unsaturated Iron-Binding Capacity (UIBC) and Lactate Dehydrogenase (LDH) testing. Refer to D5439. 3. The laboratory failed to perform two control materials for each molecular amplification procedure for its molecular Urinary Tract Infection (UTI) and Respiratory panels. Refer to D5455.
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 record review and interviews, the laboratory failed to establish policies and procedures for specimen collection, criteria for specimen acceptability and rejection for its laboratory-developed molecular Urinary Tract Infection (UTI) and Respiratory panels for 21 (August 2020 to April 2022) of 21 months the test systems have been in use. Findings include: 1. A review of the laboratory's policies and procedures "RPP by QuantStudio 12K Flex" and "UTI by QuantStudio 12K Flex" revealed a lack of specimen collection, criteria for specimen acceptability and rejection for its molecular urinary tract infection and respiratory panels. 2. A review of the laboratory's "EPIC Infectious Disease Detection by Real-Time PCR" revealed a lack of information of the specimen types used in the establishment of performance specifications. 3. An interview on 4/25/22 at 11:56 am with the GS revealed the laboratory uses a first void "dirty" catch specimen for its urinary tract infection panel. 4. An interview on 4/25/22 at 12:06 pm with Collection Staff revealed specimens collected for the urinary tract infection panel are clean-catch specimens and a nasopharyngeal specimen is collected for the respiratory panel.
D5439	CALIBRATION AND CALIBRATION VERIFICATION CFR(s): 493.1255(b)

	Unless otherwise specified in this subpart, for each applicable test system the laboratory must do the following: Perform and document calibration verification procedure - (b)(1) Following the manufacturer's calibration verification instructions; (b)(2) Using the criteria verified or established by the laboratory under 493.1253(b)(3) -- (b)(2)(i) Including the number, type, and concentration of the materials, as well as acceptable limits for calibration verification; and (b)(2)(ii) Including at least a minimal (or zero) value, a mid-point value, and a maximum value near the upper limit of the range to verify the laboratory's reportable range of test results for the test system; and (b)(3) At least once every 6 months and whenever any of the following occur: (b)(3)(i) A complete change of reagents for a procedure is introduced, unless the laboratory can demonstrate that changing reagent lot numbers does not affect the range used to report patient test results, and control values are not adversely affected by reagent lot number changes. (b)(3)(ii) There is major preventive maintenance or replacement of critical parts that may influence test performance. (b)(3)(iii) Control materials reflect an unusual trend or shift, or are outside of the laboratory's acceptable limits, and other means of assessing and correcting unacceptable control values fail to identify and correct the problem. (b)(3)(iv) The laboratory's established schedule for verifying the reportable range for patient test results requires more frequent calibration verification. This STANDARD is not met as evidenced by: . Based on record review and interview with Technical Consultant #2 (TC2), the laboratory failed to perform calibration verification at least every 6 months for Unsaturated Iron-Binding Capacity (UIBC) and Lactate Dehydrogenase (LDH) testing for 2 (April 2020 to April 2022) of 2 years reviewed. Findings include: 1. A review of the laboratory's calibration verification data revealed a lack of documentation for the analytes UIBC and LDH. 2. An interview on 4/28/22 with TC2 confirmed the laboratory had not performed calibration verification for UIBC and LDH analytes as required.
D5455	CONTROL PROCEDURES CFR(s): 493.1256(d)(3)(v)(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-- At least once a day patient specimens are assayed or examined perform the following for-- Each molecular amplification procedure, include two control materials and, if reaction inhibition is a significant source of false negative results, a control material capable of detecting the inhibition. (g) The laboratory must document all control procedures performed. This STANDARD is not met as evidenced by: . Based on record review and interviews, the laboratory failed to perform two control materials for each molecular amplification procedure for its molecular Urinary Tract Infection (UTI) and Respiratory panels for 21 (August 2020 to April 2022) of 21 months the test systems have been in use. Findings include: 1. A review of the laboratory's test menu revealed it tests for the following organisms and drug resistance markers in its molecular panels: a. Acinetobactor baumanii b. Beta Lactams c. Adenovirus d. Adenovirus F 40/41 e. Bordetella pertussis f. Candida albicans g. Candida glabrata h. Candida parapsilosis i. Candida tropicalis j. Chlamydia

	trachomatis k. Chlamydia pnemoniae l. Citrobacter freundii/braakii m. Citrobacter koseri n. Class A beta-lactamase; blaKPC o. Class A beta-lactamase; CTX-M-Group 1 p. Class B beta-lactamasel; blaNDM q. Class D oxacillinase OXA-48 r. Class D oxacillinase OXA-51 s. Coronavirus- 229E, NL63, OC43, and HKU 1 t. Coxiella burnetii u. dfr (A1, A5), sul (1,2) probes (Sulfamethoxazole and trimethoprim) v. Enterococcus Faecium, faecalis w. Enterovirus D68 x. Evertovirus species y. ermB, ermC, mefA z. Escherichia coli aa. Fusobacterium nucleatum bb. Fusobacterium necrophorum cc. Gardnerella vaglinalis dd. Haemophilus influenzae ee. Human metapneumovirus ff. Human metapneumovirus (A & B) gg. Carbapenem groups IMP, NDM, VIM hh. Influenza A H1, H3 ii. Influenza A and B jj. Klebsiella pneumoniae kk. Klebsiella oxytoca ll. Legionella pneumophila mm. Moraxella cartarrhalis nn. Methacillin-Resistant Staphylococcus aureus MecA gene oo. Mycoplasma pneumoniae pp. Neisseria gonorrhoeae qq. Parainfluenza viruses 1, 2, 3, and 4 rr. Extended-Spectrum Beta-Lactamase (ESBL) groups PER-1, VEB-1, GES-1 ss. Pneumocytis jirovecii tt. Proteus mirabilis uu. Proteus vulgaris vv. Pseudomonas aeruginosa ww. qnrA1, qnrA2, qnrB2 xx. Respiratory Syncytial Virus A and B yy. Rhinovirus zz. Serratia marcescens aaa. Coronavirus bbb. Staphylcoccus coagulase negative species ccc. Staphylococcus aureus ddd. Staphylococcus saprophyticus eee. Streptococcus agalactiae fff. Streptococcus pyogenes ggg. tetB, tetM hhh. Trichomonas vaginalis iii. VanA and VanE 2. A review of the labortatory's quality control results revealed a lack of positive controls performed for the analytes listed above at least once a day patient specimens were assayed. 3. A review of the laboratory's "RPP by QuantStudio 12K Flex" and "UTI by QuantStudio 12K Flex" procedures revealed a lack of procedure for the performance of positive controls for the analytes listed above. 4. An interview on 4/28/22 at 12:19 pm with Technical Consultant #2 confirmed the laboratory did not perform a positive control for the analytes listed above at least once a day patient specimens were assayed. 5. An interview on 4/28/22 at 12:25 pm with the General Supervisor revealed a total of 3,787 patients had been tested using the UTI and Respiratory panels since August 2020 on dates when a positive control had not been performed for the analytes listed above.