

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 23D2096521	(X3) Date Survey Completed 06/27/2022
Name of Provider or Supplier Exclusive Physicians, PLLC	Street Address, City, State 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
D5401	<p>PROCEDURE MANUAL CFR(s): 493.1251(a)</p> <p>A written procedures manual for all tests, assays, and examinations performed by the laboratory must be available to, and followed by, laboratory personnel. Textbooks may supplement but not replace the laboratory's written procedures for testing or examining specimens.</p> <p>This STANDARD is not met as evidenced by: Based on record review and interviews, the laboratory failed to make policies and procedures for specimen collection, criteria for specimen acceptability and rejection for its laboratory-developed molecular Urinary Tract Infection (UTI) and Respiratory panels available to laboratory personnel for 1 (5/27/22 to 6/27/22) of 1 month since the procedures were established. Findings include: 1. A review of the laboratory's Allegation of Compliance submission on 6/13/22 revealed the laboratory established policies and procedures for specimen collection, criteria for specimen acceptability and rejection for its laboratory-developed molecular Urinary Tract Infection (UTI) and Respiratory panels effective 5/27/22. 2. A review of the laboratory's policies and procedures on 6/27/22 revealed a lack of policies and procedures for specimen collection, criteria for specimen acceptability and rejection for its laboratory-developed molecular Urinary Tract Infection (UTI) and Respiratory panels. 3. The surveyor requested the policies and procedures for specimen collection, criteria for specimen acceptability and rejection for its laboratory-developed molecular Urinary Tract Infection (UTI) and Respiratory panels on 6/27/22 at 10:17 am and were not made available. 4. An interview on 6/27/22 at 10:17 am with General Supervisor #2 indicated the procedures were kept in the bathroom. 5. A review of the laboratory's collection procedure in the bathroom on 6/27/22 titled "Instructions for Collecting a Clean Catch Urine Sample" revealed to be a urine self-collection policy for patients and not the policies and procedures the laboratory established for specimen collection, criteria for specimen acceptability and rejection for its laboratory-developed</p>

molecular Urinary Tract Infection (UTI) and Respiratory panels on 5/27/22. 6. An interview on 6/27/22 at 10:37 am with General Supervisor #2 confirmed the policies and procedures established on 5/27/22 had not been available to laboratory personnel.

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 record review and interview with General Supervisor #2, the laboratory failed to establish the criteria for acceptability for controls used with the laboratory-developed molecular Urinary Tract Infection (UTI) and Respiratory panels (RPP Custom Control lot 3324868 and UTI Custom Control lot 3324869) for the current control materials in use. Findings include: 1. The surveyor received an email on 6/27/22 from General Supervisor #2 noting the laboratory had resumed its laboratory-developed molecular UTI and Respiratory panels. 2. The surveyor observed the positive control material for the UTI and Respiratory panels, RPP Custom Control lot 3324868 and UTI Custom Control lot 3324869, on 6/27/22 at 10:00 am. 3. An interview on 6/27/22 at 10:00 am with General Supervisor #2 revealed the laboratory its positive control results acceptability range to have a Cycle Threshold (Ct) value between 9 and 30 and pass the internal control. 4. A review of the laboratory's "Molecular Quality Control Policy" on 6/27/22 revealed a section stating, "If the controls are within the manufacturers stated range, then the run can be accepted and patient results reported." 5. A review of the laboratory's "ThermoFisher Scientific Custom DNA Control" documentation revealed the controls were developed specifically for the laboratory's panels and the manufacturer did not establish ranges for control acceptability for the custom control lots RPP Custom Control lot 3324868 and UTI Custom Control lot 3324869. 6. A review of the laboratory's "EXT POS CONTROL 3 DAY VALIDATION" revealed documentation of three runs with the control materials and did not include statistical parameters or acceptability criteria established by the laboratory. 7. An interview on 6/27/22 at 10:04 am with General Supervisor #2 confirmed the control materials did not have manufacturer ranges for acceptability and the laboratory did not have a process for establishing criteria for acceptability of control materials used in its laboratory-developed molecular Urinary Tract Infection (UTI) and Respiratory panels.