

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 39D2130307	(X3) Date Survey Completed 09/20/2023
Name of Provider or Supplier Religen Inc	Street Address, City, State 5110 Campus Drive, Suite 120, Plymouth Meeting, 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
D5221	<p>EVALUATION OF PROFICIENCY TESTING PERFORMANCE CFR(s): 493.1236(d)</p> <p>All proficiency testing evaluation and verification activities must be documented.</p> <p>This STANDARD is not met as evidenced by: Based on review of American Proficiency Institute (API) Proficiency Testing (PT) Performance Evaluation records and interview with Technical Supervisor (TS) #2 (CMS-209) the laboratory failed to document a corrective action to evaluate 1 of 1 unacceptable PT results in Microbiology in 2023. Findings include: 1) On the day of survey 09/20/2023 at 12:14 pm, review of API PT performance evaluation records revealed the laboratory obtained 80% in Microbiology for the 2nd event in 2023 for Respiratory Virology SARS-Cov-2 molecular testing (SFR-10). 2) The laboratory failed to document a corrective action to evaluate the unacceptable result. 3) Interview with TS #2 on 09/20/2023 at 1:30 pm confirmed the above findings.</p>
D5403	<p>PROCEDURE MANUAL CFR(s): 493.1251(b)</p> <p>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</p>

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 a lack of procedure manual and interview with Technical Supervisor (TS) #1 (CMS 209), the laboratory failed to establish a procedure manual for entering results in the patient record and reporting patient results for Chemistry testing from 09/20/2023 to the day of survey. Findings Included: 1. On the day of survey, 09/20/2023 at 11:35 AM, the laboratory failed to provide a procedure manual for manually entering patient results in the Electronic Medical Record system for Protein Extraction Testing. 2. The laboratory performed 1900 Protein Extraction tests in 2022 (CMS 116 Estimated Annual Volume). 3. TS #1 Confirmed the findings above on 09/20/2023 at 13:29 PM.