Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	39D2130307	08/18/2021
Name of Provider or Supplier	**Street Address, City, State**	
Religen Inc	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
D5209	PERSONNEL COMPETENCY ASSESSMENT POLICIES CFR(s): 493.1235 As specified in the personnel requirements in subpart M, the laboratory must establish and follow written policies and procedures to assess employee and, if applicable, consultant competency. This STANDARD is not met as evidenced by: A. Based on review of the laboratory's Competency Assessment procedure, review of Competency Assessment (CA) records, and interview with Technical Supervisor (TS) #1, the Laboratory failed to follow the Laboratory's written procedure to assess the competency of 3 of 3 testing personnel (TP) who performed Mitochondrial Enzyme Activity assays for 2019, 2020, and 2021 Findings Include: 1. The laboratory's Competency Assessment procedure (page 2) under evaluations (points 1, 2, 3, 4, 5, and 6) states: " 1. Direct observation of routine patient test performance to include patient preparation (if applicable), specimen handling, processing and testing. 2. Monitoring the recording and reporting of test results. 3. Review of intermediate test results or worksheets, quality control records, proficiency testing results, and preventive maintenance records. 4. Direct observation of performance of instrument maintenance and function checks. 5. Assessment of test performance through previously analyzed specimens, internal blind samples or external proficiency testing samples. 6. Evaluation of problem solving skills. 2. On the day of survey 08/18/2021, review of the CA records revealed the following: 2019: - 1 of 3 TP (CMS209 personnel #2) CA did not evaluate point 4. - 1 of 3 TP (CMS209 personnel #3) CA did not evaluate points 3, 5, and 6. 2020: - 1 of 3 TP (CMS209 personnel #2) CA did not evaluate point 3 and 5. - 1 of 3 TP (CMS209 personnel #3) CA did not evaluate points 3, 5, and 6. 2021: - 1 of 3 TP (CMS209 personnel #4) CA did not evaluate points 3, 5, and 6. 3. The TS#1 confirmed the findings above on 8/18/2021 at 10:15 a. m. B. Based on review of competency assessment records and interview with the

	technical supervisor (TS)#1, the laboratory failed to assess 3 of 3 testing personnel (TP) for each assay in chemistry performed from 08/18/2019 to the date of survey. Findings Include: 1. On the day of Survey 08/18/2021, review of the competency assessment records revealed, the forms used to document competency did not separate the two assays (Citrate synthase and Respiratory chain complex-IV) for 3 of 3 TP from 08/18/2019 to the day of survey. 2. The TS#1 confirmed the finding above on 8 /18/2021 at 10:15 a.m.
D5217	EVALUATION OF PROFICIENCY TESTING PERFORMANCE CFR(s): 493.1236(c)(1) At least twice annually, the laboratory must verify the accuracy of any test or procedure it performs that is not included in subpart I of this part. This STANDARD is not met as evidenced by: Based on lack of documentation and interview with the technical supervisor (TS)#1, the laboratory failed to verify twice annually the accuracy for Citrate Synthase and Respiratory chain complex-IV assays performed in 2020. Findings include: 1. On the day of survey, 08/18/2021, the laboratory could not provide documentation of verification of accuracy performed for Citrate Synthase and Respiratory chain complex-IV assays in 2020. 2. The TS#1 confirmed the findings above on 08/18/2021 at 10:50 a.m.
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 review of the laboratory procedure manual and interview with the Technical Supervisor (TS)#2, the laboratory failed to include a procedure for reporting positive and negative SARS-CoV-2 testing to the appropriate health agencies (PA NEDSS) as required from November 25, 2020 to the day of survey. Findings include: 1. On the day of survey 08/18/2021, the laboratory could not provide a procedure for reporting positive and negative SARS-CoV-2 testing to the appropriate health agencies as

	required from November 25, 2020 to the day of survey. 2. The laboratory tested 42,219 specimens for SARS-CoV-2 from November 25, 2020 to the day of survey. 3. The TS#2 confirmed the findings above on 08/18/2021 around 01:25 p.m.
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 lack of documentation and interview with Technical Supervisor (TS)#1, the laboratory failed to have a system to evaluate biannually the relationship between the mitochondrial enzymes (Citrate synthase and Respiratory chain complex-IV) test results using 2 of 2 Hitachi Spectrophotometers from 08/18/2019 to the day of survey. Findings include: 1. On the day of survey 08/18/2021, the laboratory could not provide documentation for comparison studies between 2 of 2 Hitachi spectrophotometers for Citrate synthase and Respiratory chain complex-IV. 2. The TS#1 confirmed the finding above on 08/18/2021 at 12:00 p.m.