Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	19D1102217	03/23/2022
Name of Provider or Supplier	**Street Address, City, State**	
Pediatric Center Of Southwest Louisiana, The	2800 Country Club Road, Lake Charles, LA	

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
D0000	A Recertification survey was performed at The Pediatric Center of Southwest Louisiana, CLIA ID # 19D1102217, on March 23, 2022. The Pediatric Center of Southwest Louisiana was found not in compliance with the following CONDITION LEVEL DEFICIENCIES: 42 CFR 493.1250 CONDITION: Analytic systems 42 CFR 493.1403 CONDITION: Laboratories Performing Moderate Complexity Testing, Laboratory Director 42 CFR 493.1409 CONDITION: Laboratories Performing Moderate Complexity Testing, Technical Consultant
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 observation by surveyor, review of patient final test reports, manufacturer's instructions, test menu, and interview with personnel, the laboratory failed to include complete "Fact Sheets" to patients for Emergency Use Authorization (EUA) SARS COV-2 testing. Findings: 1. Observation by surveyor during the laboratory tour on March 23, 2022 at 9:00 am revealed the laboratory utilizes the following kits for SARS COV-2 testing: a) Lumira Dx SARS COV-2 antigen b) Quidel Quickvue SARS COV-2 2. Review of the manufacturers' instructions revealed "Authorized laboratories using your product 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." 3. Review of the laboratory's patient final test reports for SARS COV-2 revealed the reports are labeled "Fact Sheets For Patients; however, the information provided to patients was not complete. The fact sheet information provided to patients did not match the information provided in the manufacturer's fact sheets. 4. In interview on

	March 23, 2022 at 9:00 am, Testing Personnel 1 confirmed the SARS COV-2 fact sheets the laboratory provided to patients did not match the manufacturers'. 5. Review of the laboratory's test menu revealed the laboratory performs fourteen (14) Lumira Dx SARS COV-2 antigen tests and 545 Quidel Quickvue SARS COV-2 antigen tests.
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: I. Based on review of the laboratory's policies, CMS 209 form, personnel records, and interview with personnel, the laboratory failed to establish written policies and procedures to assess competency of the Technical Consultant. Findings: 1. Review of the laboratory's CMS-209 form (Laboratory Personnel Report) revealed one (1) Technical Consultant. 2. Review of the laboratory's "Employee Competency" policy revealed the laboratory did not include performance of competency for the Technical Consultant, to include, but not limited to the frequency. 3. Review of personnel records for the Technical Consultant revealed a competency assessment for her duties as Technical Consultant performed in 2017 by the previous Laboratory Director, not the current. Laboratory Director. 4. In interview on March 23, 2022 at 9:30 am the Technical Consultant confirmed the laboratory's competency policy did not include competency for the Technical Consultant. The Technical Consultant confirmed the current Laboratory Director did not perform a competency assessment for her duties as Technical Consultant. II. Based on review of the laboratory's personnel competency records and interview with personnel, the laboratory failed to perform competency assessments at each specific laboratory testing location for nine (9) Testing Personnel. Findings: 1. In interview on March 23, 2022 at 9:30 am, Testing Personnel 1 stated the laboratory utilizes the same employees at each of their three (3) locations. Testing Personnel 1 stated the competency assessments are performed at whichever location the staff is working at the time and the forms are brought to the main location to sign. Testing Personnel 1 confirmed the competency assessments for testing personnel are not performed on site at each laboratory site. 2. Review of the laboratory's testing personnel competency assessment forms revealed the laboratory's location was not specified.
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 observation by surveyor, record review, and interview with personnel, the laboratory failed to ensure the quality of testing within the analytic systems. Findings:

	1. The laboratory failed to establish written policies for reporting SARS COV-2 results. Refer to D5401. 2. The laboratory failed to perform complete performance verification studies for complete blood count (CBC) testing on the Medonic M series analyzer. Refer to D5421. 3. The laboratory failed to perform quality control (QC) for Group A B-hemolytic Streptococcus (Bacteriology) testing per their IQCP for five (5) of five (5) lot numbers reviewed. Refer to D5445. 4. The laboratory's quality assessment monitors failed to correct issues identified with the analytic system. Refer to D5793.
D5401	PROCEDURE MANUAL CFR(s): 493.1251(a) 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. This STANDARD is not met as evidenced by: Based on review of the laboratory's policies and procedures and interview with personnel, the laboratory failed to establish written policies for reporting SARS COV-2 results. Findings: 1. Review of the laboratory's policies and procedures revealed the laboratory did not have written procedures for reporting SARS COV-2 results, to include, but not limited to who is responsible, and frequency of reporting. 2. In interview on March 23, 2022 at 9:30 am, Testing Personnel 1 confirmed the laboratory did not have a written policy for reporting positive and negative SARS COV-2 results to the state.
D5421	ESTABLISHMENT AND VERIFICATION OF PERFORMANCE CFR(s): 493.1253(b)(1) Each laboratory that introduces an unmodified, FDA-cleared or approved test system must do the following before reporting patient test results: (1)(i) Demonstrate that it can obtain performance specifications comparable to those established by the manufacturer for the following performance characteristics: (1)(i)(A) Accuracy. (1)(i)(B) Precision. (1)(i)(C) Reportable range of test results for the test system. (1)(ii) Verify that the manufacturer's reference intervals (normal values) are appropriate for the laboratory's patient population. This STANDARD is not met as evidenced by: Based on observation by surveyor, review of validation studies, test menu, and interview with personnel, the laboratory failed to perform complete performance verification studies for complete blood count (CBC) testing on the Medonic M series analyzer. Findings: 1. Observation by surveyor during the laboratory tour on March 23, 2022 at 9:00 am revealed the laboratory utilizes the Medonic M series analyzer for CBC testing. 2. In interview on March 23, 2022 at 10:50 am, Testing Personnel 1 stated the laboratory replaced their previous Medonic analyzer with a new one in May 2021. 3. Review of the laboratory's "Verification of Performance Specifications" revealed "Each laboratory that introduces a new, non-waived, unmodified, FDA-cleared or approved test is required to check (verify) the manufacturer's performance specifications provided in the package insert for the following before reporting patient test results: Demonstrate that it can obtain performance specifications comparable to

	those established by the manufacturer for the following performance characteristics: a) accuracy b) precision c) reportable range of the test results for the system Verify that the manufacturer's reference intervals (normal values) are appropriate for the laboratory's patient population Quantitative Tests: Precision: Perform five repetitions of at least three samples with different values, spanning the reportable range. Test the samples: In the same run (2 of the 5 repetitions; in a different run on the same day (3rd repetition); and on different days (4th and 5th repetitions performed on different days). If possible have different staff perform the 3rd, 4th, and 5th repetitions to check for operator variance Reportable Range: Using the same process used to evaluate accuracy, evaluate reportable range. If a zero calibrator is available for the analyte, then you may extend the low end of your reportable range down to zero, provided you actually obtain a zero result when you test that sample. Reference Range: Collect specimens from twenty (20) normal patients (a minimum of ten (10) patient specimens my be used if necessary. Test each specimen only once, and spread the testing over a minimum of three days. Calculate the normal patient mean. Calculate the standard deviation (SD) and determine the range of the plus and minus two SD from the mean. Compare this range to the manufacturer's range. 4. Review of the "Medonic M Series Method Validation Evaluation" form revealed the following: "The Lab Director should review the the results of the Reportable Range/Linearity study. No patient results may be reported outside this linear range unless procedures /protocols are developed to use when results are outside the validated linear (reportable) range. Reference Range Validation: The Laboratory Medical Director must examine all reference ranges provided by the manufacturer and determine if they are appropriate for the lab's patient population. This can be done empirically , or by using the methods outlined in the CLSI Document C28-A2E 'How to Define and Determine Reference Intervals in the Clinical Laboratory.' " 5. Review of the laboratory's validation records for the Medonic M series analyzer revealed the laboratory did not include the following: Precision studies: to include run-to run, day to day, within-run, operator variance studies Reference Range studies Reportable Range: to include the range the laboratory verified for each blood cell parameter 6. In interview on March 23, 2022 at 11:11 am, Testing Personnel 1 stated the precision studies were performed all on the same day, May 20, 2021. Testing Personnel 1 further stated she was the only testing personnel that assisted the technical service representative in the studies. 7. In further interview on March 23, 2022 at 11:11 am, the Technical Consultant stated she did not see anything in the laboratory's validation studies concerning what was done for the reference ranges in use. The Technical Consultant stated she thinks the laboratory is using the same ranges as their previous Medonic analyzer. 8. In interview on March 23, 2022 at 1:35 pm, the Technical Consultant stated she did not see anything in the laboratory's validation studies or procedures that stated the laboratory's reportable ranges. 9. Review of the laboratory's test menu revealed the laboratory performs 2,130 CBC tests annually.
D5445	CONTROL PROCEDURES CFR(s): 493.1256(d)(1)(2)(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--(d)(1) Perform control procedures as defined in this section unless otherwise specified in the additional specialty and subspecialty requirements at 493.1261 through 493.1278. (d)(2) For each test system, perform control procedures using the number and frequency specified by the manufacturer or established by the laboratory when they meet or exceed the requirements in paragraph (d)(3) of this section. (g) The laboratory must document all control procedures performed.

	This STANDARD is not met as evidenced by: Based on observation by surveyor, review of the laboratory's policies, Individualized Quality Control Plan (IQCP), control records, test menu, and interview with personnel, the laboratory failed to perform quality control (QC) for Group A B-hemolytic Streptococcus (Bacteriology) testing per their IQCP for five (5) of five (5) lot numbers reviewed. Findings: 1. Observation by surveyor during laboratory tour on March 23, 2022 at 9:00 am, the laboratory utilizes the Quidel Solana GAS Assay for Group A B-hemolytic Streptococcus testing 2. Review of the laboratory's "Solana GAS Assay" policy under "Quality Control" section revealed "It is recommended that the reactivity of each new lot and each new shipment of the Solana GAS Assay be verified on receipt and before use. External control tests should be performed thereafter every time patient samples are assayed." 3. In interview on March 23, 2022 at 12:07 pm, Testing Personnel 1 stated external QC for the Solana GAS Assay are tested every new lot and shipment. 4. In interview on March 23, 2022 at 12:07 pm, the Technical Consultant stated the laboratory had an IQCP for the Solana GAS Assay. Testing Personnel 1 stated she was unaware of the laboratory's IQCP. 5 Review of the laboratory's IQCP for the Solana GAS Assay revealed "It is recommended that the reactivity of each new lot and each new shipment of the Solana GAS Assay be verified on receipt and before use and every 30 days." 6. Review of random selection of the laboratory's QC records for the Solana GAS assay revealed the laboratory did not perform QC at least every thirty (30) days for the following five (5) lot numbers: Lot 179486 Lot 173482 Lot 204022 Lot 206627 Lot 180383 7. Review of the laboratory's test menu revealed the laboratory performs 1,271 Group A Streptococcus testing annually on the Solana GAS assay.
D5793	ANALYTIC SYSTEMS QUALITY ASSESSMENT CFR(s): 493.1289(b)(c) (b) The analytic systems quality assessment must include a review of the effectiveness of corrective actions taken to resolve problems, revision of policies and procedures necessary to prevent recurrence of problems, and discussion of analytic systems quality assessment reviews with appropriate staff. (c) The laboratory must document all analytic systems assessment activities. This STANDARD is not met as evidenced by: Based on observation by surveyor, record review, and interview with personnel, the laboratory's quality assessment monitors failed to correct issues identified with the analytic system. Findings: 1. Review of the laboratory's "Monthly Check List" and "QA Monitors" revealed the following tasks and monitors: Perform monthly maintenance on CBC machine Review monthly CBC LIMS log Review monthly Media QA log Review monthly Bacteriology QA monitors Review(ed) with lab director/technical consultant any changes in package inserts Check for expired supplies Review QC-Levy Jennings-and have it signed by the lab director If PT testing is performed-have the attestation statement and results signed by testing personnel & lab director Review competency records and perform competency testing of personnel that require it Review Daily Logs (temperature log, incubator logs, hematology qc log, daily checklist) Urine culture review QA of Media Chart Review 2. Observation by surveyor, review of records, and interview with personnel revealed the laboratory did not identify the following issues with the analytic system: a) The laboratory failed to establish written policies for reporting SARS COV-2 results.

	Refer to D5401. b) The laboratory failed to perform complete performance verification studies for complete blood count (CBC) testing on the Medonic M series analyzer. Refer to D5421. c) The laboratory failed to perform quality control (QC) for Group A B-hemolytic Streptococcus (Bacteriology) testing per their IQCP for five (5) of five (5) lot numbers reviewed. Refer to D5445.
D5805	TEST REPORT CFR(s): 493.1291(c) The test report must indicate the following: (c)(1) For positive patient identification, either the patient's name and identification number, or a unique patient identifier and identification number. (c)(2) The name and address of the laboratory location where the test was performed. (c)(3) The test report date. (c)(4) The test performed. (c)(5) Specimen source, when appropriate. (c)(6) The test result and, if applicable, the units of measurement or interpretation, or both. (c)(7) Any information regarding the condition and disposition of specimens that do not meet the laboratory's criteria for acceptability. This STANDARD is not met as evidenced by: I. Based on observation by surveyor, review of patient final test reports and interview with personnel, the laboratory failed to include the name and address of the laboratory performing the SARS COV-2 testing. Findings: 1. Observation by surveyor during the laboratory tour on March 23, 2022 at 9:00 am revealed the laboratory utilizes the following kits for SARS COV-2 testing: a) Lumira Dx SARS COV-2 antigen b) Quidel Quickvue SARS COV-2 2. Review of the following random selection of final patient test reports revealed the laboratory's name and address were not included on the report: Patient ID 283410 3. In interview on March 23, 2022 at 9:00 am Testing Personnel 1 confirmed the name and address of the laboratory were not included on patient final reports. 4. Review of the laboratory's test menu revealed the laboratory performs fourteen (14) Lumira DX SARS COV-2 antigen tests and 545 Quidel Quickvue SARS COV-2 antigen tests. II. Based on review of the patient final test reports and interview with personnel, the laboratory failed to ensure the name and address of the reference laboratory performing urine culture identification and susceptibility were included on patient final test reports for two (2) of two (2) patients reviewed. Findings: 1. In interview on March 23, 2022 at 10:50 am, Testing Personnel 1 stated that urine culture identification is performed at a hospital in Sulphur. 2. Review of the following random review selection of patient test results for urinalysis revealed the name and address of the reference laboratory performing the urine culture identification and susceptibility testing were not included: Patient 60417 Patient 102650 3. In interview on March 23, 2022 at 10:50 am, Testing Personnel 1 confirmed the name and address of the reference laboratory performing the urine culture identification and susceptibility tests were not included on the patient final test reports. Testing Personnel 1 stated the reference laboratory's results automatically transfers into the laboratory's reporting system.
D6000	MODERATE COMPLEXITY LABORATORY DIRECTOR CFR(s): 493.1403 The laboratory must have a director who meets the qualification requirements of 493. 1405 of this subpart and provides overall management and direction in accordance with 493.1407 of this subpart.

	This CONDITION is not met as evidenced by: Based on observation by surveyor, record review, and interview with personnel, the Laboratory Director failed to provide overall management and direction for the laboratory. Findings: 1. The Laboratory Director failed to ensure performance verification studies were complete. Refer to D6013. 2. The Laboratory Director failed to ensure that a quality control program was maintained to assure quality laboratory services were provided. Refer to D6020. 3. The Laboratory Director failed to ensure patient final reports included required pertinent information. Refer to D6026. 4. The Laboratory Director failed to ensure policies and procedures for assessing personnel competency were maintained. Refer to D6030. 5. The Laboratory Director failed to ensure that an approved procedure manual was available to all personnel. Refer to D6031.
D6013	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(3)(ii) The laboratory director is responsible for the overall operation and administration of the laboratory, including the employment of personnel who are competent to perform test procedures, and record and report test results promptly, accurate, and proficiently and for assuring compliance with the applicable regulations. (e) The laboratory director must-- (e)(3) Ensure that-- (e)(3)(ii) Verification procedures used are adequate to determine the accuracy, precision, and other pertinent performance characteristics of the method; This STANDARD is not met as evidenced by: Based on observation by surveyor, record review, and interview with personnel, the Laboratory Director failed to ensure performance verification studies were complete. Refer to D5421.
D6020	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(5) The laboratory director is responsible for the overall operation and administration of the laboratory, including the employment of personnel who are competent to perform test procedures, and record and report test results promptly, accurate, and proficiently and for assuring compliance with the applicable regulations. (e) The laboratory director must-- (e)(5) Ensure that the quality control program is established and maintained to assure the quality of laboratory services provided. This STANDARD is not met as evidenced by: Based on observation by surveyor, record review, and interview with personnel, the Laboratory Director failed to ensure that a quality control program was maintained to assure quality laboratory services were provided. Refer to D5445.
D6022	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(5) The laboratory director is responsible for the overall operation and administration of the laboratory, including the employment of personnel who are competent to perform test procedures, and record and report test results promptly, accurate, and proficiently

	and for assuring compliance with the applicable regulations. (e) The laboratory director must-- (e)(5) Ensure that the quality control and quality assessment programs are established and maintained to identify failures in quality as they occur. This STANDARD is not met as evidenced by: Based on observation by surveyor, record review, and interview with personnel, the Laboratory Director failed to ensure that a quality assessment (QA) program was maintained to assure the quality of laboratory services provided and to identify failures as they occur. Refer to D5793.
D6026	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(8) The laboratory director is responsible for the overall operation and administration of the laboratory, including the employment of personnel who are competent to perform test procedures, and record and report test results promptly, accurate, and proficiently and for assuring compliance with the applicable regulations. (e) The laboratory director must-- (e)(8) Ensure that reports of test results include pertinent information required for interpretation. This STANDARD is not met as evidenced by: Based on observation by surveyor, record review, and interview with personnel, the Laboratory Director failed to ensure patient final reports included required pertinent information. Refer to D5805 I and D5805 II.
D6030	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(12) The laboratory director is responsible for the overall operation and administration of the laboratory, including the employment of personnel who are competent to perform test procedures, and record and report test results promptly, accurate, and proficiently and for assuring compliance with the applicable regulations. (e) The laboratory director must-- (e)(12) Ensure that policies and procedures are established for monitoring individuals who conduct preanalytical, analytical, and postanalytical phases of testing to assure that they are competent and maintain their competency to process specimens, perform test procedures and report test results promptly and proficiently, and whenever necessary, identify needs for remedial training or continuing education to improve skills; This STANDARD is not met as evidenced by: Based on record review and interview with personnel, the Laboratory Director failed to ensure policies and procedures for assessing personnel competency were maintained. Findings: 1. The laboratory failed to establish written policies and procedures to assess competency of the Technical Consultant. Refer to D5209 I. 2. The laboratory failed to perform competency assessments at each specific laboratory testing location for nine (9) Testing Personnel. Refer to D5209 II. 3. The Technical Consultant failed to evaluate the competency of three (3) of eight (8) testing personnel. Refer to D6046.
D6031	LABORATORY DIRECTOR RESPONSIBILITIES

	CFR(s): 493.1407(e)(13) The laboratory director is responsible for the overall operation and administration of the laboratory, including the employment of personnel who are competent to perform test procedures, and record and report test results promptly, accurate, and proficiently and for assuring compliance with the applicable regulations. (e) The laboratory director must-- (e)(13) Ensure that an approved procedure manual is available to all personnel responsible for any aspect of the testing process; This STANDARD is not met as evidenced by: Based on record review and interview with laboratory personnel, the Laboratory Director failed to ensure that an approved procedure manual was available to all personnel. Refer to D5401.
D6033	TECHNICAL CONSULTANT-MODERATE COMPEXITY CFR(s): 493.1409 The laboratory must have a technical consultant who meets the qualification requirements of 493.1411 of this subpart and provides technical oversight in accordance with 493.1413 of this subpart. This CONDITION is not met as evidenced by: Based on observation by surveyor, record review, and interview with personnel, the Technical Consultant failed to provide technical oversight of the laboratory for moderate complexity testing. Findings: 1. The Technical Consultant failed to provide technical and scientific oversight to the laboratory. Refer to D6036. 2. The Technical Consultant failed to ensure performance specification verification studies were complete. Refer to D6040. 3. The Technical Consultant failed to ensure the quality control program was maintained to assure the quality of laboratory testing. Refer to D6042. 4. The Technical Consultant failed to evaluate the competency of three (3) of eight (8) testing personnel. Refer to D6046.
D6036	TECHNICAL CONSULTANT RESPONSIBILITIES CFR(s): 493.1413 The technical consultant is responsible for the technical and scientific oversight of the laboratory. This STANDARD is not met as evidenced by: Based on observation by surveyor, record review, and interview with personnel, the Technical Consultant failed to provide technical and scientific oversight to the laboratory. Findings: 1. The laboratory failed to include the name and address of laboratory performing the SARS COV-2 testing. Refer to D5805 I. 2. The laboratory failed to ensure the name and address of the reference laboratory performing urine culture identification and susceptibility were included on patient final test reports for two (2) of two (2) patients reviewed. Refer to D5805 II.
D6040	TECHNICAL CONSULTANT RESPONSIBILITIES CFR(s): 493.1413(b)(2)

	The technical consultant is responsible for-- (b)(2) Verification of the test procedures performed and the establishment of the laboratory's test performance characteristics, including the precision and accuracy of each test and test system. This STANDARD is not met as evidenced by: Based on observation by surveyor, record review, and interview with personnel, the Technical Consultant failed to ensure performance specification verification studies were complete. Refer to D5421.
D6042	TECHNICAL CONSULTANT RESPONSIBILITIES CFR(s): 493.1413(b)(4) (b) The technical consultant is responsible for-- (b)(4) Establishing a quality control program appropriate for the testing performed and establishing the parameters for acceptable levels of analytic performance and ensuring that these levels are maintained throughout the entire testing process from the initial receipt of the specimen, through sample analysis and reporting of test results; This STANDARD is not met as evidenced by: Based on observation by surveyor, record review, and interview with personnel, the Technical Consultant failed to ensure the quality control program was maintained to assure the quality of laboratory testing. Refer to D5445.
D6046	TECHNICAL CONSULTANT RESPONSIBILITIES CFR(s): 493.1413(b)(8) (b) The technical consultant is responsible for-- (b)(8) Evaluating the competency of all testing personnel and assuring that the staff maintain their competency to perform test procedures and report test results promptly, accurately and proficiently. This STANDARD is not met as evidenced by: Based on review of personnel records and interview with personnel, the Technical Consultant failed to evaluate the competency of three (3) of eight (8) testing personnel. Findings: 1. Review of the following personnel records revealed the testing personnel competency assessments were performed by Testing Personnel 1 not the laboratory's Technical Consultant: Testing Personnel 6: Annual competency in February 2022 Testing Personnel 7: Semi-annual competency in August 2021 and Annual competency in February 2022 Testing Personnel 8: Annual competency in February 2021 and February 2022 2. In interview on March 23, 2022 at 930 am, Testing Personnel 1 confirmed she performed the competency assessments for the identified testing personnel, not the Technical Consultant.