Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	19D0459641	04/13/2023
Name of Provider or Supplier	**Street Address, City, State**	
Family Doctor Clinic Of Thibodaux	804 South Acadia Drive, Thibodaux, 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 Validation survey was performed April 12, 2023 through April 13, 2023 at Family Doctor Clinic of Thibodaux, CLIA ID # 19D0459641. The laboratory was found in compliance with 42 CFR 493 Requirements for Laboratories; however, standard level deficiencies were cited.
D2009	TESTING OF PROFICIENCY TESTING SAMPLES CFR(s): 493.801(b)(1) The individual testing or examining the samples and the laboratory director must attest to the routine integration of the samples into the patient workload using the laboratory's routine methods. This STANDARD is not met as evidenced by: Based on review of proficiency testing records and interview with personnel, the laboratory failed to ensure the Laboratory Director and Testing Personnel signed the proficiency attestation statements for one (1) of seven (7) proficiency testing (PT) events. Findings: 1. Review of the College of American Pathologists (CAP) proficiency testing records for 2021, 2022, and 2023 revealed the following one (1) attestation statement did not include the signature of the Laboratory Director or Testing Personnel: ID3-A 2022 Nucleic Acid Amplification, Respiratory Limited Survey 2. Interview on April 12, 2023 at 3:35 PM, the Technical Consultant confirmed the attestation was not signed.
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 policies and procedures, personnel records, and interview with personnel, the laboratory failed to establish written policies and procedures to assess competency for testing personnel. Findings: 1. Review of the laboratory's policy and procedure manual revealed the laboratory did not have a policy addressing competency assessment to include, but not limited to, corrective actions for unsatisfactory assessment, frequency of performance, the individual responsible for assessing the performance, the physical location of the laboratory where competency is being assessed, and the following six (6) procedures as a minimal requirement for assessing the competency of all personnel performing laboratory testing: a) Direct observations of routine patient test performance, including patient preparation, if applicable, specimen handling, processing and testing. b) Monitoring the recording and reporting or test results. c) Review of intermediate test results or worksheets, quality control records, proficiency testing results, and preventative maintenance records. d) Direct observation of performance of instrument maintenance and function checks. e) Assessment of test performance through testing previously analyzed specimens, internal blind testing samples or external proficiency testing samples. f) Assessment of problem solving skills. 2. In interview on April 12, 2023 at 11:30 AM, the Technical Consultant confirmed they do not have a policy for competency assessments. II. Based on review of policies and procedures and interview with personnel, the laboratory failed to ensure policies and procedures were established for assessing technical consultant competency. Findings: 1. Review of the laboratory's policy and procedure manual revealed no policy or process specific to competency assessment of the Technical Consultant to include, but not limited to, qualification, basis of determination of competency, position responsible for performing competency assessment, and frequency of assessment. 2. Review of the laboratory's CMS 209 form (Laboratory Personnel Report) revealed the Personnel 2 as Technical Consultant. 3. In interview on April 12, 2023 at 11:30 AM, the Technical Consultant confirmed they do not a policy for Technical Consultant competency assessment.
D5211	EVALUATION OF PROFICIENCY TESTING PERFORMANCE CFR(s): 493.1236(a) The laboratory must review and evaluate the results obtained on proficiency testing performed as specified in subpart H of this part. This STANDARD is not met as evidenced by: Based on review of proficiency testing records and the laboratory's policy and procedure manual, as well as, interview with laboratory personnel, the laboratory failed to ensure the Laboratory Director reviewed the proficiency testing performance evaluation results for one (1) of seven (7) events reviewed. Findings: 1. Review of the American Academy of Family Physicians (AAFP) Proficiency Testing records revealed AAFP-PT Reinstatement samples were performed due to multiple failures for AAFP proficiency testing Hematology Event 3 2022. 2. Further review of the "AAFP-PT Reinstatement Proficiency Testing" revealed the Laboratory Director did not document review of the reinstatement evaluation. 3. Review of the laboratory's policy "QA Policy Thibodaux Office" under the section "Proficiency Testing" revealed "Method of Review - Review of the PT checklist for each event. Proficiency Testing Checklist will be used to track all steps each {sic} event from start to finish, including review of the evaluation report within 30 days by testing personnel and laboratory director and investigation of any failures. All required paperwork must be

	retained with the checklist and evaluation report." 4. In interview on April 13, 2023 at 9:45 AM, the Technical Consultant confirmed the review of the proficiency testing result evaluation cited above was not documented.
D5291	GENERAL LABORATORY SYSTEMS QUALITY ASSESSMENT CFR(s): 493.1239(a) The laboratory must establish and follow written policies and procedures for an ongoing mechanism to monitor, assess, and, when indicated, correct problems identified in the general laboratory systems requirements specified at 493.1231 through 493.1236. This STANDARD is not met as evidenced by: Based on review of the laboratory's policy and procedure manual and interview with personnel, the laboratory failed to maintain a complete policy for proficiency testing. Findings: 1. Review of Laboratory Policy and Procedure Manual revealed the laboratory had a Quality Assurance policy with a section on Proficiency Testing; however, the policy failed to include: a) Receipt and handling of proficiency testing samples b) Prevention of testing personnel shared between multiple locations from performing the same proficiency testing samples at multiple locations. 2. In interview on April 12, 2023 at 3:39 PM, the Technical Consultant confirmed the laboratory policy and procedure manual did not have the information cited above.
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 policy and procedure manual and interview with personnel, the laboratory failed to have a written procedure for verification of performance specifications. Findings: 1. Review of the policy and procedure manual revealed the laboratory did not have a detailed procedure for verifying performance specifications to include, but not limited to, the following: a) Instructions for testing personnel of what to do for studies for accuracy, precision (day-to-day, run-to-run, and within-run variation, as well as operator variance), reportable and reference ranges and analytical sensitivity and specificity. b) How to handle when data from the studies for precision, accuracy, reportable range, reference range, analytical sensitivity and analytical specificity fail to meet acceptability criteria. 2. In interview on April 12, 2023 at 3:39 PM, the Technical Consultant confirmed the laboratory did not have written instructions for verifying new instruments.
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's policies, quality control (QC) records, manufacturer's instructions, and interview with personnel, the laboratory failed to establish a complete policy for QC for Chemistry and Complete Blood Count (CBC) testing. Findings: 1. In interview on April 12, 2023 at 10:25 am, the Technical Consultant stated for a new lot of CBC QC the laboratory runs the controls five to ten times and uses the manufacturer's range as their own if their calculated mean falls within the manufacturer's. 2. In interview on April 12, 2023 at 12:23 pm, Testing Personnel 2 stated prior to putting new lots of controls into use for CBC testing, quality controls are run ten times. Testing Personnel 2 further stated for Chemistry and Hematology testing the laboratory utilizes the ranges provided by the manufacturer and just verifies their means fall within the manufacturer's ranges. Testing Personnel 2 stated prior to putting new lots of controls into use for Chemistry testing, quality controls are run twenty times then the laboratory's established standard deviation (SD) and manufacturer's ranges are used. 3. Review of the laboratory's "Concurrent (Lot to Lot) Evaluation" policy revealed the purpose of the policy was "to define the process of running concurrent (lot to lot) studies to ensure a new lot of QC material is within acceptable assayed ranges prior to putting them into use. Over the next several days (preferably at least 5 days), run New Lot QC (these are NOT the day's official QC and should be filed in the 'test' lot file). QC should be run by different operators to detect any operator related differences in results. Once there are at least 5 concurrent runs, new lot QC should be evaluated as follows: If the results of the current and new lot QC are within manufacturer's range, the new lot is verified. If results fall outside the manufacturer's ranges take corrective action to determine the issue. Lab Director or Technical Consultant must review and approve the study before new lots are put into use." 4. Review of the manufacturers' package inserts for Chemistry and Hematology testing revealed the following: a) BioRad Liquichek Immunoassay Plus Controls and Liquid Assayed Multiqual: "It is recommended that each laboratory establish its own acceptable ranges and use those provided only as guides." b) Thermo Scientific MAS Diabetes: "Values listed are specific for this lot of control only. Good laboratory practice suggests that each laboratory establish its own parameters." c) Sysmex EIGHTCHECK: "Sysmex recommends that each laboratory use the targets and limits provided on the assay sheet included with each lot or EIGHTCHEK-3WP X-TRA, or establish laboratory specific targets and limits." 5. Review of the laboratory's quality control records for Chemistry testing revealed the laboratory does not utilize the manufacturers' ranges. 6. The laboratory's policy differed from interview with personnel, manufacturer's requirements, and what was in

	practice. 7. In further interview on April 12, 2023 at 2:49 pm, Testing Personnel 2 stated the laboratory's "Concurrent (Lot to Lot) Evaluation" policy was for Chemistry and Hematology testing. Testing Personnel 2 confirmed the laboratory's quality control policy did not match what the laboratory practices. 8. Review of the laboratory's "Quality Control on Vitros 5600" policy revealed the laboratory utilizes Liquichek Immunoassay Plus Levels 1, 2, and 3. The policy did not specify the levels of controls utilized for Endocrinology testing. 9. Review of the laboratory's QC records revealed the following Liquichek Immunoassay Plus controls are utilized for Endocrinology testing: a) FT4: level 1& 2 b) PSA & TSH 1 & 3 10. In interview on April 13, 2023 at 9:31 am, the Technical Consultant and Testing Personnel 2 confirmed the laboratory's policy did not specify the levels of controls utilized for the identified endocrinology tests.
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, validation records review, review of the laboratory policy and procedure manual, and interview with laboratory personnel, the laboratory failed to verify complete performance specification verifications for the Vitros 5600 Integrated System. Findings: 1. Observation by the surveyors on April 12, 2023 revealed the laboratory utilized the Vitros 5600 Integrated System analyzer Serial #56004449. 2. Review of the laboratory test menu on April 13, 2023 revealed the laboratory utilized the Vitros 5600 for Albumin (ALB), Alkaline phosphatase (ALP), Alanine aminotransferase (ALT), Aspartate aminotransferase (AST), Blood Urea Nitrogen (BUN), Calcium (CA), Cholesterol (Chol), Chloride (CL), Carbon Dioxide (CO2), Creatinine (Creat), Direct Bilirubin (DBil), Free Thyroxine (FT4), Glucose (Glu), Glycosylated Hemoglobin (Hgb A1C), Potassium (K), Magnesium (Mg), Sodium (NA), Total Prostate Specific Antigen (TPSA), Bilirubin (TBil), Total Protein (TP), Triglycerides (Trig), Thyroid Stimulating Hormone (TSH), Uric Acid (Uric), High Density Lipoprotein Cholesterol (HDL), and Phosphorous (Phos) testing. 3. Review of the performance specification documents for the Vitros 5600 revealed there was no detailed instructions for verification of precision, accuracy, reportable range, or reference range to include, but not limited to, criteria for acceptability, number of samples, and materials used. 4. Further review of the performance specification documents revealed the laboratory did not have the following documentation: a) Complete precision (Day to day and operator variance) b) Raw data to match sample charts and graphs provided by the vendor for method comparison. 5. In interview on April 13, 2023 at 9:39 AM, the Technical Consultant confirmed they did not have a summary of how the laboratory verified the performance specifications, day to day precision, operator variance, and could not match the method comparison chart with the raw data.
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 review of the laboratory's quality assessment form, quality control records, and interview with personnel, the laboratory failed to ensure assessment activities for quality control (QC) were documented for two (2) of three (3) months reviewed. Findings: 1. Review of the laboratory's "Quality Review Form" revealed the following monthly monitors: general, maintenance, calibration/calibration verification, and quality control. Quality control tasks include: a) Proper type of QC material used b) New lot verified prior to use (QC 8) c) Required # done prior to testing patients d) Documents have lot #, expiration date, acceptable ranges e) Quantitative results graphed f) Reviewed for shifts and trends g) Corrective Action taken for out of range results h) Waived testing performed per mfg instructions: External QC done as mfg requirements i) Lab Director review of all non-waived QC results j) Lab Director review of all waived QC results 2. Review of the following QC records and monthly "Quality Review Forms" revealed the corrective actions/incidents were not documented: a) December 14, 2021 Complete Blood Count (CBC) level 2 control b) June 21, 2022 Total bilirubin and conjugated bilirubin level 1 control 3. In interview on April 12, 2023 at 3:44 pm, Testing Personnel 2 stated for December 14, 2021 the level 2 CBC control was labeled incorrectly in the instrument as "Sample ID 1." Testing Personnel 2 further stated in the laboratory's LIS the label was changed to "norm" by tech. Testing Personnel 2 confirmed the corrective action performed was not documented for the identified December 14, 2021 CBC control issue. 4. In further interview on April 13, 2023 at 9:59 am, Testing Personnel 2 stated for Jnue 21, 2022 the total bilirubin control was repeated in error and the reviewing tech did not accept the value from the instrument into the LIS. Testing Personnel 2 confirmed the corrective action performed was not documented for the identified June 21, 2022 bilirubin control issue.
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, validation record review, review of the laboratory policy and procedure manual, and interview with laboratory personnel, the Laboratory Director failed to ensure performance verification studies were complete. Refer to D5421.

D6016	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(4)(i) 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)(4)(i) Ensure that the proficiency testing samples are tested as required under Subpart H of this part; This STANDARD is not met as evidenced by: Based on record review and interview with personnel, the Laboratory Director failed to ensure proficiency samples are tested as required. Refer to D2009.
D6018	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(4)(iii) 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)(4)(iii) Ensure that all proficiency testing reports received are reviewed by the appropriate staff to evaluate the laboratory's performance and to identify any problems that require corrective action; This STANDARD is not met as evidenced by: Based on review of proficiency testing records and the laboratory's policy and procedure manual, as well as, interview with laboratory personnel, the Laboratory Director failed to ensure all proficiency testing reports received are reviewed by the appropriate staff to evaluate the laboratory's performance and to identify any problems that require corrective action. Refer to D5211.
D6021	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 quality assessment programs are established and maintained to assure the quality of laboratory services provided. This STANDARD is not met as evidenced by: Based on 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. Findings: 1. The laboratory failed to maintain a complete policy for proficiency testing. Refer to D5291. 2. The laboratory failed to ensure assessment activities for quality control (QC) were documented for two (2) of three (3) months reviewed. Refer to D5793.

D6029	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(11) 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)(11) Ensure that prior to testing patients' specimens, all personnel have the appropriate education and experience, receive the appropriate training for the type and complexity of the services offered, and have demonstrated that they can perform all testing operations reliably to provide and report accurate results. This STANDARD is not met as evidenced by: Based on review of personnel records, laboratory documents, policies and procedures, and interview with personnel, the Laboratory Director failed to ensure Testing Personnel had documentation of training prior to patient testing for two (2) of two (2) testing personnel reviewed. Findings: 1. Review of personnel records revealed no documents labeled as training, and documents labeled as "6 month" and/or "Annual" competency did not match a 6 month or annual timeframe from the employee's initial start date. a) Testing Personnel 1- start date of March 2022 - 6 month competency signed by Laboratory Director June 23, 2022 - Annual competency signed by Laboratory Director November 9, 2022 b) Testing Personnel 5- laboratory assistant license issued October 2022 - Annual competency signed by Laboratory Director November 3, 2022
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: I. Based on personnel records, CMS-209 (Laboratory Personnel Report), and interview with laboratory personnel, the Laboratory Director failed to evaluate competency semi-annually in 2022 for the Technical Consultant serving as Testing Personnel. Findings: 1. Review of the CMS-209 revealed the Technical Consultant also serves as Testing Personnel. 2. Review of personnel records revealed the Technical Consultant began employment in March 2022. 3. Review of the laboratory's "Competency Assessment" form revealed "reviewer date and initial when completed" at the top of the columns on the forms. 4. Further review of the 2022 competency assessment documents for the Technical Consultant labeled as "6 month" and "Annual" revealed initials for testing personnel two through five. 5. In interview on April 12, 2023 at 11:30 AM, Testing Personnel 2 confirmed her initials and the initials

	of other testing personnel not designated as Technical Consultant. 6. Review of personnel records revealed no other testing personnel qualified as Technical Consultants. 7. In interview on April 12, 2023 at 11:30 AM, Testing Personnel 2 confirmed the Laboratory Director did not perform the competency for the Technical Consultant. II. 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 for testing personnel. Refer to D5209 I. 2. The laboratory failed to ensure policies and procedures were established for assessing technical consultant competency. D5209 II. 3. The Technical Consultant failed to evaluate the competency for five (5) of five (5) Testing Personnel in 2021 and 2022. Refer to D6046. 4. The Technical Consultant failed to ensure competency assessments for four (4) of five (5) laboratory testing personnel included review of intermediate test results or worksheets, quality control records, proficiency testing results, and preventive maintenance in 2021 and 2022. Refer to D6049. 5. The Technical Consultant failed to ensure competency assessments for four (4) of five (5) laboratory testing personnel included direct observation of performance of instrument maintenance and function checks in 2021 and 2022. Refer to D6050. 6. The Technical Consultant failed to ensure competency assessments for four (4) of five (5) laboratory testing personnel included assessment of test performance through testing previously analyzed specimens, internal blind testing samples or external proficiency testing samples in 2021 and 2022. Refer to D6051. 7. The Technical Consultant failed to ensure competency assessments for four (4) of five (5) laboratory testing personnel included assessment of problem solving skills in 2021 and 2022. Refer to D6052.
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. Findings: 1. The laboratory failed to have a complete policy and procedure manual. Refer to D5401. 2. The laboratory failed to establish a complete policy for QC for Chemistry and Complete Blood Count (CBC) testing. Refer to D5403.
D6032	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(14) 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)(14) Specify, in writing, the responsibilities and duties of each consultant and each person, engaged in the performance of the preanalytic, analytic, and postanalytic phases of testing, that identifies which examinations and procedures

	each individual is authorized to perform, whether supervision is required for specimen processing, test performance or results reporting, and whether consultant or director review is required prior to reporting patient test results. This STANDARD is not met as evidenced by: Based on review of the laboratory's CMS-209 form (Laboratory Personnel Report), personnel records, and interview with personnel, the Laboratory Director failed to delegate responsibilities to the Technical Consultant. Findings: 1. Review of the Technical Consultant's personnel records revealed the laboratory did not include written responsibilities delegated by the Laboratory Director to her. 2. In interview on April 12, 2023 at 11:20 a.m., the Technical Consultant and Testing Personnel 2 confirmed the laboratory did not have documentation of the Laboratory Director delegating duties of the Technical Consultant to her.
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, 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 record review and interview with personnel, the Technical Consultant failed to ensure the quality control program was established and maintained to assure the quality of laboratory testing. Refer to D5403.
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 the laboratory's CMS 209 (Laboratory Personnel Report) form,

	personnel records, and interview with personnel, the Technical Consultant failed to evaluate the competency for five (5) of five (5) Testing Personnel in 2021 and 2022. Findings: 1. Review of personnel records for testing personnel in 2021 and 2022 revealed "reviewer date and initial when completed" at the top of the columns on the "Competency Assessment" forms. 2. In interview on April 12, 2023 at 11:30 AM, Testing Personnel 2 confirmed the initials on the competency assessment forms were those of herself and other testing personnel and not the Technical Consultant.
D6049	TECHNICAL CONSULTANT RESPONSIBILITIES CFR(s): 493.1413(b)(8)(iii) The procedures for evaluation of the competency of the staff must include, but are not limited to review of intermediate test results or worksheets, quality control records, proficiency testing results, and preventive maintenance records. This STANDARD is not met as evidenced by: Based on review of personnel records and interview with laboratory personnel, the Technical Consultant failed to ensure competency assessments for four (4) of five (5) laboratory testing personnel included review of intermediate test results or worksheets, quality control records, proficiency testing results, and preventive maintenance in 2021 and 2022. 1. Review of competency assessments for the following personnel revealed review of intermediate test results or worksheets, quality control records, proficiency testing results, and preventive maintenance was not documented for the following: - Testing Personnel 1 -2022 4 Plex Cepheid - Testing Personnel 3 - 2022 urine sediment and 4 Plex Cepheid - Testing Personnel 4 - 2021 urine sediment - Testing Personnel 7 -2021 urine sediment 2. In interview on April 12, 2023 at 2:52 PM, the Technical Consultant confirmed the above competency was not documented.
D6050	TECHNICAL CONSULTANT RESPONSIBILITIES CFR(s): 493.1413(b)(8)(iv) The procedures for evaluation of the competency of the staff must include, but are not limited to direct observation of performance of instrument maintenance and function checks. This STANDARD is not met as evidenced by: Based on review of personnel records and interview with laboratory personnel, the Technical Consultant failed to ensure competency assessments for four (4) of five (5) laboratory testing personnel included direct observation of performance of instrument maintenance and function checks in 2021 and 2022. Findings: 1. Review of competency assessments for the following personnel revealed direct observation of maintenance was not documented for the following: - Testing Personnel 1 -2022 urine sediment and 4 Plex Cepheid - Testing Personnel 3 - 2022 urine sediment and 4 Plex Cepheid - Testing Personnel 4 - 2021 urine sediment - Testing Personnel 7 -2021 urine sediment 2. In interview on April 12, 2023 at 2:52 PM, the Technical Consultant confirmed the above competency was not documented.
D6051	TECHNICAL CONSULTANT RESPONSIBILITIES CFR(s): 493.1413(b)(8)(v)

	The procedures for evaluation of the competency of the staff must include, but are not limited to assessment of test performance through testing previously analyzed specimens, internal blind testing samples or external proficiency testing samples. This STANDARD is not met as evidenced by: Based on review of personnel records and interview with laboratory personnel, the Technical Consultant failed to ensure competency assessments for four (4) of five (5) laboratory testing personnel included assessment of test performance through testing previously analyzed specimens, internal blind testing samples or external proficiency testing samples in 2021 and 2022. 1. Review of competency assessments for the following personnel revealed assessment of test performance through testing previously analyzed specimens, internal blind testing samples or external proficiency testing samples was not documented for the following: - Testing Personnel 1 -2022 4 Plex Cepheid - Testing Personnel 3 - 2022 urine sediment and 4 Plex Cepheid - Testing Personnel 4 - 2021 urine sediment - Testing Personnel 7 -2021 urine sediment 2. In interview on April 12, 2023 at 2:52 PM, the Technical Consultant confirmed the above competency was not documented.
D6052	TECHNICAL CONSULTANT RESPONSIBILITIES CFR(s): 493.1413(b)(8)(vi) The procedures for evaluation of the competency of the staff must include, but are not limited to assessment of problem solving skills. This STANDARD is not met as evidenced by: Based on review of personnel records and interview with laboratory personnel, the Technical Consultant failed to ensure competency assessments for four (4) of five (5) laboratory testing personnel included assessment of problem solving skills in 2021 and 2022. 1. Review of competency assessments for the following personnel revealed assessment of problem solving skills was not documented for the following: - Testing Personnel 1 -2022 4 Plex Cepheid - Testing Personnel 3 - 2022 urine sediment and 4 Plex Cepheid - Testing Personnel 4 - 2021 urine sediment - Testing Personnel 7 -2021 urine sediment 2. In interview on April 12, 2023 at 2:52 PM, the Technical Consultant confirmed the above competency was not documented.